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IN THIS ISSUE

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A medium of expression for the exchange of thought in the fields of patents, trademarks and copyrights; a forum for the presentation and discussion of legal and technical subjects relating to the useful arts; a periodical for the dissemination of knowledge of the functional attribute of the patent, trademark, and copyright laws, in order to effect a more uniform practice thereof and through which all interested in the development and appreciation thereof may work to a common end. Published quarterly by members of the Patent and Trademark Office Society.

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Questions and concerns regarding submitted articles should be directed to the Editor-in-Chief at editor@jptos.org or the Executive Director at exec.dir@jptos.org. All articles will be automatically considered for the Rossman Award. See JPTOS, September 2002, Volume 84, No 9, pp. 703-704.

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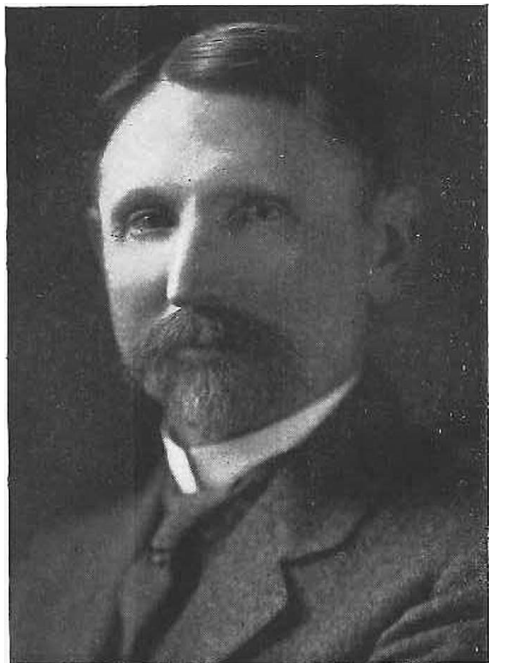

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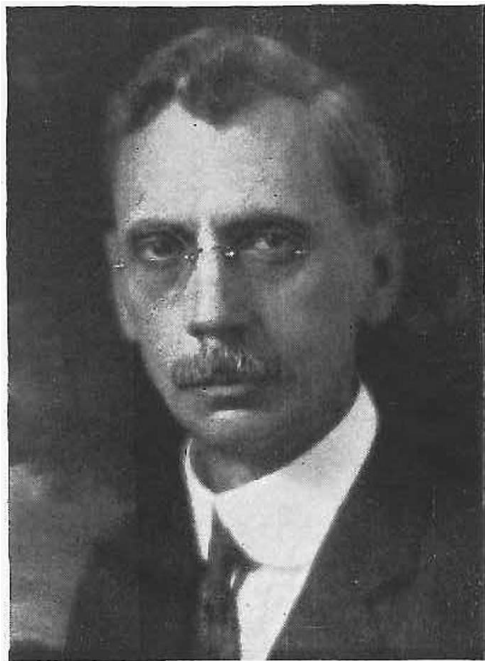

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FREDERICO AND ROSSMAN AWARDS 2019

Joshua Schwartz, Chairman

Federico Memorial Award

The Federico Committee was privileged to present the 2019 Pasquale J. Federico Memorial Award to The Honorable (Ret.) Randall Rader during the 2019 Annual Meeting of the Patent and Trademark Office Society.

In 1993, the SOCIETY established the Pasquale J. Federico Memorial Award. The Federico Award is intended to recognize outstanding contributions to the Patent and Trademark Systems of the United States of America. It may be given to an individual, a group of individuals, a corporation or an institution. Awards to individuals may be made posthumously. No more than one award may be given in each year. Anyone may make a nomination.

The award is named in honor of Pasquale J. (Pat) Federico who was an institution within the Patent and Trademark Office. Pat entered then Patent Office in 1923 as a junior examiner in Division 43. By 1935, he was the Assistant Chief of his division and he became the Division Chief in 1940. He was appointed to the Board of Appeals in 1947 and remained there until his retirement from the Office in 1977. Pat Federico was a prolific author of articles dealing with intellectual property. Perhaps his greatest achievement was writing the first draft of the 1952 Patent Act. He was also, according to Giles Rich, the man most responsible for getting the 1952 Patent Act through Congress and enacted into law.

The first Federico Award was presented to the late Giles S. Rich, who had served on the Court of Appeals for the Federal Circuit and its predecessor court, the Court of Customs and Patent Appeals for over four decades. Honorees from other years include Nick Godici, Paul Michel, Donald Banner, Charles E. Van Horn, Pauline Newman, C. Marshall Dann, Herbert Wamsley, Helen Wilson Nies, Mike Kirk, Tom Arnold, Howard T. Markey, Rene D. Tegtmeyer, Isaac Fleischmann, John Whealan, Anne Chasser, Raymond Chen. Bernie Knight, Mark Lemley, and Teresa Stanek Rea.

The judges were:

Joshua Schwartz, Chairman, Federico Committee

Alexander Sofocleous, USPTO and Editor-In-Chief JPTOS.

Judge Randall Rader is a graduate of Brigham Young University and the George Washington University Law School. Judge Rader served as Counsel, to the House of Representatives, Interior and Ways and Means Committees from 1975-1980. Then served as Chief Counsel, to the Senate Judiciary Committee Subcommittees from 1980-1988. President Ronald Reagan appointed Rader to the United States Court of Federal Claims in 1988, to succeed Robert M. M. Seto. The United States Senate confirmed the nomination by unanimous consent on August 11, 1988. He served there for approximately two years. On June 12, 1990, Rader was nominated by President George H. W. Bush to a seat on the United States Court of Appeals for the Federal Circuit vacated by Judge Jean Galloway Bissell. Rader was confirmed by the Senate on August 3, 1990, and received his commission on August 9, 1990. In 2010, Rader became Chief Judge of the Federal Circuit succeeding Chief Judge Paul Redmond Michel upon his retirement. He served in that capacity through May of 2014. Since leaving the bench in 2014, Judge Rader has founded the Rader Group, initially focusing on arbitration, mediation, and legal consulting and legal education services.

Judge Rader has taught courses on patent law and other advanced intellectual property courses at The George Washington University Law School, University of Virginia School of Law, Georgetown University Law Center, the Munich Intellectual Property Law Center, and other university programs in Tokyo, Taipei, New Delhi, and Beijing.

Judge Rader has also co-authored several texts including the most widely used textbook on U. S. patent law, Cases and Materials on Patent Law, (St. Paul, Minn.: Thomson/West 3d ed. 2009) and Patent Law in a Nutshell, (St. Paul, Minn.: Thomson/West 2007) (translated into Chinese and Japanese).

Rossman Memorial Award

The Rossman Committee was privileged to present the 2019 Joseph Rossman Memorial Award to Judge Hung Bui during the 2019 Annual Meeting of the Patent and Trademark Office Society.

The award was established in 1972 by the Society and the family of Dr. Joseph Rossman. Joseph Rossman started his career as a patent examiner and was Editor-in-Chief of The Journal back in the 1930s. He had degrees in chemical engineering and law, as well as a doctorate in psychology. In addition, Dr. Joseph Rossman was an author with a life-long interest in creativity, engineering and law. Dr. Joseph Rossman was the author of many articles in the Journal from the 1930s through the 1960s. Because the Journal was such a big part of Dr. Rossman's life, his family approached the Society with the idea of establishing the Rossman Award in 1972. The Society enthusiastically embraced the idea and the rest is history. The Rossman Award is given to the author of the article in the Journal that, in the opinion of the judges, makes the greatest contribution to the fields of Patents, Trademarks or Copyrights. Factors that are taken into consideration include originality, timeliness of the subject, depth of research,

accuracy, readability, and the potential for impact on the existing system.

I would like to thank the three judges who reviewed all of the articles published in the Journal during the second half of 2017 and the first half of 2018. Our Judges gave a great amount of their time and consideration to select a winning article.

The judges were:
Alexander Sofocleous, USPTO and Editor-In-Chief JPTOS.
Joshua Schwartz USPTO, Rossman Award Chair.

This year's winning article "A Common Sense Approach to Implement the Supreme Court's *Alice* Two-Step Framework to Provide 'Certainty' and 'Predictability'" written by PTAB Judge Hung Bui, appeared in Volume 100, No. 2 of The Journal on page 165.[1]

Judge Bui serves as an Administrative Patent Judge (APJ) at the Patent Trial and Appeal Board (PTAB) since 2012. As an APJ, he adjudicates ex parte and reexamination appeals, conducts trial proceedings in legacy interferences, and presides over AIA trials challenging patents post grant. Before joining PTAB, he was in private practice for about 20 years as a patent attorney. During his private practice career, he was a partner at Antonelli, Terry, Stout & Krauss LLP, and a name partner at Stein, McEwen & Bui LLP. His practice included developing patent portfolios, drafting opinions regarding validity and infringement, litigation, and licensing.

[1] Hung H. Bui, *A Common Sense Approach to Implement the Supreme Court's* Alice *Two-Step Framework to Provide "Certainty" and "Predictability"*, 100 J. Pat. & Trademark Off. Soc'y 165 (2018). {Ed. Note: article citation added to facilitate electronic linking of this Rossman Award Announcement to the article by our online content providers, such that future readers may recognize the award when forward-citing the article.}

From left to right: the Honorable Hung H. Bui, Administrative Patent Judge for the United States Patent and Trademark Office's Patent Trial and Appeal Board stands proudly next to the Honorable Randall R. Rader, former Chief Judge of the United States Court of Appeals for the Federal Circuit, co-author of West's Cases and Materials on Patent Law, and professor of law. Congratulations.

PTOS Annual Meeting Keynote Address Will You Be My Valentine: Celebrating the USPTO Examiner Through History*

Laura A. Peter†

Good morning everyone, and thank you Rachel for that generous introduction. Happy Valentine's Day! The USPTO and the Patent and Trademark Office Society have had a long and rewarding relationship spanning over a hundred years.

Today it is my honor to address so many patent and trademark examiners, and to celebrate you. You are the reason why our U.S. intellectual property system is so incredible. You are all highly educated experts in your fields. Every day, you work diligently to ensure that the patents and trademarks that this agency issues are strong and reliable. So today, I want to thank you and show you how much our agency has evolved over the last two centuries.

On this Valentine's Day, let us start with taking a closer look at some of the jewelry, flowers, and candy associated with today through the lens of intellectual property.

When you get home tonight and your valentine gives you a special blue jewelry box, you will instantly know it's from Tiffany & Co. Tiffany received a registered trademark for that particular blue color over 20 years ago. And the original Tiffany & Co. trademark dates back to 1893. Tiffany also holds 36 design patents and even a utility patent for a clip-on earring force tester.

The bouquet of red roses you sent to your sweetheart may even be patented. In 1931, the first plant patent issued for a climbing rose. In fact, 4% of *all* plant patents are for varieties of roses.

*Keynote speech delivered to the members of the Patent & Trademark Office Society at their 2019 Annual Meeting, February 14, 2019 (as prepared for delivery).

†Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

And don't forget about the chocolate! You no doubt will pay just a few dollars more for the brands you know. Godiva currently holds 41 trademarks, 2 utility patents, and 8 design patents, including one for a heart-shaped candy adorned with the Godiva trademark.

One of the most popular Valentine's Day treats, with over eight billion sold every year, is Sweethearts® conversation hearts. Sadly, for the first time since 1901, you won't be able to buy any this year. But don't worry, they will be back in 2020!

NECCO, the oldest continually operating candy company in the U.S. went bankrupt this year. However, a buyout by Spangler ensures that Sweethearts® conversation hearts will continue to delight our valentines for years to come.

Sweethearts® candy has a long history. Boston pharmacist Oliver Chase received U.S. Patent 17,262 in 1857 for a "Lozenge Machine," considered to be the first candy-making machine patented in the U.S. Similar to a pasta roller, this machine pressed and cut wafers made of gum Arabic, peppermint, and brown sugar. At the time, pharmacists frequently prepared medicine in the form of medicinal lozenges. However, Oliver discovered that the customers liked the taste of the lozenges themselves, and began selling a medicine-free wafer as candy.

In 1866, Oliver's brother Daniel Chase patented a "Lozenge Printing Machine," which pressed words onto wafers using a felt roller pad moistened with vegetable coloring. These printed lozenges were frequently used at weddings, and had long-winded sayings such as: "Married in satin, Love will not be lasting"; "Married in pink, He will take to drink"; and "Married in white, you have chosen right."

In 1901, Oliver, and his brothers Daniel and Silas, created the New England Confectionary Co. and the original sugar lozenge became the infamous NECCO® wafer, trademarked in 1906. Known for their chalky hard exterior, NECCO® wafers have a two-year shelf life, are temperature resistant, and are virtually indestructible. This made them ideal for use on Arctic expeditions and as a staple in soldier's rations, as far back as World War I.

In 1901, NECCO also began producing heart-shaped printed wafers, which were trademarked in 1996 as Sweethearts® —the conversation hearts that we all love to share on Valentine's Day. Original sayings included "Be Mine," "Kiss Me," and "True Love." However, the sayings were updated for the new generation in the 1990s to include: "Fax Me," "Page Me," and "Email Me." More recent sayings include: "#Love," "Txt Me," and "LOL."

Intellectual property plays a huge role in the success of any company. The patents and trademarks we have issued are likely part of why Tiffany, Godiva, NECCO and Sweethearts have all endured for so long.

As you know, the roots of our intellectual property system date back to the founding of the United States; however, the USPTO and the role of the examiner have evolved dramatically over time. Intellectual property right protection is in the Constitution itself; however, the first patent statute was actually passed by Congress on April 5, 1790 and signed into law by President George Washington on April 10, 1790.

Initially, there were very few rules for determining what inventions were patentable. The MPEP, which we heavily rely on today, did not exist. The first "Patent Board" decided whether a particular invention was new and "*sufficiently useful and important*." The initial Patent Board in 1790 consisted of three prestigious members: Secretary of State Thomas Jefferson, Secretary of War Henry Knox, and Attorney General Edmund Randolph. Perhaps these names sound familiar—you may have passed the Jefferson, Knox, or Randolph buildings on the USPTO campus on your way here today.

The application for a patent initially required a specification, including a written description and drawings, and an exact model of the invention if possible. The patent model requirement existed up until 1880. In the early 1800s, the public would commonly tour the rooms filled with innovative patent models as a Sunday afternoon excursion. Today, you can see a few of these patent models on exhibit in the upper Madison lobby and in the National Inventors Hall of Fame Museum.

Originally, patent application review was not a full-time job. The members of the Board generally read the patent applications at home after their normal workday. So you could say that telework existed even back then! On the last Saturday of each month, the Board would meet to discuss the applications from the last month. Then, they would have a month to make their decisions. This sounds like a long time, but remember this was in addition to their full-time jobs as high-ranking government officials, and no one was electronically connected 24 x 7 back then.

Two of the three members of the Board had to agree to approve every patent, and the President of the United States would then personally sign each one. Of course, today that task would be impossible. But, in 1790, only 3 patents issued during the entire year. By 1793, there was a grand total of 57 issued patents.

In 1790, it cost about $4–5 for the total prosecution of a patent application. It was 50 cents for receiving and filing the petition; 10 cents per 100 words for copying the specification to copy sheets; $2 to write the patent; $1 to affix the Great Seal; and 20 cents for other services. Perhaps we should revisit charging applicants per word! To put this in context, today's basic Patent Office filing and issue fees are about $3000. Interestingly enough, these fees did not go to the federal government, but rather were directly part of an employee's salary. So in a way, employees were paid based on their production even back then!

After a few years, the Patent Board realized that they could not adequately examine patents only in their spare time. Thus, in 1793, Congress passed a law drastically modifying the patent system. It became a registration system with no examination, similar to the British system. For the next 40 years, any U.S. citizen could receive a patent, just by swearing their invention was new, filing the required papers, and paying $30.

As you can imagine, many patents issued on inventions that were not *really new* or *really useful*. The courts determined patent validity only after the fact. In 1802, President Jefferson appointed William Thornton as a full-time clerk in charge of issuing patents with a salary of $1,400 a year. This is when the *Patent Office* really began, although the role of the patent examiner as we know

it today did not actually exist until 34 years later.

Although patent examination for novelty was not required under the law of that time, Thornton took it upon himself to inform the applicant of any prior art he found, giving them a chance to withdraw their application and get a refund. Thornton sometimes even tried to help the applicant improve their invention. For instance, he personally added new matter to the specification of Jacob Cist's application describing a black printing ink. But, Cist rejected his suggestion, believing his original invention was better! The ethics rules prohibiting examiners from being inventors did not exist back then. Thornton actually granted quite a few patents to himself and added his name as a co-inventor to others.

Exactly 60 years after the Founding Fathers signed the Declaration of Independence, Congress passed the Patent Act of 1836 creating the patent system, as we know it today. This Act officially created the position of a full-time patent examiner. In 1836, the first patent Commissioner, Henry Ellsworth, wrote, "the office of examiner was one of great importance and high responsibility, requiring industry, skill and experience." And his words ring true today! The display in the National Inventors Hall of Fame Museum aptly describes examiners as "the guardians of the patent system." In 1836, Charles Keller became the first and only full-time patent examiner, tasked with examining applications in all technologies. Today each one of you is an expert in your respective art—can you imagine if you had to examine applications from every field?

The 1836 Act required the examination of applications for novelty and utility, however claims were not actually statutorily required until 1870. The prosecution history of a patent application in those days was quite short. There were no office actions or amendments. Inventors simply submitted the application and awaited a decision. If the examiner rejected the application, the inventor could get a partial refund! Or, they could appeal to a board of examiners for an extra $25.

The time from filing to issuance was only a few months. However, even then, applicants bemoaned such a long delay. Inventors would travel to Washington with their application and patent models in hand to file their applications in person.

Of course, the universe of searchable prior art was quite a bit smaller than today. On December 15, 1836, a great fire destroyed the Office, and much of the existing prior art was forever lost—over 10,000 patents and over 7,000 patent models. In an effort to recover these documents, the Patent Office sought out the inventors and asked them for the original documents. However, the Office was able to find and restore only about 2800 of these old patents, which became the "X" series of patents. The remainder of these patents were cancelled. An effort to recover these "X patents" continues to this day.

The Office did not print patents until 1866, and the public had to request a specific patent in order to receive a copy. There was no classification system back then—no USPC or CPC! There was no EAST. There were not even patent shoes yet. Examiners would have go to the draftsman's office to flip through and view the original drawings stored in large portfolio cases, often waiting in

line for their turn.

We certainly have come a long way. Today, anyone can log on to a computer and find an issued patent or published application in just seconds. But, we now have the opposite problem. The universe of prior art has expanded exponentially, with an accessibility and a publication explosion over the last few decades. Today, we are developing artificial intelligence tools to help you search this ever-increasing mountain of information, and expedite finding the most relevant prior art.

Although you no doubt know that we recently issued "patent 10 million," did you know that this was not actually the 10 millionth patent? This number does not include plant or design patents, and before 1836, the Office did not assign numbers to utility patents. Previously, a patent would be referenced only by the issue date and inventor name. So, although the first patent issued in 1790, the Patent Office granted Patent No. 1 in 1836 for a steam engine in 1836 to Maine Senator John Ruggles, who coincidentally was one of the sponsors of the 1836 Patent Act.

By 1850, the examining corps still consisted of only four principal examiners and some assistant examiners and clerks. Since there were so few examiners, when an inventor did not agree with an examiner's decision, the examiners were often personally criticized in the media. Compare this to the over 8,000 patent examiners and over 600 trademark examiners we currently have today.

You may be wondering, when did we add "trademark" to the Patent Office's duties? In 1870, Congress passed the first federal Trademark Act, giving the Commissioner of Patents the jurisdiction to register trademarks. Under this Act, the Averill Chemical Paint Company received the first trademark registration for a design mark in 1870. In the first three months, applications were filed for 36 trademarks. Patent Office staff recorded these marks by hand in a large ledger book.

However, the 1870 trademark law was short-lived—the Supreme Court declared the law unconstitutional in 1879 because it was based on the patent and copyright clause in the Constitution, rather than the commerce clause. In 1881, Congress enacted a new Trademark Act that passed the Constitutional test, and the Patent Office resumed its responsibilities for trademark registration. However, this 1881 Act included no provision for marks used in interstate commerce, and therefore had limited value.

It was not until 1905 that applicants could register marks used in interstate commerce under federal trademark law. And finally in 1946, trademark protection became much more robust with the passage of the Lanham Act. The Patent Office did not officially become the Patent *and Trademark* Office until 1975, and did not become the USPTO until 2000.

The Patent and Trademark Society itself has its origins over a hundred years ago, as well. Founded in 1917 as the Patent Office Society, it was the first group to focus on improving the intellectual property system. Since 1918, the Society has published their esteemed trade journal, which is one of the most respected publications on intellectual property in the U.S.

In 1920, the Society published the precursor to the MPEP—the *Patent Office*

Society Manual of Details of Patent Office Procedure, which was written by two examiners, Hugh Wilcox and Eustace Glascock. It was only 67 pages long! This manual was the only procedural manual on patent examination available until 1949, when the Patent Office began publishing the MPEP. Although you may wish the MPEP was still only 67 pages long, today's manual is now over 500 pages! However, today's electronic MPEP (eMPEP) allows for quick keyword searching not possible in a paper version.

On the trademark side, the Office did not publish the Trademark Manual of Examining Procedure until 1974, which coincidentally was the same year that the one-millionth trademark was registered.

I hope you have enjoyed this brief glimpse into our history today. Looking back on the origins of our agency helps give us perspective. We have made great strides in ensuring the protection of intellectual property over the last 229 years.

We look forward to an auspicious future with robust intellectual property protection to help foster innovation and entrepreneurship in our global economy. You, the patent and trademark examiners, are a very important part of making that happen!

Thank you for inviting me to join you today.

The Current State of Innovation within the U.S. Legal System – Views on Evolving Protection for Intellectual Property Rights in the United States from the USPTO and the Courts*

Andrei Iancu†

Good afternoon everyone! Thank you, Pete Thurlow, for that generous introduction. It's a great honor to open today's panel discussion on the current state of innovation within the U.S. legal system, and I appreciate NYIPLA's gracious invitation to be part of this outstanding annual event.

This very day 59 years ago, on March 22, 1960, the United States Patent Office issued patent number 2,929,922 to New York native Arthur Schawlow of Bell Labs and Charles Townes, a Columbia University professor and consultant to Bell Labs, for co-inventing the optical maser—now called a laser. While doing postdoctoral research at Columbia University, Schawlow met Townes, and together they sought ways to extend the maser principle of amplifying electromagnetic waves into the shorter wavelengths of infrared and visible light.

In 1958, the two scientists published a proposal for the invention in an issue of *Physical Review*, prompting an international competition to build a working laser. Today, of course, lasers have countless applications and make it possible to play CDs, correct eyesight, scan labels in a grocery store, enable autonomous vehicles, measure time precisely, survey planets and galaxies, and even witness the birth of stars.

Their invention changed the world.

Dr. Townes was inducted into the National Inventors Hall of Fame (NIHF) in 1976 and Dr. Schaulow joined him 20 years later. These two New Yorkers

*30-minute pre-panel address delivered to the members of the New York Intellectual Property Law Association at the "Day of the Dinner" Luncheon CLE, March 22, 2019 (as prepared for delivery).

†Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

join a long list of Americans who, backed by our patent system for the last 229 years, have fueled human progress on a scale and at a pace that far exceeds anything humanity has ever seen—at any time in the past, or anywhere else in the world. American heroes who—through their ingenuity, hard work and perseverance—have improved the state of the human condition.

Just last June, we had occasion to celebrate the patent system's contributions to the human condition, when the USPTO issued U.S. Patent Number 10 Million. As it happens, patent 10 million was on LIDAR technology. LIDAR is similar to RADAR, but it uses *Laser* instead of radio waves to measure distances to objects and the like. So in some sense, patent 10 million descended from the work done by Townes and Schaulow here in New York—some 60 years ago—and some 7 million patents earlier.

Beyond the specific technology, though, patent 10 million was a significant milestone for the United States. It marked, in a way, the unprecedented innovation that has taken place in this country since our founding. We commemorated that event with a signing ceremony at the White House, where patent 10 million was signed by President Trump in the Oval Office, along with Secretary of Commerce Wilbur Ross, and myself.

You can view the original signed document the next time you visit the PTO. It is on display at the National Inventors Hall of Fame museum at our headquarters in Alexandria.

After the signing, we held a reception at George Washington's Mount Vernon in Alexandria, Virginia, and specifically, at Washington's Gristmill—just a few miles down the road from USPTO headquarters. You can also visit that the next time you come to Virginia.

Washington's gristmill is still functional today. This is a milling system designed by Oliver Evans in the late 1700s. It's also the invention behind the third U.S. patent, issued in December 1790 and actually signed by George Washington himself.

Oliver Evans was born in Delaware and then moved to Philadelphia where he became the most prominent American steam engine engineer and inventor. When he was younger and after opening a store with his brother, Evans learned about the slow, inefficient and labor-intensive nature of the traditional grist operation through his dealings with local millers. Back then, millers would have to transport freshly-ground flour sacks up ladder-like stairways to the top floor of the mill. Using ropes, buckets and sacks, the miller would then dump the flour on the floor, where it was spread with a rake to cool and dry it. The flour often remained on the floor for hours as the moisture evaporated, and after it was dried and cooled, the flour would again be deposited in hoppers or bins to age and whiten.

By the time the flour was sifted and re-sacked, the flour had been—as Evans recalled—"*mixed with a great quantity of dirt . . . from the dirty feet of every one who trampled in it, trailing it over the whole mill and wasting much*." So Evans decided to automate the process.

In Evans' automated flour mill, all the work was done not by manual labor, but rather, by a system of interconnected machines geared to the same water

wheel. The Gristmill is effectively a multi-storied building with gears, pulleys and elevators, filters, and the like, for processing grain and making flour. Only two men were needed, one to empty bags of wheat at one end of the machine, and one to close and roll away barrels of flour at the other end.

Evans' process proved so efficient that over time, mill owners in the Delaware Valley began to replace their older, laborious mills with Evans' automated system. Later, while on a trip in Wilmington, Delaware, President Washington visited one of Evans' mills and after seeing it in action, decided to install one at Mount Vernon.

As I said, it is still there and it is still working.

I think about this and similar stories as we contemplate some of the thorniest issues that face us today. For example, I suspect nobody ever thought—back then or now—that Evans' automated manufacturing method (and machine) for processing flour would be abstract and, therefore, ineligible to be patented under Section 101 of the Patent Code.

I suspect nobody would argue that "collecting, analyzing and manipulating" the grain is an abstract idea! Or that automating this process, which was previously done by hand, is insufficient to render it eligible. These seem easy decisions.

But when it comes to modern technologies, the decisions are somehow no longer easy. *Why*?

At the time of Evans' invention, the United States was an agricultural society and we were at the beginning stages of the original industrial revolution. Machines that processed grain, and that *automated* the processing of grain, were then at the heart of our growing economy.

Since then, we've been processing and automating much more than agricultural products. For example, in addition to grain, we now process data and DNA. And as we now enter what some have called a "Fourth Industrial Revolution," we are automating much more than flour mills. For example, our scientists and engineers are working at forever faster rates to make advancements in artificial intelligence (AI), robotics, biotechnology, autonomous vehicles, quantum computing, and so much more.

We are today in a globally-competitive innovation race, and, for us to maintain our technological leadership, the United States must incentivize and protect our inventors as they work in these new areas. Among other things, we must be careful not to decide that the automation that is at the heart of the technologies of the future is somehow not eligible for patenting.

Sure, there are differences between the Fourth Industrial Revolution and the technologies of the past. But just because we are no longer automating using large machines that are tangible and easy to see and feel, does not mean that today's machines and processes should be any less worthy of patent protection.

Let me say it differently: Just because we are no longer focused on processing grain, and are instead processing data and DNA, does not mean that today's machines and processes are somehow not the "useful arts" worthy of patent protection as contemplated by the American Constitution.

Unfortunately, however, our patent system has gotten bogged down in re-

cent years, and we are now having a difficult time deciding whether some of the matter at the heart of the Fourth Industrial Revolution is eligible for patenting.

The PTO is working to clarify this area of law for our examiners and applicants and all others who come before us.

Some argue that recent Supreme Court cases on Section 101 have created our current predicament. Perhaps. But to some extent, I wonder whether some may have been over-reading these recent cases.

For example, the *Alice* case dealt with an escrow transaction that was performed on a general purpose computer. The Supreme Court held that escrow transactions are abstract, and therefore not eligible for patenting. Further, the Court said that simply doing this activity on a general purpose computer—automating it, if you will—does not render it less abstract.

From this, some have concluded that "doing it on a computer" is not eligible for patenting, without any reference to what the "it" might be. But the Court didn't go that far. The claim in *Alice* was ineligible because the invention dealt with a fundamental economic principle—escrow transactions. Just like the Court found hedging abstract in *Bilski*.

The Supreme Court said that we should not give patents to such principles, no matter how original and important they might be. The Court did *not* say that "doing it on a computer" is always ineligible, no matter what the "it" might be. The Court simply said that the environment where the escrow or hedging transaction is performed—whether it is done in private with a handshake, or in a bank with pen and paper ledger, or automated on a computer—makes no difference. In other words, merely doing the excluded activity on a general purpose computer is not eligible for patent—but that's because there was excluded activity in the first place.

Put differently, the Court never said that all automation with computers is *per se* not eligible. And why would it be? Why should we draw an eligibility line between automation with computers on one hand, and automation with other machines, on the other?

The key, therefore, is this: before determining whether "doing it on a computer" is problematic under Section 101, we should determine whether the claim at issue recites excluded matter in the first place. Because if it does not, Section 101 should not be implicated.

If the claim is about using a computer to automate a process that is not itself excluded, the patentability analysis should be left to Sections 102, 103 and 112.

For example, automating a known, non-excluded process can be a classic obviousness combination of the old process plus the computer, and the traditional Section 103 analysis should be employed to determine whether doing that old process on a computer is worthy of a patent. We have decades of experience with the *Graham* factors, and we know how to do a 103 analysis. The automation analysis need not be done at 101, unless it involves excluded matter in the first place.

Separately, but also from recent Supreme Court cases, some have concluded that claims that are functional in nature and without the specificity necessary to recite how the claimed function is achieved may also be ineligible under

Section 101. But where is that in the recent Supreme Court cases? Again, the claims in *Alice* were found to be ineligible because they were on a fundamental economic principle, not because they were functionally drafted.

That does not mean that functional claims are necessarily patentable. For example, the claims can be so broad and vague that they could be infringed just by thinking—just by doing mental processes. If so, we should reject under Section 101 for claiming a mental process. Plus, the claims must still pass muster under the other patent statutes, including Section 112 that deals squarely with the treatment of functional claiming. Let's do that analysis under that statute, since we have decades of experience doing so and standards on how to do it.

Some argue that older cases, like the old Morse patent, for example, refused to grant a patent for functional claims. Perhaps. But even if true, that was before the 1952 Patent Act, which separated the bases for invalidity. Whether a claim is definite enough or recites sufficient structure or is properly supported by the specification, should be dealt with under Section 112. Not Section 101.

The genius of the 1952 Patent Act was that it clearly categorized the conditions for patentability, in addition to and separate from the categories of invention. It separated in distinct statutes the issues raised by Sections 101, 102, 103 and 112. We should not mix them all up again.

In an attempt to untangle all this, the PTO in January issued revised patent subject matter eligibility guidance, which we believe will improve this situation in a few ways. Perhaps most importantly, the guidance provides an analytical framework to help focus the 101 discussion. This framework is a synthesis of, and is consistent with, Section 101 case law to date.

Under the framework, we first ask whether the subject matter at issue is itself eligible or not. Do the claims deal with matter that is *per se* problematic? In all Supreme Court cases, there was subject matter that was problematic *per se*. For example, fundamental economic principles in *Alice* and *Bilski*; natural phenomena in *Mayo* and *Myriad*; math in *Benson*, *Flook* and *Diehr*. And some of these also had mental processes.

I do not believe that a single Supreme Court case on Section 101 dealt with matter that is not *per se* ineligible. The Section 101 analysis should, therefore, start there. Start with a consideration of whether the claims recite matter that, on its own, is always ineligible—irrespective of how new, non-obvious or definite the claims might be.

I believe that this is what the case law is aimed at, but without structure, it's easy for the analysis to be confused. So the PTO's new analytical framework first lists specifically the categories of ineligible subject matter, as we have distilled from the cases:

- Laws of nature and natural products;
- Math;
- Certain methods of organizing human activity (such as fundamental economic principles and others); and
- Mental processes.

These are the subject matter categories identified by the courts as *per se* ineligible. We should not make up new ones. If the claims do not have excluded matter in one of these categories, they should not be subject to a subject matter exception.

Of course, the claims may be so broad and so vague that they could encompass excluded matter in these categories, even if the claim is otherwise technological. If so, it is of course appropriate to reject under 101.

Now even if the claims do have excluded subject matter, they are not automatically ineligible. After all, nearly all innovation is built on some basic tool of science or technology. So the new guidance further explains that, consistent with over 200 years of case law, "practical applications" of otherwise excluded matter should be eligible. And so, if the claims do have excluded matter, we need to see whether they're really about the excluded matter *per se*, or are they about the application of that matter to a practical end?

But let me go back to the categories of excluded matter, and why we believe that categorization under current law is so important. Let me give you an example that seems troubling to folks analyzing some modern technologies: data manipulation or processing. Interestingly, while virtually nobody has trouble with the eligibility of grain processing as in Washington's gristmill, folks struggle with the manipulation and analysis of data or information.

But why is that? What really is the difference—from an eligibility perspective—between grain processing in the First industrial revolution, and data processing in the Fourth? After all, neither grain nor information *per se* is statutorily eligible by itself. But how about the *processing* of that grain or information? Why would the processing of grain be eligible, but the processing of information not? I believe that our guidance helps to frame this analysis.

First, is data processing *per se* ineligible? That is, is it always ineligible when presented on its own? This is an important question. After all, the vast majority of what a computer does is data processing. And by the way, as grain processing was at the heart of our agricultural economy during the first industrial revolution, data and DNA processing are key to some of the technologies, and the economy, of the future.

In any event, I don't believe that the Supreme Court ever held that data processing on its own is ineligible, no matter what data we are processing. *Alice*, *Bilsky*, *Benson* and *Flook* all dealt with math or economic principles—matter that is excluded *per se*, not technology and the like. Why should we add an entirely new category of excluded matter?

And here is the critically important part: None of this is to say that claims on data processing are **always** *eligible*. Given the nature of data—intangible, ephemeral, often cerebral—such claims are at times indeed problematic. And maybe this is the difference between the processing of information and the processing of grain, and maybe why some find data processing claims more troublesome.

But this does not mean that all information processing claims are problematic. And in order to figure out which ones are problematic, we need to expressly identify the *real* problem.

For example, many claims on information processing are so broad and vague that they can be infringed by performing them in one's head. In other words, they do not require technology. If so, they would be in the mental steps category. Indeed, the Federal Circuit pointed directly to "mental processes, whose implicit exclusion from § 101 undergirds the information-based category of abstract ideas." So if that's what is happening in a claim, we should say so. Or, much information processing is just pure math with no practical application. If so, they would be in the "pure math" category of exclusion. Or, some claims about information gathering and the like are actually basic methods of organizing human activities, technology-free, in which case they are in *that* category.

On the other hand, if a claim on data processing does not recite matter in one of these exempted categories, why would it not be eligible for patent? Put differently, if a claim recites a *technological* process for the gathering, analysis, manipulation or display of data—a process that is not and cannot be performed mentally, for example—why would such a claim not be considered part of the "useful arts" and eligible for patenting?

So to sort all this out and keep the analysis consistent and predictable, we now ask our examiners and APJs to first identify the actual problem with the claim—to first consider whether the claims recite matter that, on its own, is per se ineligible. Without knowing the categories of matter that is *per se* excluded, it is very difficult to determine if a computer process—in the many thousands of claims we see every year at the PTO—is eligible or not. And the same is true with all other areas of technology.

With the new guidance, because we now know what we're looking for, this is a much more predictable and consistent approach. Virtually all of our examiners and judges have been trained on the new guidance, and they've welcomed the new approach. It drastically improves the analysis. It streamlines the process, clarifies the approach, and leads to more consistent results.

And the public agrees.

The public comment period for the new guidance has now closed. We have received lots of comments, and we are still reviewing them. The overwhelming majority of comments we received from companies and organizations are very supportive. (We also received hundreds of letters from individuals that follow two or three scripts. It appears that a couple of entities organized form-letter campaigns. So let me leave these aside for now, other than to say that they are both pro and against.)

Not everyone, of course, agrees with everything in the guidance. Some have suggestions for improving the listing of items in our categories. Or to add or subtract categories.Some would like more examples. And some, while believing that the guidance is a good approach under current law, would still prefer a legislative fix to effectively overrule current law.

But most importantly, the majority of companies and organizations that submitted comments believes that our *framework* is correct under current law. And this general consensus cuts across industries. This is great news. We can continue to discuss the best way to frame the categories, as long as we have an

agreed-upon framework. And having a consistent analytical *framework* will go a long way towards resolving our quandary on Section 101.

This remains the most important issue in patent law today, and I believe that we now have a path to resolution. So I hope that other authorities will help us, as we all work together to bring predictability to this area of law. It's critically important.

Our patent system fueled America's technological leadership for more than two centuries. It will do the same as we enter the next technological revolution—if we let it.

A scientific publication written in 1878 said that Thomas Edison, "with his marvelous inventions, is pushing the whole world ahead in its march to the highest civilization."

This is what American inventors do—from Oliver Evans to Townes and Schaulow, from Thomas Edison to those currently tinkering on the inventions of the future. With their creations, inventors help us march to the highest civilization. We owe them and the public a system of laws that they can understand, that they can predict, and that they can rely upon.

Thank you for the invitation to be here today, and I look forward to the panel discussion with Judges Chen, Andrews and Castillo.

PTAB Practice Tips: Comparing a Motion to Strike and a Motion to Exclude

James A. Worth*

Upon instituting an AIA trial proceeding, a panel of the Board issues a scheduling order that provides a timeline for discovery, for the filing of briefs, and for the date of an oral hearing. Parties may contact the Board to request an initial conference call if there is a need to propose changes to the scheduling order or propose motions that have not been provided for by the scheduling order or by the PTAB Rules. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765–66 (Aug. 14, 2012) ("TPG"); Trial Practice Guide Update ("Update") at 24. Otherwise, parties may proceed with discovery and briefing without consulting the Board. Occasionally, parties will have a dispute about the scope of discovery or briefing that they cannot resolve on their own, and will ask the panel to resolve the issue, usually in the run up to the hearing. Disputes over the scope of argument and evidence may result in a motion to strike or a motion to exclude.

This article reviews the nature of a motion to strike and a motion to exclude, with an eye towards comparing and contrasting their functions. To aid the comparison, this article addresses the difference between the motions in terms of their substance, timing, and procedure.

I. *What is the difference between a motion to strike and a motion to exclude?*

A party may file a motion to exclude evidence when it believes that evidence is inadmissible, e.g., under the Federal Rules of Evidence, as they apply to Board

*James A. Worth is an Administrative Patent Judge at the Patent Trial and Appeal Board (PTAB) of the USPTO. This article is part of a series of articles sponsored by the PTAB to provide updates and practice tips to the public.

proceedings. *See* 37 C.F.R. §§ 42.61, 42.62.[1] The Federal Rules of Evidence are, by USPTO rule, generally applicable to AIA trial proceedings, with the exception of certain evidentiary rules relating to juries and criminal law that are not otherwise applicable to Board proceedings. *See id.* § 42.62.

Other requests to exclude argument or evidence would generally be submitted in the form of a motion to strike. *See* Update at 17.[2] Motions to strike are heterogeneous but fall into certain categories: (a) a party might seek to withdraw one of its own papers or a portion thereof; (b) a party might challenge the other party's filing as untimely or as exceeding the page limits; and (c) a party might seek to strike a witness's testimony when a witness refuses to submit to cross-examination.

A. *A motion to withdraw a paper or a portion of a paper may take the form of the motion to strike.*

A party may seek to strike a paper that it has filed itself, or a portion thereof. *See, e.g.*, *Stingray Digital Group Inc. v. Music Choice*, Case IPR2017-01191, slip. op. at 2 (PTAB Apr. 4, 2018) (Paper 27) (granting patent owner's unopposed motion to strike and expunge a portion of patent owner's own response dealing with secondary considerations of nonobviousness); *see also Under Armour, Inc. v. Adidas AG*, Case IPR2015-00698 (PTAB Apr. 25, 2016) (Paper 70) (granting petitioner's motion to expunge petitioner's own confidential information from the record after settlement).[3]

B. *A party might file a motion to strike to challenge the other party's filing as untimely, exceeding the page limits, or otherwise not provided for.*

What, if any, is the remedy when one party files a brief in an untimely fashion? Files a brief that exceeds the page limits? Or files an additional brief in surreply? (i.e., in excess of the PTAB Rules, not provided for by the scheduling order, and not otherwise authorized by the panel.) The Board might simply reject such a filing, or the opposing party might bring the issue to the Board's attention, i.e., by seeking leave to file a motion to strike. *See, e.g.*, 37 C.F.R. § 42.7 ("*Management of the record.* (a) The Board may expunge any paper directed to a proceeding or filed while an application or patent is under the jurisdiction of the Board that is not authorized under this part or in a Board order or that is filed contrary to a Board order.").

[1] Evidence may also be inadmissible if a party seeks to introduce evidence on patent law itself. *See id.* § 42.65(a) ("Testimony on United States patent law or patent examination practice will not be admitted.").

[2] *Cf. Celltrion, Inc. v. Genentech, Inc.*, Case IPR2017-01139, slip op. at 27 (PTAB Oct. 3, 2018) (Paper 68) (treating a motion to exclude as a motion to strike).

[3] Sometimes parties may withdraw a filing without resort to a formal motion by contacting the Clerk of the Board and her staff, e.g., by emailing Trials@uspto.gov, when there has been a ministerial issue with an (electronic) filing. The Board staff will consult with the panel, e.g., to ensure that all filings are timely and that parties are not attempting to make more than a ministerial correction. If there is more than a ministerial correction at issue, then the panel may convene a conference call and/or authorize a formal motion to resolve the issue.

Sometimes a party may seek to strike only a portion of a brief. In practice, some parties have filed motions to strike when they believe that a portion of a reply is untimely because it attempts to introduce new evidence at a late stage in the proceeding. For example, a challenging party might argue that there is an inadequate opportunity to reply to late-introduced evidence or argument, or that it goes beyond the scope of the petition and response. *See* Update at 14 (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015)).

Rulings on a motion to strike a portion of a reply (or surreply) tend to be based on fact-specific determinations as to whether the material in question is timely and responsive, e.g., regarding the scope of the petition, the scope of the patent owner response, and timing considerations. *Compare Arista Networks, Inc. v. Cisco Sys., Inc.*, Case IPR2016-00308, slip op. at 13–15 (PTAB Feb. 17, 2017) (Paper 42) (striking portion of reply as nonresponsive) *and Veeam Software Corp. v. Symantec Corp.*, Case IPR2013-00141, slip op. at 3–5 (PTAB Apr. 7, 2014) (Paper 35) (striking certain reply declarations as beyond the scope of a reply), *with Acrux DDS PTY Ltd. v. Kaken Pharma. Co., Ltd.*, Case IPR2017-00190, slip op. at 5 (PTAB June 6, 2018) (Paper 81) (denying motion to strike rebuttal declaration and portion of reply as legitimate reply).

C. *A party might seek to strike a witness's testimony when a witness is unavailable for or refuses to submit to cross-examination.*

Cross-examination is especially important because of the provisions of the Administrative Procedure Act (APA) and the structure of Board hearings. The APA provides for cross-examination as follows: "A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d).

As a general matter, testimony is submitted to the Board in written form, with direct testimony in the form of an affidavit (or declaration) and cross-examination in the form of a deposition transcript. *See* 37 C.F.R. § 42.53(a). In certain circumstances, the Board may authorize live or video-recorded testimony, i.e., where the Board determines that the demeanor of a witness is critical to evaluating that witness's credibility. *See id.*; TPG Update at 22 (citing *K-40 Electronics, LLC v. Escort, Inc.*, Case IPR2013-00203 (PTAB May 21, 2014) (Paper 34) (precedential)).

PTAB Rules authorize, as routine discovery, the cross-examination of affidavit testimony prepared for a Board proceeding, e.g., by deposition. *See* 37 C.F.R. § 42.51(b)(1)(ii). On two occasions, the Board has granted a motion to strike a declaration where the witness could not be cross-examined. *See John's Lone Star Distribution, Inc. v. ThermoLife Int'l, LLC*, Case IPR2014-01201, slip op. at 2 (PTAB May 13, 2015) (Paper 31) (striking declaration where Petitioner refuses to make declarant available for cross-examination); *HTC Corp. v. NFC Tech., LLC*, Case IPR2014-01198, slip op. at 5 (PTAB Nov. 6, 2015) (Paper 41) (striking declaration where witness was not available for cross-examination).

II. *What is the timing for filing a motion to strike or a motion to exclude?*

Motion to Strike

Authorization to file a motion to strike should be requested within one week of the allegedly improper submission. Update at 18. According to the Update, "[w]hen authorized, the Board expects that it will decide a motion to strike as soon as practicable, and preferably before oral hearing, so that the parties need not devote time during the hearing to addressing improper arguments." *Id.*

Motion to Exclude

A motion to exclude is the final step in a series of steps, each with a specific timing. If a party seeks to challenge the admissibility of evidence, the challenging party must serve a written objection onto an opposing party within five days of receiving documentary evidence it seeks to challenge (or if there is an evidentiary issue that arises prior to institution, the challenging party must serve a written objection within ten days of institution). 37 C.F.R. § 42.64(b)(1). The party relying on evidence has ten business days after service of the objection to attempt to cure an evidentiary defect by serving supplemental evidence on the challenging party. *Id.* § 42.64(b)(2). There is a parallel process for challenging deposition testimony, i.e., the challenging party must state its objection during the deposition, and the party relying on evidence must cure the objection during the deposition (unless the parties stipulate on the deposition record to a different time). *Id.* § 42.64(a). If the challenging party is not satisfied that the alleged evidentiary defect has been cured, the challenging party must then perfect its objections by filing a motion to exclude. *Id.* § 42.64(c).

The timing for a motion to exclude (and a response and a reply) are provided for in the standard scheduling order. The Board typically will defer ruling on a motion to exclude until after the oral hearing when it reviews the record in its entirety. Update at 17. Nevertheless, a party may request a prehearing conference with the panel to seek early resolution of a motion to exclude on a limited number of objections, e.g., where the evidence is so central to the parties' dispute that early resolution is warranted and mootness is unlikely. *Id.*

III. *What is the procedure for filing a motion to strike or motion to exclude?*

Motion to Strike

A party seeking to file a motion to strike is required to consult the Board and obtain authorization to file the motion, prior to filing the motion, as is the general rule for motions at the Board. 37 C.F.R. § 42.20(b). To obtain authorization, the

parties should first consult with each other and propose mutually acceptable times for a conference call with the panel. The panel may conduct a conference call with the parties to ascertain the nature of the dispute. According to the Update, as an alternative to a motion to strike belated argument or evidence, "a party may request authorization for further merits briefing, such as a sur-reply, to address the merits of any newly-raised arguments or evidence." Update at 17. On the conference call, the panel will see if the parties have agreed on, or can agree on, a proposed course of action. After a conference call, the panel might authorize a motion to strike with attendant briefing. *See id.*

Motion to Exclude

A motion to exclude, however, "may be filed without prior authorization from the Board." 37 C.F.R. § 42.64(c). Nevertheless, parties sometimes consult the panel prior to filing a motion to exclude. Although not required, a conference call may still be helpful for the parties and the panel, e.g., if parties are unsure as to whether a motion to exclude is the proper type of motion to file. A motion to exclude should (a) identify where in the record the objection originally was made; (b) identify where in the record the evidence sought to be excluded was relied upon by an opponent; (c) address objections to exhibits in numerical order; and (d) explain the basis and grounds for each objection. Update at 16. A motion to exclude is not a vehicle for addressing the weight to be given evidence – arguments regarding weight should appear only in the merits documents. *Id.*

Conclusion

A motion to strike is different from a motion to exclude in subject matter, timing, and procedure. When a party seeks to exclude argument or evidence, it must determine which type of motion applies so that it may take appropriate steps in a timely fashion. Although authorization to file a motion is not required for a motion to exclude, parties may request a conference call with the panel prior to filing either type of motion. In all cases, parties are encouraged to consult with each other to attempt to resolve their disputes and see if they can agree upon a proposed course of action prior to seeking relief from the Board.

The New Highwayman: Enforcement of U.S. Patents on *Cannabis* Products

William J. McNichol, Jr.*

Patents play an important role in American business. Their stated purpose is to incentivize innovation[1] and there is a large body of scholarship concerning how they perform this function.[2] Scholars have noted the patent system's "natural connection to innovation."[3] Patents long played an important role in in the related function of capital formation.[4] This is no less true in the industries now emerging around sales of *Cannabis* products.[5] However, under a long line of authorities going back to *The Highwayman's Case* in 1725, the illegality

*Adjunct Professor, Rutgers University School of Law. Member of the bars of the States of New York and Washington. Admitted to practice before the U.S. Patent and Trademark Office, and the Canadian Intellectual Property Office.

[1] Article I, Section 8, Clause 8 of the U.S. Constitution prefaces its grant of Congressional power to enact patent legislation with the following statement of purpose: "To promote the progress of science and useful arts " The innovation-incentive function of patents was discussed at length by the U.S. Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). It remains the subject of academic interest. See, Adam Mossoff, *Who Cares About What Thomas Jefferson Thought About Patents? - Reevaluating the Patent Privilege in Historical Context*, 92 Cornell L. Rev. 953 (2007).

[2] For example, Michael A. Carrier, Innovation For The 21st Century (2009); Michael Kremer & Heidi Williams, *Incentivizing Innovation: Adding to the Tool Kit*, 10 Innovation Pol'y & Econ. 1 (2010).

[3] Carrier, *supra* note 2, at 2

[4] *See, e.g.* Bart Clarysse, Mike Wright, Andy Lockett, Philippe Mustar & Mirjam Knockaert, *Academic spin-offs, formal technology transfer and capital raising*, 16 Indus. & Corp. Change 609 (Aug. 2007). In addition to being assets that justify outside capital investment in a business, patents are also used by businesses to generate capital internally by licensing. *See*, Gordon V. Smith & Russell L. Parr, Intellectual Property Licensing and Joint Venture Profit Strategies (1st ed. 1993).

[5] Juliana Minn, *Patents and Pot*, Cannabiz Media, June 15, 2018, https://cannabiz.media/patents-and-pot/; Chris Arsenault, *Investors rush to patent genetically modified cannabis molecules*, CBC News, Oct. 13, 2018, https://www.cbc.ca/news/business/cannabis-genetic-biotech-patents-gmo-1.4854746; Mason Marks, *Want Your Marijuana Startup to Succeed? Study Patent Law*, Nov. 5, 2016, Wired, https://www.wired.com/2016/11/wanna-make-weed-startup-better-patent-stash/; Vanmala Subramaniam, *Cannabis companies race to clinch an edge in pot industry's next phase of growth: Intellectual property*, Nov. 18, 2018, Fin. Post, https://business.financialpost.com/cannabis/cannabis-companies-race-to-clinch-an-edge-in-pot-industrys-next-phase-of-growth-intellectual-property; Max A. Cherney, *Marijuana stocks to watch: Canopy Growth is the cannabis business's $4 billion gorilla*, Oct. 20, 2018, MarketWatch, https://www.marketwatch.com/story/marijuana-stocks-to-watch-canopy-growth-is-the-cannabis-businesss-4-billion-gorilla-2018-10-15 (noting the company's portfolio of 84 patent applications).

of the use, possession, and distribution of these products probably creates an insurmountable barrier to the enforcement of most patents that claim *Cannabis* products or their use. This means that, with respect to the *Cannabis* industry, the U.S. patent system is unlikely to play its customary roles of incentivizing innovation and encouraging investment.

Contents

I. Introduction.

The legal status of the *Cannabis* plant and that of products made from the *Cannabis* plant,[6] have been much in the news. Several state governments have amended their laws dealing with *Cannabis* to allow the production, sale, and use of *Cannabis* and *Cannabis* products for medicinal[7] or even recreational[8] purposes – at least as a matter of state law. The federal government has not changed in its laws governing *Cannabis* and *Cannabis* products. With certain exceptions described below, their possession, use, transport, and sale remain illegal under federal law.[9]

Despite *Cannabis*'s illegality under federal law, the United States Patent & Trademark Office (U.S. PTO) has issued patents in this area. According to one report, at least 3000 cannabis patents have been issued over the last 20 years and the pace of issuance of these patents is accelerating.[10] These patents deal with strains of *Cannabis*,[11] extracts of the *Cannabis* plant,[12] blends of cannabinoids,[13] methods of using or administering *Cannabis* or cannabinoids,[14] and devices for delivering *Cannabis* or cannabinoids.[15] Many patents claim methods of using *Cannabis* or cannabinoids to treat diseases, with one remarkable patent claiming the use of a cannabinoid/cyclodextrin mixture to treat "nausea, muscular spasms, multiple sclerosis, uterine cramps, bowel cramps, a movement disorder, pain, migraine headache, glaucoma, asthma, inflammation, insomnia, high blood pressure, cancer, anxiety, convulsions, depression or psychosis."[16]

Sellers of medical *Cannabis* have publicly advanced claims that their products treat a wide array of diseases and conditions. These claims are so numer-

[6]The Controlled Substances Act (discussed below) uses the term "*marihuana*," which it defines as follows: "(A) Subject to subparagraph (B), the term "marihuana" means all parts of the plant *Cannabis sativa L.*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. (B) The term marihuana does not include (i) hemp, as defined in [7 U.S.C. § 1621] ; or (ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." 18 U.S.C. § 802(16). The CSA was amended by the 2018 Farm Bill to exclude "hemp" from the definition of marijuana. Hemp is *Cannabis* that contains essentially no THC. For convenience, this paper refers to items that fall within the Act's definition of marihuana and to cannabinoids listed in Schedule I of the CSA as "*Cannabis*," and to products made from them as "*Cannabis* products."

[7]For example, the Pennsylvania Medical Marijuana Act, Act of Apr. 17, 2016, P.L. 84, No. 16.

[8]For example, California's Control, Regulate and Tax Adult Use of Marijuana Act (Prop 64), Cal. Civ. Code § 26000 *et seq.*, and Colorado's Retail Marijuana Code, codified at Colorado Rev. Statutes § 12-43.4-101 *et seq.*

[9]In *Gonzales v. Raich*, 545 U.S. 1 (2005) the U.S. Supreme Court considered whether Congress has the authority to make *Cannabis* illegal in the face of state laws allowing intrastate medical use of *Cannabis*. The Court concluded that Congress does indeed have that power under the Commerce Clause, and that the Controlled Substances Act (discussed below) was a valid exercise of that power, even to the point of criminalizing intrastate distribution and use of *Cannabis* because this affects interstate commerce.

[10]Joshua Glucoft, *Patenting Cannabis: A Look at the Numbers,* January 10, 2019, Intell. Prop. Law360, https://www.law360.com/articles/1116906/patenting-cannabis-a-look-at-the-numbers.

[11]For example, U.S. Pat Nos. 9,642,317, 9,370,164, & 9,095,554.

[12]For example, U.S. Pat Nos. 10,117,891 & 9,913,868.

[13]For example, U.S. Pat Nos. 10,117,891, 10,105,343, & 9,730,911.

[14]For example, U.S. Pat Nos. 10,118,006 & 9,308,208.

[15]For example, U.S. Pat Nos. 10,099,020 & 8,980,942.

[16]U.S. Pat No. 7,423,026.

ous and rapidly growing that it is impossible to provide a complete and up to date list of what medical *Cannabis* is supposed to treat. For example, under the Pennsylvania Medical Marijuana Act, *Cannabis* is used to treat cancer, HIV/AIDS, amyotrophic lateral sclerosis (Lou Gehrig's Disease), Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, Crohn's disease, post-traumatic stress disorder, intractable seizures, glaucoma, sickle cell anemia, severe chronic or intractable pain, and autism.[17] United Cannabis Corporation asserts on its web site that its *Cannabis* products can be used to manage "chronic pain, inflammation, sleep, appetite, glaucoma, migraine, PTSD, neuropathy, multiple sclerosis, fibromyalgia, seizures, epilepsy, paralysis, autoimmune, autism, tumors, HIV/AIDS, and many types of cancer."[18] The popular web site Leafly.com provides information on the medical properties claimed by *Cannabis* suppliers for their *Cannabis* strains, including strains said to fight muscle cramps,[19] manage migranes,[20] and treat arthritis.[21]

Sales of medical *Cannabis* have grown rapidly in recent years, especially in states where the recreational use of *Cannabis* remains illegal under state law. Well documented estimates of medical *Cannabis* sales are hard to come by, but estimates from the State of Colorado's Department of Revenue indicate that sales of medical cannabis are smaller than those of recreational Cannabis.[22] A large and growing combined medical and recreational *Cannabis* market is emerging in the states that have changed their laws to allow it. The combined medical and recreational California markets alone is estimated to be $3.7 billion in 2018 and $5.1 billion in 2019.[23] According to the Colorado Department of Revenue, the combined value of that state's medical and recreational *Cannabis* markets in 2017 was $1.5 billion.[24]

The *Cannabis* industry has attracted significant capital investment. This has ranged from multi-billion dollar capital contributions from publicly-traded companies,[25] to small investments by individual investors.[26] As is the case in

[17] Section 103, Pennsylvania Medical Marijuana Act, Act of Apr. 17, 2016, P.L. 84, No. 16.

[18] UnitedCannabis.us, United Cannabis – Products, https://www.unitedcannabis.us/products/ (last visited Jan. 15, 2018) (under sub-intro, feature-title: *A.C.T. Now*, *Who can benefit from it*).

[19] Leafly.com, Fight Your Cramps, https://www.leafly.com/start-exploring/fight-your-cramps (last visited Jan. 15, 2018).

[20] Leafly.com, Manage Migraine, https://www.leafly.com/start-exploring/manage-migraines (last visited Jan. 15, 2018).

[21] Leafly.com, Treat Arthritis, https://www.leafly.com/start-exploring/treat-arthritis (last visited Jan. 15, 2018).

[22] Colorado.gov, Marijuana Sales Reports | Department of Revenue https://www.colorado.gov/pacific/revenue/colorado-marijuana-sales-reports (last visited Jan. 15, 2018).

[23] Jeremy Berke, *California's cannabis market is expected to soar to $5.1 billion — and it's going to be bigger than beer*, Bus. Insider., Feb. 28, 2018, https://www.businessinsider.com/california-legalizing-weed-on-january-1-market-size-revenue-2017-12.

[24] Colorado.gov. Marijuana Sales Reports | Department of Revenue, https://www.colorado.gov/pacific/revenue/colorado-marijuana-sales-reports (last visited Jan. 15, 2018).

[25] Jennifer Maloney & Saabira Chaudhuri, *Corona Brewer Bets $4 Billion on Cannabis Startup*, Wall St. J., Aug. 15, 2018, https://www.wsj.com/articles/constellation-brands-expands-investment-in-cannabis-company-canopy-growth-1534332997.

[26] For example, The Arcview Group connects investors with small companies in the Cannabis industry. It claims on the homepage of its website that "Our members have invested more than $230 million in 200 ventures." ArcviewGroup.com, *The Arcview Group | Cannabis Investment & Market Research*, https://arcviewgroup.com/ (last

other industries,[27] investors who provide capital for the *Cannabis* industry place significant reliance on IP (including patents), to justify their investment and to set its price.[28]

The Cannabis industry also works to monetize its patents by pursuing licensing programs. For example, United Cannabis Corporation offers licenses under its worldwide patent portfolio on "terms that are customized to each licensee"[29]

As might be expected, the emerging *Cannabis* industry is highly competitive. Innovators in the *Cannabis* industry strive to protect their investment in new products from copying by others. This has made the enforcement of *Cannabis* patents in the federal courts[30] almost inevitable, and one such action has recently been filed: *United Cannabis Corp. v. Pure Hemp Collective, Inc.*,[31] The complaint in *United Cannabis* was filed on July 31, 2018. It alleges that the defendant infringes U.S. Pat. No. 9,730,911, which claims certain cannabinoid formulations. The complaint requests relief in the form of an injunction, treble damages (together with pre- and post-judgement interest), attorneys's fees, and costs.[32] Since the complaint was filed, the defendant has answered,[33] and the Court has entered a scheduling order[34] and a protective order.[35] The defendant has filed a motion for partial summary judgement on the ground of patent invalidity,[36] and the plaintiff has opposed that motion.[37] None of the filings from either party has raised the issues addressed in this paper.

United Cannabis Corp is thought to be the first of many patent infringement actions involving *Cannabis* patents. In each such patent infringement action, the plaintiff will ask a federal court to protect the plaintiff's monopoly in a criminal enterprise.

Thus, the federally illegal *Cannabis* industry is relying on the U.S. patent system perform its traditional roles of fostering innovation and encouraging capital investment in a non-traditional context. This paper examines two issues with respect to the effect of the continuing illegality of *Cannabis* under federal law on the ability of the patent system to perform these functions.

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visited Jan. 14, 2018).

[27] *See, e.g.*, Ted. Hagelin, T., *Valuation of Intellectual Property*, 52 Syracuse L. Rev. 1133 (2002); Richard S. Gruner, Shubha Ghosh & Jay P. Kesan, Transactional Intellectual Property: From Startups to Public Companies (2012).

[28] *See*, *supra* note 5.

[29] Unitedcannabis.us. United Cannabis – Patent & Licensing, https://www.unitedcannabis.us/patent-licensing/ (last visited Nov. 15, 2018).

[30] Federal courts have exclusive jurisdiction over patent infringement actions. 18 U.S.C. § 1338.

[31] United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 18-cv-01922-NYW (D. Colo. filed July 30, 2018).

[32] Docket entry No. 1, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 18-cv-01922-NYW (D. Colo. filed July 30, 2018).

[33] Docket entry No. 27, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 18-cv-01922-NYW (D. Colo. filed July 30, 2018).

[34] Docket entry No. 24, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 18-cv-01922-NYW (D. Colo. filed July 30, 2018).

[35] Docket entry No. 29, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 18-cv-01922-NYW (D. Colo. filed July 30, 2018).

[36] Docket entry No. 32, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 18-cv-01922-NYW (D. Colo. filed July 30, 2018).

[37] Docket entry No. 36, United Cannabis Corp. v. Pure Hemp Collective, Inc., No. 18-cv-01922-NYW (D. Colo. filed July 30, 2018).

First, this paper examines the issue of whether the U.S. PTO has the power to grant patents that claim things (i.e. *Cannabis* products) or methods of treatment (i.e. use of *Cannabis* products to treat diseases/conditions) that, under federal law, cannot be legally sold or carried out in the United States. Put simply, can the U.S. PTO grant a patent that gives the patent owner the exclusive right to commit a crime?

Second, this paper examines whether a federal court will entertain an action to enforce (by way of damages, injunctions, or both) a U.S. Patent that claims *Cannabis* products or their use. Put simply, will a federal court assist one criminal enterprise by shielding it from competition from other criminal enterprises that want to commit the same crimes?

II. The Legal Status of *Cannabis*.

Cannabis and *Cannabis* products are the subjects of federal laws which can make their transport, sale or use illegal. The two most important such laws are the Controlled Substances Act ("CSA"), and the Food Drug and Cosmetics Act ("FDCA"). These laws provide complementary but independent bases for the illegality of *Cannabis* and *Cannabis* products.

A. Illegality Under the Controlled Substances Act.

The CSA was enacted in 1970.[38] The CSA groups substances into "Schedules" according to their known usefulness and their potential for abuse.[39] These are known as Schedules I through V.[40]

Substances in the CSA's Schedule I have "no currently accepted medical use" and have a "high potential for abuse."[41] Substances in the CSA's Schedules II – V have currently accepted medical uses, and have varying degrees of potential for abuse.[42] Except for the specific "rescheduled" *Cannabis* products discussed below, *Cannabis* and all *Cannabis* products are Schedule I substances.[43] The DEA reconsidered *Cannabis's* Schedule I status in 2016 and reaffirmed its conclusion that (with exceptions discussed below) *Cannabis* products have "no currently accepted medical use" and therefore must be placed on Schedule I.[44] Also, several specific cannabinoids (chemical compounds found in the Cannabis plant, and some man-made derivatives), including THC, are Schedule I substances.[45]

[38] PL 91-513, Oct.27, 1970, codified at 21 U.S.C. Ch. 13.

[39] 21 U.S.C. § 812.

[40] 21 U.S.C. § 812(b).

[41] 21 U.S.C. § 812(b)(1).

[42] 21 U.S.C. § 812(b)(2-5).

[43] Deadiversion.usdoj.gov, Controlled Substances - Alphabetical Listing, https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf (last visited Nov. 10, 2018).

[44] Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 Fed. Reg. 53690 (Aug. 12, 2016).

[45] DEAdiversion.usdoj.gov, Controlled Substances - Alphabetical Listing, https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf (last visited Nov. 10, 2018).

Section 812 of the CSA makes it a crime to "manufacture, distribute, or dispense" Schedule I *Cannabis*,[46] subject to penalties ranging from imprisonment for up to 5 years and a fine of up to $250,000 for amounts up to 50 kg,[47] and imprisonment for 10 years to life and a fine of up to $10,000,000 for larger amounts.[48] Simple possession of Schedule I *Cannabis* is a crime, subject to imprisonment for up to 1 year and a fine of $1,000 (increased to as much as imprisonment for up to 3 years and a fine of at least $5,000 in for repeat offenders).[49]

The CSA deals with Schedule II – V substances much differently than it deals with Schedule I substances. Possession, manufacture, distribution, or dispensing of Schedule I substances are crimes. Schedule II – V substances are subject to limits on who may use them and the purposes for which they may be used, but possession, transport, use or sale of Schedule II – V substances within those limits is permitted.

Some specific *Cannabis* products have been shown to have a currently accepted medical use and a manageable potential for abuse or addiction. These specific *Cannabis* products have been "rescheduled" from Schedule I to another CSA Schedule.

For example, the active ingredient in the drug product Epidiolex is cannabadiol, a non-psychoactive cannabinoid.[50] The FDA has determined that Epidiolex is safe and effective in the treatment of certain types of seizures.[51] Epidiolex has been rescheduled to be a Schedule V substance.[52] The drug product Marinol contains the cannabinoid dronabinol (synthetic THC), which is potentially psychoactive.[53] The FDA has determined that Marinol is safe and effective in the treatment of certain forms of nausea[54] and AIDS-associated appetite loss.[55] Marinol and its FDA-approved generic copies are Schedule III substances.[56]

It is important to understand how broadly Schedule I *Cannabis* is described in the CSA, and how narrowly specific *Cannabis* products like Epidiolex and Marinol are described in Schedule II and V. The CSA defines Schedule I

[46] 21 U.S.C. § 841(a).

[47] 21 U.S.C. § 841(b)(1)(D).

[48] 21 U.S.C. § 841(b)(1)(A).

[49] 21 U.S.C. § 844(a).

[50] FDA News Release, FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy, June 25, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm.

[51] *Id.*

[52] DEA Press Release, FDA-approved drug Epidiolex placed in schedule V of Controlled Substance Act, Sept. 27, 2018, https://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act; IR.GWPharm.com, GW Pharmaceuticals plc and its U.S. Subsidiary Greenwich Biosciences Announce the DEA has Rescheduled EPIDIOLEX, Sept. 27, 2018, http://ir.gwpharm.com/node/10156/pdf.

[53] *Researching the Potential Medical Benefits and Risks of Marijuana*: *Hearing Before the S. Comm. on Crime & Terrorism*, Jul 13, 2016) (statement of Douglas C. Throckmorton, M.D., Deputy Director for Regulatory Programs, Center for Druge Evaluation & Research, Food & Drug Administration, Department of Health & Human Services) *available at* https://www.fda.gov/NewsEvents/Testimony/ucm511057.htm.

[54] *Id.*

[55] FDA.gov. Approved therapies for the treatment of complications of HIV, https://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm118949.htm (last visited Jan. 15, 2018).

[56] DEAdiversion.usdoj.gov, Controlled Substances - Alphabetical Listing, https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf (last visited Nov. 10, 2018).

Cannabis ("marihuana") in sweeping terms.[57] On the other hand, Epidiolex is described in Schedule V as:

> A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains Cannabidiol derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. [58]

The FDA-approved Epidiolex formulation is an "oral solution" that contains 100 mg/ml of cannabidiol, administered in a dose of 2.5-10 mg of cannabidiol per kg of body weight, and is labeled for use in the treatment of Lennox-Gastaut syndrome or Dravet syndrome. The definition of "rescheduled" Epidiolex does not broadly legalize the possession, manufacture, distribution, or dispensing of products containing *Cannabis* or cannabidiol.

B. Illegality Under the Food Drug & Cosmetics Act.

As its name suggests, the FDCA regulates food,[59] drugs,[60] and cosmetics[61] in interstate commerce. This paper is concerned with the FDCA's provisions that deal with drugs.

The FDCA defines a "drug" as:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
>
> (B) articles *intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals*; and
>
> (C) articles (other than food) *intended to affect the structure or any function of the body* of man or other animals; and
>
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).[62] (emphasis added)

Any product sold as a drug must be safe[63] and effective,[64] which must be established to the Food and Drug Administration's satisfaction through an application process.[65] Each drug must comply with the specific use and labeling requirements set by the FDA for that product (that is, it must not be "misbranded").[66] Each drug must also meet FDA standards of purity and consistency in its manufacture and composition (that is, it must not be "adulter-

[57] *See*, *supra* note 6.

[58] DEAdiversion.usdoj.gov, Controlled Substances - Alphabetical Listing, https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf (last visited Jan. 15, 2018).

[59] 21 U.S.C. § 241 *et seq.*

[60] 21 U.S.C. § 251 *et seq.*

[61] 21 U.S.C. § 361 *et seq.*

[62] 21 U.S.C. § 321(g)(1).

[63] 21 U.S.C. § 355(b).

[64] 21 U.S.C. § 355(b).

[65] 21 U.S.C. § 355(a).

[66] 21 U.S.C. § 352.

ated").[67] Failure to comply with these requirements is a criminal offense under the FDCA,[68] and can result in a fine of up to $10,000.00 and imprisonment for up to 3 years.[69]

Cannabis products sold pursuant to state statutes allowing the sale of "medical *Cannabis*" are clearly sold "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "to affect the structure or any function of the body of man"[70] and fall within the FDCA's definition of a drug. As such, "medical *Cannabis*" is subject to the FDCA's regulatory scheme. No medical *Cannabis* sold pursuant to these state programs purport to comply with the FDCA's regulatory requirements.[71] The FDA has an active enforcement program with respect to medical *Cannabis* and takes enforcement actions against sellers of medical *Cannabis* on the ground that they are selling unapproved drugs in violation of the FDCA.[72] The FDA also issues public warnings about medical *Cannabis* that is sold in violation of the FDCA.[73]

III. Does The U.S. PTO Have Authority To Issue Patents That Claim *Cannabis* Products or Their Use?

In this section we will consider whether the illegal subject matter of *Cannabis* patents affects the authority of the U.S. PTO to have granted them.

A valid U.S. patent must claim new[74] and useful[75] subject matter that is so great an advance over what was old that it would not have been obvious to one of ordinary skill in the art (i.e. an invention).[76] Here, we are concerned with the requirement of usefulness (*aka* utility).

A. The Early Cases on Illegal Inventions.

Justice Story's 1817 statement of the relationship between utility and illegality in *Lowell v. Lewis* is our starting point:

[67] 21 U.S.C. § 351.

[68] 21 U.S.C. § 331.

[69] 21 U.S.C. § 333.

[70] *See*, *supra* notes 16 – 20 and associated text.

[71] Marinol and Epidiolex are not sold pursuant to state medical *Cannabis* programs. They were developed and approved under the FDCA drug approval scheme. *See*, *supra* notes 46-51 and associated text.

[72] See, for example: Warning Letter from FDA to Greenroads Health, Green Roads of Florida LLC (Oct. 31, 2017) *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583188.htm; Warning Letter from FDA to Natural Alchemist, Alurent, Inc. (Oct. 31, 2017) *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583205.htm; Warning Letter from FDA to Stanley Brothers Social Enterprises, LLC (Oct. 31, 2017) *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm583192.htm; Warning Letter from FDA to Green Garden Gold, LLC (Feb. 4, 2016) *available at* https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm484947.htm.

[73] FDA.gov, Warning Letters and Test Results for Cannabidiol-Related Products, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm (last visited Jan. 13, 2018).

[74] 35 U.S.C. § 102.

[75] 35 U.S.C. § 101.

[76] 35 U.S.C. § 103.

> All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral. *For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention*.[77] (emphasis added)

Later that same year, in *Bedford v. Hunt* Justice Story restated the requirement that an invention's utility be legal as follows:

> By useful invention, in the statute, is meant such a one as may be applied to some beneficial use in society, *in contradistinction to an invention which is injurious to the morals, the health, or the good order of society.* It is not necessary to establish, that the invention is of such general utility, as to supersede all other inventions now in practice to accomplish the same purpose. It is sufficient, that it has no obnoxious or mischievous tendency ... The law, however, does not look to the degree of utility; it simply requires, that it shall be capable of use, *and that the use is such as sound morals and policy do not discountenance or prohibit*.[78] (emphasis added)

Justice Story's incorporation of a "legality and morals" requirement into the statutory requirement for utility gained immediate acceptance. Justice Bushrod Washington cited it with approval three years later in *Kneass v. Schuylkill Bank*.[79] While Justice Story's legality requirement has survived to the present day, its application has been neither frequent nor easy.

National Automatic Device Co. v. Lloyd et al. arose seventy-two years after *Lowell*. It involved a patent on a "Toy Automatic Race Course" that was described as follows:

> The proof shows that the only use to which complainant's, or, for that matter, the defendants', machines, have been so far applied, is to place them in saloons, bar-rooms, and other drinking places, where the frequenters of such places make wagers as to which of the toy horses will stop first, or which will stop nearest to a designated point, after the machine has been put in motion, by dropping a nickel in the slot; in other words, the machine in question is only used for gambling purposes.[80]

The court cited Justice Story's decision in *Bedford*, and held that, absent a legal use for the invention, it was not patentable:

> It is urged that this machine is susceptible of being utilized as a toy, or child's plaything; but it is a sufficient answer to this suggestion that no such use has been as yet made. The patent has been very

[77] Lowell v. Lewis, 15 F. Cas. 1018 (D. Mass. 1817).
[78] Bedford v. Hunt, 3 F. Cas. 1217 (D. Mass 1817).
[79] Kneass v. Schuylkill Bank, 14 F. Cas. 746, 748 (C.C. D. Pa. 1820).
[80] National Automatic Device Co. v. Lloyd *et al.*, 40 F. 89 (N.D. Ill 1889).

> recently issued, and it is possible that a useful application may yet be found for it; but as the case now stands, the only use to which the invention has been put being for gambling purposes, I must hold that it is not a useful device, within the meaning of the patent law, as its use so far has been only pernicious and hurtful. Injunction refused.[81]

Application of the rule against patents on inventions that are not legally useful continued into the 20th Century. In *Rickard v. DuBon*[82] the Second Circuit dealt with a patent on an "Improvement in the Art of Treating Tobacco Leaves." The "improvement" of this invention was to alter the appearance of low-quality tobacco so that it could be passed off as high-quality tobacco.[83] According to the court, there was no use for the invention other than to defraud customers who sought high-quality tobacco. The court held that this invention had no legal utility, was not patentable:

> In authorizing patents to the authors of new and useful discoveries and inventions, congress did not intend to extend protection to those which confer no other benefit upon the public than the opportunity of profiting by deception and fraud. To warrant a patent, the invention must be useful; that is, capable of some beneficial use as distinguished from a pernicious use.[84]

In *Fuller v. Berger*,[85] the 7th Circuit dealt with a patent on a device for detecting counterfeit coins in coin-operated devices.[86] The invention could be used in almost any coin-operated device. As it happened, the only use actually made of the invention was to detect counterfeit coins in illegal gambling machines.[87] The court considered this invention as analogous to a patent on a revolver, which it acknowledged is an "instrument of death" that could be used for many illegal purposes. This illegality was not a barrier to patentability:

> [T]o continue with Colt's revolver as an example, if at the time of a suit for infringement the defendant should prove that the only uses to which "that instrument of death" had been put were vicious, the patent should not be held void for want of utility, if the court for itself should see, or be convinced by experts; that the instrument was susceptible of good uses, though in fact never put to such before the suit was begun.[88]

In the *Fuller* court's view, as long as an invention is *capable* of a legal use, then the utility requirement is satisfied. The fact that the invention could also be used for an illegal purpose is irrelevant. Because the invention in *Fuller* could

[81] *National Automatic Device Co.*, 40 F. at 90.
[82] Rickard v. DuBon, 103 F. 868, (2d Cir. 1900).
[83] *Rickard*, 103 F. at 869, 871.
[84] *Rickard*, 103 F. at 873.
[85] Fuller v. Berger, 120 F. 274 (7th Cir. 1903).
[86] *Id.* at 274.
[87] *Id.*
[88] *Id.* at 276.

be used to protect perfectly legal coin-operated devices from counterfeit coins, it satisfied the legal utility requirement.[89]

Fuller can be seen as a case that led the introduction of what we may call the "Dual Use" exception to Justice Story's rule against patenting inventions that have illegal or immoral uses. According to the Dual Use exception, the rule against inventions that do not have legal utility does not apply to inventions that *can* be used to an illegal end. Rather, the rule applies only to inventions that *can only* be used to an illegal end.

In the 1922 case of *Brewer v. Lichtenstein* [90] the 7th Circuit again dealt with the gambling industry. In *Brewer* the patent claimed a gambling device – a variation on the classic "punch board."[91] The patent owner in *Brewer* argued that its invention fell within a Dual Use exception by pointing out some possible legal uses for the improved punch board, such as deciding tied elections or running a draft lottery.[92] The court refused to accept this argument, noting that the purported legal uses were "beyond the range of any practical utility."[93] *Brewer* can be seen as refining the Dual Use exception so that the rule against patenting inventions that can only be used to an illegal end is not defeated by merely impractical or improbable legal uses.

In *Chicago Patent Corporation v. Genco*[94] the 7th Circuit dealt with another patent on a device that could be used for gambling, this time an improved pinball machine. The Court of Appeals noted the rule against patenting inventions that are without lawful utility, but also noted that pinball can be played for nothing more than fun. Thus the patent in *Chicago Patent Corporation* did not run afoul of the rule against patenting inventions that can *only* be used to an illegal end. *Chicago Patent Corporation*'s application of the Dual Use exception is in contrast to the decision 52 years earlier in *National Automatic Device*. Both cases involved toys that could be used legally for amusement or illegally for gambling, but by the time of *Chicago Patent Corporation,* the Dual Use exception and the existence of a plausible legal use saved the patent.

B. The Modern Cases on Illegal Inventions.

The 1960 case of *Application of Nelson*[95] is rooted in case law going back to *Lowell* and *Bedford* in 1817. *Nelson* also marks the beginning of the modern treatment of this subject, and not solely because of its comparatively recent vintage.

Nelson was decided by the Court of Customs and Patent Appeals (CCPA), a predecessor court of the Court of Appeals for the Federal Circuit. The Federal Circuit has exclusive jurisdiction over appeals in patent infringement cases.[96] The Federal Circuit adopted CCPA precedents as binding in matters within its

[89] *Id.* at 276-77.
[90] Brewer v. Lichtenstein, 278 F. 512 (7th Cir. 1922).
[91] *Id.* at 512-13.
[92] *Id.* at 514
[93] *Id.*
[94] Chicago Patent Corp. v. Genco, Inc., 124 F.2d 725 (7th Cir. 1941).
[95] *In re* Nelson, 280 F.2d 172 (CCPA 1960).
[96] 28 U.S.C. § 1295(a)(1).

jurisdiction.[97] A case in which a patent owner asserts a *Cannabis* patent will fall within the Federal Circuit's appellate jurisdiction and will be decided in light of the Federal Circuit's precedents – including the CCPA precedents that it has adopted.

Nelson dealt with the scope of the utility requirement of then-new 1952 Patent Act.[98] Judge Rich traced the history of the utility requirement from the Patent Act of 1790, through Justice Story's decision in *Lowell*, the commentaries of 19th and 20th century scholars, and the development of the case law through that time.[99] In *Nelson* it was decided that the quantum of utility required to satisfy the standard set in the 1952 Act was not high, provided that the utility not be, in Justice Story's words, "injurious to the morals, the health, or the good order of society." Thus, *Nelson* carried into the modern era Justice Story's 1817 rule against patenting inventions having only illegal uses.

The law governing "illegal patents" has continued to evolve under the Federal Circuit.

The U.S. PTO continues to issue Dual Use patents. For example, in *Ex Parte Murphy et al.*, the PTO Board of Appeals reversed an Examiner's refusal to grant a patent on an improved "one armed bandit" slot machine, noting that, while illegal in much of the country, the use of slot machines "has been lawful for many years in several localities."[100]

In *Whistler Corp. v. Autotronics*,[101] a District Court was asked to enforce a patent on an improved radar detector that motorists could use to avoid being caught speeding by police radar. The policy issue that this raised was not lost on the court:

> [The Court notes] the seeming incongruity of asking a court of law to protect a device used to circumvent the law. Notwithstanding Whistler's evidence that the instant detectors have other uses, the court remains of the view that the primary and almost exclusive purpose for the radar detectors in question is to circumvent law enforcement attempts to detect and apprehend those who violate the law.

The court saw this as a Dual Utility case, much as *Fuller* and *Murphy*:

> [O]nly two states have seen fit to prohibit such devices. Unless and until detectors are banned outright, or Congress acts to withdraw patent protection for them, radar detector patentees are entitled to the protection of the patent laws.

Under the Federal Circuit, there has been an acceleration of the modern trend towards a narrower application of the requirement of legal utility. In *Juicy Whip, Inc. v. Orange Bang, Inc.*, the Federal Circuit directly addressed the modern status of this rule:

[97] South Corp. v. United States, 690 F.2d 1368 (Fed. Cir. 1982).
[98] 35 U.S.C. § 101.
[99] *Nelson,* 280 F.2d at 178-180.
[100] *Ex Parte* Murphy, 200 U.S.P.Q. 801 (Pat. Off. Bd. App. 1977).
[101] Whistler Corp. v. Autotronics, Inc., 14 U.S.P.Q. 1885 (N.D. Tex. 1988).

> To be sure, since Justice Story's opinion in *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C. D. Mass. 1817), it has been stated that inventions that are "injurious to the wellbeing, good policy, or sound morals of society" are unpatentable. As examples of such inventions, Justice Story listed "a new invention to poison people, or to promote debauchery, or to facilitate private assassination." Courts have continued to recite Justice Story's formulation, but the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.[102] (citations omitted)

In *Juicy Whip* the Federal Circuit made it clear that only a very narrow the range of illegal utility will activate this rule. *Juicy Whip* involved a patent on a juice dispenser that was designed to mislead consumers by hiding the fact that it dispensed juice that was made from a concentrate in an unattractive way. It was argued that these facts were on all fours with the Second Circuit's decision in *Rickard*. The Federal Circuit rejected the Second Circuit's reasoning in *Rickard*:

> We decline to follow *Rickard* ..., as we do not regard [it] as representing the correct view of the doctrine of utility under the Patent Act of 1952. The fact that one product [low-quality tobacco] can be altered to make it look like another [high-quality tobacco] is in itself a specific benefit sufficient to satisfy the statutory requirement of utility.[103]

The Federal Circuit explained why it turned away from the reasoning of *Rickard* by noting that the modified tobacco product in *Rickard* was not itself illegal. According to the Federal Circuit, if this tobacco ever happened to be used in furtherance of acts of unfair competition, that would be a matter for agencies charged with responsibility for that area of law:

> The requirement of "utility" in patent law is not a directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices. Other agencies, such as the Federal Trade Commission and the Food and Drug Administration, are assigned the task of protecting consumers from fraud and deception in the sale of food products.[104]

Juicy Whip, and other recent cases, illustrate another exception to the prohibition against patenting illegal subject matter. We may call it the "Regulatory Deference" exception. Where the determination of the legality of the uses that may be made of an invention is outside the expertise of the PTO, and that determination has been vested in another government agency, the PTO will grant the patent, and defer to the agency with specific expertise and authority in that area to determine whether it should take enforcement action in light of the

[102] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366-67 (Fed. Cir. 1999).
[103] *Id.* at 1367.
[104] *Id.* at 1368.

possible illegality associated with making, using or selling embodiments of the invention.

The case of *In re: Brana* expressed the Regulatory Deference exception in the context of drugs which cannot be legally marketed without prior FDA approval.

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed.Cir. 1994). Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require [FDA mandated] Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions...[105]

Thus, when an invention purports to have therapeutic or pharmacological utility, the PTO will ignore the fact that the sale of the invention will be illegal under the FDCA without prior regulatory approval[106] and defer to the FDA's eventual determination of this question.

The same reasoning applies to inventions relating to pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that a pesticide cannot be sold in the United States unless first registered by the Environmental Protection Agency after a review to determine whether it is safe.[107] Violators of FIFRA are subject to criminal penalties ranging up to a fine of $50,000 and imprisonment for 1 year.[108] The U.S. PTO grants patents on pesticide inventions, leaving it to the EPA to determine whether the pesticide can be registered under FIFRA.[109]

In recent years, the "morals" leg of Justice Story's formulation has been part of a lively debate concerning the patenting of living organisms. While enjoying considerable academic support,[110] the alleged immorality of constructing genetically engineered organisms as a bar to patentability has not been persuasive in the U.S. Congress or the U.S. courts.[111]

On the other hand, in at least one recent instance the "illegality" leg of Justice Story's formulation has been persuasive in the context of genetic engineering. Soon after the *Chakrabarty* decision, the U.S. PTO began to issue patents on engineered organisms. The U.S. PTO required that these patents define their

[105] *In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995).

[106] See, *supra* notes 43-46 and accompanying text.

[107] 7 U.S.C. § 136a(a).

[108] 7 U.S.C. § 136l(b).

[109] For example, U.S. Pat. Nos. 10,117,433, 9,918,470, & 9,756,858.

[110] For example, Kathleen Liddell, *Immorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality*, *in* New Frontiers in the Philosophy of Intellectual Property (Annabelle Lever ed., 2012), University of Cambridge Faculty of Law Research Paper No. 55/2016 *available at* https://ssrn.com/abstract=2865820.

[111] *See*, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), which rejected the contention that genetically engineered microorganisms could not be patented.

inventions in such a way as to exclude genetically engineered humans.[112] The rationale for this exclusion was that a patent gives its owner the exclusive right to make use and sell the invention,[113] and the extension of this right to making, using or selling a human being would be illegal under the 13th Amendment to the U.S. Constitution.[114] In 2011 the Leahy-Smith America Invents Act amended to the Patent Act to incorporate this prohibition into the Patent Act.[115] The U.S. PTO takes the position that this amendment to the Patent Act merely codified its existing practice under the 13th Amendment.[116] Some have questioned whether this prohibition should apply to genetically engineered human embryos on the ground that embryos are not persons.[117] This interesting suggestion has been disputed,[118] but it appears to recognize that, at least upon assuming personhood at birth, a genetically engineered human would indeed come within the protection of the 13th Amendment, and a patent on that person would violate the rule that patentable inventions have legal utility.

Thus, while it has been modified in ways that Justice Story may not have anticipated, and certainly applied in a context that he could not have imagined in 1817, the requirement that an invention have legal utility in order to be eligible for patenting still has vitality.[119]

C. The U.S. PTO's Limited Authority To Grant Patents on Illegal *Cannabis* Inventions.

With this understanding of the requirement of "legal utility" in mind, it appears that the U.S. PTO has the authority to grant *Cannabis* patents that claim *Cannabis* drugs and/or the use of *Cannabis*-containing compositions to treat disease, but not other *Cannabis* patents.

Current law provides at least the possibility of legal uses of *Cannabis* as a *drug* under the CSA and the FDCA. As we have seen with *Cannabis* products like Epidiolex and Marinol, FDA approval of a *Cannabis* drug can lead to rescheduling of that specific drug formulation by the DEA. Under the Regulatory Deference exception, this window of potential legality is sufficient to allow the U.S. PTO to grant patents on *Cannabis* drug formulations and medical uses

[112]For example, U.S. Pat. No. 4, 736,866 covering the "Harvard Mouse" or "Oncomouse," an organism that was genetically engineered to be especially useful in cancer research. This patent defined its invention as "A transgenic *non-human* mammal . . . ."

[113]35 U.S.C. § 154.

[114]See, 1077 Off. Gaz. Pat Off. 24 (1987).

[115]This act provides that: "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism." Pub. Law 112-29, § 33(a).

[116]See, the U.S.P.T.O. Manual of Patent Examining Procedure (MPEP) § 2105.

[117]Dan L. Burk, *Patenting Human Embryos: A Nonuse Cost Perspective*, 30 Hous. L. Rev. 1597 (1993).

[118]Esther Slater McDonald, *Patenting Human Life and the Rebirth of the Thirteenth Amendment*, 78 Notre Dame L. Rev. 1359 (2003).

[119]The continued vitality of this rule in the United States is consistent with international trends in patent law. For example, Article 53(a) of the European Patent Convention provides that "European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to '*ordre public*' or morality." This has been interpreted to exclude human cloning and human embryos from patentability. EPC Rule 23(d). Article 27 of the TRIPS Agreement (a 1995 treaty to which the U.S. is a party) provides that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality . . . ."

of *Cannabis*, leaving other legal issues to the FDA and the DEA.

Patents on *Cannabis* products that do not have a purported medical use are another matter.[120] "Recreational" or "adult" use of *Cannabis* is not legal under current federal law in any circumstances. The FDA does not have jurisdiction over recreational substances and cannot approve them under its drug regulation authority. Consequently, the DEA has no authority to move recreational *Cannabis* to a less restrictive Controlled Substances Act Schedule, because those Schedules require a recognized medical use – something that a purely recreational substance does not have. Since there is no possibility under current law that combined action by the FDA and the DEA in exercise their special regulatory expertise could legalize recreational *Cannabis*, there is no justification for the U.S. PTO to defer to these regulatory agencies with respect to the possible legal utility of inventions directed towards recreational *Cannabis*.

Any attempt to patent *Cannabis* products other than "medical *Cannabis*" presents the U.S. PTO with an invention that has no present or potential legal utility under current law and is therefore ineligible for patenting. Such applications must be rejected. A different result would require the complete abrogation of the rule that requires inventions to have legal utility, something that no U.S. court has ever been willing to do.[121]

IV. Are Infringement Actions Based On *Cannabis* Patents Barred *As Ex Turpi Causa*?

Even if the U.S. PTO has the authority to grant patents that claim a *Cannabis* product or its use, there is a serious policy objection to the enforcement of such a patent in the U.S. courts. This objection arises under the doctrine of *Ex turpi causa non oritur actio* ("From a dishonorable cause an action does not arise."). In recent times this has also become known as the Illegality Rule. It is deeply rooted in the common law and operates to protect the integrity of the law and the courts. Any attempt to enforce a *Cannabis* patent must take account of it.

A. Origins Of The Illegality Rule.

The earliest recorded application of the doctrine of *Ex turpi causa* is the 1725 English case of *Everett v. Williams*, better known as *The Highwayman's Case*.[122] In that case, two highwaymen committed a series of robberies. Later, one highwayman sued the other, claiming that he had been cheated out of his agreed share of the proceeds of the robberies. The Court refused to consider the suit,

[120] Examples of non-drug inventions include: *Cannabis* products that purport to produce particularly preferred or satisfying states of intoxication, speed of onset or duration of intoxication, and products that allow one to regulate the degree of intoxication.

[121] Not even the *Juicy Whip* case was willing to discard the requirement for legal utility. The farthest that it was willing to go was to observe that Justice Story's rule "has not been applied broadly in recent years." *Juicy Whip*, 185 F.3d at 1367.

[122] This case is noted at 9 L.Q. Rev. 197 (1893).

turned the highwaymen over to the sheriff, and fined their lawyers for bringing a suit "both scandalous and impertinent."[123]

The Illegality Rule is applied to this day, most often but by no means exclusively in contract cases. Given its origins in the received common law, it is worthwhile to examine how the Illegality Rule has developed in England and in other common law jurisdictions before we attempt to predict how the Illegality Rule will be applied in the novel context of the enforcement of *Cannabis* patents in the United States.

B. The English Cases.

Fifty years after *The Highwayman's Case*, the Illegality Rule arose again in *Holman v. Johnson*,[124] where Lord Mansfield stated its rationale and effect as follows:

> No court will lend its aid to a man who founds his cause of action on an immoral or an illegal act. If, from the plaintiff's own stating or otherwise, the cause of action appears to arise *ex turpi causa*, or the transgression of a positive law of this country, there the court says that he has no right to be assisted. It is upon that ground the court goes; not for the sake of the defendant, but because *they will not lend their aid to such a plaintiff.* ... The objection, that a contract is immoral or illegal as between plaintiff and defendant, sounds at all times very ill in the mouth of the defendant. It is not for his sake, however, that the objection is ever allowed; but it is founded in general principles of policy, which the defendant has the advantage of, contrary to the real justice, as between him and the plaintiff . . .[125]
>
> (emphasis added)

Lord Mansfield's statement of the Illegality Rule in *Holman* remains influential to this day[126] and is probably the most often cited statement of the Illegality Rule in the common law world. According to Lord Mansfield's judgement in *Holman*, the court must turn the parties out of court because to do otherwise would involve the court in furthering an illegality – an activity that would be contrary the very purpose of the court's existence and would offend the dignity of the court.[127] No attempt is made to decide questions of justice as between the parties.

The English courts wrestled with this indifference to just outcomes as between the parties in *Tinsley v. Milligan*,[128] a case where two unmarried women used their joint funds to purchase a home, but they recorded its legal ownership in only one of their names so that the other could continue to receive Social

[123] *Id.*
[124] Holman v. Johnson, (1775) 98 Engl. Rep. 1120, 1 Cowp. 341.
[125] *Id.* at 343.
[126] Patel v. Mirza, [2016] UKSC 42 at ¶ 227.
[127] Les Laboratoires Servier v. Apotex, [2014] UKSC 55, at ¶ 24.
[128] Tinsley v. Milligan, [1993] 68 P.&C.R. 412.

Security benefits. The woman who wrongly obtained the Social Security benefits later repented of this small illegality and made right with the government, which "did not regard the situation with any alarm."[129] The two women had a falling out and in the ensuing dispute over the ownership of the home, the woman who was not recorded as a legal owner asserted her equitable ownership of the house. The sole legal owner raised the Illegality Rule as a defense to that claim. Seeking to avoid a harsh and unjust result, the Court of Appeal held that the Illegality Rule should be applied only when the illegality was so great that it was an "affront to the public conscience," which was not the case on these facts. On appeal, the House of Lords noted that the Illegality Rule is "indiscriminate"[130] and "does not ... involve any balancing exercise."[131] Accordingly, the Illegality Rule did not allow courts to "distinguish between degrees of iniquity."[132] The House of Lords avoided the harsh effect of the Illegality Rule by adopting the view that the claim in *Tinsley* was made pursuant to a perfectly legal trust arrangement that arose when the parties first pooled their money to buy the house, not on their subsequent illegal agreement to defraud the government.[133]

The Illegality Rule's disregard for whether there is a just result between the parties has continued to trouble the English courts. In *Les Laboratoires Servier v. Apotex*,[134] Lord Sumption described this discomfort: "The [Illegality Rule] necessarily operates harshly in some cases, for it is relevant only to bar claims which would otherwise have succeeded. For this reason it is in the nature of things bound to confer capricious benefits on defendants some of whom have little to be said for them in the way of merits, legal or otherwise."[135]

These uncomfortable results have led the English courts to try to find ways to restrict the application of the Illegality Rule. In *Les Laboratoires Servier,* Lord Sumption noted that "The paradigm case of an illegal act is engaging in a criminal offence"[136] and argued for limitation of the Illegality Rule to cases involving criminal or quasi-criminal offenses.[137]

In 2016 the English courts's discomfort with the sometimes unjust results of the Illegality Rule led the U.K. Supreme Court in *Patel v. Mirza*[138] to abandon the use of a "formal approach" in the application of the Illegality Rule in favor of a flexible, case-by-case evaluation of whether refusal to enforce a claim founded on an illegal act or agreement would be in the public interest. The U.K. Supreme Court adopted the following framework for that case-by-case evaluation:

> In assessing whether the public interest would be harmed in that way, it is necessary a) to consider the underlying purpose of the prohibition which has been transgressed and whether that purpose

[129] *Id.* at 417.
[130] *Id.* at 419.
[131] *Id.* at 423.
[132] *Id.* at 426.
[133] *Id.* at 430-31.
[134] Les Laboratoires Servier v. Apotex, [2014] UKSC 55
[135] *Id.* at ¶ 13.
[136] *Id.* at ¶ 23.
[137] *Id.* at ¶ 28.
[138] Patel v. Mirza, [2016] UKSC 42.

> will be enhanced by denial of the claim, b) to consider any other relevant public policy on which the denial of the claim may have an impact and c) to consider whether denial of the claim would be a proportionate response to the illegality, bearing in mind that punishment is a matter for the criminal courts. Within that framework, various factors may be relevant, but it would be a mistake to suggest that the court is free to decide a case in an undisciplined way. The public interest is best served by a principled and transparent assessment of the considerations identified, rather by than the application of a formal approach capable of producing results which may appear arbitrary, unjust or disproportionate.[139]

While this sort of flexibility in determining the cases in which English courts will apply the Illegality Rule will inevitably create some degree of uncertainty,[140] even the *Patel* judgement made it clear that certain criminal activities will surely activate the Illegality Rule:

> There may be circumstances in which a court will refuse to lend its assistance to an owner to enforce [a claimant's] title as, for example, where to do so would be to assist the claimant *in a drug trafficking operation* ...[141]
> (emphasis added)

Thus, whatever uncertainty the "range of factors" approach adopted in *Patel* may introduce into the application of the Illegality Rule, the U.K. Supreme Court seems to have sent a clear signal as to how the *Patel* test will be applied in cases involving "paradigmatic illegality," such as drug trafficking: (a) where specific commercial activities (e.g. trafficking in illegal drugs) are specifically prohibited by criminal law (e.g. drug dealing), the refusal to adjudicate disputes concerning those commercial activities will further the public policy underlying that criminal prohibition, (b) no other policy argues in favor of a court adjudicating disputes concerning the fruits of paradigmatic criminal illegality, and (c) refusal to adjudicate disputes concerning the fruits of paradigmatic criminal illegality would still leave the enforcement of the criminal law to institutions and officials charged with responsibility in such matters.

C. Canadian Application of the Illegality Rule.

The Canadian Supreme Court's 1993 decision in *Hall v. Herbert*[142] dealt with how the Illegality Rule should be applied in the context of a tort action. It also considered the broader question of whether the Illegality Rule should be restricted or even abandoned altogether in Canada.[143] After exploring the purposes of the Illegality Rule, Justice McLachlan concluded that there existed

[139] *Id.* at ¶ 120.
[140] *Id.* at ¶ 263.
[141] *Id.* at ¶ 110.
[142] Hall v. Herbert, [1993] 2 S.C.R. 159.
[143] *Id.* at ¶¶ 3-4.

a "fundamental rationale for the defence of *ex turpi causa*, that based on the need to maintain internal consistency in the law, in the interest of promoting the integrity of the justice system."[144] In her view, the Illegality Rule exists so that courts may avoid creating an "intolerable fissure in the law's conceptually seamless web"[145] by "giving with one hand what it takes away with the other."[146] According to the Canadian Supreme Court's judgement in *Hall*, the Illegality Rule must be applied whenever necessary to avoid inconsistency in the law, typically where adjudicating the claim would further criminal acts or enterprises:

> The doctrine of *ex turpi causa non oritur actio* properly applies in tort where it will be necessary to invoke the doctrine in order to maintain the internal consistency of the law. Most commonly, this concern will arise where a given plaintiff genuinely seeks to *profit from his or her illegal conduct*, or where the claimed compensation would amount to *an evasion of a criminal sanction*.[147]
> (emphasis added)

In *Hall*, the plaintiff was injured as a result of the negligence of the defendant. These injuries were the culmination of an evening during which the parties jointly engaged in excessive drinking, and operation of a vehicle while under the influence.[148] The Supreme Court concluded that, because ordinary principles of contributory negligence (in this instance a 25/75 split of responsibility) operated to prevent the plaintiff from benefiting from his own misconduct, application of the Illegality Rule to "maintain the internal consistency of the law" was unnecessary.[149]

Hall is controlling precedent in Canada. It has also been cited with approval elsewhere, such as the U.K., where it has been described as "much admired."[150]

D. *Ex Turpi Causa* And The Illegality Rule In The United States.

In the United States, cases applying the Illegality Rule first arose in the 19th Century and continue to do so today.

1. The Early U.S. Cases.

In the 1886 case of *Higgins et al. v. McCrea*,[151] the defendant's counterclaim was based on a series of contracts dealing with illegal gambling transactions.[152] The U.S. Supreme Court held that the illegality of these contracts precluded the defendant's counterclaim on them:

[144] *Id.* at ¶ 21.
[145] *Id.* at ¶ 21.
[146] *Id.* at ¶ 21.
[147] *Id.* at ¶ 40.
[148] Fully set out in *Hall*, [1993] 2 S.C.R. 159 at ¶ 44 – 48.
[149] *Hall*, [1993] 2 S.C.R. 159 at ¶ 40.
[150] *Patel*, [2016] UKSC 42 at ¶ 230.
[151] Higgins et al. v. McCrea, 116 U.S. 671 (1886).
[152] The contract in question was a commodity option contract, which at that time was considered a form of gambling that was specifically declared illegal by statute. *Id.* at 674.

> [B]y the statutes of Illinois, where the contracts were made, they were treated as gaming contracts, and declared illegal and void, and the making of them a criminal offense. ... We do not see on what ground a party who says in his pleading that the money which he seeks to recover was paid out for the accomplishment of a purpose made an offense by the law, and who testifies and insists to the end of his suit that the contract on which he advanced his money was illegal, criminal, and void, can recover it back in a court whose duty it is to give effect to the law which the party admits he intended to violate.[153]
> (citations omitted)

The *Higgins* court relied on Lord Mansfield's judgement in *Holman*, agreeing that when a cause of action arises out of a "transgression of a positive law of the country," the courts "will not lend their aid to such a plaintiff."[154] Judgement was entered dismissing the counterclaim based on the illegal gambling contract.[155]

The application of the Illegality Rule in *Higgins* produced a harsh result. The counterclaimant advanced money under the contract, but received neither performance nor restitution of the advanced money. The court simply left the parties as they were when they came before the court. This was justified by the paramount policy that the court not aid the violation of a law that it was otherwise bound to enforce. Thus, *Higgins* is very much in harmony with its contemporaries *The Highwayman's Case,* and *Holman*. *Higgins* viewed consistency in the court's adherence to and enforcement of the law as supremely important.

In 1899 the U.S. Supreme Court again applied the Illegality Rule in *McMullen v. Hoffman*.[156] *McMullen* dealt with a series of contracts between bidders that were made in furtherance of an illegal bid-rigging scheme.[157] The Supreme Court surveyed the law going back to *The Highwayman Case*, and stated the Illegality Rule as follows:

> There are several old and very familiar maxims of the common law which formulate the result of that law in regard to illegal contracts. They are cited in all law books upon the subject, and are known to all of us. They mean substantially the same thing and are founded upon the same principles and reasoning. ... The authorities from the earliest time to the present unanimously hold that no court will lend its assistance in any way towards carrying out the terms of an illegal contract. In case any action is brought in which it is necessary to prove the illegal contract in order to maintain the action, courts will not enforce it, nor will they enforce any alleged rights directly springing from such contract.[158]

[153] *Id.* at 684-85.
[154] *Id.* at 686.
[155] *Id.* at 687.
[156] McMullen v. Hoffman, 174 U.S. 539 (1899).
[157] *Id.* at 646 - 649.
[158] *Id.* at 654.

The *McMullen* court praised the deterrent effect of the Illegality Rule, noting that "To refuse to grant either party to an illegal contract judicial aid for the enforcement of his alleged rights under it tends strongly towards reducing the number of such transactions to a minimum."[159] The *McMullen* court refused to enforce the contracts, concluding that "the law will leave the parties as it finds them."[160]

2. The Modern U.S. *Ex Turpi Causa* Cases.

In the 20th and 21st Centuries, the Illegality Rule has been applied regularly in the U.S. courts. Unlike the courts in the U.K.[161] and Canada,[162] the U.S. courts have not undertaken a through reexamination of the policy basis for the Illegality Rule or of its continued relevance. Modern U.S. cases recognize and apply the Illegality Rule, but do so without analyzing its foundation in policy, typically relying upon a talismanic reference to *Higgins* and/or *McMullen*.[163] That said, there is no doubt that the Illegality Rule is alive and well in the U.S. federal courts.

In the 1961 case of *United States v. Mississippi Valley Generating Co.*,[164] the Supreme Court held that a contract made in violation of a criminal conflict of interest statute ran afoul of the Illegality Rule and would not be enforced. In 1966, the Supreme Court held in *United States v. Acme Process Equipment Co.*[165] that a contract made in violation of the criminal provisions of the Anti-Kickback Act tainted the contract and it would not be enforced. As recently as 2018, the Supreme Court cited its 1899 *McMullen* decision for the proposition that "illegality is a public policy defense" in a civil action.[166]

The Illegality Rule was applied in *Mississippi Valley* and *Acme Process*, cases that involved violations of criminal statutes – paradigmatic illegality. In the 1987 case of *United Paperworkers International Union v. Misco, Inc.*, the Supreme Court was asked to apply the Illegality Rule where the misconduct was not criminal. The Court cautioned that whether the illegality is sufficient to invoke the Illegality Rule must be "ascertained by reference to the laws and general precedents and not from general considerations of public interests."[167]

United Paperworkers was an appeal from a decision setting aside an arbitral

[159] *Id.* at 670.

[160] *Id.* at 670.

[161] The U.K. Supreme Court has carefully reexamined the purpose and scope of the Illegality Rule four times since 1994: in *Tinley* (1994), *Laboratoires Servir* (2012), *Patel* (2014) and *Jetivia* (2015). Additionally, the UK Law Commission published an extensive analysis of the Illegality Rule in 2010 (*The Illegality Defense* (Law Com. 320)) which informed the U.K. Supreme Court's analysis.

[162] Hall v. Herbert, [1993] 2 S.C.R. 159.

[163] When examining the English cases decided before 1994, Lord Sumption observed this same tendency to cite seminal cases, such as *Holman*, and then apply the Illegality Rule in "each case in its own factual and legal context without regard to broader legal principle." *Jetivia v. Bilta*, [2015] UKSC 23 ¶ 61. Lord Sumption has also noted that over this same time, judicial examination of the Illegality Rule "has rarely risen above the level of indignant judicial asides." Patel v. Mizra, [2016] UKSC 42 at ¶228.

[164] United States v. Mississippi Valley Generating Co., 364 U.S. 520 (1961).

[165] *United States v. Acme Process Equipment Co.*, 385 U.S. 138 (1966), *reh'g den*ied 385 U.S. 1032.

[166] *Epic Systems Corp. v. Lewis*, 584 U.S. __, 138 S.Ct. 1612, 1633 (2018) (Thomas, concurring).

[167] United Paperworkers Int'l Union v. Misco, Inc., 484 U.S. 29, 43 (1987) (citing W.R. Grace v. Rubber Workers, 461 U.S. 757, 766 (1983)).

decision that set aside an employee's dismissal. The employee's union contract allowed dismissal only for certain reasons, including violation of a rule that forbade bringing drugs onto the employer's property.[168] The employee, who operated dangerous, heavy equipment, had been arrested for possession and use of *Cannabis* at home and for being in another employee's car in the employer's parking lot while *Cannabis* was in use. An arbitrator found that neither of these acts by the employee constituted a violation by the employee of the prohibition against bringing drugs onto the employer's property, and ordered the employee reinstated.[169] The employer sought to be relieved from its contractual obligation to accept the arbitrator's decision, contending that the contract furthered the employee's illegal conduct outside the workplace which might affect his conduct in the workplace. The Fifth Circuit agreed and held that reinstating the employee would be "contrary to the public policy against the operation of dangerous machinery by persons under the influence of drugs or alcohol."[170] The Supreme Court reversed, holding that "Although firmly rooted in common sense, ... a formulation of public policy based only on "general considerations of supposed public interests" is not the sort that permits a court to set aside [a contract]"[171]

United Paperworkers may be said to stand for the proposition that the Illegality Rule is not an open commission for judges to refuse to adjudicate claims that seem to them to be generally unwise as a matter of public policy. Instead, application of the Illegality Rule is reserved to cases where the cause of action arises out of, or is in furtherance of, a clear violation of existing law. In cases like *Mississippi Valley* and *Acme Process*, where the plaintiff's claim is founded on a criminal offense – paradigmatic illegality – the Illegality Rule seems to always apply. In cases like *United Paperworkers*, where a claim is not asserted in furtherance of criminality, courts should not refuse to adjudicate disputes on that claim.

In *Formby-Denson v. Dept. of the Army*,[172] the Federal Circuit (which has exclusive appellate jurisdiction over patent infringement actions[173]) was confronted with a litigation settlement that included a non-disclosure agreement. The non-disclosure agreement was said to include an obligation to not disclose/refer the parties' actions to prosecutors. One party did volunteer information to prosecutors, and the other party sought sanctions for that breach of the settlement agreement.[174] The Federal Circuit cited *McMullen* for the proposition that "courts may not enforce contracts that are contrary to public policy."[175] The Federal Circuit went on to observe that "As the Supreme Court has noted, [c]oncealment of crime has been condemned throughout our history. The citizen's duty to raise the 'hue and cry' and report felonies to the author-

[168] *United Paperworkers Int'l Union*, 484 U.S. at 33.

[169] Evidence that the employee may have had Cannabis in his own car in the employer's parking lot was excluded. *Id.* at 34.

[170] *Id.* at 42.

[171] *Id.* at 44.

[172] Formby-Denson v. Dept. of the Army, 247 F.3d 1366 (Fed. Cir. 2001).

[173] 28 U.S.C. § 1295(a)(1).

[174] *Formby-Denson*, 247 F.3d at 1370.

[175] *Id.* at 1374.

ities was an established tenet of Anglo Saxon law at least as early as the 13th century."[176] The Court also noted that a failure to meet this "duty to raise the hue and cry" over a crime is itself a crime (i.e. misprision of felony).[177] The Federal Circuit concluded that "it is a long-standing principle of general contract law that courts will not enforce contracts that purport to bar a party ... from reporting another party's alleged misconduct to law enforcement authorities for investigation and possible prosecution."[178] The Federal Circuit held that this contract to commit what would be a crime would not be enforced by the federal courts. *Formby-Denson* thus joins the line of cases reaching back to *McMullen* where federal courts abstained from adjudicating disputes concerning claims that arise out of or are in furtherance of criminal acts.

3. Owners of *Cannabis* Patents Are The New Highwaymen.

It is likely that any patent infringement action brought in federal court will run afoul of the Illegality Rule and be dismissed as *ex turpi causa*.

i) *Cannabis* Patent Infringement Actions Are Tainted As Furthering Criminal Acts.

When a *Cannabis* patent owner seeks damages in a patent infringement action, the patent owner seeks compensation in the amount of (1) the royalty that the infringer should have paid for the Patent Owner's cooperation/permission for committing criminal offenses (i.e. making, using or selling *Cannabis* products), or (2) the profits that the patent owner would have made by performing those same criminal offenses but lost because the infringer did so instead. Under either damages theory, the patent owner seeks the profits that came from committing a crime. In the case of medical *Cannabis* products, the profits would be the fruit of two crimes: violations of the CSA[179] and the FDCA. In the case of recreational Cannabis products, the profits would be the fruit of only one crime: a violation of the CSA.

The same problem arises if the *Cannabis* patent owner seeks the remedy of an injunction against future patent infringement. In order to obtain an injunction, the patent owner must show that 1) the patent owner will suffer an irreparable injury without the injunction, 2) that money damages will be inadequate compensation, 3) that the balance of hardships between the parties favors an injunction, and 4) that the public interest would be served by the

[176] *Id.* at 1375.

[177] 18 U.S.C. § 4 Misprision of Felony. Whoever, having knowledge of the actual commission of a felony cognizable by a court of the United States, conceals and does not as soon as possible make known the same to some judge or other person in civil or military authority under the United States, shall be fined under this title or imprisoned not more than three years, or both.

[178] *Formby-Denson*, 247 F.3d at 1378.

[179] There is a possibility that cannabinoids not derived from the *Cannabis* plant would not fall within the CSA's prohibitions concerning *marihuana*, which do not cover cannabinoids *per se*, but only compounds derived from certain parts of the *Cannabis* plant. See, *supra* note 6. On the other hand, the DEA has listed certain specific cannabinoids, including THC, as a Schedule I substances *per se*, no matter how they are produced or how they are obtained. In any case, even if the CSA does not apply, the FDCA will still apply if the cannabinoids are sold as drugs (i.e. "medical marijuana").

injunction.[180] It is difficult to imagine a scenario where a patent owner could avoid arguing that the "irreparable injury" is an injury to a criminal enterprise, under the CSA, the FDCA, or both. It is similarly difficult to imagine a scenario where a *Cannabis* patent owner could avoid arguing that it is somehow in the "public interest" to protect the patent owner's criminal enterprise.[181]

Cases from the U.S. federal courts send a clear message: courts will not lend their aid to a criminal enterprise by adjudicating disputes over entitlement to the fruits of a criminal enterprise (e.g. trafficking in Schedule I controlled substances and/or unapproved medicines). In this respect, a *Cannabis* patent infringement action differs very little from *The Highwayman's Case*, and the reasoning of Lord Mansfield in *Holman* seems directly applicable: "If, from the plaintiff's own stating or otherwise, the cause of action appears to arise *ex turpi causa*, or the transgression of a positive law of this country, there the court says that he has no right to be assisted."[182] Note also *Higgins's* endorsement of the observation that: "No court will lend its aid to a man who founds his cause of action on an illegal act."[183] The *Cannabis* patent owner's infringement action clearly arises out of or is in furtherance of "the transgression of a positive law of this country," perhaps several laws.[184]

It may be pointed out that *The Highwayman's Case*, *Holman*, *Higgins*, *Formby-Denson* and many other cases in this vein were contract cases, and an attempt may be made to distinguish them on that basis. This argument fails for two reasons.

Historically, the Illegality Rule has never been limited to contract actions.[185] Further, the Illegality Rule is not founded in principles that pertain to contract law. Rather, it is a doctrine by which a court can avoid advancing a violation of the very law that courts exist to enforce. "The policy is one of judicial abstention, by which the judicial power of the state is withheld where its exercise in accordance with the ordinary rules of law would give effect to advantages derived from an illegal act."[186] As was said in *Hall*, the Illegality Rule is "based on the need to maintain internal consistency in the law, in the interest of promoting the integrity of the justice system [and avoid] an intolerable fissure in the law's conceptually seamless web."[187] With this reasoning in mind, there is no principled basis for restricting the operation of the Illegality Rule to contract cases. It is fully applicable to any case – including patent infringement cases.

[180] eBay Inc. v. MercExchange, LLC, 547 U.S. 388, 391 (2006).

[181] Indeed, the *Cannabis* patent owner's request for the court's assistance is premised on the argument that it is in the public interest that the patent owner enjoy monopoly pricing for its illegal products.

[182] Holman v. Johnson, *supra* note 124, 1 Cowp. 341, 343.

[183] *Higgins*, 116 U.S. at 686.

[184] In a different context, the Bankruptcy Court of the District of Colorado has already reached a similar conclusion. In *In re: Way to Grow*, the court dismissed the debtor's bankruptcy petition because, *inter alia*, it would have required the U.S. bankruptcy trustee to operate a business that is illegal under the CSA for the benefit of creditors – even if only temporarily. Docket entry No. 379, *In re* Way to Grow, No. 18-14330-MER (D. Colo filed May 18, 2018).

[185] For example, *Hall* was a tort case and explicitly rejected the idea that the Illegality Rule should not be applicable in tort cases.

[186] *Jetivia*, [2015] UKSC at ¶60.

[187] *Hall*, [1993] 2 S.C.R. at ¶ 21.

ii) Adjudicating A Cannabis Patent Infringement Action Would Introduce An Inconsistency In The Law.

Consideration of the following hypothetical will be a worthwhile exercise: A U.S. District Judge finds persons A and B brought to court one morning, each separately convicted of violating the CSA by distributing large quantities of *Cannabis* products. The judge sentences both A and B to prison for 2 years. That afternoon, attorneys for A appear in that same judge's courtroom to argue that A should be awarded damages in a *Cannabis* patent infringement case for the profits that A lost because of B's sales of illegal *Cannabis* products – sales for which the judge sent B to jail that morning. A's attorneys argue that A is entitled to an award of profits that A lost to B because A would have made those sales of illegal *Cannabis* products himself – and added to A's criminal distribution of *Cannabis* for which the judge sent A to jail that morning. This scenario illustrates a principal concern that underlies the Illegality Rule. Adjudicating A's patent infringement claim would introduce a manifest inconsistency in the law, and "would amount to the law giving with one hand what it takes away with the other,"[188] the very scenario warned against in the much admired *Hall* decision. It is hard to imagine a judge who would be comfortable being a part of this scenario.

A particularly difficult variation on this scenario involves the overlay of the Federal Civil Forfeiture statute. Under this law, the proceeds of any "specified unlawful activity" including "the manufacture, importation, sale, or distribution of a controlled substance"[189] are subject to forfeiture to the U.S. government.[190] Thus, B could be required to both (a) pay B's profits to A as damages, and (b) forfeit an amount equal to those same profits to the U.S. government. In turn, A would be required to forfeit to the U.S. government the proceeds of A's own criminal sales and also the lost criminal profits damages award obtained from B. At this point, the wisdom of Justice McLaghlin's warning in *Hall* concerning the inconsistency of simultaneously punishing and rewarding a person for their criminal enterprises becomes painfully apparent. The law's "conceptually seamless web" becomes absurdly tangled, reduced to enforcing *Cannabis* patent rights for no apparent purpose other than to create an irrationally amplified forfeiture windfall for the government. The specter of this absurd forfeiture scenario is certain to repel the court, and to lead it to embrace the application of the Illegality Rule.

iii) The Illegality Rule Can Not Be Waived By The Parties And Should Be Raised By The Court *Sua Sponte*.

If the defendant in a *Cannabis* patent infringement action does not raise the Illegality Rule, the court can and should raise this issue itself. As with any matter involving the public interest and the integrity of the court, it may raise the Illegality Rule *sua sponte*. This was certainly what happened in *The Highwayman's Case*, where lawyers on both sides were punished for bringing the case to

[188] *Hall*, [1993] 2 S.C.R. at ¶ 21.
[189] 18 U.S.C. § 1956 (c)(7)(B0(i).
[190] 18 U.S.C. § 981 (a)(1)(C).

court. As the U.S. Supreme Court observed in *Higgins*, "The [trial] court was bound to take judicial notice that the dealings recited in the counter-claim were forbidden by law, and of its own motion should have directed a verdict . . . ."[191] In *Krieger*, the court held that "[U]nder both federal and New York law, it is not absolutely necessary to plead the illegality . . . the court may, *sua sponte*, step in and deny the right to relief . . . ."[192] (citations omitted)

4. Effects On Innovation And Investment In The Cannabis Industry.

It is likely that the first application of the Illegality Rule to a *Cannabis* patent infringement action will have ripple effects throughout the *Cannabis* industry, which thus far has place great reliance on the availability of patent protection. The large number of patents obtained by the *Cannabis* industry undoubtedly reflects an expectation that they will be enforced. Once it is established that *Cannabis* patents will not be enforced by the courts, business plans and asset valuations based on those patents will be reconsidered. Existing patent portfolios, which were acquired at great expense, will most likely be immediately and significantly devalued, and efforts to acquire *Cannabis* patents will be scaled back.

The *Cannabis* industry will likely increase its reliance on trade secret protection. Trade secrets are protected under state law and are not pre-empted by federal law.[193] Consequently, trade secret actions can be brought in state courts in states that have amended their laws to remove prohibitions on the sale and use of *Cannabis* – courts which will be likely to look only to their own state's laws when applying the Illegality Rule. This will probably not be an entirely satisfactory option. Trade secret law offers no protection from independent discovery of the secret or from "reverse engineering."[194] Reverse engineering is a particular weakness of trade secret protection when the "secret" can be discerned by a careful inspection of the product.[195]

With *Cannabis* businesses having reduced proprietary product positions, there will probably be a shift towards competition on price between suppliers of price-sensitive commodities. Fewer innovative products will be created. This is not to say that all innovation will cease. Innovation will still occur where the "first mover" advantage is significant, and also where businesses can trade on a trusted brand identity.

A shift in the *Cannabis* industry toward more price-sensitive commodities and fewer high-margin, innovative products will likely make the industry less profitable (though not unprofitable). Investors in *Cannabis* businesses will likely adjust the pricing of their investments accordingly, and the availability of capital will be reduced.

Going forward, the *Cannabis* industry would be well advised to regard the

[191] *Higgins*, 116 U.S. at 685.
[192] United States v. Krieger, 773 F.Supp. 580, 583 (SDNY 1991).
[193] Kewanee Oil v. Bicron Corp., 416 U.S. 470 (1974).
[194] *Id.* at 475-76.
[195] Chicago Lock Co. v. Fanberg, 676 F.2d 400, 405 (9th Cir. 1982).

expense of obtaining patents as a bet placed on the possibility of eventual federal legalization of *Cannabis*, at which time *Cannabis* patents will become readily enforceable and have significant value.

V. Conclusion.

The likely refusal of the Federal Courts to entertain *Cannabis* patent infringement actions reflects a principle generally applicable to the *Cannabis* industry and having far reaching consequences that are beyond the scope of this paper. The Illegality Rule will likely operate to close the Federal Courts to all manner of business disputes. Some of these, such as bankruptcy, are like patent infringement actions in that they can be entertained only in Federal Court. Other business matters, such as licensing disputes and complex contract disputes involving diverse parties, are typically and most conveniently handled by Federal Courts. In bringing patent infringement actions, the *Cannabis* industry draws attention to the Illegality Rule and so hastens its application, which may operate broadly to the *Cannabis* industry's detriment.

LOOKING FOR A NEEDLE IN A HAYSTACK: LIMITATIONS OF SEARCHING FOREIGN TRADEMARK ON TESS

Yan Song*

Contents

*Yan Song is an IP attorney at AEON Law in Seattle, WA. She has a Juris Master from Tsinghua University and an LL.M. from the University of Washington, both focused on IP law and policy. The article was finished during her study at UW, supervised by the former USPTO Examiner Chad M. Smith.

I. Introduction

Every element of a design mark in a US federal trademark application is assigned a design search code, a numerical classification index that codifies design figurative elements into categories, divisions and sections. There are 29 categories with hundreds of sub divisions and sections per category. Design search codes act as the equivalent of a filing system by which all possible design elements can be searched. However, symbol-based foreign languages are classified in one of only five categories. Since all syllable-based logographies (Chinese, Japanese, etc.) are assigned only five design search codes, an Examiner's ability to search the mark as a design is extremely limited. To avoid approval of similar marks, an Examiner would have to compare the foreign mark to every other existing mark in the same category–an impracticality given that there are tens of thousands of logographic marks that exist. As such, an Examiner can search only the literal translation and phonetic translation of a foreign mark, so confusingly similar marks may be very well approved by the USPTO. This paper draws attention to the problem and investigates the abilities of other foreign trademark offices to perform comparable searches for foreign words. This paper begins by discussing how lingual communication functions in trademark and the difference between trademark in alphabetic language and logographic language. Next, it introduces functionality and limitation of USPTO for searching for foreign trademarks. By showing an example of foreign trademark search, it visualizes the problem of the TESS (Trademark Electronic Search System) database, from which reason of failure from linguistic perspective is also discussed. Ultimately, it suggests that technology of search system should be exchanged for the improvement on the reliability of TESS which would reduce the possibility of similar foreign marks being approved.

II. Language and Trademark

Language is the principal vehicle for transmission of cultural knowledge, and the primary means by which we gain access to the contents of others' mind.[1] With interactive conversations and correspondence, people are able not only to express what they think but also receive what others think. They talk, deliver speeches, or write letters, with the assistance of words and phrases, to convert an abstract idea into a vivid expression. Similarly, trademarks, in forms of a specified word or a visual picture, they carry an implicit message that is received and processed by the recipient, and such fall into the realm of linguistic pragmatics,[2] meaning that people understand trademarks not only relying on the meaning of the words or pictures per se, but how words or pictures associate with the goods or services. For example, MAC as a symbol may represent a short version of MacBook to tech geeks, but it may also mean MAC Cosmetics to fashion lovers. Based on their previous knowledge, people link the symbol of the trademark to the goods or services that they are familiar with. In this sense, trademark as a sign representing objects as representative, turns upon all the inferential process.[3] Additionally, trademarks which serve as a form of communication deliver two-fold messages. On the surface, trademarks with common semantic meanings enable consumers immediately understand the meaning and link the meaning to the products. In deeper sense, trademarks as indicators represent the quality and reputation of goods and services, so consumers can quickly make their purchasing decision. This is easily understood that you may choose a Burberry tote because you resonate with its luxury and Burberry using its trademark takes a shortcut to straightforwardly deliver this feature to you.

Ideally, the communicative purpose of trademarks should deliver only one fold message and merely indicate the source of goods or services. The best marks are those that solely indicate the source of the product or service at issue.[4] Such marks are known as fanciful, coined or arbitrary marks, which are either totally unknown in the language or are completely out of common usage at the time.[5] Fanciful or arbitrary marks are the best because the semantic detachment from the source makes them unique and distinctive, another's use of which may confuse consumers the most[6] so that those marks are entitled with the strongest protection. If trademarks also carry semantic meanings which suggest, describe or even embody the associated goods or services, the strength of trademarks as indicators gradually weakens. Those are suggestive, descriptive and generic marks.

Foreign trademarks, the semantic meanings of which are meaningless to

[1] Robert M. Krauss & Chi-Yue Chiu, *Language and Social Behavior*, *in* The Handbook of Social Psychology 42 (Daniel T. Gilbert, Susan T. Fiske & Gargner Lindzey eds., 1998).

[2] Martin Solly, *'Once a Trademark, Not Always a Trademark': Using Language to Avoid Legal Controversy*, *in* Conflict and Negotiation in Specialized Texts: Selected Papers of the 2nd CERLIS Conference 215 (Maurizio Gotti, Dorothee Heller & Marina Dossena eds., vol. 32002).

[3] *Id.*

[4] Karol A. Kepchar, *Selecting and Searching Trademarks*, SH085 ALI-ABA 13, 15 (April 10-11, 2003).

[5] Anderson v. Upper Keys Business Group, Inc., 61 So.3d 1162, 1168 (Fla. Dist. Ct. App. 2011).

[6] Entrepreneur Media, Inc. v. Smith, 279 F.3d 1135, 1141 (9th Cir. 2002).

naïve readers (people who do not speak the language), therefore, are able to serve as pure indicators of goods and services as well. In this regard, foreign trademarks have equivalent functions as fanciful trademarks. In this section, I will explain the communicative function of language, show how the communicative function differs when it comes to trademarks and foreign marks, and reveal the impact of foreign trademarks in alphabetic and in logographic languages to the public recognition.

A. Function of language: communication

1. *Linguistic function and dysfunction of communication*

The primary function of language is communication; it is a means of conveying information to another.[7] Communication is about giving and receiving of signs which have meanings attached to them.[8] Letters, alphabets, punctuation marks, ideograms, logos and words are examples of signs,[9] which contain information. With different signs, people are able to understand the outside world and eventually accomplish the purpose of communication. For example, STOP as a sign to stop people from crossing the street can be manifested as either a red light, a repeated audio sound, or a board writing STOP on it. People who speak English normally understand the sign in a similar way and agree that STOP is a sign for halt, so the communication is meaningful. A sign can only be a sign if we assign meaning to it, or it will be useless if one does not know the meaning.[10] This is true especially for foreign languages that we have never exposed to, with which communication will fail because signs lose their meanings to us.

Language, especially in its written form, is thought to contain special powers, which only the initiated are allowed to understand or control.[11] This idea was deemed highly in ancient times when law makers preserved the ultimate right to interpret laws and rules. It is also the case in modern time because the speaker knows better than anyone else about what he says and what he means. Communication will break down if there is no continuity or coherence to a speaker's discourse.[12] For example, in a dialogue, the speaker needs to use similar vocabulary, refer to what the previous speaker just said and develop the topic to keep the conversation going.[13] Mutually, if lack of comprehension falls on the listener, communication cannot continue as well. The dysfunction of communication happens because the message delivered by the sender is either purposefully covert[14] or unconditionally incomprehensible. When message be-

[7] Elizabeth Armstrong & Alison Ferguson, *Language, Meaning Context and Functional Communication*, 24 Aphasiology 480, 482 (May 18, 2010).

[8] Richard Dimbleby & Graeme Burton, More Than Words: An Introduction to Words 27 (3rd ed. 1998).

[9] Solly, *supra* note 2.

[10] Dimbleby & Burton, *supra* note 8.

[11] Solly, *supra* note 2, at 214.

[12] Armstrong & Ferguson, *supra* note 7.

[13] *Id.* at 482.

[14] Dimbleby & Burton, *supra* note 8, at 24.

ing purposefully covert in a piece of communication, it is possible that within this communication there are more messages included.[15] Semantic meaning is on the surface, but the receiver of the hidden messages is expected to decode the meanings behind, so the communication is ideally effective. For example, a cosmetic commercial could expressly introduce functions of a facial cleanser but the covert message might be that consumers using the product are able to have the same flawless skin as the actress in this commercial. It is risky for sellers to promote the idea of flawless skin, but the actress in commercial can hint this exaggerated function. However, consumers as the recipients, if they are not aware of the hidden meanings delivered in this commercial, the communication is not fully successful. Another reason for dysfunction of communication is when the message is unconditionally incomprehensible. One possibility is that the recipient is incapable of command of the language that the sender uses to deliver the message, so the receipt of the message is meaningless. For example, a monolingual who speaks French cannot talk with another monolingual who speaks Chinese. They need a bilingual interpreter to help switch the codes and bridge the gap, otherwise dysfunction of communication is unavoidable.

In short, language can assist communication, but purposefully covert and unconditionally incomprehensive messages will possibly destroy the flow of communication.

2. *ALPHABETIC LANGUAGE VS. LOGOGRAPHIC LANGUAGE*

The number of languages in this world is estimated from 5,000 to 7,000, but writing systems are mainly classified into three c ategories: logographic characters, syllabic characters and alphabetic characters. Chinese or Japanese Kanji (the adopted Chinese characters) is logographic characters. Japanese Kana, the character of which corresponds to one sound in the Japanese language, is syllabic characters. English letters are alphabetic characters.[16]

Characters in different writing systems have their own features. For logography, it compasses both ideography and phonography.[17] Ideography means that the graphic sign contains meanings. Chinese character "虫" is a graphic sign, the meaning of which is insect and usually used in other characters to imply the meaning of insect or animal. Phonograph indicates a phoneme or a syllable.[18] The same phonograph can be used in different characters to represent the same sound but words that it constitutes have different meanings. Take "下" in Chinese, whose pronunciation is Xia, as an example. "虫" and "下" can constitute another character "虾", whose pronunciation is Xia and meaning is "shrimp". In this character, "虫" indicates the meaning while "下" represents the sound.

Chinese characters have traditionally been considered to be made up of

[15] *Id.* at 25.

[16] Hsuan-Chih Chen & James F. Juola, *Dimensions of Lexical Coding in Chinese and English*, 10 Memory & Cognition 216 (1982).

[17] Taro Kogure, *Dynamics of Logography*, 37 Sophia Linguistica 103, 105 (1994).

[18] *Id.* at 104.

three elements: graphic forms, phonic forms, and meaning,[19] a combination of phonography and ideography, since ideography includes both aspects of meaning and graphic form. Early studies show that the visual aspects of Chinese characters are particularly important in terms of helping to differentiate and identify a character among other,[20] therefore confusion often happens when two characters look similar. One stroke might cause a huge difference in meanings. Compare "人" and "入": the first character means "people" while the second one means "enter". They look confusingly similar but meanings of both are hugely different. Regularly, pupils in elementary school are tested to distinguish characters with similar forms in order to strengthen fundamental skills of Chinese writing. Since ideography serves the purpose of delivering messages based its graphic forms, visual aspect is a significant element to logographic language.

Unlike logographic writing systems which demand a greater dependence on visual strategies, phonetic-based writing systems tend to depend more on phonological strategies.[21] The appearance of Chinese characters is more focused whereas English concentrates more on the sound of a word. This is because alphabetic languages and logographic languages have different levels of phonological transparency and morphological transparency, as they provide more or less phonological and morphological information.[22] English is more phonologically transparent than Chinese while Chinese is more morphologically transparent than English. An interesting example is child learners of alphabetic writing systems need the ability to segment spoken language into phonemes, whereas Chinese children need the ability to identify morphemes.[23] Another example is that it is impossible for readers to pronounce a coined Chinese character with random combination of strokes, or even an unfamiliar character. In contrast, rules of pronunciation in alphabetic language enable readers to pronounce a made-up word, the meaning of which may be unknown or nonexistent. It is safe to say that the sound of a word is essential to alphabetic languages.

3. *IMPACT OF FOREIGN LANGUAGES*

As mentioned before, signs are useless if no meanings are assigned to them. Foreign languages can be useless signs to people who cannot speak the language. Visual aspect of signs, however, is the only element among sight, sound and meaning of a word that can make some sense to naïve readers due to its nature of display. Though readers have no idea of the sound and the meaning of a foreign word or character, they tend to focus on how it looks. In their eyes, foreign words or characters are basically pictorial. This is worth the attention because foreign languages cannot compete against native languages to

[19] *Id.* at 105

[20] Chen & Juola, *supra* note 16, at 223.

[21] *Id.* at 217.

[22] Benedetta Bassetti, *Bilingualism and Writing Systems*, *in* Handbook of Bilingualism and Multilingualism 1 (2nd ed. 2012).

[23] *Id.*

well serve the purpose of communication to naïve readers. No meaning is attached to foreign word or character without translation, so it is almost impossible for naïve readers to understand what the word or character means. Under this circumstance, foreign languages fall into the unconditional incomprehension category of the dysfunction of communication. Without meaning, foreign words or characters reduce to sheer visual signs.

B. WORD TRADEMARK AND FOREIGN WORDS AS TRADEMARKS

1. *COMMUNICATION THROUGH TRADEMARKS*

Although trademarks are traditionally viewed as identifying the origin or source of the goods to which it is affixed, another function of which in recent years is assuring the purchaser of a certain degree of uniformity or quality.[24] For consumers, trademarks should be able to identify those particular producers with whom they desire to contract and those they choose to avoid.[25] The communication between consumers and products or services is, therefore, accomplished through trademarks.

The communication through trademarks, however, is different from language. The only reason for society to afford a seller exclusive rights in a trade emblem is to foster accurate associative and denominative messages.[26] More messages other than source and quality of goods or services bring the risk of predomination in market communication,[27] which is detrimental to both sellers and consumers because the strength of source identification is undermined and expressions related to products and services are monopolized. Language, in contrast, expects clear and specific semantic meanings for the purpose of communication.

2. *WORD MARK AND LINGUISTIC INTERPRETATION OF ITS DISTINCTIVENESS IN LAW*

There are various forms of trademarks: words constitute most form of trademarks, while stylized logos, artistic signs, and graphic symbols are also commonly used.[28] However, word marks are different from logos, artistic signs and graphic symbols because words may contain semantic meanings. Therefore, besides quality and source, word marks also deliver information contained in words themselves. For example, the word "Juicy" has its own meaning of "the food is full of juice and enjoyable to eat". To be compatible with functions of trademarks aforementioned, words as trademarks should have essentially only two potential functions: the ability to communicate qualities, and the function

[24] Szajna v. General Motors Corp., 115 Ill.2d 294, 319 (1986).

[25] Chad M. Smith, *Undressing Abercrombie Defining When Trade Dress is Inherently Distinctive*, 87 TRADEMARK REP. 160, 164 (1997).

[26] John T. Cross, *Language and the Law: The Special Role of Trademarks, Trade Names, and Other Trade Emblems*, 76 NEB. L. REV. 95, 117 (1997).

[27] *Id.*

[28] Solly, *supra* note 2.

of communicating source.[29] I have discussed in previous section that once signs are attached with meanings, messages can be conveyed so communication is formed. When the information is purposefully hidden or unconditionally incomprehensive in the messages, the failure of communication may occur. For word marks, however, the more hidden or incomprehensive the meaning of the word is, the stronger the word mark can be. This is because meaningless word marks are purely associative and denominative, the qualities of which cater to the purpose of trademarks.

In legal perspective, the well-known Abercrombie spectrum offers a dimension to determine distinctiveness of trademarks by categorizing them as: fanciful/arbitrary, suggestive, descriptive and generic,[30] with which the degree of trademark protection also declines. Abercrombie spectrum focuses on the correlation between word and product:[31] the closer the correlation is, the less protection the mark could obtain. This is because the close correlation between the word and the product, mainly linguistically, other than the purpose of source or quality identification may bring the risk of predomination of the market communication.[32]

A fanciful mark, as a coined word with no meaning assigned to it, is deemed as the strongest trademark. This is because meaningless words, as mentioned before, well serve the purpose of trademarks as indicators of source and qualities. An arbitrary mark has a significance recognized in everyday life, but the thing it normally signifies is unrelated to the product or service to which the mark is attached.[33] The correlation between the word and the product is incredibly distant.

In contrast, suggestive, descriptive and even generic marks reflect the function of language for communication, because it takes almost little efforts for consumers to correlate the word used in trademark and the goods or services.

A suggestive mark "suggests, rather than describes, some characteristic of the goods to which itapplie[s] and requires the consumer to exercise his imagination to reach a conclusion as to the nature of the goods. "[34] The imagination is triggered by the choice of the word. Suggestive mark, though it has some correlation with the goods or services, is still good enough as a source identifier, because a person still would have difficulty in ascertaining the nature of the products that the marks represent.[35]

A descriptive mark is descriptive of the intended purpose, function or use of the goods, the size of the goods, the class of users of the goods, a desirable characteristic of the goods, or the end effect upon the user.[36] The description effect derives from the semantic meaning of words.

[29] Smith, *supra* note 25, at 186.

[30] Abercrombie & Fitch Co. v. Hunting World, 537 F.2d 4 (2d Cir. 1976) (Friendly, J.).

[31] Greame B. Dinwoodie, *Reconceptualizing the Inherent Distinctiveness of Product Design Trade Dress*, 75 N.C. L. Rev. 471, 509 (1997).

[32] Cross, s*upra* note 26.

[33] Champions Golf Club, Inc. v. The Champions Golf Club, Inc., 78 F.3d 1111, 1116 (6th Cir. 1996).

[34] Streamline Production Systems, Inc. v. Streamline Manufacture, Inc., 851 F.3d 440, 452 (5th Cir. 2017) (quoting Soweco, Inc. v. Shell Oil Co., 617 F.2d 1178, 1184 (5th Cir. 1980)).

[35] Sara Lee Corp. v. Kayser-Roth Corp., 81 F.3d 455, 464 (4th Cir. 1996).

[36] Anderson v. Upper Keys Business Group, Inc., 61 So.3d 1162, 1169 (Fla. Dist. Ct. App. 2011).

Generally speaking, the distinctiveness of word marks in law is mainly from linguistic standpoint that the closer correlation is between the word and the product, the less protection the word mark obtains. Semantic meanings of a word debilitates the strength of a word mark.

3. *FOREIGN WORDS AS TRADEMARKS*

Foreign words, without assistance of translation, to naïve readers are unconditionally incomprehensive, the nature of which enables foreign words to serve the purpose of trademarks because they are semantically meaningless to naïve consumers (who cannot speak the language in which trademark is written) and purely associative and denominative.

Foreign words are equivalent to fanciful marks in a sense that both of them fail to reveal semantic meanings of the words. For example, Kodak is a combination of five letters created with no meaning being assigned to except that consumers considered it as trademark. The well-known mark in China "五粮液" is a trademark used on classy white wine, but it is only a sign to those con-sumers who cannot speak Chinese. The meaning of "五粮液" is unknown to naïve consumers.

C. UNIQUENESS OF FOREIGN WORDS AS TRADEMARKS

The distinctiveness of a trademark can be influenced from the selection of a particular shape of word, spelling, and lettering or punctuation, with the use of modality and stylistic techniques, such as rhyme, alliteration, assonance and consonance.[37] I have discussed the difference between logographic language and alphabetic language in the previous section that the sight of a word is important to logographic languages while the sound is essential to alphabetic languages, so distinctiveness vests in different elements of a word in terms of different writing systems as w ell. For trademarks written in logographic language, the sight of a mark takes priority so distinctiveness is more found in shape of word, spelling, and lettering in logographic words. When it comes to trademarks written in alphabetic words, sound is crucial so the spelling of a word, punctuation, rhyme, alliteration, assonance and consonance need to be considered for distinctiveness.

These linguistic characteristics works fine if the trademark written in a languages the same as which consumers speak. In logographic language speaking countries, such as China, consumers may confuse two marks with similar shapes that are combined with similar characters, especially when the mark is a meaningless coined word. For example, "花中王" and "花中玉" are considered as similar enough to cause confusion among consumers.[38] If the sound of two marks are similar as well as the sight, they are also confusingly similar; however, if the sight of two marks is distinctive, they are not confusingly similar even with similar sounds. For example, "高太丝" and "高泰斯"[39] are

[37] Solly, *supra* note 2 at 222.

[38] Trademark Examination Standard, the State Administration of Industry and Commerce of China at 62 (2005).

[39] *Id.* at 64

two marks with the same pronunciation but they look different, so they are not considered to be confusingly similar in China. The two examples from Trademark Examination Standard issued by the State Administration of Industry and Commerce of China indicate that sight of a word mark is vital not only because of its linguistic trait but also it helps Chinese consumers to distinguish marks.

However, this differentiation mechanism of consumers also influences their habit when an English trademark appears, so they may habitually and essentially distinguish the sight of the English words. For example, "Marc O'Polo" and "MACAO POLO" are considered as confusingly similar in China[40] because of similar sights and pronunciations, though the two marks are effortlessly distinguishable for English speakers. In this foreign word mark scenario, characteristics of alphabetic language are not the elements influencing Chinese consumers' recognition, but their native language Chinese does, or broadly speaking, the characteristics of logographic languages do.

Similarly, for English-speaking consumers, they incline to look for the sound of a word. When it comes to Chinese trademarks, they view Chinese characters as meaningless signs because the sound of marks is unknown to them. This results from the influence of their native language as well.

The observance of linguistic characteristics and consumers' psychology proves the uniqueness of foreign words as trademarks, which is consumers view marks following a habitual cognitive pattern and this pattern is decided by the writing system to which consumers' native language belong. Due to this reason, the distinctiveness of foreign marks should cater to consumers' cognitive habit instead of following the linguistic characteristics of the language in which foreign marks are written. This discovery should be incorporated in the trademark search systems and trademark examinations. I will explain the reason in later chapters.

III. Limitations of TESS to Search Foreign Trademarks

TESS, in its full name of Trademark Electronic Search System, is a USPTO trademark search database which allows people to search the USPTO's database of registered trademarks and prior pending applications to find marks that may prevent registrations due to a likelihood of confusion refusal. It is a thorough and complicated system with various database serving different search approaches and purposes. However, when searching for foreign marks, one cannot always successfully achieve the results as searching for English marks. This is section will describe the function of TESS on searching English marks, how it fails regarding foreign words, and why the failure happens.

[40] *Id.* at 63

A. FUNCTIONALITY OF TESS

1. *REGULAR SEARCH FOR WORD MARKS*

One can search for a trademark using its various information including the filing date, the name of trademark holder and his address, or the name of the attorney who filed the application. The TESS system labels its database with fifty-two titles categorized by different types of information contained in trademarks,[41] such as [FD] for the filing date, [OW] for owner name and address, and [AT] for attorney of record. [BI] as "basic index" database is the mostly often used to search for English marks and marks written in other alphabetic languages. If there is a French mark, Examiner will not only search in [BI] database, but also [TI] "translation index" database, which contains English equivalents to foreign words or characters used in a trademark. For example, if one applies for registration of a French mark "espoir", he needs to submit the translation and transliteration (the phonetic equivalent) of the mark "espoir", the translation of which is "hope" in English and the transliteration of which could be "es-pwa". Examiner will search the [BI] and [TI] database to look for any existed trademarks similar to "espoir", "hope" and "es-pwa".[42]

2. *SEARCH FOR DESIGN MARKS*

Trademarks can also consist of images and signs, which are specifically referred as design marks. Design search code is established to search for design marks, which are stored in database labeled as [DC]. Design marks with similar sights can be found in this database. Each design search code is a numerical classification index that codifies design figurative elements into categories, divisions and sections. There are twenty-nine main categories of designs,[43] such as animals, plants, foodstuff and tobacco. Under each category, numerous divisions exist and under each division, each design element is assigned a six-digit number. In the category of animal coded as 03, for example, there are divisions like cats, horses, birds, or fish. In the division of cats coded as 0301 (dogs, wolves, foxes, bears, lions and tigers are also included in this division) , for example, six-digit number 030101 is assigned to refer to lions, 030102 is for lion insignia, 030103 is for Tigers and other large cats, and 030104 is for domestic cats.

To search design trademarks, one should first identify the significant design elements and look for the design code for those elements. Next, one should combine and put in different design codes to search for trademarks which contain the same and similar elements. If there is a mark composed of a swan and the word "espoir", Examiner will search database of [BI], [TI] and [DC] to find a similar mark by putting a string of instructions to the search window. A possible string could be like: "espoir [bi,ti] and 031506 [dc]", which means to search word marks containing letters of "espoir" in database of [BI] and [TI], and search for design marks under the division of Ducks (Geese and Swans

[41] Trademark Electronic Search System (TESS): http://tmsearch.uspto.gov/ (follow Word and/or Design Mark Search hyperlink).

[42] The transliteration may have more variations of "es-pwa".

[43] USPTO Design Search Code Manual: http://tess2.uspto.gov/tmdb/dscm/index.htm.

are also included in this division). In this way, the trademark which has both the elements of the word "espoir" and the image "swan" will show up.

In conducting a design search, one may focus on an extremely narrow group of similar design marks by using one or more six-digit codes for design codes. One may also look at broader categories or divisions of marks by using either two-digit or four-digits codes, such as 03 for animals or 0301 for cats. The quantity of trademarks searched by using the string of instructions varies according to Examiners' discretion. Different Examiners might come up with different search results, but they are trained similarly enough to locate valid trademarks as a comparison to the applying ones.

B. Dysfunctionality of TESS in search for foreign marks

TESS functions well when Examiners search for alphabetic word marks and design marks, but when it comes to logographic characters, the functionality is questionable. First of all, the workload for Examiners to search for foreign word is huge and it also increases the possibility of confusingly similar trademarks being approved. There is no such an isolated database as [BI] or [TI] established for logographic characters. Instead, in the design code search database [DC], Category 28 is titled with Inscriptions in various characters. Under Category 28, there five divisions relevant to logographic characters. They are 280101 for Arabic characters, 280103 for Chinese, Japanese, Korean, Vietnamese or other Asian characters, 280105 for Greek characters, 280107 for Hebrew characters, and 280105 for other non-Latin characters, including Cyrillic or hieroglyphic characters. Precisely speaking, logographic characters are deemed as design marks assigned with design codes but are put into roughly sketchy divisions. Division 280103, alone, has 34043 records[44] of trademarks written in Chinese, Japanese, Korean, Vietnamese or other Asian characters. This is a problem because if one applies a mark written in Chinese, Examiner has to go through all 34043 results shown up on 100 pages to find appropriate trademarks as references to approve or deny the application, which practically impossible.

Second, the submitted information of foreign marks is not enough to conduct a concise search in TESS. As mentioned before, one needs to submit both translation and transliteration of a foreign mark. If the foreign mark has no literal meaning, only transliteration is needed. Think about Chinese marks "康师傅" and "康帅傅" both seeking federal registration. The former mark means Uncle Kang or Professor Kang, the transliteration of which could be Kung-Xi-Fu. The latter mark, however, is meaningless in Chinese, the transliteration of which could be Kung-Chuai-Fu. Examiner uses design search code 280103 to search for Chinese marks, and also cross-search [BI] and [TI] database for similar translations and transliterations. Kung-Xi-Fu might not be found under [BI] and [TI] as a reference to Kung-Chuai-Fu because of their different pronunciations. Therefore, characters with similar sight cannot be found and compared, an opposite result of the fundamental idea of design code

[44] The record varies as time goes by. This record is conducted on September 8, 2018.

search database.

In conclusion, the dysfunctionality of TESS in search for foreign marks is two folds: foreign marks treated as design marks are roughly categorized in a way that search cannot be effectively conducted; search for translation and transliteration of foreign marks is unable to reveal marks with a similar sight.

C. Linguistic reasons behind the dysfunctionality of TESS

The dysfunctionality of TESS in search for foreign marks is mainly linguistic. I will discuss the mechanism of TESS from linguistic perspective, explain how this mechanism differs from how consumers view foreign marks, and answer why TESS fails on foreign marks searching in this section.

1. *Analyze TESS from linguistic perspective*

When one files an application of a foreign trademark, the translation and transliteration of the foreign trademark should be submitted together as well. This requirement straightforwardly coveys two elements in a word: the meaning and the sound. It is in accordance with the way that Examiners search for English trademarks. Examiners write down the applied English trademark, change the spelling of several syllables and search for variations of the mark. If one applies "Zeitgeist" as a trademark, Examiner will switch all the vowels in this word. For example, "E" might be switched with "I" or "Y", because they could make similar sounds. As a result, the mark "Zeetgitst" might show up as a reference for Examiner to decide. Only several syllables are worth the change because letters in certain positions in words are privileged when it comes to recognition, which means that letters in certain positions are more important for recognition than other letters in a word.[45] The first syllable in a word, for example, is distinguishable: "Desire" and "Jesire", or "Relgan" and "Selgan". For Examiners, if the first letters of two words are different, they will not consider them as confusingly similar because consumers can effortlessly differentiate them.

This searching process also denotes the significant role that the sound of a word plays in English and US trademark world. The sight of a word, however, is not taken into consideration under US application system and the TESS. That is to say, TESS is in fact an alphabetically oriented system.

2. *Review psychology of consumers towards foreign marks*

English-speakers as consumers may not worry much about the appearance of an English word. This is mainly because alphabetic languages are more phonologically transparent. Even with a coined trademark, English-speaking consumers habitually memorize the sound of the word in their mind, though they

[45] Rebecca L. Johnson & Morgan E. Eisler, *The importance of the first and last letter in words during sentence reading*, 141 Acta Psychologica 336, 336 (2012).

are blinded to the meaning. The rules of pronunciation influence them to assign the sound to a word. If a consumer who can speak English but cannot speak French sees the mark "espoir", he will automatically pronounce the word as "es-pour" because of the English rules of pronunciation. If there is another mark "espur", a slight chance for consumer confusion between the two may exist, because "espur" has a different sound as " es-per". Though they might look similar, to English-speaking consumers, the similarity is not substantially close. As to logographic characters, English-speaking consumers would consider them as meaningless signs or images. When English-speakers read Chinese trademarks, it is impossible for their minds to process the meaning and the sound of the word due to the lack of knowledge, with sheer impression at the sight of the word. The appearance of characters are the only visible and direct element left in a word.

In contrast, Chinese-speaking consumers tend to memorize the sight of a word because Chinese characters are ideographical. They distinguish trademarks written in other languages from the visual aspect as well. For example, English marks "Carolflex" and "Carpoflex" are considered as confusingly similar in China[46], but it might not be the same case for Examiners in the United States, because they have different pronunciations.

No matter what writing systems a mark belongs to, when the mark is "foreign", the sight of a word is a crucial element for consumers to distinguish foreign trademarks. Especially when two foreign trademarks look confusingly similar, a precise distinction by consumers is unattainable. For example, Chinese characters consist of strokes; one missing stroke can transform the character into another one. In fact, sellers tend to utilize this feature to create confusingly fake brands to trick consumers. For example, "白猫" is a well-known trademark for dish soaps so someone creates brand "日猫" written in the same font also for dish soaps. The pronunciation of the two marks are different, but because the characters are confusingly similar, Chinese consumers are easily tricked. If "白猫" dish soap and "日猫" dish soap are both on the shelf of a market in the United States, American consumers may undoubtedly get confused. Confusion can also happen if Chinese consumers are asked to distinguish "chocolat" and "chacolat" written in the same font.

Briefly speaking, consumers focus on the sight of a foreign mark if the mark is written in a language that belongs to a different writing system and this results from their cognitive patterns as we discussed in the previous chapter.

3. *Explain the reason of TESS's failure on foreign marks*

TESS is an alphabetically oriented system, which means that the sound of a trademark is the fundamental element when one conducts a trademark search. The search for alphabetic marks or logographic marks all comes from this basic idea. For alphabetic marks, Examiners will add, omit or replace certain letters in a word to find trademarks with similar pronunciations. If two trademarks

[46] *supra* note 38 at 61.

used on similar products and services also sound similar, Examiners will not approve the junior application no matter whether the two-word marks look similar or not. For logographic marks, Examiners require the translation and transliteration of the applying mark. What they look for is whether the phonetic sound of the logographic mark is similar to the registered marks, and whether the meaning of the logographic mark is equivalent to a valid trademark. The process is typically equal to the search of English marks because the translation of an English mark is regularly unnecessary, and transliteration is a substitute means to phonetically examine a logographic mark as an English mark. Though logographic marks are put into the category of design marks in design code database, Examiners treat logographic marks the same as alphabetic marks, so the function of design codes for logographic characters is almost miniscule. More directly, the sight of logographic marks is not effectively evaluated under TESS system, the missing element of which, however, is crucial to logographic languages.

For consumers, foreign marks written in a language that belongs to a different writing system are meaningless signs or images. The meaning and the sound of a foreign mark are incomprehensive, so only the sight of a foreign mark is approachable for consumers to identify the products. Confusion, therefore, happens to two foreign marks with similar sights.[47] To avoid confusingly similar foreign marks being approved, the sight of foreign marks should be the element examined. However, Examiners can merely examine the translation (the meaning) and transliteration (the sound) of a foreign mark due to the dysfunctionality of TESS, which is unable to provide concise search results by roughly placing logographic marks into five divisions within the database of design marks.

As previously discussed, the distinctiveness of foreign trademarks reside in their sights and reflects consumers' cognitive habit. The key to the problem is that foreign marks can be thoroughly examined if the appearance of marks, or consumers' cognitive habit, is taken into consideration by TESS and Examiners.

D. Case study: "绵竹大曲" v. "锦竹大曲"[48]

I introduce a trademark infringement case in China as an example of how a confusingly similar mark can be infringing mark in China but might be approved under TESS system.

1. *CASE BRIEF*

The case is briefly about a well-known wine company as the holder of trademark "绵竹大曲" used on bottled wine brought the lawsuit against another wine company who holds the registered mark "锦竹". The latter uses "锦竹" together with Chinese word "大曲", which is a generic term of a type of wine

[47]This is not to say the confusion will not happen to marks with similar meanings or sounds, but even though meanings or sounds are similar, consumers would not know due to their lack of knowledge of the language.

[48]Shenzhen City Baosongli Industrial Co., Ltd. v. Sichuan Province Mianzhu Jiannan Chun Wine Plant Co., Ltd., Higher People's Court of Hunan Province, March 16, 2010, CLI.C.291859(EN).

made from wheat, as the name for bottled wines. As a consequence, "绵竹大曲" and "锦竹大曲" are used on bottled wheat wine in the market, with similar packages as well. The court found that "绵" and "锦" are similar in sight. The right side of "绵" and "锦" is the only difference: "纟" and "钅". There-fore, "绵竹大曲" and "锦竹大曲" are confusingly similar, in which ordinary con-sumers and sellers cannot recognize the difference.

2. *Hypothesis*

We assume that "绵竹大曲" has been approved by USPTO and registered as a valid trademark in the database, and now someone applies for the registration of "锦竹大曲". Since "大曲" is a generic term for wheat wine, we analyze the distinctive segments: "绵竹" and "锦竹".

"绵竹" is a place name in China, pronounced as "Mianzhu", but "锦竹" has no semantic meaning. If one files the application for "锦竹", he needs to submit the representation of "锦竹" written in Chinese characters and transliteration of it "Jinzhu". Examiner will search "Jinzhu" in the database of [BI] and [TI], or ideally [DC] using design code 280103 to look over all foreign marks written in Asian characters. "Mianzhu" and "Jinzhu" are considered as phonetically different, so even Examiner sees "Mianzhu" as a listed result, it might not be the reference to reject "Jinzhu". It is also impractical for Examiner to go through all the marks under 280103 section to pinpoint "锦竹" because there are hundreds of pages of results. High probability is "锦竹" bypasses the comparison with "绵竹" gets approved, appears on the market, and confuses consumers who purchase wheat wine because it has a different sound and "绵竹" is difficult to find in the database by using design codes.

3. *Conclusion*

The case discussed in this section is meant to show that though phonetic sound is important to search for trademarks written in alphabetic languages, visual aspects of foreign marks should be examined. The distinctiveness of foreign trademark rely on their visual aspects because of consumers' cognitive habits.

IV. Recommendations for Improving Reliability of TESS

A. A comparison to logographic-language country

Trademark search system in China is user-friendly. Unlike TESS divides information of a trademark application into different categories containing the filing date, the name of trademark holder and his address, or the name of the attorney who filed the application, trademark search system in China have four main portals[49] for users to search the information of a trademark, which includes

[49]Trademark Office of The State Administration for Industry & Commerce of the People's Republic of China: http://wsjs.saic.gov.cn/txnT01.do?y7bRbp=qmFFYCf.5EXcFNAiA3IzNfU.EiLhGEkOGC_XFBNs_5BR9AX1xrCK1TdozcNFKusA0WrgWkTsXXRUHYKh38xcugf.TXnjLQMPqtinSS5IpY6K7vR8Sglo5Hii6V.cUqEb8GHipS1i9HUmZ3iYLklLdK0kacR.

search for similar marks, search for marks based on application information, search for the status of marks, and search for trademark bulletins. Four search portals enable users to search with different p urposes. As an equivalent function of TESS when Examiners needs to make likelihood of confusion refusal, search for similar marks offers more convenient steps to o perate. Users have two options: quick search and complete search.

1. *QUICK SEARCH*

To use quick search, one should put in the number (between 1 to 45) of international trademark classes[50] in which area the trademark is used. For example, Class 15 represents musical instruments and Class 37 represents installation services. The number of international trademark classes is required to do quick search. Though there are sub-classes under each class also assigned with numbers, for example, under Class 37, there is a sub-class 370031 representing building construction and supervision, number of sub-classes is not necessary for quick search. Quick search allows users to search six types of marks: marks written in Chinese characters, marks written in Chinese phonetic alphabets (Pinyin), marks in English, marks written in numbers, marks written in initials, and design marks, among which a mark can only be labeled as one of the six types. For design marks, users should first identify the elements of the design and then put in numbers[51] that represent the elements. For example, 1.15.14 is the number for raindrop and 1.17.12 is the number for islands. If a mark has the two elements of raindrops and islands incorporated in its design, users can put in "1.15.14; 1.17.12" to the search box to search trademarks that carry the two elements. However, the search is merely available for a design mark with no more than five elements in its design.

Similarly, trademarks written in foreign languages are considered as design marks so numbers are also assigned to them as TESS does. Number 28 is the general section for marks in foreign languages as well as 8 subsections containing marks in Arabic, Latin, Cyrillic, Japanese, Greek and Hebrew. For example, if a trademark is written in Japanese used on musical instruments, 15 indicating musical instruments should be put into the search box of international trademark classes and 28.3 representing marks in Japanese is put into the search box of design mark number, after which 50 search results[52] with images are shown up. Users can choose two or more marks for further comparison, so more detailed information about the trademark including name of the applicant, name of the agent, the date of application and the registration number can be reviewed.

[50] Nice Classification: http://www.wipo.int/classifications/nice/en/.
[51] Design Code: http://www.fzsbj.com/sbcx/tx.htm#.
[52] The record varies as time goes by. This record is conducted on September 8, 2018.

2. *Selective search*

This type of search offers more choices for users to conduct a search to enlarge or narrow the search scope. English marks, for example, can be changed by adding or deleting letters in word, or reversing the order of letters to embrace as many results as possible to avoid confusingly similar marks.

If a user intends to search all English trademarks used on musical instruments with similar phonetic sounds as "Good", he could use complete search by putting in Number 15 for music instruments, typing in word "Good" and clicking the function item of "similar phonetic sound". 18 search results are listed in chart, which comprises trademarks like "GWOOD", "GWTEE", "G-AID" or "GOODWAY."[53] The quantity of the search results is satisfying because it enables an Examiner to efficiently make the decision after a thorough review within a reasonable time. The quality of the search results seems questionable, though. If a USPTO Examiner searches TESS for similar marks as "Good", there are few chances for "GWTEE" and "G-AID" to be references because according to rules of pronunciation they are different in sound.

However, "GWTEE" or "G-AID" can sound similarly confusing for Chinese consumers. This is because it is possible for a Chinese consumer who cannot speak English pronounces "Good" as "GWTEE" or "G-AID", not from the standpoint of English pronunciation but out of the habit of Chinese pronunciation. Though those marks are considered as phonetically similar, they are not rejected as similar marks. As mentioned before, Chinese as logographic language influences consumers in a sense that visual aspects of mark takes priority. "G-AID" and "GWTEE" do not look the same, so consumers can distinguish the two marks. Additionally, Chinese consumers might not even pronounce the two marks since they are written in another language, so the sight of the two marks becomes the crucial element to decide likelihood of confusion.

Trademarks written in Chinese characters have the same procedure as the search of English marks. Words can be added or reduced with characters, the order of characters can be reversed, and characters with phonetically similar sound can also be found. If we want to find all marks that contain characters "白猫" used on electronic apparatus and instruments, we put in the number of international trademark classes which is 9 for electronic apparatus, type in the mark "白猫" and choose to search marks that contain the characters, 23 results come up.[54] All word marks contain characters of "白猫". Three of them are even the same marks using the word of "白猫" but on different products. The search results are still in a reasonable amount.

3. *Summary*

To conduct search of similar marks, trademark search system in China basically requires the following information: the number of international trademark classes to locate a certain kind of goods or services, the type of the marks

[53]The record varies as time goes by. This record is conducted on May 25 of 2017.

[54]The record varies as time goes by. This record is conducted on September 8, 2018.

(whether it is a mark written in Chinese characters, or in Chinese phonetic alphabets, English marks, or design marks), and the mark itself. If the mark is a design mark, one should break down the mark into pieces of elements, and find the numbers assigned to those elements. One can search five elements at a time. For marks in foreign languages except English, numbers are also assigned to represent different languages so that users can put in the number to search foreign marks as design marks. For English mark, in contrast, one can search the mark by adding or deleting letters in the word, changing the orders of the letters or finding the marks with similar phonetic sound. The search results are more linguistically prone to the habit of Chinese consumers.

B. Recommendation: technology exchange cross-borders

The study of the trademark search system in China is an example of how marks in foreign languages can be searched in a foreign language database. It does not indicate that the Chinese system is flawless but it on some level provides the idea that Chinese marks can be searched and compared without using the design mark code. Meanwhile, even English words can be searched the same way as USPTO Examiners by adding or deleting letters, but all users do is clicking the function item instead of writing down the string of instructions. That is to say, a trademark search can be conducted in a more convenient and direct way with the assistance of technology.

Therefore, it is recommended to consider an exchange of technology between countries with different writing systems. For example, USPTO can use the technology of Chinese trademark search system to conduct Chinese mark search instead of treating Chinese marks as design marks with a design code which is ineffective.

V. Conclusion

Though USPTO TESS could perform a well-functional search for word marks, it has limited functionality when searching for foreign marks. With more foreign business settling down in the US, it is important to establish a search system for foreign trademarks in order to avoid confusingly similar trademarks being approved, which would result in disorders and chaos in the consumers' market. The reason for the malfunction of the TESS is predominantly linguistic. The TESS is an alphabetically biased search system, in which only the sound and the meaning of a word is highly concerned. However, logographic language is a different writing system that requires the sight of a word to be taken into consideration. At the same time, consumers can only read foreign marks by its sight instead of its sound, where confusion will often happen, so the distinctive sight of foreign word is also a requirement of market. TESS needs to focus of the sight of foreign marks to cater to consumers' cognitive habits. More optimum options could be considered for a well-operated system and cooperation between countries might be a good solution. Technology of search system should be exchanged cross borders.

Who Owns A Fox?
Possession is the root of title in patent law

Christine Johnson*

Contents

*Christine Johnson, J.D. State University of New York at Buffalo School of Law 1995. The views expressed in this paper are my own. I am not writing in any official capacity. Thanks to Alexander Sofocleous, David Gardner and Sara Johnson for their insightful discussions, comments and feedback.

I. INTRODUCTION

"What is it to possess? This appears a very simple question- there is none more difficult of resolution, and it is in vain that its solution is sought for in books of law: the difficulty has not even been perceived."[1]

The most valuable public resource in America today may lie in the public common[2] of human ingenuity and ideas.[3] Like *ferae naturae*[4] ideas in the public common are not subject to individual ownership in their wild state.[5] In English law private ownership of *ferae naturae* is acquired by taking possession of them.[6] The state of possession raises *prima facie* title.[7] The Copyright and Patent Clause of the Constitution empowers Congress to secure to inventors exclusive rights to their inventions.[8] A patent is a deed that conveys title to an invention as private property.[9] The title is granted in a *quid pro quo* exchange involving public rights.[10] When the PTO issues a patent, it "take[s] from the public rights of immense value, and bestow[s] them upon the patentee."[11] At the end of the patent's term the invention described in the patent's written description is conveyed to the public.[12] Describing that invention in writing is an

[1] Frederick Pollock & Robert Samuel Wright, An Essay on Possession in the Common Law (MacMillin & Co. 1888).

[2] The public common is 'the cultural and natural resources accessible to all members of a society'. https://en.wikipedia.org/wiki/Commons, distinguished from the 'public domain' which consists of all creative works to which no exclusive property rights apply. https://en.wikipedia.org/wiki/Public_domain.

[3] See, e.g., James Kanter, *A new battlefield: Ownership of Ideas*, New York Times, Oct. 3 2005. *Available at* https://www.nytimes.com/2005/10/03/technology/a-new-battlefield-ownership-of-ideas.html.

[4] *Ferae naturae* is a Latin legal term referring to wild animals, in contrast to *domitae naturae* (domestic animals). Am. Jur. 2d *Animals* § 2. In property law, *ferae naturae* residing on unowned real property are not predisposed to one party or another in regards to possession.

[5] Le Roy v. Tatham, 55 U.S. (14 How.) 156, 174–175 (1853).

[6] Pierson v. Post, 3 Caines 175, 2 Am.Dec. 264 (N.Y. 1805).

[7] Possession vaut titre: "In English law, as in most systems of jurisprudence, the fact of possession raises a *prima facie* title or a presumption of the right of property in the thing possessed. In other words, the possession is as good as the title (about.)" https://thelawdictionary.org/possession-vaut-titre/.

[8] The Constitution of the United States, first adopted on September 17, 1787 contained a Copyright and Patent Clause ('Progress Clause') that authorized Congress to grant patents "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries" U.S. Const. art. I, § 8 col. 8.

[9] This article adopts a well-recognized definition of "private property" as property owned by one person or a small number of persons. *See*, *e.g.*, James E. Krier, *Evolutionary Theory and the Origin of Property Rights*, James E. Krier, 95 Cornell L. Rev. 139, 144 n.10 (November 2009) (quoting Thomas W. Merrill, *Property and the Right to Exclude*, 77 Neb. L. Rev. 730, 733 (1998)). The invention is private property. The patent deed is personal property.

[10] Oil States Energy Servs., LLC. v. Greene's Energy Group, LLC, 138 S.Ct. 1365, 1373 (2018) (*citing United States v. Duell*, 172 U.S. 576, 582-83 (1899), which quotes *Murray's Lessee v. Hoboken Land & Improvement Co.*, 18 How. 272, 284 (1856)) for the Court's long recognition of "[T]he grant of a patent is a 'matter involving public rights.'") (Citing *United States v. Duell*, 172 U. S. 576, 582–583 (1899) *Murray's Lessee v. Hoboken Land & Improvement Co.*, 18 How. 272, 284 (1856)); *see Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272, 284 (1856) ("At the same time there are matters, involving public rights, which may be presented in such form that the judicial power is capable of acting on them, and which are susceptible of judicial determination, but which congress may or may not bring within the cognizance of the courts of the United States, as it may deem proper.")."

[11] *Oil States*, 138 S.Ct. at 1373 (citing *United States v. American Bell Telephone Co.*, 128 U.S. 315, 370 (1888)).

[12] The patent system is viewed as "a carefully crafted bargain that encourages both the creation and the public

inventor's burden in the *quid pro quo* exchange.[13] The public benefits from the exchange to no more extent than the inventor meets this burden.[14] To describe one's invention one must have invented. Patents describing ideas for effects and results in the abstract of any completely conceived invention[15] cause grave public harm.[16]

A title-eligibility model is proposed which aims to avoid this public harm. The model inquires whether a claimant's written description raises *prima facie* title to qualify the claimant as an inventor to place the claimant within a statutory category of applicants who may obtain a patent under 35 U.S.C. § 101. The model highlights the role of possession in raising *prima facie* title to an invention. The model suggests a title eligibility inquiry may be more efficient and effective than a subject matter eligibility inquiry to determine compliance with 35 U.S.C. § 101. **Part II** relies on the capture doctrine of *Pierson v. Post*[17] for the 'first to possess' rule of property ownership and for the proposition a factual inquiry on capture resolves the legal issue of possession to raise *prima facie* title to *ferae naturae*.[18] A subject matter eligibility inquiry is distinguished from a title eligibility inquiry in the context of a *quid pro quo* exchange in which the public pays a bounty for captured *ferae naturae*. **Part III** suggests 35 U.S.C. § 100 and 35 U.S.C. § 101 implement the Progress Clause of the Constitution to define a statutory category of claimant who may obtain a patent and that 35 U.S.C. § 112(a) articulates a requirement to describe an invention to raise *prima facie* title to place a claimant in that category. *Mergenthaler v. Scudder*[19] is relied upon to define conception of an invention. A written description that shows conception of an invention shows capture to raise *prima facie* title to the inven-

disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." Pfaff v. Wells Elecs., Inc., 525 U.S 55, 63 (1998).

[13] Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1345 (Fed. Cir. 2010) ("Finally, a separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the *quid pro quo* of a patent. . . ."); *see also*, Evans v. Eaton, 20 U.S. 356, 380 (1822) ("It is the business and duty of the inventor, then, at the time of applying for his patent, and before he can receive a patent, to deliver a written description of his invention . . . .").

[14] Evans v. Eaton, 20 U.S. 356, 434 ("It is, therefore, for the purpose of warning an innocent purchaser or other person using a machine, of his infringement of the patent; and at the same time of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.").

[15] *Thomas Jefferson to Oliver Evans, Esq.*, (Jan. 16, 1814) *in* 6 The Works of Thomas Jefferson, at 298 (H. A. Washington ed. 1884) ("I can conceive how a machine may improve the manufacture of flour; but not how a *principle* abstracted from any machine can do it. . . . If this be the meaning, my opinion that the legislature never meant by the patent law to sweep away so extensively the rights of their constituents, to environ everything they touch with snares, is expressed in the letter of August 13 from which I have nothing to retract, nor ought to add but the observation that if a new application of our old machines be a ground for monopoly, the patent law will take from us much more good than it will give.").

[16] *Id.* at 380 (Argument of Mr. Sergeant for defendant: "A patent for an entire machine covers the whole-a patent for an improvement, on the contrary, covers only the improvement, and necessarily supposes there are parts which are not patented. It is the line between these, and the parts which are patented, that defines the respective pretensions of the patentee and the public; and unless that line be somehow marked, it is impossible to say, where the one terminates, and the other begins. Confusion, uncertainty, extortion, fraud and litigation would be the inevitable consequence."

[17] Pierson v. Post, 3 Caines 175.

[18] *See* Earl C. Arnold, *The Law of Possession Governing the Acquisition of Animals* Ferae Naturae, 55 Am. L. Rev. 393 (1921) ("[T]he fact of possession raises a *prima facie* title or presumption of ownership of the thing possessed.").

[19] Mergenthaler v. Scudder, 1 App. D.C. 264, 1897 C.D. 724.

tion. *Voelker v. Gray*[20] is relied upon to distinguish conception of an invention from conception of an idea. Conception of results alone fails to raise *prima facie* title. **Part IV** presents the proposed title eligibility model and applies it to patents describing functionally claimed results at issue in the Supreme Court's decisions in *Evans v. Eaton*[21] and *Alice v CLS Bank.*[22]

The paper concludes a title eligibility inquiry may be more efficient and effective than a subject matter eligibility inquiry to determine compliance with the provisions of 35 U.S.C. § 101. The paper suggests 35 U.S.C. § 100 and 35 U.S.C. § 101 define a statutory category of claimant who may obtain a patent. Claimants who fail to raise *prima facie* title in an invention are an implied exception to the statutory category. Patent applications with insufficient factual evidence to raise *prima facie* title could be rejected under 35 U.S.C. § 101 on grounds the claimant is not an inventor with their invention. The Progress Clause does not empower Congress to grant exclusive rights to individuals without their inventions. A claimant without their invention is not 'whoever invents' to be within a statutory category of claimant who may obtain patents under 35 U.S.C. § 101. A patent title is bad where *prima facie* title in an invention is not raised by its written description. Pending claims may be adjusted to have a scope commensurate with a claimant's *prima facie* title. The title eligibility inquiry is dispositive of the issue of subject matter eligibility and is more compact. The model approach aims to avoid granting patents with claims excluding the public from more than a patent's written description shows the claimant would contribute to the public domain as the claimant's own invention. In patent law possession is the root of title.

II. POSSESSING A FOX

A. *Capture doctrine*

On December 10, 1802 Lodowick Post formed an intent to possess "one of those noxious beasts called a fox."[23] Post went fox hunting "upon a certain wild and uninhabited, unpossessed and waste land called the beach."[24] There Post sighted a particular fox he desired to possess. Post and his hounds gave chase to the fox. The chase became a 'hot pursuit' as they closed in.

As Post and the hounds were closing in, a school teacher named Jesse Pierson came walking along on his way home from school. Contrary to the etiquette of the hunting elite[25] Pierson interfered in a hunt already in progress. Instead of deferring to the hunter Pierson pursued the fox on foot, cornered it and killed it. Then he slung the dead fox over his shoulder and continued along

[20] Voelker v. Gray, 30 O.G. 1091, 1885 C.D. 16 (Comm'r Pat.).

[21] Evans v. Eaton, 20 U.S. 356 (1822).

[22] Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347 (2014).

[23] Pierson v. Post, 3 Caines 175 (Thompkins, J.).

[24] This is how Post described the land in his declaration. This "uninhabited, unpossessed and waste land" is now some of the most valuable real estate in the country. See, e.g., Bethany R. Berger, *It's Not About The Fox: The Untold History of* Pierson v. Post, 55 Duke L.J. 1089, 1091 n.2 (April 2006).

[25] *Id.* at 1092 n.11 (April 2006).

his merry way within full view of Post. Post confronted Pierson, demanding Pierson hand over the dead fox. In Post's view he Post, was the rightful owner of the fox. Not only was Post the first to spot the fox, Post was first to pursue the fox. Post was closing in for the kill before Pierson arrived on the scene. Pierson was a wrong-doer who had rudely interfered and shouldered for himself the spoils' of Post's hunt.[26] Pierson refused to surrender the beast to Post. So Post sued Pierson for trespass on Post's right of property in the dead fox. The two men litigated the issue 'who owns the fox' all the way to the New York Supreme Court.

A fox is an animal *ferae naturae*. Things *ferae naturae* exist in the wild as things not subject to ownership by anyone. Under *ferae naturae* law a wild thing ceases to be wild when it is brought into someone's possession.[27] It is ancient law that the first to possess a thing *ferae naturae* is entitled to ownership.[28] As an undisputed fact Pierson was the first to possess the body of 'poor Reynard'.[29] The undisputed fact of Pierson's first physical possession and the ancient 'first possession' law did not yield a clear resolution to the ownership dispute between Lodowick Post and Jesse Pierson. The district court focused on the facts of Post's first sighting and his hot pursuit of the fox. On those facts the district court found Post was first to possess the fox. Pierson appealed the district court decision to the New York Supreme Court. The issue of law considered by the New York Supreme Court was in essence the question posed by Pollock.[30] "What is it to possess?"[31] Justice Thompkins writing for the majority framed the issue as follows:

> "The question submitted by the counsel in this cause for our determination is, whether Lodowick Post, by the pursuit with his hounds in the manner alleged in his declaration, acquired such a right to, or property in, the fox, as will sustain an action against Pierson for killing and taking him away?" "It is admitted that a fox is an animal *ferae naturæ*, and that property in such animals is acquired by occupancy only. These admissions narrow the discussion to the simple question of what acts amount to occupancy, applied to acquiring right to wild animals?"

After careful consideration of the wisdom of ancient philosophers such as Justinian Institutes,[32] Fleta[33] and Bracton[34] the court concluded:

[26] Pierson v. Post, 3 Caines at 180 (Livingston, J., dissenting).

[27] Arnold, *supra* note 20 at 397.

[28] *Id.* at 393.

[29] Although the majority opinion in *Pierson v. Post* refers to the fox as a "wild beast" and in the pleadings a "noxious and wild beast," the dissent invites fond memories of medieval fables by referring to the fox as "poor [R]eynard." Pierson v. Post, 3 Caines at 180 (Livingston, J., dissenting).

[30] Pierson v. Post, 3 Caines 175.

[31] *Id.*

[32] Fleta is a treatise, written in Latin, with the sub-title seu Commentarius juris Anglicani, on the common law of England; *see* https://en.wikipedia.org/wiki/Fleta.

[33] The Institutes of Justinian (Latin: *Institutiones Justiniani*) is a unit of the *Corpus Juris Civilis*, the sixth century codification of Roman law ordered by the Byzantine emperor Justinian I; *see* https://en.wikipedia.org/wiki/Institutes_of_Justinian.

[34] Henry of Bracton, also Henry de Bracton, also Henricus Bracton, or Henry Bratton also Henry Bretton (c.

> "[P]ursuit alone vests no property or right in the huntsman; and that even pursuit, accompanied with wounding, is equally ineffectual for the purpose, unless the animal be actually taken".

Here the court explicitly articulated particular facts that could *not* be relied upon to demonstrate possession. First sighting, first pursuit and even partial success in capturing do not show possession to vest title in an animal *ferae naturae*. The opinion went on to articulate the relevant facts and suggest how they might weigh in the inquiry:

> "That is to say, that actual bodily seizure is not indispensable to acquire right to, or possession of, wild beasts; but that, on the contrary, the mortal wounding of such beasts, by one not abandoning his pursuit,[35] may, with the utmost propriety, be deemed possession of him; since, thereby, the pursuer manifests an unequivocal intention of appropriating the animal to his individual use, has deprived him of his natural liberty, and brought him within his certain control. So also, encompassing and securing such animals with nets and toils, or otherwise intercepting them in such a manner as to deprive them of their natural liberty, and render escape impossible, may justly be deemed to give possession of them to those persons who, by their industry and labour, have used such means of apprehending them."

In the court's view the fact of capture is conclusive of possession. The court provides examples of facts showing capture such as 'bringing within certain control' and 'rendering escape impossible.' Interestingly the court suggests a title eligibility condition related to the individual seeking to acquire title. "[Capture acts] may give possession of them to those persons *who*, *by their industry and labour*, have used such means of apprehending them." (Italics mine) The court not only finds capture is sufficient to demonstrate a possessory relationship between a captured animal and an individual claiming ownership. It further suggests a basis for justifying the capture doctrine. Capture is justly deemed to give possession to vest title in those who use their industry and their labor in taking possession. A rule granting possession based on some criteria other than capture, e.g., first sighting or first pursuit, could not be justified on the same basis.[36]

The dispute in *Pierson v. Post* may simply have been a dispute between two men over ownership of a dead fox. Or it may actually been a reflection of escalating social tensions around allocation of property rights in shared resources

1210 – c. 1268) was an English cleric and jurist; s*ee* https://en.wikipedia.org/wiki/Henry_de_Bracton.

[35]This same language is found in patent law governing interference proceedings to determine the first inventor in a contest between two inventors claiming ownership rights in the same invention under the pre-AIA 'first to invent' regime.

[36]The language of 35 U.S.C. § 101 suggests a similar kind of possessory relationship based on capture by mental industry and labor; 35 U.S.C. § 101 states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

as suggested by Berger.[37] Either way the lessons of this case are a legacy to students of patent law. Today if one looks in books of law for resolution to the legal question 'What is it to possess?', at least for things like foxes and inventions[38] guidance may be found in first year property law textbooks. The New York Supreme Court's opinion in *Pierson v. Post* provides a factual 'capture' inquiry to resolve the legal question of possession.[39] Evidence of capture raises *prima facie* title. Anything less is insufficient.

B. *Quid pro Quo Incentives*

In *Pierson v. Post* two parties claimed ownership rights in the same fox. The facts surrounding capture of the fox were not in dispute. The question was one of law: What does it mean to possess a fox to be entitled to own it? In other circumstances the law might be settled but an inquiry on the facts is warranted. History provides an example of a town law implementing a *quid pro quo* exchange between the public and its individual members. The law articulates a statutory requirement for an individual claiming the benefit to demonstrate his possession of a thing before the public rewards him for capturing it. It seems foxes were a public nuisance in the late 18th century. Berger[40] uncovered records of proceedings conducted by public officials in 1791[41] in which a town agreed to pay four shillings for every fox killed between March 20 and June 20.[42] The town offered the payment on behalf of the public as an incentive to individual members of the public to perform the public service of killing a fox. Here, the *quid pro quo* exchange was one noxious beast killed by an individual in exchange for four shillings paid to the individual by the public.

According to Berger's research 'this bounty was enough to induce some to chicanery in claiming it.'[43] The town contemplated the possibility that an individual might claim to have killed a fox without actually having performed the public service of killing one. Perhaps the same dead fox might be presented more than once. To ensure the public received the benefit of the *quid pro quo* exchange, the town crafted a law. To claim the reward claimants with their captured foxes:

[37] Berger, *supra* note 28 at 1110 ("In the Southampton community as well, property rights did not fall into the individual ownership/open –access dichotomy, but reflected a continuum of shared property rights amount varying groups." "The fox did not make his famous dash over unclaimed land, in other words, but over land that had defined the residents' social and economic status for over a century. *Pierson v. Post* arose in the midst of an escalating conflict over that land's ownership and control.").

[38] Both are things that have no previous owner. They have not previously been occupied (possessed) by anyone.

[39] Gia Barboza, *Property Law Outline*: "Rule of Capture: Wild Animals are not owned by anyone, but once a person has gained possession of such an animal, he has rights in that animal superior to those of the rest of the world. Capture is sufficient. The mere fact that one has spotted or chased an animal is not sufficient to constitute possession. Property in wild animals is only acquired by occupancy, pursuit alone does not constitute occupancy or vest any right on the pursuer." https://msu.edu/~barbozag/Web/property.pdf

[40] Berger, *supra* note 28.

[41] Perhaps not coincidentally this law was enacted one year after enactment of the Patent Act of 1790. America was small world back then.

[42] Berger, *supra* note 28 at 1130 (*citing* 3 Records of the Town of Southampton with Other Ancient Documents of Historical Value (William S. Pelletreau ed., 1874); *see also*, Berger, *supra* note 28 at 1092 (*citing* James Truslow Adams, Memorials of Old Bridgehampton 166 (1962)).

[43] Berger, *supra* note 28 at 1130.

> "[S]hall first carry them before the nearest magistrate being yet green and unstuffed,[44] and shall satisfy the said magistrate that the said fox or foxes were taken within the time afore limited, and the said magistrate shall cut of the tip of the nose of said fox and forward a certificate by the bearer of said fox to the Town Clerk that he is satisfied in respect to the time when the fox was taken."[45]

This law requires an individual to provide evidence of the fact of his complete performance of the public service for which the reward is offered. To determine whether the reward should be paid out the magistrate examines the individual's evidence by direct observation. Directly observing a freshly killed (new) dead fox carried before him by an individual, a magistrate can conclude as a matter of fact this individual possesses the new dead fox for which he claims a reward. A possessory relationship between the individual claiming the reward and a new instance of the kind of thing (a freshly killed fox) for which the reward is offered is thereby demonstrated. Whether the fox is novel in the sense of not being the same fox previously presented to a different magistrate for a reward, is determined by a different inquiry. Every fox for which the reward is paid is marked by cutting off the tip of its nose. To determine whether the claimant's new fox is novel the magistrate checks the nose of the claimant's new (freshly killed) fox. If the tip is missing the claimant's new fox is nonetheless a new fox, but it is not a novel fox.[46]

1. *Subject Matter Eligibility*

There are similarities in the town law and the patent statutes. Both laws explicitly articulate particular categories of things for which the public provides an incentive. Both laws contain implicit exceptions to the explicit statutory categories. For example, the town law does not explicitly exclude squirrels from eligibility for the incentive. Nonetheless, a squirrel *per se* is not a fox *per se*. In that sense 'squirrel' is an *implicit* exception to the category of things for which the law explicitly provides an incentive.

Suppose there so many bounty claimants the magistrates have to streamline the claiming process. They make a rule requiring every claimant to place their freshly killed quarry in a bag. Each bag must have an attached label summarizing their quarry's characterizing features with a heading stating the category of animal to which the quarry belongs. A bag bearing a label reciting:

[44] To show the fox is new in the sense of 'freshly killed'.

[45] Berger, *supra* note 28 at 1131.

[46] There is an old story about a contracting officer frustrated in his efforts to procure new tires for his fleet of vehicles. It seems his overseas suppliers always fill his orders with used tires. In his latest order, despite the language barrier the contractor believes he has finally clearly communicated his requirement that the tires be 'new'. When the shipment of tires arrives he is dismayed to once again find used tires in the cargo crates. He calls the supplier threatening to sue, citing his specification explicitly requires 'new' tires. The supplier replies, "The tires are new". The contractor argues, "The tires are *not* new. They are visibly worn." The supplier repeats, "The tires are new!" The contractor can't understand how his carefully worded contract left any room for argument that the 'old' tires he received met the contract requirement for 'new' tires. That is until the supplier argues: "Look. You wanted new tires. We sent you tires. You did not see these tires before. The tires are new to you." The patent statutes appear to make a similar distinction between 'new to you' (new to the inventor under 35 U.S.C. § 101) and novel (not known to anyone in the prior art under 35 U.S.C. § 102).

'I claim a squirrel comprising a furry body having coupled thereto four legs, a tail, and a nose' fails to claim to the kind of thing (fox) for which a reward is granted. Here the summarizing features match a fox. Nonetheless, on the basis of the claimant's admission alone ('I claim a squirrel comprising...') a magistrate might deny the reward. Now the statute does not explicitly state 'no squirrels allowed'. However, squirrels are implicit exceptions from the category of things for which the reward is paid, by virtue of 'squirrel' not being explicitly recited along with 'fox' in the language of the statute. The claim explicitly reciting 'squirrel' is rejected as directed to an implicit exception to the statutory category.

In theory this approach should streamline the bounty claiming process for all concerned. In practice suppose those who mark their labels with the words 'I claim a squirrel comprising...' begin to see this is an admission against their own interest. Soon all labels recite "I claim a fox comprising..." Magistrates presented with a label explicitly directed to 'fox' followed by a list of squirrel features have two choices. The first choice is to simply pay the claim. If the heading says 'fox' that's what it is. This is the path of least resistance. The magistrate's other choice is to charge the claimant with making a false claim. That choice has significant drawbacks. The claimant may simply have made a mistake in the heading or might not know the difference between a squirrel and a fox. Further, the magistrate cannot possibly know or prove any claimant's intent. Finally, catching untruthful claimants is not the magistrate's job.

Before long the town amasses a large number of dead squirrels while live foxes are roaming everywhere. The townspeople complain to the town judiciary. The judiciary find occasion to declare 'squirrel' an *explicit* exception to the fox bounty law. Now a magistrate presented with a claim to fox and a list defining a squirrel can tactfully reject the application stating: "Your feature list *prima facie* encompasses a squirrel. Squirrels are an *explicit* exception from the town law's statutory category of bounty-eligible quarry." The judiciary believe the problem is solved, having underestimated the creativity of claimants' professional label drafters. It isn't long before magistrates begin to see labels reciting 'squirrel-implemented fox' with lists mixing fox and squirrel features. This time both the magistrates and the townspeople complain to the judiciary. The judiciary can't agree on a solution. Finally the Town Supreme Court is called upon to decide whether claims to squirrel-implemented foxes are directed to the kind of thing for which the law offers a bounty. The Court in its wisdom articulates a 'squirrel or fox claim' legal test to scrutinize the language of the label. No magistrate could possibly apply this test within the time allotted.

The magistrates are left to develop their own test. They develop a test that inquires whether the feature list of a claim directed to a 'squirrel-implemented fox' contains any squirrel element. If it does the inquiry asks whether the label integrates the squirrel element into a fox. If it does the inquiry asks whether the label recites any practical application for the squirrel. If so the claim is considered directed to a fox. The outcome of this test differs little from the outcome of the approach taken by magistrates before the judiciary came up with their explicit exception for 'squirrels'. The problem has come full circle.

Meanwhile bags with dead squirrel bodies crumble the town's infrastructure as live foxes eat all the town's chickens. The townspeople see little benefit from their *quid pro quo* fox bounty bargain.

2. Claimaint Eligibility

There may be more efficient and effective ways for magistrates to determine whether to pay a fox bounty claim. The proposed title eligibility model offers an alternative. The title eligibility approach focuses on a claimant's status as a fox possessor based on the contents of the claimant's bag, instead of considering the subject matter eligibility of whatever the descriptive label asserts his bag contains The title-eligibility approach inquires whether there is sufficient evidence in the bag to support a *prima facie* conclusion the bag contains a fox. If there is sufficient evidence for that *prima facie* conclusion, the claimant is eligible. Examination of the claim proceeds directly to the 'nose-tip' inquiry to determine whether the claimant's assertedly new fox is a novel and unobvious fox. If there is insufficient evidence for the *prima facie* conclusion, the application is rejected on the grounds the claimant does not *prima facie* appear to be within a statutory category of claimant to whom the magistrates may pay the bounty. The claimant is not someone who carries their freshly killed fox before a magistrate. A claimant with their fox is what the law requires.

This is a more objective approach than one considering eligibility of a label's subject matter. Certainly, examination of the contents of the bag is facilitated by a clear label drafted in good faith by a competent label drafter. Still, over the years, knowledge of the underlying reasons for arcane label drafting conventions erodes. These conventions seemed nonsensical but they ensured consistent label interpretation. A label can be crafted with innocent intent or deceptive intent, with no skill or exceptional skill. There is no way for a magistrate to know what any claimant intended. But the townspeople are not well served if the magistrate makes decisions based on preconceived notions of truth or falseness of assertions made on claimants' labels. Focusing on subjective interpretations of descriptive labels tips the scales against the public interest in *quid pro quo* exchanges with fox bounty claimants. It would seem prudent for magistrates to check claimants' eligibility to collect a bounty as a matter of fact, by magistrates directly inspecting contents of claimants' bags for objective evidence of their fox possession.

This alternative approach offers the added benefit of obviating the need for the magistrate to perform any subjective or complex test on the label's description. It isn't relevant what the label describes where a check of the contents of a claimant's bag shows what the claimant in fact captured is most likely a fox. On the other hand where the bag is devoid of evidence of a fox the proceeding terminates and the application is rejected. Only where there is a *prima facie* showing of 'fox' does the examination proceed. Otherwise the claimant does not meet the statutory condition because he has not shown in fact he is anyone who possesses a fox. There is an implicit exception in the law that makes a squirrel possessor ineligible for a bounty payment. No amount of creative label drafting would change the outcome of a title-eligibility inquiry. Hunters of

ordinary skill conducting the factual inquiry can readily distinguish a squirrel from a fox by examination of the body. The claimant does not raise *prima facie title* to a fox to qualify for the bounty as a matter of law, where he fails to show facts sufficient to conclude he is someone who captures a fox.

3. *Enablement and Possession in Quid pro Quo Exchanges*

In both the town law and patent law, there is requirement for a claimant to demonstrate his status as one who has performed the service for which an incentive is offered. A claimant does not meet the statutory requirement where the claimant carries to the nearest town official instead of a bag containing a fox, a bag containing a map showing hunters of ordinary skill how to capture the fox he describes on his label. That his map would enable a townsperson of ordinary skill to capture the fox without undue effort is not relevant to the claimant's eligibility for the reward. Capturing foxes is the task for which the incentive is provided.

The townspeople are harmed where they pay the incentive to the claimant who enables the public to capture but who does not himself capture a fox. The town coffers are depleted by four shillings and the townspeople are left to capture the fox for themselves. That isn't the only harm. The individual who follows the enabling map and does in fact become the first to capture the fox described on the label will not receive any part of the four shillings. The reward for that particular fox has already been paid out. There might be even more harm. Suppose the person who was awarded four shillings in exchange for his enabling map, then charges a fee to any member of the public who tries to follow the map to capture the fox. If the public officials routinely ignore the possession requirement and pay rewards in exchange for enabling maps, the public might accumulate a large collection of enabling maps without much public benefit.

In *Pierson v. Post* a similar distinction is seen in the role of 'possession' and the role of 'enablement' in raising title to an animal *ferae naturae*. The connotation of Pierson 'shouldering the spoils' of Post's hunt evinces an enablement thread in Post's losing argument. Post's prior hunting acts almost certainly enabled Pierson to capture the fox. But for Post's pursuit forcing the fox to flee, Pierson likely would not have noticed the fox. Perhaps Post enabled Pierson to capture the fox without undue effort on Pierson's part. Or maybe considerable effort by Pierson was required. In capture doctrine the level of Pierson's effort isn't relevant to the ownership dispute. For the purpose of acquiring title to the fox Post can't demonstrate his own possession by showing he was the first to enable Pierson to capture the fox.

In the proposed title eligibility model the first to show his own capture is entitled to own the invention, not the first to enable another to capture.[47] In this model a claimant who seeks to demonstrate his own possession by showing he

[47] *See, i.e.*, Martin v. Mayer, 823 F.2d 500, 505 (Fed.Cir.1987) ("It is 'not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device.'" (quoting *Jepson v. Coleman*, 314 F.2d 533, 536 (CCPA 1963)). *See also* Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571-72 (Fed.Cir.1997).

enabled any member of the public to become the first to capture, defeats his own title eligibility.

III. POSSESSING AN INVENTION

A. *Invention Possession is the Root of Patent Title*

American property law and American patent law have common threads in their ideological notions of property.[48] In theory the law starts with a world in a natural state and a common stock from which definite, distinguishable items are severed through expenditure of individual labor.[49] Observable possessory relationships between individuals and severed items play a role in maintaining social order when allocating public resources to private owners. When an individual severs a tangible thing like a wild animal from a common stock, the state of possession defines an observable, unambiguous relationship between the individual and the particular item taken.[50] The possessory relationship signifies a home advantage to the possessor should a challenger contemplate a fight for occupancy.[51]

The notion that society should have a rule declaring the possessor the winner before the fight begins thereby obviating the fight, is one theory about the origin of property.[52] One purpose of laws might be to establish clear rules that obviate the necessity of fighting. The court in *Pierson v. Post* explicitly acknowledges this purpose as a basis for the capture doctrine:

> "If the first seeing, starting, or pursuing [animals *ferae naturae*] without having so wounded, circumvented or ensnared them, so as to deprive them of their natural liberty, and subject them to the control of their pursuer, should afford the basis of actions against others for intercepting and killing them, it would prove a fertile source of quarrels and litigation"[53]

1. *35 U.S.C. § 101 — Prima Facie Title*

In the ideological notions of property, a property right is created when an individual applies her labor to sever an item from a public common. The individual's labor in taking something from the public common into the individual's possession establishes a possessory relationship between the individual

[48] Both ideologies have origins in English common law. "The Constitution's Patent Clause was written against the "backdrop" of English patent practices, *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1, 5 (1966), and early American patent law was "largely based on and incorporated" features of the English patent system. Edward C.Walterscheid, To Promote the Progress of Useful Arts: American Patent Law and Administration, 1789–1836 109 (1998) (Quoted in Justice Stevens' concurring opinion in *Bilski v. Kappos*, 561 U.S. 593, 627 (2010)).

[49] "All creation is a mine, and every man a miner." Abraham Lincoln, *Discoveries and Inventions*, reprinted in 10 J. Pat. Off. Soc'y 314 (May 1928).

[50] *See*, *e.g.*, James E. Krier, *Evolutionary Theory and the Origin of Property Rights*, 95 Cornell L. Rev. 139 (2009).

[51] *Id.* at 151, 152 ("They observe that members of many species-various spiders, insects, birds, and mammals, for example-commonly resolve territorial disputes by a simple rule: the resident always wins.").

[52] *See*, *e.g.*, Krier, *supra* note 55.

[53] Pierson v. Post, 3 Caines 175.

and the item. The individual is the first possessor of the item. The item is her new item. The possessory relationship between the first possessor and her new item demonstrates to others in society the individual's status as *de facto* owner of her new item. The same motif appears in the capture doctrine articulated in *Pierson v. Post*. The fact of an individual's capture is 'justly deemed to give possession' to those who use their 'industry and their labor to take possession' of new (previously wild) animals. Whoever publicly demonstrates his possessory relationship with an item he severs from the public common raises *prima facie* title to the item. The Progress Clause reflects the same possessory relationship motif.

> "[t]o promote the Progress of Science and useful Arts, by securing for limited Times *to Authors and Inventors the exclusive Right to their respective Writings and Discoveries*" (Italics mine)

The exclusive right Congress has power to secure is one reserved for a particular category of individual. That category is 'Inventor'. Inventors shall have exclusive rights to 'their Discoveries'. The word 'their' is a possessive pronoun indicating a possessory link between 'Inventors' and 'Discoveries.' This is the same possessory relationship identifiable in ideological notions of property and the capture doctrine of *Pierson v. Post*. It is also recognizable in the language of 35 U.S.C. § 101 which states:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

In this larger framework of the Progress Clause there is more to 35 U.S.C. § 101 than enumeration of statutory categories[54] of things[55] that can be claimed as an invention in a patent application. The language of the statute also links an actor ('whoever') to a new and useful [thing] by an act ('invents'). An act ('invents') brings the new and useful [thing] into possession of the actor. Here, 35 U.S.C. § 101 does not explicitly refer to this new and useful [thing] as an 'invention'. Nor does it refer to the actor ('Whoever invents') an 'inventor'. However, 35 U.S.C. § 100 defines the term 'invention' as 'invention or discovery.' 35 U.S.C. § 100 appears to weave the language of the Progress Clause into the language of 35 U.S.C. § 101. The Progress Clause refers to 'Inventors' and 'their Discoveries.' In 35 U.S.C. § 100 an 'invention' is an 'invention or discovery'. Applying that definition, the 'Inventors' in the Progress Clause have an exclusive right to 'their inventions.' Returning to 35 U.S.C. § 101, 'Whoever invents or discovers' is an inventor or discoverer of inventions or discoveries. Thus the 'Inventors' in the Progress Clause are 'Whoever invents or discovers' in 35 U.S.C. § 101. Whoever discovers has a discovery. An invention is an invention or discovery.

[54] There are four enumerated categories of subject matter process, machine, manufacture, or composition of matter. Improvements to these things are also within the categories.

[55] The word 'thing' appearing in brackets '[thing]' is used hereinafter as shorthand to denote 'process, machine, manufacture, or composition of matter or improvement thereto'.

The 'Discovery' in the Progress Clause is an invention according to the definition in 35 U.S.C. § 100. Deciphering this convoluted language might yield some potentially useful definitions.

An 'Inventor' is: 'Whoever invents any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof'.

An 'Invention' is: 'Any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof'.

The statute defines categories of [thing] which, if new[56] and useful will be considered 'invention' in patent law. The statute defines a category of claimant ('Whoever invents') who may obtain a patent. Whoever invents is an inventor. The Progress Clause empowers Congress to grant patents to inventors for their inventions. Whoever invents has an invention. If the 'conditions and requirements of this title' are met, that invention is patentable.[57] Whoever is with that patentable invention, and no one else, is an inventor entitled to a patent under the Constitution as implemented by 35 U.S.C. § 101. This 'inventor and their invention' relationship is the kind of possessory relationship that raises *prima facie* title in property law. It gives rise to an individual right of ownership of a thing an individual takes from a public common.

2. 35 U.S.C. § 112(a)-Evidence Raising *Prima Facie* Title

The social organization motivations in the theories of the origins of property rely significantly on demonstration to society of the fact of the possessory relationship which gives rise to the ownership right. The fact of the existence of a severed item can be confirmed by direct observation of the item. Physical labor of a particular individual with respect to the item can be observed. The resulting possessory relationship between the individual laborer and the item he severs can be confirmed by direct observation of the item in his physical possession. A captured *ferae naturae* is a directly observable tangible object. In contrast ideas and inventions are intangible. Capture of an idea does not necessarily involve physical labor. An invention may be conceived by mental acts alone. As conceived in an inventor's mind an invention is not a directly observable item.[58] How is society to observe an invention and a possessory relationship?

35 U.S.C. § 112(a) is one of the requirements to which anyone who purports to be 'Whoever invents' within the meaning of 35 U.S.C. § 101 is subject. 35 U.S.C. § 112(a) requires any new and useful [thing] a claimant assertedly

[56] To whoever discovers it.

[57] That the invention under 35 U.S.C. § 101 may be found upon examination not new under 35 U.S.C. § 102 or obvious under 35 U.S.C. § 103 means only that the invention is not patentable. The invention is still an invention if the condition of 35 U.S.C. § 101 is satisfied.

[58] A cook might completely conceive a new recipe for cookies in her mind, including all necessary ingredients, without the cook ever writing the recipe on paper, purchasing instances of the ingredients or making any cookies herself. No one can observe the recipe, the ingredients or the cookies as they exist in the cook's mind. To demonstrate possession of the new recipe the cook can provide a written description to show others the new recipe she captured in her mind. This doesn't require the cook to possess physical instances of the ingredients or to bake physical instances of the cookies. When the written description is filed it is considered a constructive 'baking of cookies' according to the recipe, i.e., constructive reduction to practice to show possession of recipe.

invents, to be described in writing. The writing is a public demonstration that shows the thing taken by describing precisely what was taken. The claimant providing that description shows himself to be in a possessory relationship with the thing described. The requirement of 35 U.S.C. § 112(a) is known as the 'written description' requirement.[59] 35 U.S.C. § 112(a) states:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."

35 U.S.C. § 112(a) requires 'the invention' to be described.[60] The antecedent for 'the invention' in 35 U.S.C. § 112(a) is found in 35 U.S.C. § 101 when the definition in 35 U.S.C. § 100 is applied in the manner described above. Significantly 'the invention' of 35 U.S.C. § 112(a) is *not* 'that which the inventor regards as the invention' in the claims required by 35 U.S.C. § 112(b). What an inventor *regards* as the invention can encompass much more than the new and useful [thing] she describes as her invention in her written description. The invention that must be described under 35 U.S.C. § 112(a) is the new and useful [thing] which 'Whoever invents' possesses as his invention. Where the claims required by 35 U.S.C. § 112(b) cover more of an invention than the written description of 35 U.S.C. § 112(a) shows the inventor possesses as her new and useful [thing], i.e., the [thing] she invents in 35 U.S.C. § 101, the claimant's *prima facie* title is not coextensive with her claims. This is a defect that causes public harm if the patent issues without claim adjustment.[61]

B. *Demonstrating Invention Possession*

How does applicant claimant describe his new and useful [thing] in writing[62] to demonstrate the inventor-invention possessory relationship to raise *prima facie* title ? How does an examiner or a judge determine whether a new and useful [thing] described in writing is an invention under 35 U.S.C. § 101? In *MacClain v. Ortmayer*[63] the Supreme Court found the word invention "cannot be defined in such manner as to afford any substantial aid in determining

[59] Courts have explicitly and consistently held the requirement for a 'written description of the invention' is a requirement separate and distinct from the requirement for a written description of 'the manner and process of making and using itto enable " The former is commonly referred to as the 'written description' requirement. The latter is referred to as the 'enablement' requirement, although both are requirements for a written description. Both requirements might be met by the same writing. However, a writing meeting one requirement does not necessarily meet the other. See, e.g., Evans v. Eaton, 20 U.S. 356; Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336.

[60] And additionally requires the described invention be enabled. Enablement is a separate and distinct requirement. *Ariad*, 598 F.3d at 1351.

[61] *See*, Evans v. Eaton, 20 U.S. 356.

[62] A drawing is considered a form of written description. *See e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555,1564-1565 (Fed. Cir. 1991).

[63] MacClain v. Ortmayer, 141 U.S. 419, 426-427 (1891) ("To say that the act of invention is the production of something new and useful does not solve the difficulty of giving an accurate definition, since the question of

whether a particular device involves an exercise of the inventive faculty or not." But the Court did not say the word 'invention' has no meaning at all. In a title-eligibility inquiry it isn't necessary to determine whether the inventor's capture of his particular new and useful [thing] involved an exercise of his inventive faculty. It is only necessary to determine whether he describes the thing he asserts he himself captured as something new to him. Whether that [thing] would have been new or obvious to anyone else is not relevant at this stage of the inquiry.[64]

The title eligibility approach first inquires what if any new and useful [thing] is asserted in the written description in light of the claims. If the written description does not assert any particular [thing] as something new to the claimant the inquiry ends. Whatever the claimant regards as the invention in the claims, there is no assertedly new and useful [thing] described in the written description. The claimant hasn't raised *prima facie* title. This is the result even if the written description provides great detail about all of the subject matter encompassed by the claims. If the written description fails to point out the claimant's new and useful [thing] the claim encompasses a whole new thing. The description must describe that whole new thing as the claimant's invention. Where the claim or the description describes only a [thing] with generic components the claimant did not invent a whole new thing. The claimant invented nothing. On the other hand if there is an assertion of a particular new [thing] distinct from the generic parts, or structural modifications to a generic part, the inquiry asks whether the description shows the claimant's own capture of that particular thing. Descriptions of particular modifications that achieve new and useful results are evidence of capture as a matter of fact. Capture as a matter of fact shows possession as a matter of law to raise *prima facie* title in the modified part described.

1. *Conception of Inventions*

Before enactment of the AIA,[65] filing a patent application was *prima facie* evidence of a claimant's status as a first inventor. That *prima facie* evidence could be challenged by someone who believed he was in fact the first to invent the thing in controversy. Between the two, the one who could show he was in fact first to conceive the thing in controversy had priority as a matter of law. Since enactment of the AIA there is no way for someone who believes they were first to invent to challenge the claim of another who was first to file a patent application for the same invention. The AIA 'first to file' rule increases the pressure on

what is new, as distinguished from that which is a colorable variation of what is old, is usually the very question in issue. To say that it involves an operation of the intellect, is a product of intuition, or of something akin to genius, as distinguished from mere mechanical skill, draws one somewhat nearer to an appreciation of the true distinction, but it does not adequately express the idea. The truth is, the word cannot be defined in such manner as to afford any substantial aid in determining whether a particular device involves an exercise of the inventive faculty or not.").

[64]The inventor is not required to conduct any investigation to discover whether the device new to him, is objectively new. Whether the device new to the inventor is in fact novel is tested elsewhere in the patent statutes. Objective novelty is tested under 35 U.S.C. § 102. Unobviousness is evaluated under 35 U.S.C. § 103. These requirements are separate from 35 U.S.C. § 101 and 35 U.S.C. § 112.

[65]America Invents Act, Public law 112-29, 125 Stat. 284 through 125 Stat. 341.

those who are inventing to file patent applications before they in fact become 'Whoever invents' within the meaning of 35 U.S.C. § 101. After the AIA it is more important than ever to determine whether the first to file a claim to have invented, did in fact invent. To avoid public harm by prematurely awarding title to someone who is not 'Whoever invents', the model applies the pre-AIA standard of 'conception of an invention'[66] to inquire whether a completely conceived invention is described in an applicant's written description. The model adopts the same kind of evidence and the same evidentiary standard applied to show conception of an invention in pre-AIA interference proceedings.

Whatever the word 'invention' is taken to mean, an invention could not exist at any time prior to completion of its conception.[67] In the title eligibility model a claim to an invention that doesn't yet exist is a claim to an abstract idea. Courts have not provided any clear definition of an 'abstract idea'. Many courts have defined what it means to conceive an invention.[68] In *Mergenthaler v. Scudder*[69] the District of Columbia Court of Appeals quoted Mr. Commissioner Leggett[70] who clearly explained the concept:

> "The point of time at which invention, in such sense as to merit the protection of law, dates is neither when the first thought of it is conceived, nor when the practical working machine is completed, but it is when the thought or conception is practically complete; when it has assumed such shape in the mind that it can be described and illustrated; when putting it in working form; when the 'embryo' has taken some definite form in the mind and seeks deliverance, and when this is evidenced by such description or illustration as to demonstrate its completeness...The true date of the invention is at the point where the work of the inventor ceases and the work of the mechanic begins. Up to that point he was inventing, but had not invented, and he must have invented before the law will come to his protection"

Further, the court identified a point in the process where whoever was inventing, becomes 'Whoever invents.' This point is significant in the context of the language of 35 U.S.C. § 101. 'Whoever invents or discovers' does not possess an invention at any time prior to the point at which he becomes one who invents. That point is the point of 'capture'. The point in time at which an invention is conceived in *Mergenthaler* corresponds to the point in time at which the fox is considered captured in *Pierson v. Post*. Conception of an invention is analogous to capture of the fox. Before someone captures the fox no one possesses the fox. Before an invention is conceived no one possesses the invention. Whoever captures is whoever invents.

[66] The phrase 'conception of an invention' has a very different meaning than the phrase 'inventive concept'. *See e.g.*, Gibson v. Scribner, 22 F. 840 (D. Maine 1885).

[67] As with an animal *ferae naturae* 'partial conception' of an invention is a logical impossibility.

[68] The term 'conception of an invention' is typically used in the context of interference proceedings, which are obviated by the AIA. However, the definition is still useful, particularly to determine whether a purported invention is in fact an invention, or merely an idea.

[69] Mergenthaler v. Scudder, 1 App. D.C. 264, 1897 C.D. 724, 731.

[70] *See* Cameron & Everett v. I.R. Brick, 6 O.G. 171, 1871 C.D. 89 (Comm'r Pat.).

Demonstrating conception as a matter of fact, demonstrates possession as a matter of law to raise *prima facie* title in foxes and inventions.[71] Awarding title before anyone captures a [thing] causes public harm and creates the 'fertile ground for quarrels and litigation' Justice Thompkins warned about in *Pierson*. In the proposed model the first to file a patent application meeting all the requirements, including a requirement to provide a written description demonstrating a completely conceived invention to raise *prima facie* title, is the inventor with his invention. This is the one who may obtain a patent therefor.

2. *Conception of ideas*

In the proposed model an idea in the abstract is distinguished from an invention by the fact of conception of an invention. Conception of an invention is capture of an abstract idea. Mr. Commissioner Butterworth[72] defined what will constitute complete conception, within the meaning of patent law. He makes a distinction between conception of an idea on one hand and conception of an invention on the other.

> "The party claiming [priority of invention] must have been "the first to conceive the thing in controversy; not merely to have conceived it possible to construct a device which would produce the result sought." "The conception *must not be the result to be obtained*, but the means (which is the patentable thing) to produce that result. As long as there is a missing ingredient, in the absence of which the means utilized is a failure, the desired result unattainable, the invention is incomplete." (Italics author)

In the proposed model where the written description describes an assertedly new and useful [thing] solely in terms of results, complete conception of an invention is not shown. What is described is not an invention. It is an idea in the abstract of a completely conceived invention. The written description of the abstract idea (incomplete conception) fails to raise *prima facie* title.[73] Without an invention one cannot be in a possessory relationship with her invention to meet the possessory condition of 35 U.S.C. § 101. A claimant without an invention is not an inventor. An argument one of ordinary skill would be able to complete the conception only defeats the *prima facie* title of the claimant. Whoever completes the conception is the first to possess the abstract idea as his invention. That one is an inventor with their invention (discovery). The Progress Clause authorizes Congress to reserve exclusive rights to inventors for *their* discoveries.

[71] The America Invents Act of 2011 implemented a 'first to file' system. In this system the written description as filed is the only opportunity to demonstrate conception of an invention. Applying the *Mergenthaler* conception model in the context of the AIA, the filing date of the patent application marks the very latest point in time at which the work of the inventor ceased with respect to a claimed invention. The law will not come to his protection if his written description as filed does not show he has invented.

[72] Voelker v. Gray, 30 O.G. 1091, 1885 C.D. 16

[73] "Would it seriously be contended that a person might acquire a right to the exclusive use of a machine, because when used in combination with others, a new and useful result is produced which he could not have acquired independent of the combination?" Evans v. Eaton, 16 U.S. 454, 477 (1818).

To adequately describe a conceived invention that achieves advantageous results using a known component, the modifications to the known component are described by which the results are achieved. In the absence of modification the only component shown is the old component. An old component cannot be an inventor's new invention. An idea for a result is not an invention. An idea for a result cannot be an inventor's new and useful [thing] in 35 U.S.C. § 101. The description of the modification provides facts showing capture. Capture is possession. Possession raises *prima facie* title in an improved component as an invention. The inventor is in a possessory relationship with an invention. The condition of 35 U.S.C. § 101 is met. The applicant is in the statutory class of applicants who may obtain a patent.

In the proposed title eligibility model, descriptions of results without description of sufficient means to ensure achievement of the entirety of the results, are descriptions of abstract (uncaptured) ideas. These remain in the public common until captured. The claimant describing only an old machine and a wish for new results merely describes a sighted fox he believes would be possible to capture. An ordinary mechanic like Jesse Pierson may yet intervene in the pursuit, capture and take possession of the fox. The one entitled to ownership is "the first to conceive the thing in controversy; not merely to have conceived it possible to construct a device which would produce the result." Until a claimant demonstrates capture by description of a completely conceived invention, he does not show possession. Until then the condition of 35 U.S.C. § 101 to show *prima facie* title fails and the applicant is not in the statutory category.

IV. TITLE ELIGIBILTY MODEL

In the *quid pro quo* patent bargain, claims determine the extent of a patentee's benefit. Claims in an issued patent define the metes and bounds of a patentee's private property. In that sense claims are a 'no trespassing' signal. Where patents would post 'no trespassing' signs in areas of the public common they discourage innovation and obstruct fair competition. These patents claim the future before it can arrive.[74] When patents post 'no trespassing 'signs in areas of the public domain, they warn the public away from the public's own property.

The written description determines the extent of the public benefit in any *quid pro quo* exchange with a claimant. The written description shows the extent of the inventor's capture of something from the public common as something distinct from the inventor's knowledge of the public domain.[75] This defines the extent of the inventor's contribution of his own invention to the public domain. The public will receive no more and no less than this in the *quid pro quo* bargain. Most claims recite elements captured from the public common along with at least some elements in the public domain.[76] The invention description

[74] *Ariad*, 598 F.3d 1336.

[75] Evans v. Eaton, 20 U.S. 356.

[76] "Inventions secured by letters patent sometimes, though rarely, embrace an entire machine, and in such cases

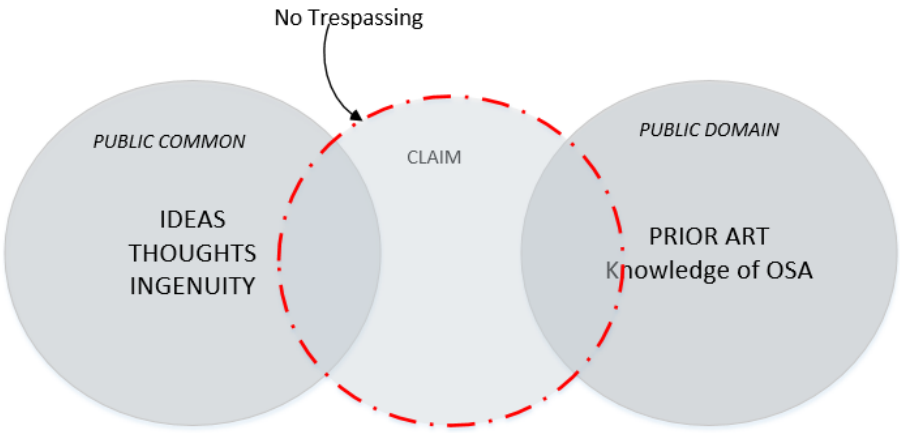

Figure 1: Venn Diagram of *proposed* Title Eligibilty Model showing hypothetical claim protecting a zone of No Trespassing as it relates to Ideas, Thoughts, and Ingenuity within the Public Common & Prior Art and Knowledge of Ordinary Skilled Artisan within the Public Domain

requirement of 35 U.S.C. § 112(a) places the burden squarely on the applicant to show precisely[77] how the claims should be interpreted to avoid 'no trespassing' signs in either the public common or the public domain.[78] The proposed title eligibility model, shown in Figure 1, illustrates this concept.

The model shows three circles circumscribing three areas of consideration. The claim circle represents the 'no trespassing' area of a claim. The public common circle represents the domain of *ferae naturae*. The public domain circle represents the public's property. For any given claim the written description determines any areas of overlap between the claim scope and the public common or the public domain. The model might be useful to envision the claim scope during examination. For example, a patent examiner might accord the claim circle its widest reasonable diameter[79] extending into both the public common circle and the public domain circle.[80] Claim language causing the claim circle

it is sufficient if it appear that the claim is coextensive with the invention. Other inventions embrace only one or more parts of a machine, and in such cases the part of parts claimed must be specified and pointed out so that constructors, other inventors, and the public may know what is withdrawn from general use." Seymour v. Osborne, 78 U.S. (11 Wall.) 516 (1870).

[77] "How can that be a sufficient specification of an improvement in a machine as a whole, mixing up the new and old, but does not in the slightest degree explain what is the nature or limit of the improvement which the party claims as its own?" Evans v. Eaton, 20 U.S. at 434.

[78] "Where an invention does not embrace an entire machine, the part should be specified and pointed out, as ex. gr. The coulter of the plough, or the divider or sweep rake of a reaping machine, so that another party may construct the plough or reaping machine provided he does not use the part specified." Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 516 (1870).

[79] Also known as 'broadest reasonable interpretation'.

[80] This exercise may be counterintuitive. The examiner widening the circle does not give the claimant a broader claim. On the contrary it causes the claim to extend to areas the claimant may not claim as his invention. The further the claim circle extends into the other two circles the less allowable subject matter the claim encompasses.

to extend into either of those areas is not accorded patentable weight in the examiner's interpretation. Subject matter in either overlapping area would not patentably distinguish a claim from the prior art.

A. *HOPPER BOY IMPLEMENTED INVENTIONS*

In the title eligibility model the claimant bears the burden of raising *prima facie* title by describing her invention in writing. The full extent of this burden is demonstrated in Evans v. Eaton.[81] In this case the Supreme Court determined the scope of a patentee's title where the patent contained a claim defining a new and useful machine in terms of its function. The patentee, Oliver Evans,[82] was in the business of flour milling. Flour milling involves the manipulation of tangible items, specifically grain. In the late eighteenth century the business of flour milling relied on gravity or manual labor to move the grain from one stage of the milling process to the next. Those engaged in the business of flour milling faced several technological challenges. One challenge was moving the input material against the force of gravity to transport it vertically from the bottom of the mill to the top of the mill. Known techniques for accomplishing this upward movement involved significant manual labor. Further processing of the material at the top of the mill was also a challenge. There, hopper boy machines[83] were employed to spread warmed meal horizontally on the floor as it exited the elevator. This machine also involved manual labor. The arms of the hopper boy had to be manually adjusted according to the amount of grain on the floor beneath the flaps.

Evans possessed many ideas and inventive concepts to solve these technical problems. He integrated his inventive concepts into machines that were considered pioneering in the art and business of flour milling at the time.[84] Oliver Evans was undoubtedly someone who invents or discovers new and useful [things]. Evans acquired several patents[85] for his machines. He li-

The area of the intersections shows the extent to which the scope of the claim is consistent with the claimant's *prima facie* title. The subject matter in the intersections cannot serve to distinguish the claim for purposes of allowance. During examination the claimant still has an opportunity to refine the claim or argue the area of the claim circle is incorrect. For claims in issued patents the claim circle is not given its widest reasonable diameter. Instead it is given a diameter consistent with the plain meaning of the claim language. In that case the area of the intersections with the other circles shows the extent to which the scope of the patent is wider than the claimant's granted title.

[81] Evans v. Eaton, 20 U.S. 356, 429 (1822).

[82] Oliver Evans (September 13, 1755 – April 15, 1819) born in Newport Delaware from 'Oliver Evans', Wikipedia, https://en.wikipedia.org/wiki/Oliver_Evans#Developing_the_automatic_flour_mill,_1783-90.

[83] "The hopper-boy is a revolving rake in a low walled tub that is located in the attic of the mill. The underside of the rake has paddles which are turned inward so when material is delivered to the outer circumference of the tub the material is moved inward with each revolving pass of the rake. As the rake revolves the flour is turned over and it cooled." http://www.angelfire.com/journal/millrestoration/schematic.html.

[84] Evans designed a system of conveyor belts, moving buckets, and screw feeds to automate grist mill operations. http://www.angelfire.com/journal/millrestoration/hopper.html. One of Evan's inventive concepts seems to have been a combination of a water-wheel, a bucket elevator and a hopper boy. Evans envisioned the bucket elevator coupled to the hopper boy via the water wheel to automatically move the input materials upwardly in the vertical plane with the elevator, while at the same time spreading the output material across the horizontal plane with the hopper boy. The motive force would be supplied by the water-wheel harnessing the energy generated by water.

[85] One of his patents was titled "Manufacturing flour and meal' issued Dec. 18, 1790. Another was ti-

censed his exclusive rights to others[86] and actively pursued infringers. One of his patents concerned an improvement in the functioning of hopper boy machines. Joseph Eaton was in the four milling business. Eaton used a hopper boy machine similar to the machine patented by Evans. Evans believed Eaton's machine infringed Evans' patent. Evans offered a license to Eaton but Eaton declined. A protracted legal battle ensued which was not resolved until after Evans' death.[87] Evans' invention is summed up in his patent specification as follows:

> "I claim as my invention the peculiar properties or principles this machine possesses, in the spreading, turning, gathering the meal at one operation, and the rising and lowering of its arms by its motion to accommodate itself to any quantity of meal it has to operate upon."[88]

The evidence of record showed prior art hopper boys were known and in use prior to Evans' discovery of his hopper boy.[89] The defendant Joseph Eaton admitted he used the very hopper boy for which Evans' patent was, in part, granted.[90] Evidence tended to show Evans' improved hopper boy was superior to prior art hopper boys.[91] The Court noted it was not disputed that Evans' specification contained a 'good and sufficient' description of his improved hopper boy and that description was enabling.[92] Evans' specification contained a detailed drawing of his hopper boy.[93] However, there was no indication in Evans' specification which part or parts of the hopper boy in the drawing constituted Evans' improvement.[94]

On those facts it wasn't relevant that Evan's written description enabled ordinary skilled artisans to make the whole hopper boy described in Evans' specification and claims. Evans did not invent a whole new hopper boy. The question was whether Evan's written description showed what Evans himself invented. The Court found the law requires this kind of showing whether or not the enablement requirement is met.[95] The Court noted this aspect of the

tled, 'Grinding Mill', issued Feb 14 1804 another titled 'Mode of manufacturing flour and meal' issued Jan 22, 1808. These patents are part of the X patents. The X-Patents are all the patents issued by the United States Patent and Trademark Office from July 1790 (when the first U.S. patent was issued), to July 1836. The records were burned in a fire in December 1836. Among those are 3X Manufacturing flour and meal', Dec. 18, 1790, 518X, Feb. 14, 1804 'Grinding Mill', both to Oliver Evans. For a list of Evan's patents see http://www.datamp.org/patents/search/xrefPerson.php?source=xrefPerson28237&start=0&id=28237

[86] "After he was granted one of the first U.S. patents, many people licensed his system, including George Washington and Thomas Jefferson for use in their business enterprises." http://jnjreid.com/cdb/oliverevans.html.

[87] His case went before the Supreme Court twice. The first time in 1818 and the second time in 1822 after Oliver Evans had died.

[88] Evans at 428

[89] Evans at 360

[90] Evans at 358.

[91] Evans at 361, 365

[92] "It is not disputed that the specification does contain a good and sufficient description of the improved Hopperboy, and of the manner of constructing it . . . ." Evans v. Eaton, 20 U.S. at 428.

[93] The written description of the invention consisted of a detailed drawing. See, e.g., Oliver Evans, The Young Mill-wright and Miller's Guide (1834); *see*https://commons.wikimedia.org/w/index.php?curid=32013426

[94] Evans 428, 433

[95] Evans 433, 434

written description requirement serves a purpose the enablement requirement does not serve.[96] The purpose of the written description is to convey to the public the same knowledge Evans had about what part of the machine was new to him and what parts were not new to him.[97] Evans' description met the enablement requirement but did not meet this other prong of the written description requirement.[98] As a result Evans' patent extended his exclusive right beyond what Evans' written description raised as his *prima facie* title. In other words the written description failed to raise *prima facie* title in either a whole new machine, or in any particular modification to an original machine.[99]

The Court viewed the functional claim language as describing a machine new in its '*modus operandi*'.[100] The functional language described new 'properties and principles.' To implement those properties and principles the hopper boy in Evans' written description must depart in its construction from an original hopper boy machine.[101] The written description did not inform the reader where that departure in construction occurred. In that case the properties and principles are ideas in the abstract of anything Evans' shows he possesses as his own invention.[102] The invention must be a whole new machine or it is nothing.[103] Where the written description does not permit distinction of the old from the new the description is insufficient[104] and the title is bad.[105]

From the perspective of subject matter eligibility the subject matter of the functional language is an effect or result, which is an abstract idea. The 'ma-

[96] Evans 434

[97] "The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the part may otherwise innocently suppose not to be patented. It is therefore, for the purpose of warning an innocent purchaser or other person using a machine, of his infringement of the patent; and at the same time of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification." Evans v. Eaton, 20 U.S. at 434, 435.

[98] Evans 435

[99] "Although in his specification he claims a right to the whole machine, in his petition he only asks a patent for the improvements in the machine. The distinction between a machine and an improvement to one, a machine or an improved machine is too clear for them to be confounded with each other." Evans v. Eaton, 16 U.S. at 516.

[100] "The plaintiff does not state it to be a specific improvement upon an existing machine, confining his claim to that improvement, but as an invention substantially original. In short he claims the machine as substantially new in its properties and principles, that is to say in the modus operandi" (at 429) (To the author this seems the very definition of 'functional claim language'.)

[101] Evans at 366

[102] Jefferson's 'Letter to Oliver Evans' (See FN 19) appears to describe this circumstance..

[103] "If he knows nothing of an original, then his invention is an original, or nothing: and the subsequent appearance of an original to defeat his claim is one of the risks which every patentee is exposed to under our law. As to the supposed distinction between an improvement on a machine patented, and on one not so, there is nothing in it. In both cases the improvement must be described, but with this difference: -That in the former case it may be sufficient to refer to the patent and specification, for a description of the original machine, and then to state in what the improvements, or such original consists: -whereas, in the latter case, it would be necessary to describe the original machine, and also the improvement. The reason for this distinction is too obvious to need explanation." Evans v. Eaton, 20 U.S. at 367-368.

[104] "How can that be a sufficient specification of an improvement in a machine as a whole, mixing up the new and old, but does not in the slightest degree explain what is the nature or limit of the improvement which the party claims as its own?" Evans v. Eaton, 20 U.S. at 434.

[105] "From this enumeration of the provisions of the act, it is clear that the party cannot entitle himself to a patent for more than his own invention;..' (Evans at 430)

chine' in the claim is a generic hopper boy. The written description provides no modifications to make the generic hopper boy achieve the effect. On those facts the claim's reference to 'machine' is nothing more than an instruction to implement the abstract idea of 'automating manual labor'[106] using a generic hopper boy machine. From the perspective of title eligibility, the written description fails to raise *prima facie* title to an invention consisting in a whole new machine because the facts show the whole new machine was not the patentee's invention. Neither did it raise *prima facie* title to an improvement to an original machine because the facts were not sufficient to show Evans' possession of any particular modification to any machine. Oliver Evans was unquestionably a remarkable inventor. But in this case he did not show he was an inventor in possession of his invention. He did not describe the invention he possessed as his own. The written description failed to raise *prima facie* title. The appearance of an original, a prior art hopper boy machine, defeated Evans title. This was the outcome even though the original machine did not achieve the advantageous results described in Evans' claim.

The title eligibility model represents these circumstances as follows:

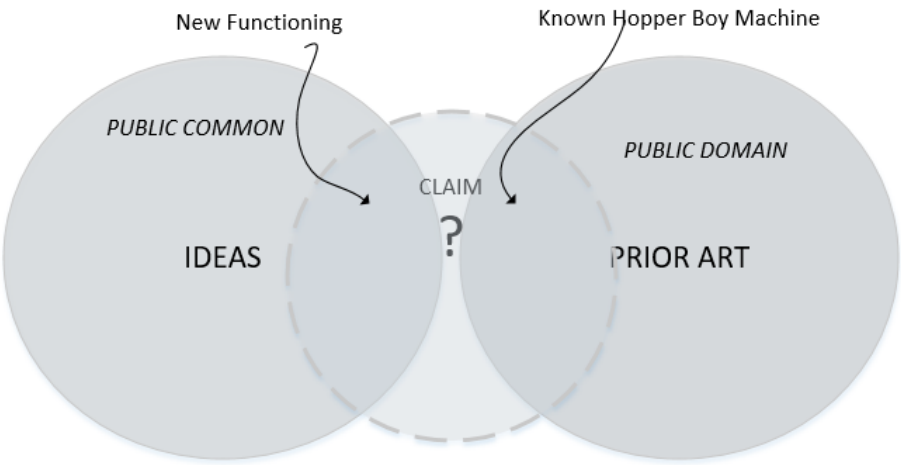

Figure 2: Venn Diagram showing Title Eligibility Model applied to Evans' Claim including New Functioning & the Known Hopper Boy Machiner as it relates to Ideas within the Public Common & Prior Art within the Public Domain

The claimed effects (modus operandi) are represented by the extension of the claim circle into the public common. The original is represented by the extension of the claim into the public domain. The only space for Evans to occupy with his invention is the gap between the public common circle and the public domain circle. Evans' written description did not admit any subject matter into that gap. Had it described modifications to achieve any of the recited functions,

[106] Evans 365

the modified parts would cause the claim circle to be retracted from the public common circle to bring those parts into the gap. This gap may be narrow. But it would have raised *prima facie* title. A narrow patent is better than no patent at all.

The proposed title eligibility model relies on *Evans v. Eaton* for the proposition a claimant alone bears the burden of distinguishing subject matter the claimant knows is old from the particular subject matter that constitutes the claimant's new and useful [thing]. According to the Supreme Court's opinion in *Evans v. Eaton* a claimant may not leave it to the public, an examiner or a court to compare the disclosed whole machine to old machines in an attempt to figure out what part of that disclosed whole machine is the new and useful [thing] the claimant captured as his invention. The claimant knows what is new to him. And he knows what is old to him. If he doesn't make the distinction and directs his claim to effects of a machine as a whole, any old machine will defeat his claim.[107]

B. *COMPUTER IMPLEMENTED INVENTIONS*

.

Nearly 200 years after the Supreme Court considered the 'hopper boy implemented invention' in *Evans v. Eaton* it considered a computer implemented invention in *Alice v. CLS Bank*.[108] The Court analyzed a method claim[109] to find both the method claims and the system claims in the patent added nothing of substance to an underlying abstract idea.[110] In many ways the system claim of the '479 patent in *Alice* is similar to the machine claim in *Evans v. Eaton*. Claim 16 of the '479 patent recites:

> A system to enable the formulation of customized multi-party risk management contracts, the system comprising:
>
> a plurality of main data processing devices interconnected by at least one data communications link, each said data processing device running an operating system and applications software;
>
> one or more data storage devices to which each data processing device has access;
>
> a plurality of data input/output channels providing connection to a plurality of stakeholder locations, each said location having data processing means, and
>
> the system being programmed for:
>
> regulating input of data, specifying a risk phenomenon, a range of outcomes for the phenomenon, and a time of maturity;
>
> stakeholders inputting to a said data storage device by ones of the stakeholder data processing locations contract data for an of-

[107] "If he knows nothing of an original, then is invention is an original, or nothing; and the subsequent appearance of an original to defeat his patent is one of the risks, which every patentee is exposed to under our law" (Evans, 367)

[108] Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347 (2014).

[109] US5970479 (the '479 patent), claim 33.

[110] *Id.* at 2353.

> fered contract, specifying an entitlement due at maturity for each outcome in the range of outcomes for a one of the predetermined phenomena, and an amount payable to a seller;
>
> counter-party stakeholders inputting to a data storage device by ones of the stakeholder data processing locations registering data, independent of contract data entered by stakeholders, as to a likelihood of occurrence of each outcome in the range of outcomes for at least one of the predetermined phenomena;
>
> pricing and matching a contract by the main data processing devices for at least one of the offered contracts from the seller registered data by: for an offered contract, selecting the registering data for the respective phenomenon and, in response to entitlements specified for each outcome in the range of outcomes for the phenomenon, calculating a counter-consideration, and, by comparison of the calculated counter-consideration with the consideration, matching an offered contract with at least one counter-party stakeholder.

The question certified to the *Alice* Court was one of subject matter eligibility: "Whether claims to computer-implemented inventions — including claims to systems and machines, processes, and items of manufacture – are directed to patent-eligible subject matter within the meaning of 35 U.S.C. § 101 as interpreted by this Court?"[111] In *Evans v. Eaton* the question the Court considered was one of title eligibility. Could Oliver Evans entitle himself to more of a machine than he invented?[112] The subject matter eligibility inquiry conducted by the *Alice* Court focused almost exclusively on the claims to ask whether the claims are directed to a patent ineligible concept.[113]

To conduct this inquiry the *Alice* Court first looked at the activity described in the claim language. The Court concluded the claims were drawn to the abstract idea of intermediated settlement.[114] The Court found the idea of intermediated settlement is an abstract concept.[115] The Court reasoned the concept was abstract because it was "a fundamental economic practice long prevalent in our system of commerce."[116] The Court further found the use of a third-party intermediary to reduce settlement risk was a building block of the modern economy.[117]

Next the Court turned to the second step of a test articulated in its earlier *Mayo*[118] decision. This step examines elements of the claim to determine

[111] *See* Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 734 (2013); *see also*, Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347, 235152 (2014).

[112] *Evans*, 20 U.S. at 430.

[113] *Alice*, 134 S.Ct. at 235253, § (I)(A).

[114] *Id.*

[115] *Id.* at 2356 ("On their face, the claims before us are drawn to the concept of intermediated settlement . . . .").

[116] *Id.* (quoting from *Bilski v. Kappos*, 561 U.S. 593 (2010)).

[117] *Alice*, 134 S.Ct. at 2356 (citing Yesha Yadav, *The Problematic Case of Clearinghouses in Complex Markets*, 101 Geo. L. J. 387, 406–412 (2013) and John C. Hull, Risk Management and Financial Institutions 103–104 (3d ed. 2012)).

[118] *Alice*, 134 S.Ct. at 2357, § (I)(B) (using the framework from Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U. S., 66 (2011)).

whether the claim contains an 'inventive concept' sufficient to transform the abstract idea into a patent-eligible invention.[119] The Court explained this step was necessary to ensure the claim is more than a drafting exercise designed to monopolize the abstract idea.[120] The Court found the method in claim 33 merely required generic computer implementation.[121] On that basis the Court concluded the claim failed to transform the abstract idea into a patent-eligible invention.[122] The Court found the system claims failed for substantially the same reasons.[123]

In contrast the Court in *Evans* conducted a less complex inquiry. The *Evans* Court first asked which of the broad categories, 'machine', or 'improvement to a machine' was being claimed. The *Evans* Court did not inquire what kind of activity was being described in the functional claim language. To the *Evans* Court the functional language was an abstract idea because it was a property or principle, an effect of a whole machine. This was an effect in the abstract of any particular means for achieving it. In a title-eligibility approach it isn't relevant what kind of effect is being described. The relevant fact is whether the inventor raised *prima facie* title in something that achieves the effect. To aid its title eligibility determination the *Evans* Court looked to the written description to see what machine was described as Evans' own invention. It found the whole disclosed machine was not Evans' invention. In that machine description the Court found the old parts could not be distinguished from the new or modified parts.[124] Evans did not show a possessory relationship with any particular parts of the only machine he disclosed. On that basis the Court concluded Evans was not entitled to the patent.[125]

The title eligibility model for the *Alice* claim is shown in Fig. 3. In *Evans* the hopper boy is in the public domain circle. In *Alice* the computer is in the public domain circle. In *Evans* the description of hopper boy effects or functioning is an idea in the public common. In *Alice* the description of computer functioning is in the public common.

[119] *Alice*, 134 S.Ct. at 2357.

[120] *Id.*

[121] It is unclear why the Court found the claims 'required' generic computer implementation. Claim 33 does not explicitly recite a computer or explicitly call for any step to be carried out using a computer.

[122] *Id.*

[123] *Id.* at 2360 ("Put another way, the system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea.").

[124] *Evans*, 20 U.S. at 429, 434.

[125] *Evans*, 20 U.S. at 430.

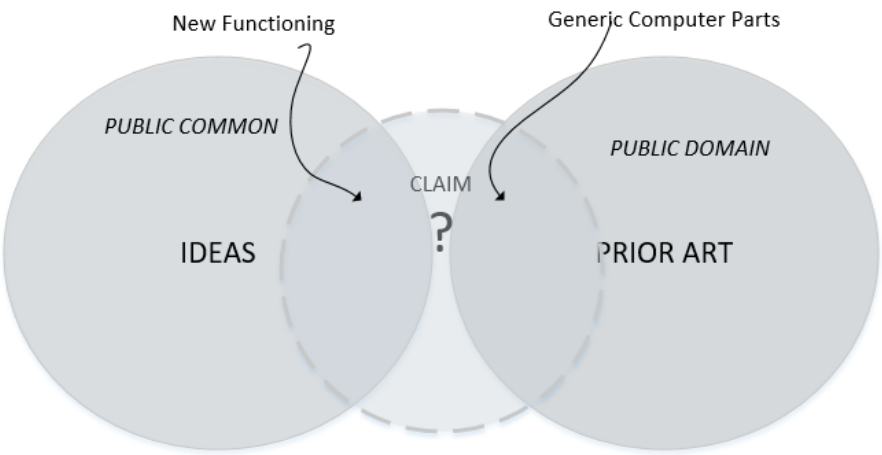

Figure 3: Venn Diagram showing Title Eligibility Model for *Alice* Claim's New Functioning & Generic Computer Parts as it relates to Ideas within the Public Common & Prior Art within the Public Domain

The idea in *Evans* was far less abstract than the 'intermediated settlement' idea in *Alice*. The hopper boy machine directly manipulated the meal in the process. Despite its less abstract subject matter, Evans' claim fared no better than the claims in *Alice* in the Supreme Courts' analyses. Perhaps Evans' functional language could have been characterized as 'automating manual labor'. Perhaps the activity in the *Alice* claims might have been characterized more broadly as 'automating mental labor'. It seems unlikely any particular characterization of the functional language in either claim would have changed the outcome. Whether or not the claim in *Alice* was directed to an abstract idea, the claimant in *Alice* was not the inventor of the generic system in claim 16 for the same reason Evans was not the inventor of the whole hopper boy machine in his claim. Neither claimant could show it was first to possess the machine in its claims. The public possessed those machines. Possession is the root of title.

V. CONCLUSION

A title eligibility inquiry may be more efficient and effective than a subject matter eligibility inquiry to determine compliance with the provisions of 35 U.S.C. § 101. The paper suggests 35 U.S.C. § 100 and 35 U.S.C. § 101 define a statutory category of claimant who may obtain a patent. Claimants who fail to raise *prima facie* title in an invention are an implied exception to the statutory category. Patent applications with insufficient factual evidence to raise *prima facie* title could be rejected under 35 U.S.C. § 101 on grounds the claimant is not an inventor with their invention. The Patent and Copyrights Clause does not empower Congress to grant exclusive rights to individuals without their inventions. The claimant without their invention is not one who invents to be within

a statutory category of claimant who may obtain patents under 35 U.S.C. § 101. A patent title is bad where *prima facie* title in an invention is not raised by its written description. Pending claims may be adjusted to have a scope commensurate with a claimant's *prima facie* title. The title eligibility inquiry is dispositive of the issue of subject matter eligibility and is more compact. The model approach aims to avoid granting patents with claims excluding the public from more than a patent's written description shows the claimant would contribute to the public domain as the claimant's own invention. In patent law possession is the root of title.

The Rumble About the Jungle: The Fight Over Dot Brand gTLDs and Geographic Names

J. Spencer Sanders II*

Abstract

In January 2012, The Internet Corporation for Assigned Names and Numbers ("ICANN"), the non-profit responsible for the maintenance and operations of the Internet, created a program designed to increase the number of generic top-level domains ("gTLDs"). The program's purpose was to address the demand problem associated with gTLDs, increase competition, customer choice, and innovation. The first expansion closed in April 2012 and brought in over 1,900 applications for new gTLDs. The program came with its fair share of problems, with some applicants running into issues when applying for brand specific gTLDs. Specifically, the e-commerce giant Amazon's application came under fire by countries in the Amazon rainforest region. The clothing company Patagonia and the hotel chain Shangri-La had similar problems with their gTLD applications for .patagonia and .shangrila. After official opposition from representative members from each of the countries on ICANN's Governmental Advisory Committee, the applications were put on hold and official processes started to decide whether the gTLD applications would be allowed to proceed. Issues over geographic name gTLDs and property rights in trademarks arose and the parties are still battling it out. The ICANN board needs to make changes in the promised second round of expansion to avoid these problems happening again.

*Symposium Editor, *American University Business Law Review*, Volume 8; J.D. Candidate, American University Washington College of Law, 2019; B.A., Marketing, Florida State University, 2015; I would like to thank the staff of the *American University Business Law Review* and Professor Christine Haight Farley for the time and effort put into reviewing, editing, and advising this comment. My sincerest gratitude to my friends and family, especially Chelsea Paige and my parents, Joel and Cheryl Sanders, for the love and support every step of the way. I wouldn't be here without you all.

Contents

I. Introduction

The Internet as we know it is changing, and it could mean trouble for some trademark owners. In 2012, the non-profit organization the Internet Corporation for Assigned Names and Numbers ("ICANN") developed an expansion program of generic top-level domains ("gTLDs").[1] gTLDs are the letters at the end of an internet address that do not represent a country or territory, such as .com or .gov.[2] The recent gTLD Program is ICANN's largest expansion of the domain name system and the largest expansion of the Internet as a whole.[3] The purpose of the program is to enhance innovation, competition, and customer choice.[4] The program has been criticized for reasons ranging from the financial toll it places on trademark owners to confusion concerns on behalf of consumers.[5]

[1] *About the Program*, ICANN, https://newgtlds.icann.org/en/about/program (last visited Dec. 28, 2017).

[2] *Id.*; Benjamin Boroughf, *The New Dot Context: How to Mitigate Trademark Concerns in ICANN's New gTLD Program*, 10 I/S: J.L. & Pol'y for Info. Soc'y 85, 90 (2014) (providing a definition and examples of gTLDs).

[3] *Largest Domain Name Expansion in Internet's History Reaches Benchmark*, ICANN, https://www.icann.org/news/announcement-2-2014-01-21-en (last visited Dec. 28, 2017).

[4] ICANN, https://web.archive.org/web/20161202080047/http://newgtlds.icann.org/en/about/program (last visited Dec. 21, 2017).

[5] *See* Bill Chappell, *ICANN's Call for New Domain Names Brings Criticism, and $357 Million*, NPR (June 14, 2012, 2:46 PM), https://www.npr.org/sections/alltechconsidered/2012/06/13/154960405/icanns-call-for-new-domain-names-brings-criticism-and-357-million (discussing possible economic harm the program is likely to cause to trademark owners and corporations).

In **Part I**, this Comment will first provide a background into ICANN and the gTLD expansion program. Then in **Part II**, it will explain the Domain Name Service ("DNS") and the complexities and problems associated with .brand gTLDs. In **Part III** this Comment will then describe specific problems with Amazon, Inc.'s application for the .amazon brand gTLD and compare these with the two others: .patagonia and .shangrila. Next, this Comment will discuss the influence of different governments in the decision-making process and whether greater deference should be given to the arguments of governments over those of the corporation applying for these gTLDs. Then this Comment will detail previous United States cases determining the legal standards and authority of ICANN. Finally, in **Part IV** it will then recommend specific changes to the current system to help mitigate the problems with standards and authority gTLD applications are currently facing.

II. The Expansion of the Internet Through ICANN

This section of the comment is meant to provide a detailed explanation of ICANN. It will first discuss ICANN's development, history, and eventual separation from direct control of the U.S. Government.[6] This section also explains the purpose and functions of ICANN as well as details the Generic Top-level Domain ("gTLD") expansion program. This section will then discuss issues with some specific applications taking place under the program and previous suits ICANN has faced.

A. The History of ICANN

ICANN is a nonprofit organization responsible for coordinating the maintenance and procedures of several databases related to the namespaces of the Internet.[7] Created on September 30, 1998, the main purpose of ICANN is to ensure the stable and secure operation of the Internet.[8] Its primary principles of operation are helping preserve the operational stability of the Internet, to promote competition, to achieve broad representation of the global Internet community, and to develop policies appropriate to its mission though bottom-up, consensus-based processes.[9] It does so with the help of other third party organizations such as the Governmental Advisory Committee ("GAC")and the Independent Review Panel ("IRP").[10] The GAC is a formal advisory body pro-

[6] *ICANN's Historical Relationship with the U.S. Government*, ICANN, https://www.icann.org/en/history/icann-usg (last visited Dec. 21, 2017).

[7] *See Bylaws for Internet Corporation for Assigned Names and Numbers*, ICANN, https://www.icann.org/resources/pages/governance/bylaws-en/ (last visited Dec. 21, 2017) (providing the duties and regulations followed by the organization).

[8] *See id.*; *What Does ICANN Do?*, ICANN, https://www.icann.org/resources/pages/what-2012-02-25-en (last visited Dec. 21, 2017).

[9] *See Memorandum of Understanding Between the U.S. Department of Commerce and Internet Corporation for Assigned Names and Numbers*, ICANN, (Dec. 31, 1999), https://www.icann.org/resources/unthemed-pages/icann-mou-1998-11-25-en, (detailing the agreement made between the U.S. government and ICANN).

[10] *See Governmental Advisory Committee*, ICANN, https://gacweb.icann.org/about-gac/ (last visited Dec. 29, 2017); *Bylaws for Internet Corporation for Assigned Names and Numbers*, *supra* note 7.

viding important advice regarding the policy implications of actions taken or decisions made by ICANN and its board.[11] The IRP is a third-party arbitrator that is responsible for reviewing the actions, in-actions, decisions, and resolutions of the ICANN Board and determining whether they are contrary to the provisions of the Corporation's Articles of Incorporation or By-Laws.[12]

On November 25, 1998, ICANN entered into a Memorandum of Understanding with the U.S. Department of Commerce.[13] The Memorandum established ICANN's role of focusing on managing technical DNS functions,[14] the numbering of Internet addresses, the coordination of port assignments, and assisting with the maintenance of the stability of the Internet's unique identifiers.[15] Then, in February 2000, ICANN entered into an agreement with the U.S. Department of Commerce to perform all of the Internet Assigned Numbers Authority's ("IANA") duties, including the regulation of IP addresses and domain names.[16] In September 2016, the contract expired, removing ICANN from U.S. government oversight and putting ICANN, a private nonprofit organization, in charge of the regulation of Internet domain names for the world.[17]

B. The Domain Name System and gTLDs

A very important part of the domain name regulation, and a cause of many of the problems, is the Domain Name System ("DNS"). The DNS is a hierarchical namespace controlled by ICANN.[18] The purpose of the DNS is to associate domain name addresses with easier to remember, alphanumeric text rather than their long, arbitrary, and nearly impossible to remember Internet Protocol ("IP") addresses.[19] There are two elements to each domain name, the top-level and second-level domains.[20]

Top-level domains ("TLDs") are the letters found at the end of an internet address, for instance, the .com in www.facebook.com.[21] Second-level domains ("SLDs") are the words or numbers that come before the TLD, such as facebook in www.facebook.com.[22] Any of the TLDs that do not represent a

[11] *Governmental Advisory Committee*, *supra* note 10.

[12] *See Bylaws for Internet Corporation for Assigned Names and Numbers*, *supra* note 7.

[13] *Id.*

[14] Ryan R. Owens, *Domain-Name Dispute-Resolution After* Sallen v. Corinthians Licenciamentos & Barcelona.com, Inc. v Excelentisimo Ayuntameiento De Barcelona, 18 Berkeley Tech. L.J. 257, 260 (2003).

[15] *Id.*

[16] *See ICANN's Historical Relationship with the U.S. Government*, *supra* note 6; *About us*, IANA, https://www.iana.org/about (last visited Dec. 21, 2017).

[17] *ICANN's Historical Relationship with the U.S. Government*, *supra* note 6 (showing the contract was renewed in 2001, 2003, 2006, and 2012 but was not renewed in 2016, expiring in September of that year).

[18] Owens, *supra* note 14, at 260 ("The United States created ICANN in November 1998 as a U.S-based, nonprofit, private entity to administer all aspects of the Internet, including the domain-name system.").

[19] *See id.* at 259; Alexa Holleran, *The World Wide Web Extension: From Dot-com to Dot... Everything*, 10 Bus., Entrepreneurship & L. 103, 106 (2017), (quoting *Beginner's Guide to Domain Names*, ICANN, https://www.icann.org/en/system/files/files/do

main-names-beginners-guide-06decl 0-en.pdf, ("[T]he DNS translates IP addresses into unique alphanumeric addresses called domain names that are easier to remember.")

[20] Boroughf, *supra* note 2, at 90.

[21] *Id.* at 90.

[22] *See id.*; Dennis S. Prahl & Eric Null, *The New Generic Top-Level Domain Program: A New Era of Risk for Trademark Owners and the Internet*, 101 L.J. Int'l Trademark Ass'n 1757, 1761 (2011).

country or territory are known as a generic top-level domain ("gTLD").[23] The main group of gTLDs are ".com," ".info," ".net," and ".org" but also include ".biz," ".name," and ".pro" the latter, however, are restricted due to proof of eligibility requirements.[24] Once the combination of SLD and TLD are registered, that exact combination of SLD and TLD cannot be registered again.[25] That same SLD can be registered under a separate TLD, however.[26] For example, two individuals could not both register the domain name www.forexample.com, but one could register www.forexample.com and the other could register www.forexample.org.[27] Initially, gTLDs were "intended to be registered and used by specific types of entities," .com for commercial entities; .net for organizations involved in networking technologies, such as Internet service providers and other infrastructure companies; .org for non-profits; and .edu for educational institutions.[28] Since ICANN's gTLD expansion program however, this has changed.

C. The ICANN Expansion Program

The expansion program was created by ICANN as a way to open up the Internet from its previously constrained domain names and overcome demand for new gTLDs.[29] Other purposes of the expansion were to provide more choices for consumers, promote competition, increase the number of non-Roman character TLDs, and create business opportunities.[30] To register a new gTLD, an institution must file an application, pay a $185,000 application fee, and indicate the type of gTLD they wish to register.[31] The four types of registration types are: brand, such as .nike, industry, such as .attorney, geographic, such .germany, and non-Latin script, such as: 香格里拉.[32]

The first round of applications opened January 12, 2012 and closed May 30, 2012.[33] ICANN received roughly 1,930 applications for new gTLDs dur-

[23] *About the Program*, *supra* note 1.

[24] *See* Rebecca W. Gole, *Playing the Name Game: A Glimpse at the Future of the Internet Domain Name System*, 51 Fed. Comm. L.J. 403, 406 (1999), (describing the DNS system and explaining the different uses of the gTLDs and their requirements).

[25] *See* Brian W. Borchert, Note, *Imminent Domain Name: The Technological Land-Grab and Icann's Lifting of Domain Name Restrictions*, 45 Val. U. L. Rev. 505, 509 (2011) (describing the DNS as a complex level system similar to a pyramid).

[26] *See* Boroughf, *supra* note 2, at 90.

[27] *Id.*

[28] *Id.* at 91, (citing Connie L. Ellerbach, *Domain Name Dispute Remedies: Tools for Taming the World Wide Web*, 759 PLI/PAT 513, 516 (2003)).

[29] About the Program, *supra* note 1.

[30] *See* Liohn Sherer, *New gTLDs Explained*, Compumatik, http://www.compumatik.com/new-gtlds-explained/ (last visited Dec. 30, 2017); Kathy Neilsen, *Domain gold rush: Why Your Company Needs to Speak Chinese Online*, Venturebeat (April 26, 2014 6:50 AM), https://venturebeat.com/2014/04/26/domain-gold-rush-why-your-company-needs-to-speak-chinese-online/ (speaking of the importance of non-roman character domains, specifically Chinese, on the internet).

[31] *How to Apply for a New Generic Top-Level Domain*, ICANN (Oct. 23, 2008), https://www.icann.org/news/announcement-2-2008-10-23-en.

[32] *See* Boroughf, *supra* note 2, at 96.

[33] Robin Wauters, *ICANN To Expand Top-Level Domain Names, Applications Start Jan 12, 2012*, TechCrunch (June 20, 2011), https://techcrunch.com/2011/06/20/icann-to-expand-top-level-domain-names-applications-start-jan-12-2012/.

ing the first round, of which 750 were contested.[34] A second expansion has been promised by ICANN, but specific details have yet to be released or announced.[35]

D. What is ".Brand?"

U.S. Trademark law generally allows identical marks to co-exist when there is no likelihood of confusion.[36] This can be seen in the existence of the mark "apple" for computers and electronics and also for Holiday travel services.[37] The marks are used in two very different markets, and thus trademark law allows the existence of both.[38] When online consumers search for a product, they must rely on the SLD to give them some idea as to the content and sponsor.[39]

Prior to ICANN's expansion program, the only option trademark owners had to differentiate themselves online was SLDs.[40] With the expansion, trademark owners can now apply for .brand gTLDs as a way of forming exclusive online presences.[41] Many companies are very excited about the existence of .brand gTLDs, and for good reason.[42] A .brand gTLD offers companies many advantages and positives.[43] With a .brand gTLD comes marketing advantages in the existence of shorter and more memorable URLs.[44] Consumers can often be confused by TLDs, for instance, whether to go to a .com or a .co.uk in the United Kingdom.[45] Brand gTLDs may lead to an elimination of this problem, giving consumers assurance as to the legitimacy of the URL.[46]

[34] ICANN, *New gTLD Fast Facts* (Feb. 28, 2014), available at https://newgtlds.icann.org/en/announcements-and media/infographics; *Program Statistics*, ICANN, https://newgtlds.icann.org/en/program-status/statistics (last visited Dec. 28, 2017); *New gTLD Current Application Status*, ICANN, https://gtldresult.icann.org/applicationresult/applicationstatus (last visited Dec. 28, 2017).

[35] *About the Program*, *supra* note 1.

[36] The Lanham Act, 15 U.S.C. § 1114(1)(a)(2001) (stating trademark infringement requires a showing that the defendant has "used in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with. . .goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive.").

[37] Graeme B. Dinwoodie, *Confusion Over Use: Contextualism in Trademark Law*, 92 Iowa L. Rev. 1597, 1658 (2007) (explaining that Apple Vacations, Inc. cannot enjoin the use of apple for computers if, despite the use of identical words, the context of the respective product markets ensures a lack of confusion).

[38] *Id*.

[39] *See* Boroughf, *supra* note 2, at 89.

[40] *See generally Id*. at 90.

[41] *See id*. at 98.

[42] Ben Davis, *Five Companies Using Branded Top-level Domains (TLDs) & Why*, Ecoconsultancy (Apr. 28, 2016), https://www.econsultancy.com/blog/67789-five-companies-using-branded-top-level-domains-tlds-why, (providing examples of companies taking advantage of the expansion to apply for .brand gTLDs).

[43] *See* Graham Charlton, *Brand TLDs: Five Potential Benefits*, Econsultancy (Mar. 12, 2015), https://econsultancy.com/blog/66191-brand-tlds-five-potential-benefits/ (explaining five benefits of registering .brand gTLDs); Tereza Litsa, *Brand TLDs vs. .Com: Why the World's Biggest Brands are Making the Switch to their Own Web Extension*, ClickZ (Jan. 17, 2017), https://www.clickz.com/brand-tlds-vs-com-why-the-worlds-biggest-brands-are-making-the-switch-to-their-own-web-extension/109000/.

[44] Chris Camps, *Brand TLDs vs. .Com (Part Two): How Can Brands Benefit from a .Brand TLD?*, ClickZ (Feb. 13, 2017), https://www.clickz.com/brand-tlds-vs-com-part-two-how-can-brands-benefit-from-a-brand-tld/109437/ (stating "shorter, simpler URLs are more memorable and easier to understand.").

[45] Davis, *supra* note 42.

[46] *See* Charlton, *supra* note 43; *The Barclays Dot Brand*, BrandDomains, http://www.thebranddomains.com/barclays.html, (last visited Feb. 16, 2018) (providing an example of a company purchasing a .brand gTLD for the purposes of consumer trust).

An example of a .brand gTLD is ".apple", ".nike" or any other company name, brand, trademark, slogan or acronym following the second dot in a URL.[47] Of the 1,930 applications received by ICANN, roughly one third of them were of this type.[48] Some argue this could cause problems, leading to extreme customer confusion, or even leading to a littering of unique, context-less, or even fallow gTLDs.[49]

E. Amazon's .amazon Application

In April 2012, during the initial expansion of gTLDs, Amazon, the famous and popular e-commerce company, applied for the most contested .brand gTLD yet, .amazon.[50] In its application, Amazon stated that "the mission of the .amazon registry is: To provide a unique and dedicated platform for Amazon while simultaneously protecting the integrity of its brand and reputation."[51] The application additionally stated that a ".amazon registry will: Provide Amazon with additional controls over its technical architecture, offering a stable and secure foundation for online communication and interaction; Provide Amazon a further platform for innovation; and Enable Amazon to protect its intellectual property rights."[52] Initially, the application proceeded normally, passing all of ICANN's criteria for approval with flying colors and was approved with no issue.[53]

In July 2013, ICANN formally decided that .amazon did not fall within the criteria for a geographic area contained within the applicant guidebook and thus would proceed as normal without governmental approval.[54]

Soon thereafter, and rather unexpectedly, the Brazilian government started an aggressive campaign against the proposed gTLD and its Chinese and Japanese language equivalents.[55] The Brazilian government, along with Peru

[47] *Learn more about applying for a new dot Brand Top Level Domain*, Afilias, https://afilias.info/dotbrand (last visited Feb. 11, 2018).

[48] *New gTLD Current Application Status*, *supra* note 34; *See .Brand Applications Account for One Third of All New gTLD Applications*, MarkMonitor (June 14, 2012), https://www.markmonitor.com/mmblog/brand-applications-account-for-one-third-of-all-new-gtld-applications/.

[49] *See* Boroughf *supra* note 2, at 98.

[50] *Application Details – Amazon*, ICANN, https://gtldresult.icann.org/application-result/applicationstatus/applicationdetails/984 (last visited Dec. 29, 2017).

[51] ICANN, *New gTLD Application Submitted to ICANN by: Amazon EU S.à r.l.* (June 13, 2012), (*available at* https://gtldresult.icann.org/application result/applicationstatus/applicationdetails/984.

[52] *Id.*

[53] *Initial Evaluation Report*, ICANN (July 12, 2013), https://newgtlds.icann.org/sites/default/files/ier/bqe3so7p3lu2ia8ouwp7eph9/ie-1-1315-58086-en.pdf; *see* Kieren McCarthy, *Dot-Amazon Spat Latest: Brazil Tells ICANN to go Fsck Itself, Only 'Govts Control the Internet'*, Register (Sep. 27, 2017 9:04 PM), https://www.theregister.co.uk/2017/09/27/brazil_dot_amazon_gtld/?page=1 ("Amazon applied for the ".amazon" name back in April 2012 and its application proceeded normally, passing the various assessments built into ICANN's process with flying colors.") [hereinafter McCarthy, *Dot-Amazon Spat Latest*].

[54] ICANN, *gTLD Applicant Guidebook*, 2-13, 18 (May 30, 2011) (stating an applied-for gTLD string is considered a geographic name if it is the capital city name of a country or territory a city name when it is clear it is to be used as such, a sub-national place, or a name listed as a UNESCO region or appearing on various geographic name lists); *See* McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

[55] McCarthy, *Dot-Amazon Spat Latest*, supra note 53; Kieren McCarthy, *What is This River Nonsense? Give .amazon to Bezos, Says US Congress*, Register (June 23, 2015 11:13 PM), https://www.theregister.co.uk/2015/06/23/what_is_this_river_nonsense_give_amazon_to_bezos_says_us_congress/, (recounting the details of the U.S. and Brazilian governments involvement in the application process) [hereinafter McCarthy,

and six other countries in the Amazonian region, argued that allowing Amazon, the corporation, to have exclusive rights over the .amazon gTLD somehow harmed the countries and the people living in the Amazon region of them.[56]

Later in July 2013, the Brazilian government made an official objection to the application through their representatives in the GAC.[57] Although the GAC gave no real rationale for their determination that the gTLD was harmful, ICANN's board gave deference to it and, as a result, banned the creation of .amazon noting that its decision "is without prejudice to the continuing efforts by Amazon and members of the GAC to pursue dialogue on the relevant issues."[58] Behind the scenes, in an attempt to reach a compromise, Amazon offered many concessions to the countries, including blocking SLDs that may be relevant to the region and offering other SLDs to groups that may want to use them, all to no avail.[59]

Amazon eventually appealed the decision up to the IRP.[60] Three years after the original ban, the IRP concluded that ICANNs board made the wrong decision and violated its own bylaws in the rejection of .amazon.[61] After reviewing all of the documents and speaking to all individuals involved, the IRP determined it was "unable to discern a well-founded public policy reason" for rejecting the application.[62] Amazon has since written directly to the ICANN board requesting that it "immediately approve" their "long-standing .amazon application" and that the board should respect the conclusion of the IRP panel.[63] ICANN's board has now put the ball back in the GAC's court, so to speak. The Board has given the GAC until March 2018 to make a final determination on the .amazon application.[64]

F. Patagonia and Shangri-La's Applications

Two other applications, that for .patagonia and that for .shangrila have also gone through objections by countries.[65] In a similar fashion to the .amazon ap-

River Nonsense].

[56] *See* McCarthy, *River Nonsense*, supra note 55; Jonathan Watts, *Amazon v the Amazon: Internet Retailer in Domain Name Battle*, Guardian (Apr. 24, 2013 7:57 AM), https://www.theguardian.com/environment/2013/apr/25/amazon-domain-name-battle-brazil#comments, (summarizing the Brazilian and other government's objections to Amazon, Inc.'s application).

[57] McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

[58] *Id.*

[59] *Id.*; Andrew Allemann, *Hardheaded Governments vs. Amazon.com*, Domain Name Wire (Dec. 10, 2013), https://domainnamewire.com/2013/12/10/hardheaded-governments-vs-amazon-com/ (enumerating the concessions and deals Amazon, Inc. attempted to make with the governments).

[60] McCarthy, *River Nonsense*, *supra* note 55.

[61] *Final Declaration – Amazon*, International Centre for Dispute Resolution, https://www.icann.org/en/system/files/files/irp-amazon-final-declaration-11jul17-en.pdf (last visited Dec. 31, 2017) (finding that the ICANN Board "acted in a manner inconsistent with its Articles, Bylaws and Applicant Guidebook because. . . [W]e conclude that the NGPC failed to exercise the requisite degree of independent judgment in making its decision as required by Article IV, Section 3.4(iii) of its Bylaws.").

[62] *Id.*

[63] McCarthy, *River Nonsense*, *supra* note 55.

[64] Alexis Kramer, *.Amazon Internet Domain Dispute to Extend Into 2018*, BLOOMBERG BNA (Oct. 31, 2017), https://www.bna.com/amazon-internet-domain-b73014471531/.

[65] GAC Early Warning – Submittal Patagonia, ICANN, *available at* https://gacweb.icann.org/display/gacweb/GAC+Early+Warnings (last visited Dec. 29, 2017); GAC Early Warning – Submittal Shangrila,

plication, the Argentinian government objected to the application for .patagonia, applied for by the clothing company Patagonia, by claiming that Patagonia is a geographic name for a region within their country and that acceptance of the application would cause harm to the citizens of that area.[66] Patagonia, rather than fight the objection like Amazon chose to, withdrew their application.[67]

Similarly, the Chinese government objected to the Hong Kong based Shangri La hotel chain's application for .shangrila.[68] The Chinese government claimed that Shangri-La is the name of a city within the country of China.[69] The .shangrila gTLD was accepted despite the opposition from the Chinese representatives on the GAC.[70] In the next section this comment will analyze the similarities and differences of the three cases.

G. Previous Challenges to ICANN's Authority

ICANN has, on numerous occasions, been challenged in United States courts.[71] More than ten years ago, Name.Space, Inc. and Image Online Design ("IOD"), Inc. both applied for ownership of new gTLDs.[72] Name.Space applied for 118 gTLDs and their application was accepted, ICANN, however, did not act on the application at the time.[73] IOD's application for .web was also accepted by ICANN but was ultimately refused registration.[74] In response to the applications, ICANN stated that "[a]ll of the applications not selected remain pending, and those submitted will certainly have the option to have them considered if and when additional TLD selections are made."[75] During the new expansion program in 2012, however, neither party's applications appeared under consideration by ICANN, leading to parties filing a lawsuit for multiple causes of action under anti-trust and trademark law.[76] Both Courts ultimately dismissed both cases for various reasons.[77]

ICANN, https://gacweb.icann.org/display/gacweb/GAC+Early+Warnings (last visited Dec. 29, 2017).

[66] Eli Sugarman, *Who Should Own '.Patagonia?'*, Atlantic (Apr. 23, 2013), https://www.theatlantic.com/international/archive/2013/04/who-should-own-patagonia/275214/ (stating that according to Argentinian President Cristina Fernandez de Kirchner, Argentina's territory is both physically and virtually "under threat").

[67] *Application Details – Patagonia*, ICANN, https://gtldresult.icann.org/application-result/applicationstatus/applicationdetails/1466 (last visited Dec. 29, 2017).

[68] GAC Early Warnings, ICANN, https://gacweb.icann.org/display/gacweb/GAC+Early+Warnings (last visited Dec. 29, 2017).

[69] *Id.*

[70] Application Details – Shangrila, ICANN, https://gtldresult.icann.org/application-result/applicationstatus/applicationdetails/1687 (last visited Dec. 29, 2017).

[71] Douglas Masters & Melanie Howard, *Suits Signal Lack of Confidence in ICANN Processes*, Law360 (Nov. 15, 2012 1:08 PM), https://www.law360.com/articles/394147/suits-signal-lack-of-confidence-in-icann-processes.

[72] Flip Petillion, John Murino, Emily Alban & Jan Janssen, *Lessons from the cases against ICANN*, Crowell Moring (March 2013), https://www.crowell.com/files/Lessons-from-the-Cases-Against-ICANN.pdf.

[73] *Id.*

[74] *Id.*

[75] Complaint at 10, Image Online Design, Inc. v. Internet Incorporation for Assigned Names and Numbers, No. CV 12–08968 DDP, 2013 WL 489899, (D. C.D. Cal. Feb. 7, 2013).

[76] Name.Space, Inc. v. Internet Corporation for Assigned Names and Numbers, 765 F.3d 1124, 1134 (9th Cir. 2015); *Image Online Design, Inc.*, No. CV 12–08968 DDP, 2013 WL 489899.

[77] *Name.Space*, 765 F.3d 1124 at 1134 (stating that "because name.space failed to state an antitrust violation, trademark claim, or other unlawful act, the district court properly dismissed this claim" and affirming the dis-

In a similar case, *Manwin Licensing International v. ICM Registry*, another anti-trust lawsuit was filed against ICANN after their registration of the .xxx gTLD to applicants ICM Registry.[78] The plaintiff, who owns and licenses one of the largest portfolios of adult-oriented websites and trademarks in the world, alleged various violations of the Sherman Anti-trust act.[79] ICANN moved to dismiss under the defense that they could not violate anti-trust laws because they are not involved in commercial transactions.[80] Surprisingly, the court decided not to dismiss the case, and after relying on *Goldfarb v. Va. State Bar*, found that despite being a non-profit, ICANN is indeed involved in commercial transactions and thus, can violate the Sherman Act anti-trust laws.[81]

III. The Issues Facing Expansion

This section analyzes the ICANN gTLD expansion program in more detail and analyzes potential problems facing applicants under ICANN's gTLD expansion program. First, it compares the applications of Amazon, Patagonia, and Shangri La. Next it discusses the deference given to the GAC by the ICANN board and the potential problems associated with doing so. Additionally, this section defines the standard which ICANN is, and should, be held to. Finally, it discusses the GAC's final determination and the impact it could ultimately have on Amazon, Inc.'s registration of .amazon.

A. How .amazon and .patagonia Compare

There are numerous similarities between the application and inevitable GAC opposition to the .amazon and .patagonia applications.[82] The Amazon, or Amazonian region, refers to both the area around the Amazon river, the second longest river in the world, and the area containing the Amazon forest.[83] Patagonia, is a sparsely populated region located at the southern end of South America shared by Argentina and Chile.[84] Both regions have low populations and both terms refer to regions of the world not specifically designated as countries or cities.[85]

missal); *Image Online Design, Inc.*, No. CV 12–08968 DDP, 2013 WL 489899, at *10 (rejecting all of IOD's claims and granting the Motion to Dismiss).

[78] Manwin Licensing International v. ICM Registry, LLC, No. CV 11–9514 PSG, 2012 WL 3962566, (D. C.D. Cal. Aug. 14, 2012).

[79] *Id.*; *see also* Petillion, *supra* note 72.

[80] *Manwin*, No. CV 11-9514 PSG, 2012 WL 3962566 at *5.

[81] *Id.* at *6 (citing Goldfarb v. Va. State Bar, 95 S.Ct. 2004, (1975) (stating a nonprofit can be liable under the U.S. anti-trust law if they "play an important role" in the area of commerce being claimed)).

[82] *See generally Application Details – Amazon*, *supra* note 50; *Application Details – Patagonia*, *supra* note 67.

[83] Alarich R. Schultz, Raymond E. Crist, & James J. Parsons, *Amazon River*, Encyclopedia Britannica (Dec. 13, 2017), https://www.britannica.com/place/Amazon-River; Rhett Butler, *10 Facts about the Amazon Rainforest*, Mongabay (Jan. 26, 2017), https://rainforests.mongabay.com/amazon/amazon-rainforest-facts.html.

[84] *See id.*; Schultz, *supra* note 83; Kempton E. Webb & Emilio Fernando Gonzalez Diaz, *Patagonia*, Encyclopedia Britannica (Nov. 28, 2017), https://www.britannica.com/place/Patagonia-region-Argentina.

[85] *See* Butler, *supra* note 83; Webb, *supra* note 84.

The Brazilian government opposed the registration of the .amazon gTLD,[86] and in a similar fashion, the Argentinian government opposed the approval of the .patagonia gTLD.[87] Despite the arguments of preservation and tourism made by the countries, it is a popular opinion that, strictly speaking, the governments of Brazil and Argentina have no right over the names.[88]

Neither of the terms "Amazon" nor "Patagonia" fall under the criteria of a geographic term as defined by the ICANN Applicant Guidebook.[89] Because of this, under the ICANN requirements, neither application was immediately rejected, nor did they require governmental approval.[90] At the same time, ICANN created rules that would allow governments to object to particular applications.[91] The question of how much deference should be paid to these objections remain unanswered. According to the IRP in the .amazon case, the ICANN board gave too much deference to the opinion of the GAC and not enough to the valid arguments made by Amazon.[92]

The Amazon is a very unpopulated place and, thus, does not have a significant online presence, if any at all.[93] Amazon's application was made in good faith; the purpose of the application is not to prevent the Amazonian territories from using the gTLD, and the corporation has shown a willingness to work with the Brazilian government to find a compromise.[94] Combined with the fact that "Amazon" does not meet the criteria as a geographic term under ICANN's applicant guidebook, the ICANN board will likely approve the .amazon application.[95] Even if the GAC continues to protest the application after their March 2018 deadline to make a determination, it seems likely the ICANN board will rule against them; finally granting Amazon, Inc. its .amazon registration.[96]

Comparatively, Patagonia, Inc. was likely to be successful as well, had they not withdrawn their application or were they to re-apply.[97] The Patagonia region is also sparsely populated, although less so than the Amazon.[98] Unlike

[86] *GAC Early Warning – Submittal Amazon*, ICANN, *available at* https://gacweb.icann.org/display/gacweb/GAC+Early+Warnings (last visited Dec. 29, 2017) (stating that "granting exclusive rights to the gTLD to a private company would prevent the use of the domain for purposes of public interest related to the protection, promotion and awareness raising on issues related to the Amazon biome.").

[87] *GAC Early Warning – Submittal Patagonia*, ICANN, *available at* https://gacweb.icann.org/display/gacweb/GAC+Early+Warnings (last visited Dec. 29, 2017) (stating "Patagonia is well known by the beauty of its landscapes, it is a relevant region for the country´s economy because it has oil, fishing, mining and agriculture resources. It is also a region with a vibrant local community and it is a major tourist destination.").

[88] *Id.*; *GAC Early Warning – Submittal Amazon*, *supra* note 86; *See generally*, Letter from J. Randy Forbes, Co-Chair Congressional Trademark Caucus, & Suzan DelBene, Co-Chair Congressional Trademark Caucus, to Fadi Chehadé, CEO ICANN, & Steven Crocker, Board of Directors Chair, ICANN (June 19, 2015) (on file with ICANN) ("In fact, neither Brazil nor Peru has any legally recognized rights, let alone intellectual property rights, in the term "Amazon" and there is no basis in international law for either country to assert rights in the term "Amazon.").

[89] ICANN, *gTLD Applicant Guidebook*, *supra* note 54.

[90] *Id.* at 2-17 (Geographic Names Requiring government support).

[91] *See* McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

[92] *Independent Review Panel – Amazon*, International Center for Dispute Resolution (July 10, 2017), https://regmedia.co.uk/2017/07/19/amazon-icann-irp.pdf (detailing the decision of the IRP).

[93] *See* Schultz, *supra* note 83; McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

[94] *See* Allemann, *supra* note 59.

[95] *gTLD Applicant Guidebook*, *supra* note 54.

[96] *See* Kramer, *supra* note 64.

[97] *See generally Application details – Amazon*, *supra* note 50; *Application Details – Patagonia*, *supra* note 67.

[98] Rhett Butler, *People in the Amazon Rainforest*, Mongabay (last updated Jan. 26, 2017), https://rain-

the Amazon, in Argentina, a Patagonian parliament does exist.[99] This is unlikely to be a decisive issue because Patagonia, Inc. has shown a willingness to work with the government of Argentina similar to Amazon, Inc.'s attempts to work with Brazil.[100]

B. How .amazon and .shangrila Compare

While the .shangrila case is similar to the .amazon case, it also includes facts that may affect the ICANN board's decision.[101] In the .shangrila case, the Chinese government, similar to the Brazilian government in the .amazon case, made a GAC early warning through their representatives.[102] The Chinese government is also making claims that the .shangrila gTLD should not be allowed because it is a geographic name.[103] However, this claim is not as well supported, because the Chinese city of Shangri-La is newly named.[104] This creates an interesting situation for ICANN's board. Under the current Applicant Guidebook, the name Shangri-La is technically a geographic name and would, thus, be immediately rejected without approval or sponsorship from the government of the country with which the name belongs.[105] However, the recent renaming of the city adds a level of difficulty to the case.[106]

The corporation, Shangri-La Hotels and Resorts has been in existence since 1971, thirty-years prior to the name change of Shangri-La city.[107] Under U.S. trademark law, the hotel corporation would have prior use.[108] However, although ICANN is incorporated in the U.S., it is an international organization and follows the rules in their own guidebook as opposed to U.S. trademark law.[109] According to ICANN's guidebook, the .shangrila gTLD should have been immediately rejected.[110] However, the gTLD has been accepted despite

forests.mongabay.com/amazon/amazon_people.html ("The number of indigenous people living in the Amazon Basin is poorly quantified, but some 20 million people in 8 Amazon countries and the Department of French Guiana are classified as 'indigenous'."); *Amazon Basin*, Food and Agric. Org. of the U.N. (2016), http://www.fao.org/nr/water/aquastat/basins/amazon/index.stm (stating that the population density of the Amazon Region is around 3-4 inhabitants per square kilometer); *Patagonia Geography*, Patagonian Foundation (last updated Mar. 12, 2018), http://thepatagonianfoundation.org/geography.php ("The population density in Patagonia is approximately 1-2 persons per square kilometers, making it one of the most sparsely populated regions in the world.").

[99] *See* Webb, *supra* note 84.

[100] *See* Sugarman, *supra* note 66.

[101] *See generally Application Details – Amazon*, *supra* note 50; *Application Details – Shangrila*, *supra* note 70.

[102] *GAC Early Warnings*, *supra* note 68.

[103] *GAC Early Warning – Submittal Shangrila*, ICANN, https://gacweb.icann.org/display/gacweb/GAC+Early+Warnings (last visited Dec. 29, 2017) ("Shangrila is a county which located in the northwest of Yunnan province of the People's Republic of China. Shangrila County is a geographic entity, which really exists.").

[104] Mark Frank, *Shangri-la: How changing its Name Kept it the Same*, China (May 20, 2010), http://china.org.cn/travel/2010-05/20/content_20079961.htm (explaining that in 2001 the Tibetan county Zhongdian officially changed its name to Shangri-La after the fictional city in the British novel, *Lost Horizon*).

[105] *gTLD Applicant Guidebook*, *supra* note 54.

[106] *See* Frank, *supra* note 104.

[107] *About Shangri-La Group*, http://www.shangri-la.com/corporate/about-us/, (last visited Dec. 29, 2017) (detailing information about the hotel chain).

[108] 35 U.S.C. § 273.

[109] *gTLD Applicant Guidebook*, *supra* note 54.

[110] *Id.*

the objection from the Chinese representatives of the GAC.[111] The .amazon and .patagonia gTLDs were immediately suspended after the opposition from the GAC.[112]

The .shangrila gTLD should be rejected by the ICANN board.[113] Unlike the Amazon region in Brazil, Shangri-La is an actual city in China, meeting the requirements for a geographic name under the guidebook.[114] This should be the case despite the fact that the Shangri-La Hotel chain is actually older and that alone should have been enough to at least suspend the gTLD.[115] With a population of roughly 130,000, Shangri-La is also more populated than the Amazon region.[116] There is likely a much more burgeoning online community there, creating a better case for harm to that population.[117] The Chinese government originally changed the name to Shangri-La in an attempt to bolster tourism to the area.[118] The use of .shangrila exclusively by the Shangri-La Hotels and Resorts takes away the ability of the Chinese government to use the gTLD to help continue efforts to boost tourism.[119] Additionally, unlike the Amazon or Patagonia applications, Shangri-La is clearly a geographic term under the Applicant Guidebook, registering .shangrila to Shangri-La Hotels and Resorts is seemingly more likely to cause the encroachment of brand names upon geographic names.[120] In this situation, the opinion of the GAC should be given much more deference and the application should be rejected.[121]

C. Too Much Deference to the GAC?

One major similarity throughout all three cases, is that the GAC has significant power in ICANN's decision-making process.[122] In each case, the ICANN board put a lot of deference to the opinion of the GAC, and in the case of .amazon, too much.[123] The Board may have even gone as far as to ignore the reports of their own expert, Professor Luca G Radicati di Brozolo, hired to investigate the objections of the GAC.[124] Professor Brozolo concluded that the people who live in the Amazon basin, largely in Brazil, would not be negatively impacted by the

[111] *Id.*

[112] *See Application details – Amazon*, *supra* note 50; *Application details – Patagonia*, *supra* note 67.

[113] *See generally Application Details – Shangrila, supra* note 70; *gTLD Applicant Guidebook*, *supra* note 54.

[114] *gTLD Applicant Guidebook*, *supra* note 54.

[115] *About Shangri-La Group*, *supra* note 107 (The hotel chain was founded in 1971).

[116] Shangri-La Facts, https://www.topchinatravel.com/shangri-la/shangri-la-facts.htm (last visited Dec. 29, 2017).

[117] *See* David Robson, *Why China's Internet Use Has Overtaken the West*, BBC (Mar. 9, 2017), http://www.bbc.com/future/story/20170309-why-chinas-internet-reveals-where-were-headed-ourselves (claiming 178 million Chinese Internet users can be found in small rural towns).

[118] *See* Frank, *supra* note 104.

[119] *See GAC Early Warning – Submittal Shangrila*, *supra* note 103.

[120] *See id.; gTLD Applicant Guidebook*, *supra* note 54.

[121] *See generally Application Details – Shangrila, supra* note 70; *gTLD Applicant Guidebook*, *supra* note 54.

[122] *See* McCarthy, *River Nonsense*, *supra* note 55.

[123] *Id.*

[124] Kiran McCarthy, *Amazon May Still get .Amazon Despite Govt Opposition – Thanks to a Classic ICANN Cockup*, Register (July 19, 2017 8:58 PM), https://www.theregister.co.uk/2017/07/19/dot_amazon_icann/ ("But the ICANN board simply ignored its own expert report, the independent panel found, and decided to uphold the objection of its governmental advisory committee while failing to give an explanation as to why.") [hereinafter McCarthy, *Classic ICANN Cockup*].

creation of .amazon or the fact it was run by a US retail company.[125] Professor Brozolo also concluded that even if Amazon was successful in its registration of the .amazon TLD other TLD's, like .amazonia would be just as effective for use by the Brazilian Government.[126] Professor Brozolo effectively eliminated all the concerns put forth by the GAC for rejection of the name.[127] The IRP found that the ICANN board simply ignored the experts findings in lieu of the GAC while failing to give an explanation as to why.[128]

Based on its .amazon decision, ICANN likely left room for the member countries to oppose applications they felt unjustly used geographical locations they had rights to.[129] However, the rights the countries have over these terms, if any, appear to outweigh the rights the companies have in their marks.[130]

In both the .amazon case and the .patagonia case the U.S. originally stated that they were in favor of the registration of the gTLD only to eventually change their position to neutral.[131] The U.S. neutrality meant the representatives from Brazil, in the opposition to .amazon, and the representatives from Argentina, in the .patagonia opposition, were unopposed and allowed the GAC to officially give the applications negative determinations.[132] Because of the opposition by the GAC, and the Argentinian unwillingness to come to an agreement, Patagonia, Inc. ended up withdrawing their application.[133] Amazon felt the opposition was more political and decided to fight it out, refusing to withdraw their application and eventually winning, at least in terms of the IRP.[134] Amazon may very well end up getting the registration in .amazon they've been waiting so long for.[135]

D. The GAC's Final Determination

The ICANN board has given the GAC until March 2018 to make a final determination regarding the .amazon application which, may finally settle Amazon, Inc.'s application.[136] After almost 7 years, countless filings, and arguments on both sides, the GAC may finally allow the .amazon application to continue unopposed.[137] Amazon, Inc. would then finally be able to register the .amazon

[125] *Expert Determination of Professor Luca G. Radicati di Brozolo*, International Chamber of Commerce International Centre for Expertise (Jan. 27, 2014), https://newgtlds.icann.org/sites/default/files/drsp/03feb14/determination-1-1-1315-58086-en.pdf ("These considerations lead the Expert to find that the [Independent Objector] has failed to make a showing of substantial opposition to the Applications within the purported Amazon Community.").

[126] *Id.* ("Were a dedicated gTLD considered essential for the interests of the Amazon Community, other equally evocative strings would presumably be available. ".Amazonia" springs to mind.").

[127] McCarthy, *Classic ICANN Cockup*, *supra* note 124.

[128] *Final Declaration – Amazon*, *supra* note 60; McCarthy, *Classic ICANN Cockup*, *supra* note 124.

[129] *See* McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

[130] *See generally Final Declaration – Amazon*, *supra* note 61.

[131] *See* Letter from Blake Farenthold, Member of Congress, and 10 other members of congress, to Fadi Chehadé, CEO ICANN, & Steven Crocker, Board of Directors Chair ICANN (June 10, 2015) (on file with ICANN) (stating "The ICANN Board succumbed to political pressure from several governments,").

[132] *See* McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

[133] *Id.*

[134] McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

[135] McCarthy, *Classic ICANN Cockup*, *supra* note 124.

[136] *See* Kramer, *supra* note 64.

[137] *See id; Application Details – Amazon*, *supra* note 50; *GAC Early Warning – Submittal Amazon*, *supra* note 86.

gTLD they applied for back in 2012.[138] However, the GAC could just as easily continue to oppose the application, prolonging the process.[139]

In this situation, it would then be up to ICANN's board to rule in favor of Amazon over the GAC.[140] However, given ICANN's previous extreme deference to the GAC, ICANN may continue to block the registration.[141] If this were to happen, a strong argument could be made that the ICANN board and members of the GAC are making decisions not on the merits and strengths of an application, but instead on the ebb and flow of political opinion.[142] Should this occur, Amazon may be able to turn to the U.S. court system. Although U.S. courts have been unwilling to answer the substantive legal questions regarding ICANN's authority in previous cases, Amazon, Inc.'s strong anti-trust argument could be successful based on earlier findings that ICANN is participating in trade and therefore subject to the Sherman Act.[143]

A successful challenge in the U.S. courts by Amazon, Inc., could potentially open the door for others, like Patagonia, Inc. to follow in their footsteps.[144] By reapplying for their .patagonia TLD that they chose to withdraw after GAC opposition, Patagonia would put ICANN in a difficult situation.[145] The ICANN board would be forced to either accept the previously opposed TLD without allowing the GAC the opportunity to make an opposition, or allow the GAC to once again halt the registration and face a similar challenge to that of Amazon.[146] A successful challenge by Amazon could be the recourse these companies need to free themselves of the arbitrary decisions of the current ICANN process.[147] Either way, it is clear that ICANN's processes need to be reformed.

E. The Standard ICANN is Held To

The recent court cases against ICANN are eye-opening, but likely unhelpful to Amazon, Inc. in its pursuit for registration.[148] These cases indicate a growing dissatisfaction for ICANN from applicants and trademark owners, but more importantly they illustrate the limitations of attempting to use the U.S. courts to pursue action against ICANN.[149] The *Name.Space* and *IOD* cases show that the U.S. courts are somewhat reluctant to disrupt the authority of the international

[138] *Application Details – Amazon*, *supra* note 50.

[139] *See* Kramer, *supra* note 64.

[140] *Final Declaration – Amazon*, *supra* note 61.

[141] *See generally id.*

[142] Adam Segal, *The Case of .Amazon and What it Means for ICANN*, Couns. on Foreign Rel. (Oct. 4, 2017), https://www.cfr.org/blog/case-amazon-and-what-it-means-icann.

[143] *See* Name.Space, Inc. v. Internet Corporation for Assigned Names and Numbers, 765 F.3d 1124, 1134 (9th Cir. 2015); Image Online Design, Inc. v. Internet Incorporation for Assigned Names and Numbers, No. CV 12–08968 DDP, 2013 WL 489899, (D. C.D. Cal. Feb. 7, 2013); Manwin Licensing International v. ICM Registry, LLC, No. CV 11–9514 PSG, 2012 WL 3962566, (D. C.D. Cal. Aug. 14, 2012).

[144] *See generally* Petillion, *supra* note 72.

[145] *Application Details – Patagonia*, *supra* note 67.

[146] *Application Details – Amazon*, *supra* note 50; McCarthy, *Classic ICANN Cockup*, *supra* note 124.

[147] *See generally* Petillion, *supra* note 72.

[148] *See generally id; Manwin*, No. CV 11-9514 PSG, 2012 WL 3962566 at *5*; Image Online Design, Inc.*, No. CV 12–08968 DDP, 2013 WL 489899, at *10*; Name.Space*, 765 F.3d 1124 at 1134.

[149] *See* Petillion, *supra* note 72.

organization.[150] Both the Ninth Circuit Court of Appeals and the United States District Court for the Central District of California used various legal means to avoid the difficult substantive legal questions about ICANN's authority and the boundaries for its behavior.[151]

However, *Manwin Licensing* may the first case to successfully challenge ICANN's authority and may expose ICANN;s Achille's Heel.[152] With the United States District Court for the Central District of California finding that ICANN can in fact be liable under anti-trust law, and denying their motion to dismiss, it is one step in the right direction for these corporations.[153] Unfortunately, because of various counterclaims and discovery motions the case seems to be backlogged and moving slowly.[154] Despite having a set date for a scheduling conference, there seems to be very little new happenings in the final outcome of the case and it will likely be a while before there is a resolution.[155]

F. The Broader Implications for Entities Working with ICANN in the Future

The Amazon, Patagonia, and Shangri-La applications highlight the much bigger problem for entities working with ICANN.[156] As long as ICANN remains only accountable to its own rules and regulations, and thus has no other entities, such as courts or international organizations, keeping it in check, future applicants will continue to have similar issues to the ones facing Amazon.[157] U.S. Courts have continually found ways to prevent ruling against ICANN.[158] Entities with business interests in the Internet and TLD world need to determine what Amazon and the others are doing right and wrong, and decide for themselves the best course of action to take.

One of the main issues facing organizations is the amount of power ICANN holds over the applications. Organizations and companies need to ensure they maintain positive relations with ICANN or future relations and applications may suffer. This could be the reason Amazon has not done more in their battle against ICANN, and it is definitely a problem facing future entities dealing with ICANN.

[150] *Name.Space*, 765 F.3d 1124; *Image Online Design, Inc.*, No. CV 12–08968 DDP, 2013 WL 489899; Petillion, *supra* note 72.

[151] *Name.Space*, 765 F.3d 1124 at 1134; *Image Online Design, Inc.*, No. CV 12–08968 DDP, 2013 WL 489899; *See* Petillion, *supra* note 72.

[152] *Manwin*, No. CV 11-9514 PSG, 2012 WL 3962566 at *5.

[153] *Id.* at *6, 12.

[154] Petillion, *supra* note 72.

[155] *Id.*

[156] *Application Details – Amazon*, *supra* note 50; *Application Details – Patagonia*, *supra* note 67; *Application Details – Shangrila*, *supra* note 70.

[157] Kieren McCarthy, *Is Domain Overlord ICANN the FIFA of the Internet? We'll Know This Weekend*, Register (Sep. 24, 2014 9:15 PM), https://www.theregister.co.uk/2015/09/24/icann_on_dangerous_path/?page=1 (comparing the power and control of the international Soccer organization, FIFA, to ICANN) [hereinafter McCarthy, *Domain Overlord ICANN*].

[158] Petillion, *supra* note 72 ("In general, it seems that US courts may be somewhat reluctant to disturb Icann's authority and have used various legal vehicles to avoid difficult substantive questions about the limits of Icann's authority and the boundaries for its behavior.").

Another issue applicants face is the potential for bad press.[159] For example, if information is released to the public that Amazon, Inc., arguably the largest tech company in the world, was using its resources to bully an international organization and "hurting citizens of the Amazon" in the process, it could likely create public backlash.[160] Public companies must do everything in their power to avoid bad press and this may require them to put up with the difficulty of working with ICANN.[161]

Organizations and companies need to find the proper claims to break the hesitation the U.S. courts have in ruling against ICANN, allowing them to develop precedent that will aid in solving the problem.[162] Anti-trust claims have worked in the past, however, may not be the proper claim for every situation or case.[163] U.S. Trademark law seems to fail most of the time, although, a trademark claim may be successful with a different set of facts.[164]

IV. How ICANN Solves the Problem

There are a number of changes that need to take place to avoid these problems in the next round of applications. The first of which is the ICANN Applicant Guidebook needs to be updated to better define geographic names, or at least standardized them across applications.[165] Also, the amount of influence governments have over the ICANN board's decision process needs to be reviewed.[166]

The definition of what a geographic name is needs to be better defined within the ICANN Applicant Guidebook.[167] ICANN's definition is not only unclear, the approach to each country's opposition to the application needs to be standardized.[168] ICANN's approach and inevitable rejection or acceptance of each application was different for all three of the Amazon, Patagonia, and Shangri-La applications.[169] It appears to be more of a case by case determination and very political.[170] The global politics should not be a determining factor in the outcome of an application. Instead, all applications and oppositions thereof should be treated in a standard manner. ICANN needs to use

[159] *See* Watts, *supra* note 56 (discussing possible negative press associated with potential geographic name gTLDs).

[160] *Id.*

[161] Robert G. Eccles, Scott C Newquist, & Roland Schatz, *Reputation and Its Risks*, Harvard Business Review (Feb. 2007), https://hbr.org/2007/02/reputation-and-its-risks (discussing the importance of reputation of a company and how bad press can negatively affect the business).

[162] *See* Petillion, *supra* note 72 (describing the U.S. Courts reservation in finding against ICANN).

[163] *Id.*

[164] Image Online Design, Inc. v. Internet Incorporation for Assigned Names and Numbers, No. CV 12–08968 DDP, 2013 WL 489899, *2 (D. C.D. Cal. Feb. 7, 2013) (dismissing the case on the grounds that Image Online Design failed to allege facts that support a finding of trademark infringement by ICANN).

[165] *gTLD Applicant Guidebook*, *supra* note 54.

[166] McCarthy, *Dot-Amazon Spat Latest*, supra note 53.

[167] *gTLD Applicant Guidebook*, *supra* note 54.

[168] *Id; Application Details – Amazon*, *supra* note 50; *Application details – Patagonia*, *supra* note 67; *Application Details – Shangrila*, *supra* note 70,(showing clear differences in the treatment of applications across the board).

[169] *Application Details – Amazon*, *supra* note 50; *Application details – Patagonia*, *supra* note 67; *Application Details – Shangrila*, *supra* note 70.

[170] *See* McCarthy, *Dot-Amazon Spat Latest*, *supra* note 53.

the Amazon case as an example for the future. ICANN should find in favor of Amazon in this situation. Precedent needs to be set that countries will need to claim a specifically protected geographic name in their opposition to the application as well as specific evidence as to the exact harm that would come to the citizen of that region should the application be accepted.

Furthermore, GAC influence of the ICANN board decisions needs to be addressed by ICANN. In order to prevent future problems ICANN needs to change the amount of deference given to GAC objections over applicant's valid claims.[171] The application provides a section specifically to explain why the applications gTLD is not a geographic name, or if it is, why the application should be approved despite the existence of this term.[172]

The amount of influence and power the GAC has over the ICANN board may be a huge problem.[173] A GAC with no real reasoning behind a determinization can have an application tied up for years with the board ignoring property rights and genuine arguments made by the corporations.[174] The IRP decision in the .amazon case is only one step in the right direction.[175] The board needs to finally approve the gTLD Amazon, Inc. has been waiting on for nearly six years despite what the final determination is by the GAC in March.[176] In the future, ICANN needs to give less deference to GAC oppositions that give no real legal reasoning for their opposition to the application and more to applicants with property rights to the claimed gTLD.[177]

In order to avoid these types of problems in the future, precedent needs to be made establishing priority in property rights over false claims of harm by GAC in cases such as .amazon and .patagonia. Only in cases like that of .shangrila, where there are definitive claims to a geographic name, should deference to the GAC outweigh the claims of the corporation.[178]

Other scholars have made arguments that .brand applications should be eliminated altogether from the program.[179] Although this would certainly solve the current problems involving the applications like the Amazon, Patagonia, and Shangri-La cases, it is unnecessary and too bold. Proponents of the .brand program state that .brand TLDs offer five benefits to companies: trust, personalization, branding, ownership and data gathering.[180] It can be said that

[171] McCarthy, *River Nonsense*, *supra* note 55.

[172] *New gTLD Application Submitted to ICANN by: Amazon EU S.à r.l.*, ICANN (June 13, 2012) *available at* https://gtldresult.icann.org/application-result/applicationstatus/applicationdetails/984.

[173] *Final Declaration – Amazon*, *supra* note 61, at 47 ("In absence of any statement of the reasons by the NGPC for denying the applications, beyond deference to the GAC advice, we conclude that the NGPC failed to act in a manner consistent with its obligation under the ICANN governance documents to make an independent, objective decision on the applications at issue.").

[174] *Id.*

[175] *Id.*

[176] *Application Details – Amazon*, *supra* note 50, (showing the date of application as June 13, 2012); Kramer, *supra* note 64.

[177] *See Final Declaration – Amazon*, *supra* note 61 (determining it was unable to find a valid reason for the rejection of the Amazon application).

[178] *See Application Details – Shangrila*, *supra* note 70; *GAC Early Warning – Submittal Shangrila*, *supra* note 104.

[179] Boroughf, *supra* note 2, at 118 ("By eliminating .brand gTLDs from ICANN's new program, the Internet can actually begin to expand as ICANN envisioned.").

[180] *See* Charlton, *supra* note 43.

.brand TLDs are authentic, trusted, measurable, scalable, and cannot be infringed by nefarious means.[181] Despite the benefits of the .brand TLDs, the solution of eliminating them completely incorrectly characterizes how consumers interact with websites.[182] If consumers are recognizing the difference, yet do not trust the new gTLD, it is up to the applicants to educate the masses as to the legitimacy or positives of the domain.[183] Completely eliminating the .brand applications is the complete opposite of what the program is designed to accomplish.[184] The program was meant to increase competition, diversity, and innovation.[185] Corporations applying for .brand gTLDs is precisely what ICANN was attempting to accomplish through the expansion program, the process and procedure need to be further developed to better serve the purpose.[186]

Although the findings in the cases mentioned above are limited to the specific facts of each, a few broad lessons can be drawn from them together.[187] First, applicants with issues about their applications should seek remedies though ICANN's internal processes because going through courts in the U.S. to solve these problems is unlikely to be successful.[188] Also, if a company wants to use the U.S. court system to enforce their rights against ICANN, it may look into doing so under an anti-trust claim, because ICANN has already been determined to engage in commercial activity by the courts.[189]

V. Conclusion

The non-profit in charge of the regulation of the DNS and other parts of the internet, ICANN, has developed an expansion program that will change the World Wide Web forever. The program, however, came with its share of problems. With the application and approval of over 1,900 new gTLDs there was bound to be issues with some of them. Companies like Amazon, Patagonia, Shangri La, and others applying for .brand gTLDs have been fighting for years against both the ICANN board and individual country members of the GAC trying to get their applications approved despite them being considered "geographic locations." Issues pertaining to definitions within ICANN's own

[181] *Id.*

[182] *See* Katherine Dusak Miller, P*reliminary Report of Dennis Carlton Regarding Impact of New gTLDs on Consumer Welfare*, ICANN (Mar. 2009), https://archive.icann.org/en/topics/new-gtlds/prelim-report-consumer-welfare-04mar09-en.pdf (arguing new gTLDs may facilitate the ability of consumers to obtain both generic information about the product they are seeking as well as the ability to access the websites of manufacturers, suppliers, and other consumers of these products that use this gTLD to host their websites).

[183] Roger Kay, *Seven Things to Think About Before You Register That New Domain*, Forbes (Jan. 30, 2014 9:19 AM), https://www.forbes.com/sites/rogerkay/2014/01/30/seven-things-to-think-about-before-you-register-that-new-domain/#5219bf4744c0 (suggesting that consumers are wary of the unfamiliar new gTLDs and companies should develop clear programs for transferring the trust from their old websites to their new ones).

[184] *About the Program*, *supra* note 1.

[185] *Id.*

[186] *Id.*

[187] Petillion, *supra* note 72.

[188] *Id.*

[189] Manwin Licensing International v. ICM Registry, LLC, No. CV 11–9514 PSG, 2012 WL 3962566, at *6 (D. C.D. Cal. Aug. 14, 2012).

guidebook, the amount of deference being given to the GAC, and confusion as to the standard or authority of ICANN's power, it has been an uphill battle for these applicants. Changes need to be made within ICANN's organization to solve these problems and prevent issues like the ones currently facing applicants from happening in future expansions.

Section 101: What's Left To Patent In The Life Sciences After *Myriad*, *Mayo*, And *Alice*?

Warren D. Woessner* and Robin A. Chadwick†
Schwegman, Lundberg & Woessner, P.A.

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*See, Warren's Patents4Life blog at http://www.patents4life.com/ for further discussion of these and other biotechnology issues.

†Warren D. Woessner, Ph.D and Robin A. Chadwick, Ph.D. are patent attorneys at Schwegman, Lundberg & Woessner, P.A., Minneapolis, MN. This chapter reflects the personal views and thoughts of Drs. Woessner and Chadwick and are not to be construed as representing in any way the views, opinions or practices of Schwegman, Lundberg & Woessner, P.A. or any of its clients. The content is solely for purposes of discussion and illustration and is not to be considered legal advice.

Introduction

Section 101 of the Patent Act (the Act)[1] states that the following categories of invention are eligible for patent protection, so long as the other standards of patentability are met: processes, machines, manufactures, and compositions of matter, as well as improvements thereof. In 1980, the Supreme Court ruled that a man-made microorganism was also eligible for patent protection under Section 101,[2] reaffirming at the same time that no patents should be granted on laws of nature, physical phenomena and abstract ideas. Instead, the Court emphasized that patent-eligible inventions must be generated by human ingenuity. Apart from its decision in 2001 that plants were also eligible for patenting,[3] the Supreme Court had not again addressed whether living organisms, or their natural components, were patent eligible until 2012.

Although the courts have grappled for years with the "abstractness" of software claims, after about 2010 the courts turned their attention to life sciences patents, finding that many diagnostic claims were patent-ineligible as abstract ideas,[4] while others were patent-ineligible for patenting as embracing natural phenomena.[5] Shortly after the *Bilski* decision[6] held that claims to a method of hedging commodity risk were patent-ineligible under Section 101 as an attempt to patent an abstract idea, the Supreme Court granted certiorari and remanded the *Classen* case[7] involving an appeal of claims to immunization schedules, and

[1] 35 U.S.C. § 101.

[2] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[3] J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).

[4] Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F.Supp.2d 181, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010); Ass'n for Molecular Pathology v. Myriad Genetics Inc., 653 F.3d 1329 (Fed. Cir. 2011) (collectively the "*Myriad*" case).

[5] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012)(the "*Mayo*" case).

[6] Bilski v. Kappos, 561 US 593 (2010).

[7] Classen Immunotherapies, Inc. v. Biogen Idec, 561 U.S. 1040 (2010)(remanded); *Classen*, 659 F.3d 1057 (Fed. Cir. 2011); GlaxoSmithKline v. Classen Immunotherapies, Inc., 133 S. Ct. 973 (2013)(cert. denied).

then decided two biotech/pharma cases, the *Mayo* case[8] in 2012 and the *Myriad* case[9] in 2013. The application of the Supreme Court's *Mayo* decision by the Federal Circuit to the prenatal testing claims in the *PerkinElmer* case[10] and in the *Ariosa* case,[11] as well as the Federal Circuit's own rejection of the Myriad diagnostic claims suggests that claims directed to the use of biomarkers in personalized medicine have increasingly become vulnerable to attack by litigants as not constituting patent-eligible inventions. The recent *Athena* case[12] further confirms the court's stance against the patent eligibility of diagnostic claims. The U.S. Patent and Trademark Office has also issued a series of their own Memoranda outlining the patent eligibility of natural products, natural phenomena, and laws of nature.[13]

This paper discusses and reflects on what the courts and the Patent Office have said illustrating the recent evolution of biotechnology-related court decisions on patent eligibility. A table is provided at the end of the chapter showing the language of various biotech patent claims and how the courts have ruled.

I. *Mayo* and *Classen*: Their Importance and Analysis

Prometheus Laboratories, Inc. v. Mayo Collaborative Services.

In the *Mayo* case,[14] the Federal Circuit held in 2010 that claims directed to a method of optimizing the dosing of a drug are eligible for patenting where the method involved observing whether or not the level of 6-thhiopurine in the patient's blood is above or below specific levels. According to the Federal Circuit, steps in the claims involving "administering" the drug or "determining" the level of the metabolite in the blood satisfied the machine or transformation (MOT) test devised by the Federal Circuit in its Bilski opinion.[15] However, in *Bilski*, the Supreme Court had refused to anoint the MOT test as the sole test for patentability and rather ruled that the *Bilski* claims failed to satisfy Section 101 because they were an impermissible attempt to claim an abstract idea.[16] This was the second time the Federal Circuit had found that the Prometheus claims were eligible for patenting.[17]

[8] Prometheus Labs. Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010); Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66 (2012).

[9] Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F.Supp.2d 181, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010); Ass'n for Molecular Pathology v. Myriad Genetics Inc., 653 F.3d 1329 (Fed. Cir. 2011); Ass'n for Molecular Pathology, et al. v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[10] PerkinElmer, Inc. v. Intema Ltd., 496 Fed. App'x 65, 73 (Fed. Cir. Nov. 20, 2012)(nonprecedential). Intema filed a petition for certiorari with the Supreme Court, which has been denied.

[11] Ariosa Diagnostics Inc. v. Sequenom Inc., 788 F.3d 1371 (Fed. Cir. 2015).

[12] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019).

[13] *See*, https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility.

[14] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010)(on remand from the Supreme Court).

[15] *Mayo*, 628 F.3d 1347; *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

[16] *Bilski*, 561 US 593 (2010).

[17] Prometheus Labs. Inc. v. Mayo Collaborative Servs., 581 F.3d 1336 (Fed. Cir. 2009).

In its 2010 ruling, the Federal Circuit reasoned that the claims were not an attempt to impermissibly patent a natural phenomenon – the correlation between metabolite levels and efficacy – and they did not wholly preempt all uses of the phenomenon. In addition, the Federal Circuit again held that the administering and determining steps were sufficiently transformative to meet the MOT test, recognizing that while the "indicative" steps were patent-ineligible mental steps, the claims, taken as a whole are directed to a patent eligible method of optimizing therapeutic efficacy.[18]

In finding the Prometheus claims patent-eligible, the Federal Circuit declined to discuss the "*Metabolite Labs, dissent*"[19] in which Justice Breyer and two other now-retired Justices urged the Court to find a claim to a diagnostic method patent-ineligible. The Metabolite Laboratories' claims involved assaying the level of an amino acid naturally occurring in the body and correlating that level to the presence or absence of a vitamin deficiency.[20] Unlike the Metabolite Laboratories' claims, the Prometheus claims required actual administration of a drug. In finding Prometheus claims patent-eligible, the Federal Circuit ruled that such methods of optimizing therapeutic efficacy did not wholly preempt all uses of the recited correlations but instead transformed the human body by administration of a synthetic drug or measurement of a metabolite that would not be present but for the administration of the drug.[21]

The Supreme Court again granted certiorari to Mayo's appeal and reversed the Federal Circuit holding on March 20, 2012.[22] Justice Breyer, writing for a unanimous court, found that the claims were no more than an attempt to patent a natural phenomenon by surrounding it with steps conventional in medical treatment, such as administering the "old" drug, or by mental steps that were not patent-eligible.[23]

While the Court indicated that new compounds, and new uses for old compounds, would remain patent-eligible,[24] this ruling that administration of a drug followed by determining the drug metabolite levels in the blood is patent-ineligible may tempt courts to terminate opportunities to patent certain treatment regimens. After all, the Prometheus claim could be easily rewritten as a method of treatment claim:

> "A method of treating an immune disorder comprising administering to a subject afflicted with said disorder, an amount of a 6-TG-supplying drug sufficient to provide a blood level in said subject of 6-TG that is between x and y ng/ml [the optimal range]."

Could such a dosage-related claim be subjected to a 101 challenge? It would probably be easy to anticipate, but would it fail a 101 challenge as well? Justice Breyer implicitly denigrates method-of-treatment claims by quoting from amici briefs that note that such methods also involve the body's natural reaction

[18] *Mayo*, 628 F.3d at 1358-59.
[19] *Mayo*, 628 F.3d at 1356; Laboratory Corp. of America Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006).
[20] *See*, *e.g.*, U.S. Patent 4,940,658 claim 13.
[21] *Mayo*, 628 F.3d at 1355-1356.
[22] *Mayo*, , 566 U.S. 66 (U.S. 2012).
[23] *Id.* at 77–80.
[24] *Id.* at 86–87.

to the treatment agent, and notes that methods of medical treatment are not patentable in many foreign jurisdictions.[25]

The key phrase in the decision may be that the adjunct steps were "specified at [too] high a level of generality."[26] But how much generality is too much generality? The reader of the opinion keeps waiting for Justice Breyer to provide some hint of the degree of unconventionality or amount of significance that would suffice in the context of a diagnostic test "to transform an unpatentable law of nature into a patent-eligible *application* of such a law,"[27] but none is forthcoming. Finally, although this decision did not address diagnostic methods involving the detection and measurement of endogenous biomarkers, the Federal Circuit invalidated an "If a/Then b" diagnostic claim based on a gene mutation in its *Myriad* decision, discussed below. Thus, diagnostic claims that were thought to be eligible for patenting prior to 2010 can now be threatened during litigation and those now drafting diagnostic claims will find little guidance from the Supreme Court's ruling.

Classen Immunotherapeutics, Inc. v. Biogen Idec.

Those watching the evolving Section 101 standards prior to 2010 saw that courts were finding natural phenomena in other patented diagnostic or treatment methods. For example, in 2006 the district court noted in the *Classen*[28] case:

> Clearly, the correlation between vaccination schedules and the incidence of immune mediated disorders that Dr. Classen claims to have discovered is a natural phenomenon. The issue, therefore, is whether the Classen patents simply describe this correlation.

The district court stated that the claims[29] "describe little more than an inquiry of the extent of the proposed correlation between vaccines and chronic disorders,"[30] and granted summary judgment of invalidity to Biogen.

In 2008, the Federal Circuit affirmed the district court's grant of summary judgment that Classen's claims are invalid under Section 101, holding that claims involving a method to lower immunization risks[31] failed the MOT test and so were patent ineligible.[32] However, in August of 2011, a three judge panel of the Federal Circuit revisited *Classen*[33] following the grant of certiorari, vacated decision and remand (in other words "GVR") discussed above.

[25] *Id.* at 90–92. Claims to administering a drug to a patient are not patent-eligible in many foreign countries. However, claims to a method of using a drug to treat a condition, or to make a medicament to treat a condition are widely patent eligible.

[26] *Id.* at 82.

[27] *Id. at 72, 79.*

[28] Classen Immunotherapies, Inc. v. Biogen Idec, 2006 U.S. Dist. LEXIS 98106 at *13 (D. Md. Aug. 16, 2006).

[29] See chart following this discussion for selected Classen claims.

[30] *Classen*, 2006 U.S. Dist. LEXIS 98106 at *13-14.

[31] *See,* Classen's U.S. Patent 6,638,739 claim 1, provided in part within the chart following this discussion.

[32] Classen Immunotherapies, Inc. v. Biogen Idec, 304 Fed. App'x 866 (Fed. Cir. 2008).

[33] Classen Immunotherapies, Inc. v. Biogen Idec, 659 F.3d 1057 (Fed. Cir. 2011).

The panel accepted, at least for purposes of this review of summary judgment, that method claims from two of Classen's patents, involving a specific, tangible, physical step of immunization on the determined schedule, traverse the coarse eligibility filter of Section 101.[34] These two claims generally involved screening immunization schedules and then immunizing a subject pursuant to the lower risk immunization schedule. According to the panel, such claims are not directed to a law of nature, like gravity, or to a physical phenomenon, like lightning. The panel also reaffirmed, as in *Mayo*, that the presence of a mental step in a claim is not fatal to patent-eligibility under Section 101.[35] Thus, the panel held that the claims of two out of three patents were not directed to abstract ideas:

> "The claims of the [two] patents are directed to a method of lowering the risk of chronic immune disorder, including the physical step of immunization on a determined schedule. These claims are directed to a specific, tangible application, as in *Research Corporation* [*v. Microsoft*, 627 F.3d 859 (Fed. Cir. 2010)] and in accordance with *Bilski v. Kappos*... exclusions from patent eligibility should be applied 'narrowly', 130 S. Ct. at 3229, we conclude that the subject matter of these two patents traverses the 'coarse eligibility filter' of § 101".[36]

The majority of the panel unfortunately found the third patent's main claim is an abstract idea because it requires no more than referring to known information about the effects of various immunization protocols but does not require immunization in light of that information.[37] However, Judges Rader and Newman cautioned that "judges should tread carefully when imposing new limits on the protection for categories of human innovation."[38] The Supreme Court denied certiorari, thus implicitly recognizing that a method of improving the outcome of an immunization protocol which involves transforming subjects from a nonimmune state to an immune state is a sufficiently "unnatural act" so that it is not excluded from 101 as was Prometheus' treatment regimen—which, as noted above, can be considered an "old use for an old compound."

II. Myriad Decision: Its Importance and Analysis

Association of Molecular Pathologists et al. v. USPTO ("Myriad").

On May 12, 2009, a group of plaintiffs ranging from professional medical organizations to individual researchers, apparently assembled and certainly represented by the ACLU, filed suit in the SDNY, seeking, *inter alia,* a declaratory

[34] *Id.* at 1066.
[35] *Id.* at 1065.
[36] *Id.* at 1066 (Judge Moore entered a vigorous dissent, arguing that such an immunization step "is nothing more than post-solution activity." *Id.* at 1079).
[37] *Id.* at 1067-68.
[38] *Id.* at 1074.

judgment that the claims of a number of patents controlled by Myriad were invalid as improperly attempting to claim natural phenomena, such as genetic mutations, or natural products, such as isolated DNA.[39] The patents were generally drawn to tests offered by Myriad that identified mutations in a patient's BRCA1 or BRCA2 genes and, in at least one claim, correlated the presence of mutations to an increased risk of breast or ovarian cancer. Also challenged were claims to isolated human genes, or fragments thereof, and cDNA derived from the wild-type genes.[40]

The suit did not attract much attention at the time, since *Bilski* had been decided by the Federal Circuit in 2008,[41] and was making its way to the Supreme Court. Many commentators opined that the plaintiffs did not even have standing[42] because Myriad had contacted only a few of the plaintiffs ten years or more before the suit was brought and Myriad had not yet sued anyone for infringement. So the biotech IP world was rocked on March 29, 2010 when Judge Sweet agreed with the plaintiffs and held that claims directed to isolated BRCA2 DNA, BRCA2 cDNA, methods of identifying mutations in a subject's BRCA2 gene, methods of correlating the mutations to an increased risk of cancer, and even a claim to a method of using transgenic cells comprising the BRCA2 DNA to screen test compounds for anti-cancer activity, all fell under the prohibition against patenting natural products or abstract ideas.[43] Judge Sweet stated that "it is irrelevant to the § 101 analysis whether Applicants' claimed process is novel or nonobvious,"[44] but accepted plaintiffs' arguments that the isolated DNA sequences were simply repositories of genetic information that performed the same function as they did in the intact genome of the subject.[45] The primary rationale for the decision was that "products of nature do not constitute patentable subject matter absent a change that results in creation of a fundamentally new product."[46] Judge Sweet relied on the Supreme Court's language in *Diamond* v. *Chakrabarty*[47] to require that a claimed composition present in nature must be "a product of human ingenuity having a distinctive name, character [and] use."[48]

Myriad appealed both the standing challenge and the decision on the merits to the Federal Circuit, and on July 29, 2011, a divided panel found that the isolated DNA molecules were patent-eligible.[49] Judge Lourie, writing for the majority, gave weight to the fact that covalent chemical bonds are broken at

[39] Complaint, Ass'n for Molecular Pathology v. Myriad Genetics Inc., 09-Civ-4515 (SDNY May 12, 2009) (http://docs.justia.com/cases/federal/district-courts/new-york/nysdce/1:2009cv04515/345544/1/).

[40] See, the chart following this discussion for some of the patent claims at issue.

[41] *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008); *cert. granted* 556 U.S. 1268 (2009).

[42] *See, e.g.,* John Conley, *ACLU and Myriad Both Seek Further Federal Circuit Review*, The Privacy Report, https://theprivacyreport.com/2011/09/02/aclu-and-myriad-both-seek-further-federal-circuit-review/ (Sep. 2, 2011).

[43] Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F.Supp.2d 181 (S.D.N.Y. March 29, 2010) ("*Myriad*").

[44] *Myriad*, 702 F.Supp.2d at 220 (citing *Bilski*, 545 F.3d at 958).

[45] *Myriad*, 702 F.Supp.2d at 229-231.

[46] *Myriad*, 702 F.Supp.2d at 222.

[47] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[48] *Myriad*, 702 F.Supp.2d at 223.

[49] Ass'n for Molecular Pathology v. Myriad Genetics Inc., 653 F.3d 1329 (Fed. Cir. 2011).

both ends of a native DNA molecule when the DNA is removed from the human genome,[50] and this point was ably emphasized and amplified by Judge Moore.[51] As stated by Judge Lourie, a chemist: "[W]e conclude that the challenged claims are drawn to patentable subject matter because the claims cover molecules that are markedly different–have a distinctive chemical identity and nature–from compounds that exist in nature."[52] Judge Lourie further emphasized that "isolated DNA is not purified DNA," instead "when cleaved, an isolated DNA molecule is not a purified form of a natural material [like adrenalin purified from adrenal gland material] but a distinct chemical entity."[53] Judge Lourie also noted that natural or novel DNA sequences can be chemically synthesized from scratch, and thus require no isolation in any way from nature.[54] The use of cells transformed with isolated BRCA2 in claim 20 to screen potential anti-cancer agents was also found to be patentable.[55] This was not surprising, as claim 20 is analogous to a claim to the use of the Chakrabarty cells to "eat oil."

However, the claims directed to comparing a subject's BRCA2 DNA sequence with a wild-type ["normal" or "reference"] sequence did not survive a review by the Federal Circuit under the new *Bilski* standard,[56] even one including the recitation that "an alteration in the germline sequence of the BRCA2 gene or the sequence of its RNA indicates a predisposition to cancer."[57] The panel members agreed that all of these mutation/wild-type comparison claims were impermissible attempts to claim abstract ideas - even claim 2 of U.S. Patent 6,033,857, which is clearly an "If (a)/Then (b)" correlative diagnostic claim.

In December 2011, the Association for Molecular Pathology petitioned the Supreme Court for certiorari, presumably to void the isolated DNA claims. However, after reversing *Mayo* in March 2012[58] as discussed above, the Court then vacated the Federal Circuit *Myriad* decision[59] and remanded (in other words GVR'd) it back to the Federal Circuit. On Aug. 16, 2012, the original Federal Circuit panel again held that claims to isolated genomic DNA sequences were patent-eligible under § 101 as directed to discrete chemical molecules.[60]

The panel spent little time on the method claims but reaffirmed that they were invalid attempts to claim an abstract idea. Judge Lourie again found that the method claims which only involve "comparing" and "analyzing" DNA sequences fail the MOT test and are no more than abstract ideas. In addition, at

[50] *Id.* at 1351-53.
[51] *Id.* at 1362-63.
[52] *Id.* at 1351.
[53] *Id.* at 1352. The Federal Circuit made it clear that it was not addressing the patentability of "natural products" such as adrenaline or certain microorganisms, that exist in nature in complex systems, and that must be extracted and purified in order to make them commercially useful. The Supreme Court did not address this type of "natural product" when it found that genomic DNA is a natural product.
[54] *Id.*
[55] *Id.* at 1357-58.
[56] *Id.* at 1355-57.
[57] U.S. Patent No. 6033857, claim 2.
[58] Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66 (2012).
[59] Ass'n for Molecular Pathology, et al. v. Myriad Genetics, Inc., 132 S. Ct. 1794 (Mar. 26, 2012).
[60] *Myriad*, 689 F.3d 1303 (Fed. Cir. 2012).

least one "diagnostic method" claim was also found patent-ineligible.[61] Claim 2 of the '857 patent reads:

> "A method for diagnosing a predisposition for breast cancer in a human subject which comprises comparing the germline sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from said subject with the germline sequence of the wild-type BRCA2 gene or the sequence of its mRNA wherein an alteration in the germline sequence of the BRCA2 gene or the sequence of its mRNA indicates a predisposition to said cancer."

This claim goes beyond simply comparing a patient sequence with a reference sequence to see if there are differences – it requires the "comparer" to draw a conclusion from the comparison, and a rather important one at that. The train of logic that might have, but did not, lead Judge Lourie to a conclusion that this claim is sufficiently concrete to be patent-eligible includes the following:

> "Limiting the comparison to just the BRCA genes orto just the identification of particular alterations, fails to render the claimed process patent eligible. As the Supreme Court has held, 'the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' [citing *Bilski* and *Diehr*, quoting Flook]. Although the *application* of a formula or abstract idea in a process may be patentable subject matterMyriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process claimed." [62]

It is simply not the case that claim 2 does not "apply the step of comparing two nucleotide sequences in a process," whether or not obtaining and sequencing the patient's DNA is a step of the process. The claim is to a method of making a diagnosis. It goes beyond "mere data gathering steps." There is absolutely no prohibition to including a "thinking step" in a method claim. It could be that the panel did not address this claim specifically because Myriad did not argue its concreteness separately from its other arguments. It may prove the most significant loss to the biotechnology industry and to "personalized medicine" in recent years. Worse yet, coupled with *Cybersource v. Retail Decisions*[63] (processes that can be carried out entirely mentally are patent-ineligible), it grades the bumpy road for the Supreme Court to eventually hold – the question is not presented in *Mayo* – that patents on diagnostic methods using single, or a few, biomarkers are patent ineligible.

The Supreme Court again granted *certiorari* after the Federal Circuit's 2012 *Myriad* decision and on June 13, 2013, in a unanimous opinion, found that claims to isolated stretches of genomic DNA, e.g., to the BRACA1/2 genes, were invalid as directed to "products of nature."[64] The Court rejected a general rule

[61] *Id.* at 1335.

[62] *Id.* at 1334-35. After making this statement, Judge Lourie goes on to reject the argument that the steps of extracting DNA and sequencing it are inherently present in the claims.

[63] 654 F.3d 1366 (Fed. Cir. 2011).

[64] Ass'n for Molecular Pathology, et al. v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

that breaking covalent bonds to yield a novel DNA molecule would always create a patent-eligible compound. The Court reasoned that the "human gene" claims focused on the information encoded in the DNA sequence and ignored the plain language of the claims, stating that the claims were "simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section DNA."[65]

The composition claims expressly directed to cDNA were found to be patent-eligible because cDNA preparation requires significant human manipulation.[66] If the Courts had engaged in careful scrutiny of Myriad's claim language, and the underlying support for such language in its specifications, they might have noticed that the term "gene" does not appear in any of the claims at issue, and that the application discloses little, if any, genomic DNA. Instead, the Myriad patents disclose cDNA sequences. If this fact had been presented in a "Question," the Court would probably have found it difficult to rule on the patent-eligibility of "isolated human genes."

The DNA "comparison" method claims were not considered by the Court. Interestingly, the Court spoke approvingly about the patent-eligibility of applications of knowledge about the native genes and stated that many of Myriad's unchallenged claims were limited to such applications.

Thus, after the *Myriad* decision, we are left with a Supreme Court ruling that genomic DNA is not eligible for patenting because it is a product of nature, and with a Federal Circuit panel ruling that claims to comparison of nucleic acid sequences, without more, are also ineligible as an impermissible effort to patent abstract ideas.

III. *Alice* Decision: Its Importance and Analysis

The focus of this paper is on biotechnology-related cases. However, the *Alice* decision[67] is often cited by the courts and the Patent Office when evaluating the patent eligibility of claims. Hence, we summarize the Supreme Court findings in the *Alice* case.

Alice's claims are drawn to a computer-implemented scheme for mitigating "settlement risk." The patents in suit claim (1) methods for exchanging obligations (the method claims), (2) a computer system configured to carry out the method for exchanging obligations (the system claims), and (3) a computer-readable medium containing program code for performing the method of exchanging obligations (the media claims). All of the claims are implemented using a computer; the system and media claims expressly recite a computer, and the parties have stipulated that the method claims require a computer as well. Claim 33 of U.S. Patent 5,970,479 is a representative method claim.

> 33. A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange

[65] *Id.* at 2118.
[66] *Id.* at 2119.
[67] Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

> institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:
>
> (a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;
>
> (b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;
>
> (c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party's shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order, and
>
> (d) at the end-of-day, the supervisory institution instructing on[e] of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions.

The court followed the *Mayo* two step patent eligibility test.[68] First, the Court concluded that it followed from the *Gottschalk v. Benson*,[69] *Parker v. Flook*,[70] and *Bilski* cases, and *Bilski* in particular, that the claims at issue were directed to an abstract idea. According to the Court, the concept of intermediated settlement is a fundamental economic practice long prevalent in our system of commerce, and the use of a third-party intermediary (or "clearing house") is a building block of the modern economy, so intermediated settlement (like the hedging against risk claims in the Bilski case) is an abstract idea beyond the scope of section 101.[71]

For the second step of the *Mayo* analysis, the Court considered whether the claims contain an "inventive concept" sufficient to "transform" the claimed abstract idea into a patent-eligible application.[72] To illuminate the issues, the Court reviewed the *Diehr* case,[73] noting that the claim at issue employed a "well-known" mathematical equation, but it used that equation in a process designed to solve a technological problem in "conventional industry practice." According to the Court, the invention in *Diehr* used a thermocouple to record constant temperature measurements inside the rubber mold–something the industry had "not been able to obtain" and the temperature measurements were then fed into a computer, which repeatedly recalculated the remaining cure time by using the mathematical equation.[74] It was these additional steps that "transformed the process into an inventive application of the formula" and the

[68] Mayo Collaborative Servs. v. Prometheus Labs. Inc., 132 S. Ct. 1289, 1297 (2012); *Alice*, 134 S.Ct. at 2355.
[69] Gottschalk v. Benson, 409 U.S. 63 (1972).
[70] Parker v. Flook, 437 U.S. 584 (1978).
[71] *Alice*, 134 S.Ct. at 2356.
[72] *Alice*, 134 S.Ct. at 2357.
[73] Diamond v. Diehr, 450 U.S. 175, 187 (1981); *Alice*, 134 S.Ct. at 2358.
[74] *Alice*, 134 S.Ct. at 2358.

claims in *Diehr* were patent eligible because they improved an existing technological process–not because they were implemented on a computer.[75]

Thus, the Court stated that mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention.[76] The Court found that the method claims, which require only generic computer implementation, do not transform that abstract idea into a patent-eligible invention. The representative method claim, the Court decided, does no more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer. When taking the claim elements separately, the function performed by the computer at each step–creating and maintaining "shadow" accounts, obtaining data, adjusting account balances, and issuing automated instructions–is, according to the Court, purely conventional.[77]

Similarly, because Alice's system and media claims add "nothing of substance to the underlying abstract idea," the Court held that they too are patent ineligible under section 101.[78]

IV. *Myriad*, *Mayo*, and *Alice* Rulings Applied

PerkinElmer, Inc. v. Intema, Ltd. ("PerkinElmer").

In the *PerkinElmer* case, a panel of the Federal Circuit reversed the district court and invalidated all of the claims of U.S. Patent No. 6,573,103 as patent-ineligible[79] in view of its *Myriad* decision and the Supreme Court's ruling in the *Mayo* case. The Intema claims were found to both "claim a law of nature" and to recite "the mental process of comparing data to determine a risk level."[80] The November 2012 *PerkinElmer* decision was deemed to be nonprecedential by the Federal Circuit, at least in part because the Supreme Court had not yet handed down its *Myriad* opinion.

The claims at issue are directed to an improved method to diagnose Down's syndrome by measuring known biomarkers and/or ultrasound data taken during both the first and the second trimesters of pregnancy, and then subjecting the data to multivariate analysis based on reference parameters to determine the odds that the fetus has Down's syndrome. The method was "improved" because some markers are more predictive at different stages of pregnancy.[81]

It is not easy to tell if the Federal Circuit panel applied the Supreme Court *Mayo* ruling or the Federal Circuit's *Myriad* ruling as the dominant precedent, in part because these two cases found ineligibility on different grounds.

[75] *Id.*

[76] *Id.*

[77] *Id.* at 2359.

[78] *Id.* at 2360.

[79] PerkinElmer, Inc. v. Intema Ltd., 496 Fed. App'x 65, 73 (Fed. Cir. 2012)(nonprecedential). Intema filed a petition for certiorari with the Supreme Court, which was denied.

[80] *Id.* at 70.

[81] U.S. Patent No. 6,573,103, col. 2, lines 37-56.

Thus, the *PerkinElmer* panel relied on the *Myriad* reasoning in characterizing the claims as involving only mental steps, stating that "[t]he stricken claims [in *Myriad*] are indistinguishable from those before us The [*Myriad*] claims were not over an *application* of the mental process of comparing. 'Rather, the step of comparing two DNA sequences [was] the entire process that [was] claimed."'[82]

In relying on *Mayo* reasoning, the panel found a law of nature in claimed subject matter: "Intema also claims a law of nature: the relationship between screening marker levels and the risk of fetal Down's syndrome."[83]

As in *Myriad* and *Mayo*, the *PerkinElmer* panel noted that claims involving only analysis without action predicated on such analysis were defective, stating that in the Intema claims "data are compared to known statistical information. No action beyond the comparison is required."[84] According to the *PerkinElmer* panel, "[A]s in *Prometheus*, there is no requirement that a doctor act on the calculated risk,"[85] and "[h]ere no 'further act' moves the recited concepts to a specific application."[86]

In suggesting that preemption[87] might be a concern, the panel referred to the Supreme Court's *Mayo* decision, stating that "anyone who wants to use this mental step or natural law must follow the claimed process."[88]

But which prohibition was applied? Apparently both mental steps and natural laws, since the *PerkinElmer* panel concludes: "Because the asserted claims recite an ineligible mental step and natural law, and no aspect of the method converts these ineligible concepts into patentable applications of those concepts, the claims cannot stand."[89]

Thus, patent applicants must now search for a "further act" or "aspect" that confers patent-eligibility, because the *Mayo* decision found that simply discovering and claiming an indicative correlation (If "a", then "b") is an impermissible attempt to claim (and thus to monopolize) a natural phenomenon, or law of nature, unless the claim contains another feature that adds something beyond a statement of the correlation.[90] The Court simply denigrated and disregarded the other steps present in the claims[91] – administering the reference drug, measuring the levels of its metabolites and drawing a conclusion about appropriate dosing from the levels that are measured:

> In particular, the steps in the claimed processes [in Prometheus's patents] (apart from the natural laws themselves) involve

[82] *PerkinElmer*, 496 Fed. App'x at 70 (citing *Myriad*, 689 F.3d at 1335). We note that this statement is only true if the diagnostic conclusion reached in one of the disputed claims is completely ignored as a limitation.

[83] *PerkinElmer*, 496 Fed. App'x at 70.

[84] *Id.*

[85] *Id.* at 71.

[86] *Id.* at 71 n.2.

[87] The Supreme Court has indicated that claims wholly preempting the use of a mathematical formula are patent-ineligible. *Benson*, 409 U.S. at 67-68 (1972). "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Id*. (citing LeRoy v. Tatham, 55 U.S. 156 (1852)).

[88] *PerkinElmer*, 496 Fed. App'x at 71 (citing *Mayo*, 132 S. Ct. at 1298).

[89] *Id.* at 73.

[90] *Mayo*, 132 S.Ct. at 1297-98.

[91] *Id*. at 1297.

> well-understood, routine, conventional activity previously engaged in by researchers in the fieldupholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.[92]
>
> * * *
>
> [D]o the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?[93]

Of course, the Court said that the answer was "No." However, the Court provided no guidance as to what that "enough" might be, except to discuss the facts of three older decisions that have nothing to do with modern medicine.[94]

So what action or application might be enough to satisfy a court on the facts available in *PerkinElmer*?[95] The Federal Circuit seems to be edging toward a definition of what is sufficient "to transform an unpatentable law of nature into a patent-eligible application of such a law."[96] The *PerkinElmer* panel tries to explain how the *Mayo* Court distinguished *Diamond v. Diehr*[97] as follows: "The key distinction, which bears on our decision today, is between claims that recite ineligible subject matter, and no more, and claims that recite specific inventive applications of the subject matter."[98] In referring to *Mayo*, the *PerkinElmer* panel noted "that the claims in *Diehr* were patent-eligible 'because of the way the additional steps of the process integrated the [ineligible] equations into the process as a whole,'"[99]and the panel notes that the *Diehr* court "nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use or purely conventional."[100]

However, in *Diehr*, the algorithm functioned in the context of curing shaped rubber widgets and caused the heated mold to open when the widgets were optimally cured.[101] Apart from the algorithm, the molding process was apparently "purely conventional."[102]

Unfortunately, *PerkinElmer* makes it clear that the step of drawing a diagnostic conclusion – the purpose of the method – is to be given no weight as a specific inventive application of a natural law in the patent-eligibility analysis. It is not an "inventive concept" to use a term from *Mayo*, but an "ineligible concept."[103]

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[92] *Id.* at 1294.
[93] *Id.* at 1297.
[94] *Id.* at 1298-99.
[95] Would an amniocentesis step be enough? Or would it merely be 'purely conventional'?
[96] *PerkinElmer,* 496 Fed. App'x at 71 (citing *Mayo*, 132 S. Ct. at 1299).
[97] 450 U.S. 175 (1981).
[98] *PerkinElmer,* 496 Fed. App'x at 68 (citing *Diehr*, 450 U.S. at 187).
[99] *PerkinElmer,* 496 Fed. App'x at 70.
[100] *Id.*
[101] *Diehr*, 450 U.S. at 178.
[102] *Id.* at 180-81.
[103] *PerkinElmer*, 496 Fed. App'x at 68.

Therefore, practitioners are tasked with the nearly impossible burden of claiming two inventions or discoveries in one claim – the first is based on the underlying discovery of an indicative correlation that permits a diagnosis to be drawn, and the second is some as-yet undefined "aspect" or "action" akin to opening the heated mold in *Diehr* and taking out the cured widget. But wouldn't the doctor's adjusting the dose in *Mayo*, suggesting breast removal in *Myriad,* or ordering an amnio in this case be conventional medical activity? The Supreme Court may think they will know what "aspect" or "action" is sufficient when they see it, but their recent decisions have not communicated a discernible standard to patent applicants.

Perkin-Elmer is the first decision in which the Federal Circuit invalidated claims that recited correlating levels of specific biomarkers to the presence or absence of a specific medical condition (Down's syndrome).[104] Although the decision was labeled "nonprecedental," probably in view of the then-pending *Myriad* appeal, it certainly won't be the last. The Supreme Court denied Intema's petition for certiorari on October 7, 2013,[105] signaling agreement with the Federal Circuit that such correlations are not patent-eligible subject matter under Section 101.

Claims 7-9 of the '103 patent recited the specific biomarkers that are measured, and they were apparently all known biomarkers for Down's syndrome. How would the Federal Circuit rule if the inventor had discovered a new biomarker and then claimed its use to diagnose a specific pathology? Since the *de facto* reversal of *In re Durden*[106] by *In re Ochiai*[107] and *In re Plueddemann*,[108] any use, even an obvious one, of a patentable compound is itself patentable.

Since the Supreme Court in the *Myriad* case affirmed that at least cDNA is patentable subject matter, the courts have created a situation in which a compound can be patented, but its use in a diagnostic procedure cannot–at least in view of the guidance that has been provided to date. This is probably not what the Supreme Court intended because, *in dicta*, it stated that useful applications of DNA molecules may well be patentable,[109] but this may conflict with the Federal Circuit's apparent hostility to patents claiming diagnostic methods based on new uses of "old-biomarkers."

BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.

The *Ambry* case[110] revisits some of the issues and claims that were not fully

[104] *See, e.g.*, U.S. Patent No. 6,573,103, claims 8-9.

[105] Intema Ltd. v. PerkinElmer, Inc., 134 S. Ct. 102, (2013). In its petition for certiorari, Intema argued that evaluating multiple samples taken at different times was a novel "inventive step" in its diagnostic claims, but this did not induce the Supreme Court to grant their petition.

[106] 763 F.2d 1406 (Fed. Cir. 1985).

[107] 71 F.3d 1565 (Fed. Cir. 1995).

[108] 910 F.2d 823 (Fed. Cir. 1990).

[109] *Myriad*, 133 S. Ct. at 2119-210.

[110] BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014).

adjudicated in the *Myriad* case. Myriad and its business partners asserted against Ambry various composition and method claims of patents not previously considered by the Supreme Court or the Federal Circuit. Claim 16 of U.S. Patent No. 5,747,282 is representative of the composition claims at issue.

> 16. A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.

The Federal Circuit found that such primers are not distinguishable from the isolated DNA ruled patent-ineligible products of nature in the *Myriad* case and such primers are not similar to the cDNA that was found to be patent-eligible by the Supreme Court.[111] It made no difference to the Federal Circuit that the primers were synthetically replicated.[112] The Federal Circuit was also not swayed by Myriad's arguments that primers are in fact not naturally occurring because single-stranded DNA cannot be found in the human body, or that primers have a fundamentally different function (starting material for polymerization) than when they are part of a DNA strand (storing biological information).[113]

The Federal Circuit also considered the patent eligibility of claims of U.S. Patent 5,753,441, where claim 7 (which depends from and includes the subject matter of claim 1) is recited below.

> A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA from a tissue sample from said subject or a sequence of BRCA1 cDNA made from mRNA from said sample with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject[,]
>
> wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.

Claim 8 also depends from claim 1 and states the germline nucleic acid sequence is compared by amplifying all or part of a BRCA1 gene from said sample using a set of primers to produce amplified nucleic acids and sequencing the amplified nucleic acids.

[111] *Ambry*, 774 F.3d at 760.
[112] *Id.*
[113] *Id.* at 760-61.

The Federal Circuit treated the first paragraphs of claims 7 and 8 separately from the second paragraphs, noting that they had already found claim 1 (i.e., the first paragraph) patent-ineligible.[114] According to the Federal Circuit, these methods for identification of alterations of the gene merely require comparing the patient's gene with the wild-type and identifying any differences that arise, and because of its breadth, the comparison step covers detection of yet-undiscovered alterations.[115] Hence, claims 7 and 8 were found to be abstract ideas.

With respect to whether the second paragraphs of claims 7 and 8 are a "further inventive concept to take the claim into the realm of patent-eligibility," the court agreed with the findings of the lower court that the elements of the second paragraphs of claims 7 and 8 "set forth well-understood, routine and conventional activity engaged in by scientists at the time of Myriad's patent applications" and these elements to not add "enough" to make the claims as a whole patent-eligible.[116]

Myriad had argued that claims should be patent eligible because they are similar to claim 21 of the '441 patent, which Judge Bryson suggested was patent eligible in his separate opinion in the 2012 Federal Circuit opinion,[117] and that the Supreme Court had approved of Judge Bryson's suggestion.[118] But, according to the Federal Circuit, claim 21 of the '441 patent is qualitatively different from method claims 7 and 8.[119] The Federal Circuit noted that claim 21 is a method of detecting alterations in which the alterations being detected are expressly identified in the specification by tables 11 and 12, which expressly identify ten predisposing mutations of the BRCA1 gene sequence discovered by the patentees. Hence, the Federal Circuit asserted that claim 21 is limited to the particular mutations the inventors discovered, whereas claims 7 and 8 are significantly broader and more abstract, as they claim all comparisons between the patient's BRCA genes and the wild-type BRCA genes.[120]

Thus, Myriad's claims were found to be directed to ineligible subject matter in violation of 35 U.S.C. § 101.

In re Roslin Institute

The issue in the *Roslin Institute* case was whether the Patent Office should find that claims to cloned mammals in U.S. Patent Application No. 09/225,233, patent eligible.[121] One such cloned mammal is Dolly the sheep, which was made by fusing the nucleus of an adult, somatic mammary cell with an enucleated oocyte, stimulating cell division to generate an embryo, and then implanting the embryo into a surrogate mammal, where it develops into a baby animal. Claims 155 and 164 are representative:

[114] *Id.* at 762.

[115] *Id.* at 763.

[116] *Id.* at 764-65.

[117] *Myriad*, 689 F.3d at 1349. Judge Bryson indicated that, "[a]s the first party with knowledge of the sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications."

[118] *Myriad*, 133 S.Ct. at 2120.

[119] *Ambry*, 774 F.3d at 765.

[120] *Id.*

[121] *In re* Roslin Inst. (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014).

> 155. A live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats.
>
> 164. The clone of any of claims 155-159, wherein the donor mammal is non-foetal.

The Federal Circuit affirmed the Patent Trial and Appeal Board finding that these claims were ineligible for patenting because such clones are constituted a "natural phenomenon" that did not possess "markedly different characteristics than any found in nature,"[122] and because the claims were anticipated and obvious by the prior art because they were indistinguishable from clones produced through prior art cloning methods, i.e., embryotic nuclear transfer and *in vitro* fertilization.[123]

The Federal Circuit contrasted the facts of the *Roslin Institute* case with the *Chakrabarty*[124] case, where non-naturally occurring bacterium were made by adding four plasmids to a specific strain of bacteria. In *Chakrabarty,* the Supreme Court held that such a modified bacterium was patentable because it was "new" with "*markedly different characteristics from any found in nature* and one having the potential for significant utility."[125]

The Roslin Institute argued that its claimed clones were patent eligible because they are distinguishable from the donor mammals used to create them, contending that "environmental factors" lead to phenotypic differences that distinguish its clones from their donor mammals.[126] However, Roslin acknowledged that any phenotypic differences came about or were produced "quite independently of any effort of the patentee."[127] The Roslin Institute also argued that the clones are distinguishable from their original donor mammals because of differences in mitochondrial DNA, which originates from the donor oocyte rather than the donor nucleus.[128] The Federal Circuit did not buy these arguments because such factors, phenotypic differences, and mitochondrial DNA differences were not recited in the claims.[129] Finally, the Roslin Institute argued that its clones were patent eligible because they are time-delayed versions of their donor mammals, and therefore different from their original mammals. But the Federal Circuit again found that this distinction cannot confer patentability because such a time-delayed characteristic is true of any copy of an original.[130]

Ariosa Diagnostics Inc. v. Sequenom Inc.

[122] *Roslin Inst.*, 750 F.3d at 1335, 1339.
[123] *Id.*
[124] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[125] *Roslin*, 750 F.3d at 1336.
[126] *Id.* at 1337-38.
[127] *Id.* at 1338.
[128] *Id.*
[129] *Id.*
[130] *Id.*

In the *Ariosa* case, a panel of the Federal Circuit in June 2015 affirmed the district court ruling that the asserted claims U.S. Patent No. 6,258,540 (the '540 patent) were ineligible for patenting.[131] Claim 1 of Sequenom's '540 patent reads as follows:

> 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
>
> amplifying a paternally inherited nucleic acid from the serum or plasma sample and
>
> detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

The panel followed a two-step method outlined by the Supreme Court in the *Mayo* case[132] to find these claims patent ineligible. First, the panel found that the claims were directed to a patent-ineligible concept, noting that it was undisputed that the existence of cffDNA in maternal blood is a natural phenomenon and that that the location of the nucleic acids existed in nature before Drs. Lo and Wainscoat found them.[133] The panel referred to several statements from the specification as evidence to support their finding of such a natural phenomenon.[134]

> "It has now been discovered that foetal DNA is detectable in maternal serum or plasma samples."
>
> '540 patent, col. 1, ll. 50-51.
>
> "This is a surprising and unexpected finding; maternal plasma is the very material that is routinely discarded by investigators studying noninvasive prenatal diagnosis using foetal cells in maternal blood."
>
> '540 patent, col. 1, ll. 51-55.

Even such benign statements as these can therefore be problematic in a patentee's specification when patent eligibility issues are raised.

The panel then considered whether claim 1 contains an inventive concept sufficient to "transform" the claimed naturally occurring phenomenon into a patent-eligible application.[135] The panel found no such transformation stating that methods like PCR were well-understood, routine, and conventional activity in 1997, and that the same applied to the detecting step.[136] With respect to the detection step, the panel cited to statements made during the prosecution of the '540 patent; the following is one example of such a statement.[137]

[131] Ariosa Diagnostics Inc. v. Sequenom Inc., 788 F.3d 1371 (Fed. Cir. 2015).
[132] Mayo Collaborative Services v. Prometheus Labs. Inc., 132 S. Ct. 1289, 1297 (2012); *Ariosa*, 788 F.3d at 1375.
[133] *Ariosa*, 788 F.3d at 1376.
[134] *Id.*
[135] *Id.*
[136] *Id.* at 1377.
[137] *Id.* at 1377-78.

> [O]ne skilled in the art is readily able to apply the teachings of the present application to any one of the well-known techniques for detection of DNA with a view to analysis of foetal DNA

Thus, a patentee's assertions that any step or aspect of a claimed inventions is "well-known" can fuel a patent-ineligibility finding.

Sequenom argued that the particular application of the natural phenomena embraced by the '540 patent claims were narrow and specific, and hence the claims should be patent eligible because they did not preempt all uses of cffDNA.[138] However, the panel found that while preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. According to the panel, in this case, Sequenom's attempt to limit the breadth of the claims by showing alternative uses of cffDNA outside of the scope of the claims did not change the conclusion that the claims are directed to patent ineligible subject matter.[139]

Judge Linn concurred but stated he did so only because he was bound by the "sweeping language" of *Mayo*. According to Judge Linn, the '540 patent claims should be patent eligible. He noted that while the instructions in the claims at issue in *Mayo* had been widely used by doctors, the amplification and detection of cffDNA had never before been done. He called the Sequenom invention "ground-breaking" and "nothing like the invention at issue in *Mayo*."[140]

Despite Judge Linn's strong concurrence, the Federal Circuit declined to review the panel decision en banc.[141] Judge Newman wrote a strong dissent, while Judges Lourie and Dyk wrote separate concurrences of the denial of en banc review.

Judge Lourie, joined by Judge Moore, urged that laws of nature are exact statements of physical relationships, all physical steps of human ingenuity utilize natural laws or involve natural phenomena, and such steps cannot be patent-ineligible solely because they are laws of nature, because nothing in the physical universe would then be patent-eligible.[142] According to Judge Lourie, methods that utilize laws of nature do not set forth or claim laws of nature. Judge Lourie also reasoned that abstract steps are, axiomatically, the opposite of tangible steps, and that which is not tangible is abstract. Hence, Judge Lourie noted that steps that involve machines are tangible, steps that involve transformation of tangible subject matter, and tangible implementations of ideas or abstractions should not be considered to be abstract ideas.[143] Judge Lourie also noted that there may be some truth to concerns that the whole category of diagnostic claims is at risk and that a crisis of patent law and medical innovation may be upon us.[144]

Judge Dyk thought that the framework of *Mayo* and *Alice* is an "essential ingredient of a healthy patent system" but he expressed concerns that are shared

[138] *Id.* at 1378.
[139] *Id.* at 1379.
[140] *Id.* at 1381.
[141] Ariosa Diagnostics Inc. v. Sequenom Inc., 809 F.3d 1282 (Fed. Cir. 2015)
[142] *Id.* at 1284.
[143] *Id.* at 1285.
[144] *Id.*

by some of his colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in Mayo) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena.[145] Judge Dyk stated that the Federal Circuit was bound by the language of *Mayo*, and any further guidance must come from the Supreme Court.[146] According to Judge Dyk Mayo/Alice framework works well when the abstract idea or law of nature in question is well known and longstanding, but a problem exists with *Mayo* insofar as it concludes that an inventive concept cannot come from discovering something new in nature such as the identification of a previously unknown natural relationship or property.[147] Judge Dyk stated that this is especially true in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems, and he worried that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the Mayo test.[148] Judge Dyk provided a partial solution to this problem by limiting the scope of patents based on new discoveries to narrow claims covering applications actually reduced to practice.[149] He reasoned that primary concern with a patent on a law of nature is undue preemption–the fear that others' innovative future applications of the law will be foreclosed – and that limiting the scope of claims to those reduced to practice would avoid the preemption issue.

Judge Newman flatly stated that the *Ariosa* case was wrongly decided and declared that she did not share the view of her colleagues such an incorrect decision is required by Supreme Court precedent.[150] According to Judge Newman, the facts of the *Ariosa* case are different from those in *Mayo*. Whereas both the claimed medicinal product and its metabolites were previously known in the *Mayo* case, the Sequenom method was not previously known, nor was the diagnostic knowledge and benefit implemented by the method.[151] In addition, Judge Newman asserted that patenting of this new diagnostic method does not preempt further study of this science, nor the development of additional applications.[152]

In view of the concerns expressed by the Federal Circuit judges, which capture many of those of the diagnostics and biotechnology industry, it would seem that the *Ariosa* ruling could be poised for review by the Supreme Court. A petition for *certiorari,* was filed in mid-March, asking for clarification of the scope of the *Mayo* opinion. As Harold Wegner has cautioned, there are serious dangers raised for the patent community if this case is taken for review by the Supreme Court, including a potential for a binding, precedential Supreme

[145] *Id.* at 1287.
[146] *Id.*
[147] *Id.* at 1289.
[148] *Id.*
[149] *Id.* at 1291.
[150] *Id.* at 1293.
[151] *Id.*
[152] *Id.*

Court affirmance of the Federal Circuit decision.[153] However, the petition for cert. was denied.

Notably, not all of the claims in the Sequenom patent were diagnostic claims. The claim of the '540 patent summarized below is only directed to the amplification and detection of cffDNA. Invalidation of such claims, coupled with statements about the ineligibility of claims to nature-based products in *Roslin*, comes perilously close to a general repudiation of "*Bergy II*", 596 F.2d 952 (CCPA 1979) in which a "biologically pure culture" of a microorganism useful to produce an antibiotic was found to be patent-eligible despite its existence in the "complex jungle of microorganisms" in the soil sample from which it was isolated. When the Supreme Court decided *Chakrabarty*, it remanded the CCPA's decision in *Bergy II* for dismissal as moot. However, the CCPA decision may have precedential weight, since the Supreme Court cited it in *Diehr*.

Genetic Technologies Ltd. v. Merial LLC

In the *Genetic Technologies* case, a panel of the Federal Circuit in April 2016 affirmed the district court ruling that the asserted claims of U.S. Patent No. 5,612,179 (the '179 patent) (amongst others) were not eligible for patenting.[154] Claim 1 of the '179 patent recites:

> 1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising:
>
> a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and
>
> b) analyzing the amplified DNA sequence to detect the allele.

According to Genetic Technologies, the methods of the '179 patent had various advantages over prior art methods involving direct analysis of a coding region. For example, Genetic Technologies stated that "analysis of relatively short regions of non-coding sequences, of a size which can be amplified, can provide more information than prior art analyses such as cDNA RFLP analyses which involve the use of significantly larger DNA sequences...." '179 Patent Prosecution History, Applicant's Amendment and Remarks of Jan. 14, 1993, at 6.

The district court granted defendants' motions, holding that claim 1 of the '179 patent is invalid for claiming a law of nature, which is patent-ineligible subject matter. "A claim is unpatentable if it merely informs a relevant audience about certain laws of nature, even newly-discovered ones, and any additional

[153] Harold C. Wegner, *A Sequenom White Paper,* http://www.laipla.net/wp-content/uploads/2016/02/SequenomFeb23.pdf (Feb. 23, 2016). He has also noted that the Court may not grant the petition, since there are, as yet, no conflicting opinions below, or within the Court.

[154] Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369 (Fed. Cir. 2016) (cert. denied).

steps collectively consist only of well-understood, routine, conventional activity already engaged in by the scientific community. The claim involved here, claim 1 of the '179 patent, does just that and no more."

The Federal Circuit used the *Mayo/Alice* test and ask first whether claim 1 is directed to a patent-ineligible concept, finding that it was. The Federal Circuit then examined the physical steps by which claim 1 implements the natural law of linkage disequilibrium between coding and non-coding regions to determine whether they provide more than "well-understood, routine, conventional activity" already engaged in by those in the field under the second step of the *Mayo/Alice* test. According to the Federal Circuit, claim 1 contains two implementation steps, "amplifying genomic DNA with a primer pair" and "analyzing the amplified DNA sequence to detect the allele."

The Federal Circuit found that "amplifying" genomic DNA with a primer pair and the "analyzing" step of the amplified DNA to provide a user with information about the amplified DNA were well known, routine, and conventional in the field of molecular biology as of 1989, when the first precursor application to the '179 patent was filed.

Rapid Litigation Mgmt. LTD v. Cellzdirect, Inc.

In the *Cellzdirect* case, a panel of the Federal Circuit in July 2016 vacated and remanded the district court ruling that the asserted claims of U.S. Patent No. 7,604,929 (the '929 patent) were not eligible for patenting.[155] Claim 1 of the '929 patent reads as follows:

> 1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:
>
> (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes,
>
> (B) recovering the separated viable hepatocytes, and
>
> (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time,
>
> wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

The Federal Circuit reversed the lower court, stating the following.

> The district court identified in these claims what it called a "natural law" —the cells' capability of surviving multiple freeze -thaw

[155] Rapid Litigation Mgmt. LTD v. Cellzdirect, Inc., 827 *F.3d* 1042 (Fed. Cir. 2016).

> cycles. We need not decide in this case whether the court's labeling is correct. It is enough in this case to recognize that the claims are simply not directed to the ability of hepatocytes to survive multiple freeze- thaw cycles. Rather, the claims of the '929 patent are directed to a new and useful laboratory technique for preserving hepatocytes. This type of constructive process, carried out by an artisan to achieve "a new and useful end," is precisely the type of claim that is eligible for patenting.

The panel delved into the prosecution history of the patent to evidence that "[T]he individual steps of freezing and thawing were well known, but a process of preserving hepatocytes by repeating those steps was itself far from routine and conventional," concluding that "[r]epeating a step that the art taught should be performed only once can hardly be considered routine or conventional." (Citing Diehr with approval.) "To require something more [than Diehr] at step two [of the Mayo/Alice test] would be to discount the human ingenuity that comes from applying a natural discovery in a way that achieves a 'new and useful end.'"

Cleveland Clinic v. True Health Diagnostics

In the *Cleveland Clinic* case, a panel of the Federal Circuit in June 2017 affirmed the district court ruling that the asserted claims of U.S. Patent No. 7,223,552 (the '552 patent) (amongst others) were eligible for patenting.[156] Claim 11 of Cleveland Clinic's '552 patent reads as follows:

> 11. A method of assessing a test subject's risk of having atherosclerotic cardiovascular disease, comprising
>
> comparing levels of myeloperoxidase in a bodily sample from the test subject with levels of myeloperoxidase in comparable bodily samples from control subjects diagnosed as not having the disease, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereo[f];
>
> wherein the levels of myeloperoxidase in the bodily [sample] from the test subject relative to the levels of [m]yeloperoxidase in the comparable bodily samples from control subjects is indicative of the extent of the test subject's risk of having atherosclerotic cardiovascular disease.

The Federal Circuit found that the claims are directed to multistep methods for observing the law of nature that myeloperoxidase correlates to cardiovascular disease. The court therefore proceeded to consider step 2 of the Mayo/Alice

[156] Cleveland Clinic v. True Health Diagnostics, 859 F. 3d 1352 (Fed. Cir. 2017).

test by examining the elements of the claims to determine whether they contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent eligible application.

The Federal Circuit concluded that the practice of the method claims does not result in an inventive concept that transforms the natural phenomena of myeloperoxidase being associated with cardiovascular risk into a patentable invention. According to the Federal Circuit, the *Mayo* and *Ariosa* decisions make clear that transforming claims that are directed to a law of nature requires more than simply stating the law of nature while adding the words "apply it."[157]

In a related case, the Federal Circuit found other Cleveland Clinic claims ineligible for patenting under section 101 even though those claims were assays for detecting elevated myeloperoxidase without a diagnosis step.[158]

Exergen Corp. v. Kaz USA

In the *Exergen* case, a panel of the Federal Circuit in March 2018 affirmed the district court ruling that the asserted claims of U.S. Patent No. 7,787,938 (the '938 patent) were eligible for patenting.[159] Claim 14 of Exergen's '938 patent reads as follows:

> 14. A method of detecting human body temperature comprising making at least three radiation readings per second while moving a radiation detector to scan across a region of skin over an artery to electronically determine a body temperature approximation, distinct from skin surface temperature.

The parties had agreed that the claims are directed to a patent-ineligible concept, so the sole issue remaining for the panel was to decide if the distinct court properly found that the claims contained a further inventive concept that was not "well-understood, routine [and] conventional activity previously engaged in by researchers in the field." This is the second step the patent office's path for resolving the 101 question.

The panel concluded:

> "Even if the concept of [the measurement of a natural phenomenon (core body temperature)] is directed to a natural phenomenon and is abstract at step one [the MPEP's Step 2A], the measurement method here was not conventional, routine, and well-understood. Following years and millions of dollars of testing and development, the inventor determined for the first time the coefficient representing the relationship between temporal-arterial temperature and core body temperature and incorporated that discovery into an unconventional method of temperature measurement. As a result, the method is patent-eligible, similar to the method of curing rubber held eligible in *Diehr*."

[157] In June 2018, the Supreme Court has declined to grant Cleveland Clinic's petition for certiorari.

[158] Cleveland Clinic Found. v. True Health Diagnostics, LLC, No. 2018-1218 (Fed. Cir. 2019).

[159] Exergen Corp. v. Kaz USA, Inc., 725 F. App'x 959 (Fed. Cir. 2018).

Mayo and *Ariosa* were distinguished as employing well-known, existing methods to determine the existence of natural phenomenon. The panel recognized that, while section 101 patent eligibility is a legal question, "sometimes the inquiry may contain underlying factual issues, citing *Mayo* for the proposition that the 101 inquirey 'might sometimes overlap' with other fact-intensive inquiries like novelty under section 102.

The Patent Office issued a Memorandum entitled *Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision* (*Berkheimer v. HP, Inc.*)(April 19, 2019), citing the *Exergen* decision as "concluding that the district court's fact finding that the claimed combination was not proven to be well-understood, routine, [or] conventional was not clearly erroneous." The Memorandum stated that, in the second step of a Mayo/Alice analysis, "an additional element (or combination of elements) is not well-understood, routine or conventional unless the examiner finds, and expressly supports a rejection in writing with references to facts such as concessions by applicant, citation to relevant court decisions, citations to relevant publications or the examiner properly takes official notice of the well-known, etc., nature of the additional elements."

In re Urvashi Bhagat

In the *In re Urvashi Bhagat* case,[160] the PTAB affirmed an Examiner's rejection of claims drawn to a lipid-containing formulation. Claim 65 of U.S. Patent Application Ser. No. 12/426,034 (the '034 application) was at issue.

> 65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein
>
> (1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty ac-ids are 0.1–30% by weight of total lipids; or
>
> (2) omega-6 fatty acids are not more than 40 grams.

The examiner found that the claimed "intermixture of lipids from different sources" is "structurally indistinct" from lipid formulations derived from a single source referring to the prior art as proof. The examiner also found that the claims are directed to natural products of walnut oil and olive oil, and that the additional limitations in the claims do not change the characteristics of the products or add "significantly more" to the claims.

The Federal Circuit simply dismissed the claim element "casing" as meaning "any orally accepted form", in the anticipation section of the decision, that does not provide patentability to the compositions because the specification

[160] *In re* Urvashi Bhagat, No. 2016-2525 (Fed. Cir. March 16, 2018) (nonprecedential); *see also*, *ex parte* Bhagat, Appeal No. 2016-004154 (P.T.A.B. April 15, 2016), (rehearing denied June 21, 2016).

states that the term is not claim-limiting and that it does not describe any novel characteristics of the components or their formulations.

This analysis may be appropriate in a patentability analysis under sections 102/103, it is unclear how a mixture of lipid from different sources encased in casings providing controlled delivery is a natural product.

Ex parte Buck

In the *Ex parte Buck* case,[161] the PTAB upheld an Examiner's rejection of claims drawn to a kit comprising vitamin D. Claim 7 of U.S. Patent Application Ser. No. 13/446,128 (the '128 application) was at issue.

> 7. A kit comprising multiple, separate weekly or monthly dosages of
>
> a) Vitamin D, and
>
> b) 25-OH D3, wherein a dosage ratio of the Vitamin D3 to the 25-OH D3 is from about 6:1 to 1:6; a single weekly dosage contains from 7μg to 350 μg each of Vitamin D and 25-OH D3; and a single monthly dosage contain from 30 μg.

The Examiner asserted that the vitamin D and 25-OH D3 of the kit were both natural products, and that the characteristics of each component were not significantly different from their naturally-occurring counterparts because they have the same structure and function as they do in nature.

The Board the Examiner has failed to provide a single example of a natural product, that comes in multiple separate weekly or monthly dosages, and which satisfies all the features of the claims.

According to Appellants, the two claimed compounds, Vitamin D3 and 25-0H D3, exhibit in combination synergistic effects, synergistically raising and sustaining 25-OH D3 levels in an individual and allowing weekly and/or monthly dosing, which is not possible using the single ingredients. not persuaded by Appellants' arguments.

However, the Board found that it was indisputable that both vitamin D3 and 25-OH D3 are naturally-occurring chemicals that co-exist in biological systems and, by themselves, are products of nature and consequently unpatentable. While all inventions, at some level, embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas, the Board found that they could not structurally distinguish the chemical compositions recited in the claims from those occurring naturally in biological systems. The Board also found that the fact that Appellants claim different dosage amounts or ratios did not suffice to add significantly more to the naturally-occurring substances than the administration of the same naturally-occurring substances themselves.

[161] *Ex parte* Buck, Appeal No. 2017-005470 (P.T.A.B. April 20, 2018).

Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Inc.

In the *Vanda* case, a panel of the Federal Circuit in April 2018 affirmed the district court ruling that the asserted claims U.S. Patent No. 8,586,610 (the '610 patent) were ineligible for patenting.[162] Claim 1 of Vanda's '610 patent reads as follows:

> 1. A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
>
> determining whether the patient is a CYP2D6 poor metabolizer by:
>
> obtaining or having obtained a biological sample from the patient; and
>
> performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
>
> if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and
>
> if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,
>
> wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

The Federal Circuit panel in the *Vanda* case distinguished the S. Ct.'s decision in *Mayo* stating: "The *Mayo* claim was not a treatment claim, it was 'not limited to instances in which the doctor actually decreases (or increases) the dosage level where the test results suggest that such an adjustment is advisable." The majority discussed the importance of the specificity of the dosages recited in the Vanda claims. The Federal Circuit panel concluded:

> "At bottom, the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.[t]hey recite a method of treating patients based on this relationship that makes iloperidone safer by lowering the risk of [the heart condition]."

Hence the *Vanda* decision appears to broadly hold that method of treatment claims are patent eligible, and the Patent Office has endorsed this position in a Memorandum to the Patent Examining Corps by Deputy Commissioner for

[162] Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Inc., 887 F.3d 1117 (Fed. Cir. 2018).

Patent Examination Policy Robert W. Bahr entitled, *Recent Subject Matter Eligibility Decision, Vanda Pharmaceuticals, Inc. v. West-Ward Pharmacueticals* (June 7, 2018).

Ex parte Young

In the *Ex parte Young* case,[163] the PTAB reversed an Examiner's rejection of claims drawn to a method of manipulating the huge amount of DNA sequence information. Claim 1 of U.S. Patent Application Ser. No. 14/489,198 (the '198 application) was at issue.

> 1. A method comprising:
> amplifying one or more nucleotide sequences in a sample using a PCR amplification process to produce an amplified sample;
> using a massively parallel sequencing (MPS) instrument to read the one or more nucleotide sequences of the amplified sample and generate one or more text strings based on the amplified sample;
> selecting a first plurality of text strings from the one or more text strings read by the MPS instrument, wherein each of the selected first plurality of text strings represent a nucleotide sequence that-corresponds to a first target locus in the amplified sample;
> comparing the selected first plurality of text strings to one another to determine an abundance count for each unique text string included in the selected first plurality of text strings;
> identifying a first number of unique text strings included in the selected first plurality of text strings as representing noise responses; and
> determining a method detection limit (MDL) as a function of the abundance counts for the first number of unique text strings identified as representing noise responses.

The Board noted that in addition to the claimed "comparing," "identifying," and "determining" steps identified by the Examiner as constituting data manipulation, the claims recite the steps of "using a massively parallel sequencing (MPS) instrument to read the one or more nucleotide sequences of the amplified sample and generat[ing] one or more text strings based on the amplified sample[, and] selecting a first plurality of text strings from the one or more text strings read by the MPS instrument."

The Board did not address the Examiner's initial finding that the claims are drawn to an "abstract process." Instead, the PTAB reversed the rejection as incorrectly applying the Mayo/Alice test at step two:

> "Thus, even if we were to agree with the Examiner that the rejected claims involve an abstract idea, i.e. manipulation of nucleic acid sequence data, we are not persuaded that the preponderance of

[163] *Ex parte* Young, Appeal No. 2017-007443 (P.T.A.B. July 18, 2018).

> evidence on this record supports a factual finding that other features of the claims, MPS in particular, were well-understood, routine conventional activities already engaged in by skilled artisans in the field, given the evidence cited by the Examiner to support such a finding, and given [statements in the specification that MPS is not routinely used to analyze DNA for forensic purposes](citing *Berkheimer v HP Inc*.[164]).

Ex parte Nagy

In the *Ex parte Nagy* case,[165] the PTAB affirmed an Examiner's rejection of claims drawn to a method for early diagnosis of Alzheimer's disease (AD). Claim 2 of U.S. Patent Application Ser. No. 14/223,113 (the '113 application) was at issue.

> A method of assessing the risk of AD progression in a human subject suspected of having AD, which method comprises:
>
> (i) obtaining lymphocytes from said human subject suspected of having AD and from an age-matched healthy subject with normal cognitive ability;
>
> (ii) inducing cell division in the lymphocytes taken from the human subject suspected of having AD;
>
> (iii) separating the dividing lymphocytes of (ii) into two pools and treating one pool of lymphocytes with rapamycin;
>
> (iv) assaying the level of protein of at least one interleukin selected of interleukin ("IL") 1 beta (IL1B), IL-2, IL-6 or IL-10 in the pool of lymphocytes treated with rapamycin and in the untreated pool;
>
> (v) comparing the level of protein of the at least one interleukin obtained in (iv) for the pool of rapamycin-treated lymphocytes and the untreated lymphocyte pool to quantify the change in protein levels in response to rapamycin;
>
> (vi) repeating steps (ii)-(iv) using control lymphocytes taken from the age-matched healthy subject with normal cognitive ability; and
>
> (vii) determining that said human subject suspected of having AD is at increased risk of AD progression when (a) the reduction of IL1B or IL10 protein levels in response to rapamycin is higher in control lymphocytes as compared to lymphocytes taken from the human subject suspected of having AD [and/or] (b) the reduction of IL-2 or IL-6 protein levels in response to rapamycin is lower in

[164] Berkheimer v HP Inc., 881 F.3d 1360 (2018) involves claims drawn to digitally processing and archiving files in a digital asset management system. The Federal Circuit ruled in the *Berkheimer v HP* case that it is not always appropriate to declare the broadest independent claim to be representative, and also held that questions of fact underlie patent eligibility determinations, which make summary judgment inappropriate in at least some cases.

[165] *Ex parte* Nagy, Appeal No. 2017-008793 (P.T.A.B. July 30, 2018).

> control lymphocytes as compared to lymphocytes taken from the human subject suspected of having AD . . . .

Claim 27 used the same methodology to determine that m-Tor signaling in a human lymphocyte is decreased if there is a decrease in the protein level of at least one of the interleukins in response to rapamycin.

The core of the Board's reasoning bears repeating:

> "Thus, here as in Mayo, the claims are not directed to a method of treating a disease. To the contrary, Appellant's claims are similar to those in *Mayo*, which "were directed to a diagnostic method based on the 'relationships between concentrations of certain metabolites [of the administered thiopurine drug] in the blood and the likelihood that a dosage of the thiopurine drug will prove ineffective or cause harm.'" *Vanda Pharms., Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018), quoting *Mayo*, 132 S.Ct. at 1289. "This 'relation is a consequence of the ways in which thiopurine compounds are metabolized in the body–entirely natural processes. And so, a patent that simply describes that relation sets forth a natural law.'" Thus, here, as in *Mayo*, the relationship between certain [IL] protein levels and either the risk of [AD] progression or the decrease in mTOR signaling are entirely natural processes and Appellant's claims do no more than simply describe that relationship, thereby setting forth a natural law." [citing *Mayo*, 132 S. Ct. 1289 (2012)].

However, the main claims appear to recite more than a relationship between certain protein levels and either the risk of Alzheimer's progression or a decrease in mTOR signaling. The main claims are more complicated, for example, including recitation of inducing lymphocyte division, creating two pools of lymphocytes obtained from both Alzheimer's disease suspects and controls, treating one pool from each pair with rapamycin, and quantifying the change in protein levels in response to the rapamycin treatment.

Ex parte Schwartz

In the *Ex parte Schwartz* case,[166] the PTAB reversed an Examiner's rejection of claims drawn to a method of modulating expression of a target gene in the genome of a human cell. Claim 21 of U.S. Patent Application Ser. No. 14/482,950 (the '950 application) was at issue.

> 21. A method [of] selectively modulating expression of a target gene in the genome of a human cell determined to be in need thereof comprising:
>
> determining the presence of an encoded antisense transcript overlapping a promoter of the target gene;

[166] *Ex parte Schwartz*, Appeal No. 2017-004975 (P.T.A.B. August 2, 2018).

> contacting the antisense transcript with an exogenous gapmer or double-stranded ag["antigene"]RNA; and
>
> detecting a resultant modulation of expression of the target gene,
>
> the gapmer comprising a DNA insert complementary to a sequence in the antisense transcript upstream relative to the transcription start site of the gene, and the agRNA being 18-28 bases and complementary to a portion of the antisense transcript upstream to a portion of the antisense transcript upstream relative to the transcription start site of the gene.

The Examiner rejected the claims under section 101 as directed to the "abstract idea of determining the presence of an encoded antisense transcript overlapping a promoter of a target gene." Having concluded that the claim failed Step 2A of the Mayo/Alice step, the Examiner conducted the Step 2B inquiry and ruled that the additional claim elements do not add "'significantly more'" than this abstract idea because they describe "'conventional techniques that do not add meaningful limits to practicing the abstract idea.'"

Considering the claims as a whole, the PTAB determined that they are directed not to a method of "determining the presence ... "but to a method of "selectively modulating expression of a target gene." Hence, the PTAB disagreed with the Examiner's finding that the claims were directed to the abstract idea of determining the presence of an encoded antisense transcript overlapping a promoter of a target gene, and because the Examiner had not identified another applicable judicially recognized exception, the PTAB reversed the Examiner's rejection of claims 21-40.

Ex parte Ho

In the *Ex Parte Ho* case,[167] the PTAB reversed an Examiner's rejection of claims drawn to an isolated cell population of human bone marrow-derived cells. Claim 133 of U.S. Patent Application Ser. No. 11/797,322 (the '322 application) was at issue.

> 133. An isolated cell population of human bone marrow-derived cells, wherein said cell population has been cultured in vitro at cell seeding densities of about 30 cells/cm2 under about 5% oxygen conditions for more than 30 population doublings, wherein said cell population continues to maintain a population doubling time of about 30 hours per doubling and wherein greater than 91% of the cells in said cell population continue to co-express cell surface markers CD49c and CD90, and wherein said cell population does not express cell surface markers CD34 or CD45, and wherein said cell population expresses telomerase at a relative expression of between about 1 transcript of telomerase per 106 transcripts of an 18s rRNA

[167] *Ex parte Ho,* Appeal No. 2016-007472 (P.T.A.B. Aug. 7, 2018).

> and about 10 transcripts of telomerase per 106 transcripts of an 18s rRNA.

Examiner asserted that the claimed cell population was patent ineligible because it is not markedly different from a progenitor cell population that exists *in vivo*. According to the Examiner, the claimed cell population is "obtained from a naturally occurring human body," and "[t]here is no indication in the specification that the isolated cells have been modified by applicants or the claimed cells have any characteristics (structural, functional or otherwise) that are markedly different from naturally occurring counterparts."

Appellants argued that the Examiner had not identified a naturally occurring counterpart of the claimed cells and that the Examiner had not provided any references showing that a cell population exists *in vivo* having the features of the claimed cell population. Appellants also asserted that the culturing step recites that the cell population has been cultured *in vitro* at cell seeding densities of about 30 cells/cm2 under about 5% oxygen conditions for more than 30 population doublings, but that the Examiner had not established that the culturing features recited in the claims were routine or conventional.

Appellants contended that the characteristics of the claimed cells were the direct result of the inventor's experimentation with low oxygen and low-density culture conditions. A Declaration by Dr. Ragaglia referred to multiple reports showing the "profound influence of culture conditions" on the mesenchymal stem cell (MSC) phenotype and behavior, and that once a cell is removed from its native environment, its phenotype and behavior are subject to change. For example, Dr. Ragaglia cited a reference by Javazon as teaching that discrepancies in the phenotypes of isolated and cultured MSCs arise due in part to differences in isolation and culture conditions. Dr. Ragaglia cited a document by Zhang as teaching that "MSCs cultured without confinement have higher levels of osteogenic markers"; a document by Kiefer as teaching that different culture media have different effects on cellular phenotype, doubling time, cytokine production, and ability to differentiate into stromal lineages; and a document by Bain as teaching that even very brief culture can alter the attachment and chemotactic behavior of MSCs. Dr. Ragaglia acknowledged that "an MSC is different and distinct from the cell population recited in claim 133 but asserted that "[t]he conclusions regarding the structural differences between in vivo and in vitro MSCs can be extrapolated to the claimed cell population."

The Board found that the Examiner had not persuasively identified any inadequacy in Appellants' rebuttal evidence, and that the Examiner had not provided scientific reasoning or evidence sufficient to support a finding that the claimed isolated cell population was a product of nature, lacking markedly different characteristics from a naturally occurring counterpart. Hence, the Board reversed the rejection under section 101.

Ex parte Parenteau

In the *Ex parte Parenteau* case,[168] the PTAB reversed an Examiner's rejection of claims drawn to isolated tumor C-RC cell populations. Claim 17 of U.S. Patent Application Ser. No. 13/774,644 (the '644 application) was at issue.

> 17. An isolated tumor C-RC cell population prepared by
>
> (a) obtaining a tumor sample from an individual;
>
> (b) cultivating the tumor sample under conditions that induce a stress response in non-C-RC differentiating and differentiated cells leading to apoptosis and necrosis but permit C-RC cells to propagate through the activation of a regenerative response;
>
> (c) isolating the dominant actively expanding, most rapidly dividing population of cells from step (b); and
>
> (d) culturing the cells to obtain a population of 51 % to 100% C-RC, in a serum-free, defined cell culture medium containing agents selected from the group consisting of agents inducing the apoptosis and/or necrosis of the cells, cAMP elevating agents, agents inhibiting cell-cell adhesion, nitric oxide, tumor necrosis factor-alpha (TNF-α), interleukin I-beta (ILI-α), interferon-gamma (IFN-γ), agents disrupting cell adhesion, agents interfering with survival of more differentiated cells, and calcium in a concentration of less than about 1 mM calcium,
>
> wherein 80-100% of the C-RC population consists of actively expanding and dividing VSEC, SDEC and SCEC cells and abnormal transit amplifying cells.

The Board found that the Examiner failed to establish an evidentiary basis to support a finding that that such culture media was well known, routine and conventionally used in the art at the time of Appellants' claimed invention. Hence, the Board reversed the rejection under section 101 and found that the tumor C-RC cell population prepared as recited in the claim was eligible for patenting.

Roche Molecular Systems, Inc. v. Cepheid

In the *Cepheid* case, a panel of the Federal Circuit in October 2018 affirmed the district court ruling that the asserted claims U.S. Patent No. 5,643,723 (the '723 patent) were ineligible for patenting,[169] illustrating that the Federal Circuit is bound by precedent to maintain that most diagnostic and DNA claims are not eligible for patenting.

Claim 17 of the '723 patent is drawn to primers, as shown below.

> 17. A primer having 14-50 nucleotides that hybridizes under hybridizing conditions to an *M. tuberculosis* rpoB gone at a site comprising at least one position-specific M. tuberculosis signature nu-

[168] *Ex parte Parenteau*, Appeal No. 2017-002191 (P.T.A.B. August 22, 2018).

[169] *Roche Molecular Systems, Inc. v. Cepheid*, 905 F.3d 1363 (Fed. Cir. 2018).

> cleotide selected, with reference to FIG. 3 (SEQ ID NO: 1), from the group consisting of:
> a G at nucleotide position 2312,
> a T at nucleotide position 2313,
> an A at nucleotide position 2373,
> a G at nucleotide position 2374,
> an A at nucleotide position 2378,
> a G at nucleotide position 2408,
> a T at nucleotide position 2409,
> an A at nucleotide position 2426,
> a G at nucleotide position 2441,
> an A at nucleotide position 2456, and
> a T at nucleotide position 2465.

Primers are short pieces of DNA that have hydroxyl groups on their ends. Despite Roche's arguments that such primers are not found in nature, for example, because *M. tuberculosis* has a circular genome so there is no "end" to the natural *M. tuberculosis* DNA, and hence from a chemical perspective no 3'-hydroxyl groups naturally present in *M. tuberculosis* DNA, the Court ruled that such primers "are not chemically or structurally different from the primer that we held patent ineligible" in *Based Hereditary Cancer Test Patent Lit.*, 774 F.3d 755 (Fed. Cir. 2014)(referred to by the Court as *BRCA1*, discussed as *Ambry* above.).

Similarly, the Court held that the diagnostic claims were ineligible for patenting as a naturally occurring phenomenon. Claim 1 of Roche's '723 patent reads as follows:

> 1. A method for detecting Mycobacterium tuberculosis in a biological sample suspected of containing M. tuberculosis comprising:
> (a) subjecting DNA from the biological sample to polymerase chain reaction using a plurality of primers under reaction conditions sufficient to simplify a portion of a *M. tuberculosis* rpoB gone to produce an amplification product, wherein the plurality of primers comprises at least one primer that hybridizes under hybridizing conditions to the amplified portion of the gone at a site comprising at least one position-specific M. tuberculosis signature nucleotide selected, with reference to FIG. 3 (SEQ D NO:1), from the group consisting
> a G at nucleotide position 2312,
> a T at nucleotide position 2313,
> an A at nucleotide position 2373,
> a G at nucleotide position 2374,
> an A at nucleotide position 2378,
> a G at nucleotide position 2408,
> a T at nucleotide position 2409,
> an A at nucleotide position 2426,
> a G at nucleotide position 2441,

> an A at nucleotide position 2456, and
> a T at nucleotide position 2465; and
> (b) detecting the presence or absence of an amplification product, wherein the presence of an amplification product is indicative of the presence of M. tuberculosis in the biological sample and wherein the absence of the amplification product is indicative of the absence of M. tuberculosis in the biological sample.

The Court characterized the method claims as a diagnostic test containing two steps: the amplification step and the determination of the presence of *M. tuberculosis* based on the presence or absence of the PCR amplification product. Following step 2 of the Mayo/Alice analysis, the court found nothing inventive about the amplification step and that the "detecting step is similarly devoid of an inventive concept because it involves a simple mental determination of the presence of MTB based on the presence of absence of a PCR amplification product."

Roche essentially argued this point: "[T]hat to use its primers to detect MTB 'is no less an inventive act than to make a specific artificial drug that is effective to treat an MTB infection."' The court dismissed this argument as not involving "a significantly new function for the primers."

Judge O'Malley filed a ten-page concurrence stating that that the BRCA1 decision forced her to concur: "Specifically I believe that our holding there was unduly broad for two reasons: (1) the question raised in BRCA1 was narrower than our holding in that case; and (2) our interpretation of the nature and function of DNA primers lacked the benefit of certain arguments and evidence that the patent owner presented in this case."

As to point 1, O'Malley noted that in the BRCA1 case, the district court had specifically stated that it had not resolved the section 101 issue since the record was necessarily incomplete, because for example the issue there was whether the district court had abused its discretion in denying the patent owner a preliminary injunction. O'Malley noted that in the present case, the question before the district court on summary judgment was the validity of the claims in view of a much more complete record.

As to point 2, O'Malley noted that the Fed. Cir. in BRCA1 had been primarily guided by the Supreme Court's decision in *Myriad*, 569 US 576 (2013), where the S. Ct. concluded that the patent owner's "principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. Critically, the Court recognized that claims are not 'saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule': the 'claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.'"

Quoting from the *Myriad* (2013) decision regarding the patent-eligibility of cDNA, O'Malley noted "[T]he lab technician unquestionably creates something new when cDNA is madeDNA is distinct from the DNA from which it was derived" because the intron sequences are removed., O'Malley stated that

the Federal Circuit's conclusion in *BRCA1* was based on the "two facts" that "[p]rimers necessarily contain the identical sequence of the BRCA sequence directly opposite to the strand to which they are designed to bind" and that "[t]hey are structurally identical to the ends of DNA strands found in nature."

O'Malley attacks this sort of fact-finding: "but it is not clear from the *BRCA1* opinion or record why we reached this conclusionSpecifically *BRCA1* concludes that primers have 'identical sequences' to the natural DNA strands directly opposite the strands to which they bind, but, as the record in this case reveals, a finding that the two have identical sequences does not entirely resolve the question of whether they are structurally identical because structure is not defined solely by nucleotide sequence.. Nor is it clear how primers 'are structurally identical to the ends of DNA strands found in nature." In other words, the fact that the isolated BRCA1 gene has an identical sequence to its genomic counterpart does not force the conclusion that a short ssDNA primer is structurally the same as the genomic ssDNA sequence to which it is designed to bind.

Judge O'Malley summarizes the structural/functional differences between the claimed primers and the nature MTB rpoB gene, and states that the primers are "markedly different" from any DNA molecules "typically found in nature." The markedly different "requirement" to avoid the natural product label is from the *Chakrabarty* decision that found genetically modified bacteria patent eligible in part because they have "potential for significant utility." Judge O'Malley concludes:

> "For these reasons, while I agree with the majority that the broad language of our holding in *BRCA1* compels the conclusion that the primer claims in this case are ineligible under 35 U.S.C. § 101, I believe that holding exceeded the confines of the issue raised on appeal and was the result of an underdeveloped record in that case. I believe accordingly, that we should revisit out conclusion in *BRCA1* en banc."

Hence, if Judge O'Malley can sway the Court in the future we may see some more decisions that are more supportive of biotechnological innovation.

Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC

The Federal Circuit has continued to find diagnostic claims ineligible for patenting in the *Athena v. Mayo* case.[170] Claim 1 from Athena's U.S. Patent 7,267,820 was drawn to diagnosing neurological disorders such as myasthenia gravis by detecting muscle-specific tyrosine kinase ("MuSK") in patient samples.

> 1. A method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of

[170] Athena Diagnostics, Inc. v. Mayo Collababorative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019).

> detecting in a bod-ily fluid of said mammal autoantibodies to an epitope of [MuSK].

Claim 1 was not at issue. But, dependent claim 7, which provides immunoprecipitation and other steps, was at issue.

The Federal Circuit panel ruled that Athena's claims were drawn to a natural law because the claimed advance was "only in the discovery of a natural law." According to the panel, the additional steps iodination and immunoprecipitation were only "standard techniques in the art" and were not improvements in the underlying immunoassay technology. Hence, the Athena claims were ineligible for patenting because the court concluded that claims only involved detecting a natural law "with no meaningful non-routine steps."

Summary

While tangible molecular structures and active steps that go beyond mere thought exercises may still be sufficient to overcome the patent eligibility hurdle, the court and PTAB rulings suggest that manipulation of a known natural product to diagnose may no longer be patent eligible, unless such manipulation involves new and non-obvious method steps. The Supreme Court ruling in the *Myriad* case was limited to genomic DNA, but Patent Office Examiners argue that other natural products (proteins, antibodies, primers, etc.) are no longer eligible for patenting. Each step of the claims at issue in *Mayo* and the concept of adjusting dosage was known in the prior art, but the courts are using the *Mayo* standards to find patent ineligibility of claims drawn to important new discoveries such as those in *Ariosa*, where the concept of checking maternal serum for fetal DNA was previously inconceivable. Section 101 now provides litigants with a potent tool for invalidating claims to pharma- or biotech-based methods and materials, often at the pleadings stage, without the need to argue more complex, fact-driven issues such as anticipation, obviousness or the increasingly tangled requirements of 35 U.S.C. § 112(1).

The primary rationale for finding patent claims ineligible for patenting is that they might preempt all uses of a natural product or correlation and thereby stifle innovation. But even claims that do not preempt the totality of uses of such a natural product or correlation are ruled ineligible for patenting because, "While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility."[171] The Patent Office and the courts now routinely find that the steps for achieving new and potentially life-saving diagnostic results are conventional or routine in medicine. Claims containing such steps are deemed *per se* patent-ineligible with little or no evidentiary support of such a conclusion, even when the reagents have never before been employed in such steps.

Increasingly, the locus of early stage innovation is within universities and small start up companies, where the only assets are typically patents or patent

[171] Ariosa Diagnostics Inc. v. Sequenom Inc., 788 F.3d 1371, 1379 (Fed. Cir. 2015) (*cert. denied*)

applications. Through their slavish adherence to rejecting any claim that recites a natural product or correlation the courts and the Patent Office are more likely to inhibit patenting by early innovators whose innovations have broad implications. The result will likely be no development of promising technologies because patenting is blocked, and no funding will be then available to such innovators. Development of promising technologies will be only be carried out by large corporations who can successfully avoid rewarding the original innovator.

Appendix: Subject Matter Eligibility Table of Biotech Cases

The following table shows how the courts have ruled on some biotechnology patent claims.

Biotech Diagnostic Claims: Which Ones are Eligible for Patenting under § 101?	
Metabolite's U.S. Patent 4,940,658 claim 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: • assaying a body fluid for an elevated level of total homocysteine; and • correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.	**Claim 13 is eligible for patenting pursuant to the Federal Circuit (2004) ruling:**[172] This claim is valid under Sections 102, 103 and 112. [No discussion of patent eligibility of the claims.] **Problem: Supreme Court granted, then withdrew, certiorari in 2006** to determine whether the patent claim is invalid on the ground that it improperly seeks to "claim a monopoly over a basic scientific relationship." But the Supreme Court withdrew the writ of certiorari as improvidently granted. **Three Justices wrote a strong dissent.**[173]

[172] Metabolite Labs. Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004).
[173] Laboratory Corporation of America Holdings v. Metabolite Laboratories Inc., 548 U.S. 124 (2006).

Classen's U.S. Patent 6,638,739 claim 1.[174] A method of immunizing a mammalian subject which comprises: (I) *screening* a plurality of immunization schedules, by (a) *identifying* a first group of mammals and at least a second group of mammals, ... each group of mammals having been immunized according to a different immunization schedule, and (b) *comparing* the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, as a result of which one of said screened immunization schedules may be identified as a lower risk screened immunization schedule and the other of said screened schedules as a higher risk screened immunization schedule with regard to the risk of developing said chronic immune mediated disorder(s), (II) *immunizing said subject* . . . in accordance with said lower risk screened immunization schedule	**Claim 1 is eligible for patenting pursuant to the Federal Circuit (2012) ruling**[175] because: • this claim includes the physical step of immunization on the determined schedule. • precedent has recognized that the presence of a mental step is not of itself fatal to § 101 eligibility. • Section 101 is only a coarse filter.
Classen's U.S. Patent 5,723,283 claim 1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.	**Claim 1 is not eligible for patenting pursuant to the Federal Circuit (2011) ruling**[176] because this claim does not require an active step after determining the effects of immunization: • this method simply collects and compares data, without applying the data • the abstraction of the claim is unrelieved by any movement from principle to application

[174] The language of this claim was shortened somewhat. Note that claim 1 of Classen's US Patent 6420139 is similar to the language of this '739 patent claim in that both claims require immunization after screening for a lower risk screened immunization schedule.

[175] Classen Immunotherapies, Inc. v. Biogen Idec, 659 F. 3d 1057 (Fed. Cir. 2011).

[176] *Id.*

Prometheus' U.S. Patent 6,355,623 claim 1.	**These claims are not eligible for patenting pursuant to the Supreme Court ruling[177] because**:
A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) *administering* a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) *determining* the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8xl08 red blood cells *indicates a need* to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8xl08 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.	• relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective is a natural law or a natural phenomenon that is not patent-eligible; • the administering step simply identifies a group of people who will be interested in the correlations • doctors have long been using these drugs for treatment of autoimmune disorders and the determining step is well known in the art • the 'wherein' clause simply tells doctors about relevant natural laws and does not require any therapeutic intervention • such well-known administering and determining steps are not sufficient to transform an unpatentable law of nature into a patent-eligible claim

[177] Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66 (2012).

U.S. Patent 6,355,623 claim 46.
A method of optimizing therapeutic efficacy and reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:
(a) *determining* the level of 6-thioguanine or 6-methylmercaptopurine in a subject administered a drug selected from the group consisting of 6-mercaptopurine, azathiopurine, 6-thioguanine, and 6-methyl-mercaptoriboside, said subject having said immune-mediated gastrointestinal disorder,
wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells *indicates a need* to increase the amount of said drug subsequently administered to said subject, and
wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells or a level of 6-methylmercaptopurine greater than about 7000 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently ad-ministered to said subject.

The Federal Circuit[178] had found these claims to be patent-eligible because:

- the claims do not preempt all uses of the natural correlations involved (other drugs might be administered to optimize the therapeutic efficacy of the claimed treatment);
- the claimed methods transform the human body and its components via chemical and physical changes to the drugs
- even claims without an administration step thought to be patent-eligible because the determining step, which is present in each of the asserted claims, is transformative and central to the claimed methods. Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation.

Federal Circuit also stated:
"we do not view the disputed claims as merely claiming natural correlations and data-gathering steps. The asserted claims are in effect claims to methods of treatment, which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."
However, the Supreme Court overruled the Federal Circuit's decision.

[178] *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 628 F.3d 1347 (Fed. Cir. 2010).

Myriad's U.S. Patent 5,710,001 claim 1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises *comparing* a first sequence (i.e., a BRCA1 gene, RNA or cDNA) from said tumor sample, with a second sequence (i.e., a BRCA1 gene, RNA or cDNA) from a non-tumor sample of said subject, wherein a difference in the sequence . . . indicates a somatic alteration in the BRCA1 gene in said tumor sample.	**The Federal Circuit[179] has found this claim to be patent ineligible because** claims to "comparing" or "analyzing" two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes.
Myriad's U.S. Patent 6,033,857 claim 2. A method for diagnosing a predisposition for breast cancer in a human subject which comprises *comparing* the germline sequence of the BRCA2 gene or the sequence of its mRNA in a tissue sample from said subject with the germline sequence of the wild-type BRCA2 gene or the sequence of its mRNA, wherein an alteration in the germline sequence of the BRCA2 gene or the sequence of its mRNA of the subject indicates a predisposition to said cancer.	**The Federal Circuit[180] has ruled that this claim is patent ineligible because** claims to "comparing" or "analyzing" two gene sequences embrace only abstract mental processes. The Court gave no weight to the diagnostic step where alteration in the germline sequence indicates a predisposition for cancer.
Myriad's U.S. Patent 5,747,282 claim 20. A method for screening potential cancer therapeutics which comprises: *growing* a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, *growing* said transformed eukaryotic host cell in the absence of said compound, *determining* the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.	**The Federal Circuit[181] has ruled that this claim is patent eligible subject matter because** he claim includes transformative steps (e.g., growing and determining), and the use of a transformed cell, which is made by man.

[179] The Association for Molecular Pathology v. Myriad Genetics Inc., 689 F.3d 1303 (Fed. Cir. 2012).
[180] *Id.*
[181] *Id.* at 1334-35.

Myriad's U.S. Patent 5,747,282 claim 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2. **Myriad's U.S. Patent 5,747,282 claim 5.** An isolated DNA having at least 15 nucleotides of the DNA of claim 1.	**The Supreme Court**[182] **has ruled that these claims are not eligible for patenting because** these claims embrace genomic DNA, which is a product of nature.
Myriad's U.S. Patent 5,747,282 claim 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.	**The Supreme Court**[183] **had held that this claim is patent eligible because:** This claim embraces cDNA, which is a product of human intervention.
Intema's U.S. Patent No. 6,573,103 Claim 1:A method of determining whether a pregnant woman is at an increased risk of having a fetus with Down's syndrome, comprising: —measuring the level of different markers from the first and second trimester of pregnancy by: (i) assaying a sample . . .; and/or (ii) measuring an ultrasound screening marker from an ultrasound scan; and determining the risk of Down's syndrome by comparing the measured levels with those in non-Down's pregnancies.	**The Federal Circuit**[184] **has ruled this claim ineligible for patenting** because it claims "a law of nature" and recites "the mental process of comparing data to determine a risk level." **Intema has filed petition for cert.;**[185] one question posed to the Supreme Court: Is a useful, novel and non-obvious diagnostic, screening or personal medicine test patent eligible under 35 U.S.C. § 101 if: a) the inventive concept is in the selection, combination and timing of the data collected in the data-gathering steps; and/or b) the final step is calculating a new and useful test result from data collected by novel data-gathering steps, but does not involve a physical activity?

[182] Association for Molecular Pathology v. Myriad Genetics Inc., 133 S. Ct. 2107 (2013).
[183] *Id.*
[184] PerkinElmer v. Intema Ltd., 496 Fed. App'x 65, 70 (Fed. Cir. Nov. 20, 2012)(nonprecedential).
[185] Intema Ltd. v. PerkinElmer, 2012 U.S. Briefs 1372; 2013 U.S. S. Ct. Briefs LEXIS 2395 (May 16, 2013).

Myriad's U.S. Patent 5,753,441 claim 7. A method for screening germline of a human subject for an alteration of a BRCA1 gene which comprises comparing germline sequence of a BRCA1 gene or BRCA1 RNA or cDNA from a tissue sample from said subject with germline sequences of wild-type BRCA1 gene, wild-type BRCA1 RNA or wild-type BRCA1 cDNA, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject, wherein a germline nucleic acid sequence is compared by hybridizing a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and detecting the presence of a hybridization product wherein a presence of said product indicates the presence of said allele in the subject.	**The Federal Circuit[186] has ruled this claim ineligible for patenting** because: The comparison step = a patent-ineligible abstract idea involving comparing BRCA sequences and determining the existence of alterations; and The non-patent-ineligible elements do not add "enough" to make the claim as a whole patent-eligible.
Myriad's U.S. Patent 5,753,441 claim 16. A pair of single-stranded DNA primers for determination of a nucleotide sequence of a BRCA1 gene by a polymerase chain reaction, the sequence of said primers being derived from human chromosome 17q, wherein the use of said primers in a polymerase chain reaction results in the synthesis of DNA having all or part of the sequence of the BRCA1 gene.	**The Federal Circuit[187] has ruled this claim ineligible for patenting** because:the primers are not distinguishable from the isolated DNA ruled patent-ineligible products of nature in the *Myriad* case and not similar to the cDNA that was found to be patent-eligible by the Supreme Court; it made no difference that the primers were synthetically replicated; and the Federal Circuit was not swayed by Myriad's arguments that primers are in fact not naturally occurring because single-stranded DNA cannot be found in the human body, or that primers have a fundamentally different function (starting material for polymerization) than when they are part of a DNA strand (storing biological information).

[186] BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 774 F.3d 755 (Fed Cir. 2014).

[187] BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 774 F.3d 755 (Fed Cir. Dec. 17, 2014).

Roslin Institute's U.S. Ser. No. 09/225,233 claims 155 and 164: 155. A live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats. 164. The clone of any of claims 155-159, wherein the donor mammal is non-foetal.	**The Federal Circuit[188] has ruled this claim ineligible for patenting** because such clones are constituted a "natural phenomenon" that did not possess "markedly different characteristics than any found in nature."The claims were also unpatentable over the prior art because they were indistinguishable from clones produced through prior art cloning methods, i.e., embryotic nuclear transfer and *in vitro* fertilization.
Sequenom's U.S. Patent 6,258,540 claim 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.	**The Federal Circuit[189] has ruled the claim ineligible for patenting** because the claims were directed to a patent-ineligible concept - it was undisputed that the existence of cffDNA in maternal blood is a natural phenomenon and that that the location of the nucleic acids existed in nature before the inventors found them; and methods like PCR and the detecting step were well-understood, routine, and conventional activity in 1997.
Genetic Technologies' U.S. Patent 5,612,179 claim 1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising: a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and b) analyzing the amplified DNA sequence to detect the allele.	**The Federal Circuit[190] has ruled the claim ineligible for patenting** because amplifying genomic DNA with a primer pair and the analyzing the amplified DNA to provide a user with information about the amplified DNA were well known, routine, and conventional in the field of molecular biology as of 1989, when the first precursor application to the '179 patent was filed.

[188] *In re* Roslin Institute (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014).
[189] Ariosa Diagnostics Inc. v. Sequenom Inc., 788 F.3d 1371 (Fed. Cir. 2015).
[190] Genetic Technologies Ltd. v. Merial L.L.C., 818 F.3d 1369 (Fed. Cir. 2016) (cert. denied).

Rapid Litigation's U.S. Patent No. 7,604,929 Claim 1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising: (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes, (B) recovering the separated viable hepatocytes, and (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time,wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.	**The Federal Circuit**[191] **has ruled the claim eligible for patenting** because the claims are simply not directed to the ability of hepatocytes to survive multiple freeze- thaw cycles. Rather, the claims of the '929 patent are directed to a new and useful laboratory technique for preserving hepatocytes. This type of constructive process, carried out by an artisan to achieve "a new and useful end," is precisely the type of claim that is eligible for patenting.

[191] Rapid Litigation Mgmt. LTD v. Cellzdirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016).

Cleveland Clinic's U.S. Patent No. 7,223,552 claim 11. A method of assessing a test subject's risk of having atherosclerotic cardiovascular disease, comprisingcomparing levels of myeloperoxidase in a bodily sample from the test subject with levels of myeloperoxidase in comparable bodily samples from control subjects diagnosed as not having the disease, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereo[f]; wherein the levels of myeloperoxidase in the bodily [sample] from the test subject relative to the levels of [m]yeloperoxidase in the comparable bodily samples from control subjects is indicative of the extent of the test subject's risk of having atherosclerotic cardiovascular disease.	**The Federal Circuit**[192] **has ruled the claim ineligible for patenting** because the claims are directed to multistep methods for observing the law of nature that myeloperoxidase correlates to cardiovascular disease and the practice of the method does not result in an inventive concept that transforms the natural phenomena of myeloperoxidase being associated with cardiovascular risk into a patentable invention.
Exergen's U.S. Patent No. 7,787,938 claim 14. A method of detecting human body temperature comprising making at least three radiation readings per second while moving a radiation detector to scan across a region of skin over an artery to electronically determine a body temperature approximation, distinct from skin surface temperature.	**The Federal Circuit**[193] **has ruled the claim eligible for patenting** because **e**ven if the concept of the measurement of a natural phenomenon (core body temperature) is directed to a natural phenomenon and is abstract at step one, the measurement method here was not conventional, routine, and well-understood. Following years and millions of dollars of testing and development, the inventor determined for the first time the coefficient representing the relationship between temporal-arterial temperature and core body temperature and incorporated that discovery into an unconventional method of temperature measurement. As a result, the method is patent-eligible,

[192] Cleveland Clinic v. True Health Diagnostics, 859 F.3d 1352 (Fed. Cir. 2017).
[193] Exergen Corp. v. Kaz USA, Inc., 725 F. App'x 959 (Fed. Cir. 2018).

Urvashi Bhagat's Application Ser. No. 12/426,034 claim 65:65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein (1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty ac-ids are 0.1–30% by weight of total lipids; or (2) omega-6 fatty acids are not more than 40 grams.	**The Board**[194] **found the claim ineligible for patenting** because the intermixture of lipids from different sources was structurally indistinct from prior art lipid formulations and the casing not provide patentability to the compositions because the specification stated that the term is not claim-limiting and did not describe any novel characteristics for the formulations.
Buck's Application Ser. No. 13/446,128 claim 7. A kit comprising multiple, separate weekly or monthly dosages of a) Vitamin D, and b) 25-OH D3, wherein a dosage ratio of the Vitamin D3 to the 25-OH D3 is from about 6:1 to 1:6; a single weekly dosage contains from 7μg to 350 μg each of Vitamin D and 25-OH D3; and a single monthly dosage contain from 30 μg.	**The Board**[195] **found the claim ineligible for patenting** because it was indisputable that both vitamin D3 and 25-OH D3 are naturally-occurring chemicals that co-exist in biological systems and, by themselves, are products of nature and consequently unpatentable. While all inventions, at some level, embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas, the Board found that they could not structurally distinguish the chemical compositions recited in the claims from those occurring naturally in biological systems. The Board also found that the fact that Appellants claim different dosage amounts or ratios did not suffice to add significantly more to the naturally-occurring substances than the administration of the same naturally-occurring substances themselves.

[194] *Ex parte* Bhagat, Appeal No. 2016-004154 (P.T.A.B. April 15, 2016), (rehearing denied June 21, 2016); *see In re* Bhagat, No. 2016-2525 (Fed. Cir. March 16, 2018) (nonprecedential).
[195] *Ex parte* Buck, Appeal No. 2017-005470 (P.T.A.B. April 20, 2018).

Vanda's U.S. Patent 8,586,610 claim 1. A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day, wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.	**The Federal Circuit[196] has ruled the claim eligible for patenting** because the S. Ct.'s decision in *Mayo* was distinct. The Federal Circuit stated that "The *Mayo* claim was not a treatment claim, it was 'not limited to instances in which the doctor actually decreases (or increases) the dosage level where the test results suggest that such an adjustment is advisable." This decision appears to broadly hold that method of treatment claims are patent eligible.

[196] Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Inc., 887 F.3d 1117 (Fed. Cir. 2018).

Young's Patent Application claim 1. A method comprising: amplifying one or more nucleotide sequences in a sample using a PCR amplification process to produce an amplified sample; using a massively parallel sequencing (MPS) instrument to read the one or more nucleotide sequences of the amplified sample and generate one or more text strings based on the amplified sample; selecting a first plurality of text strings from the one or more text strings read by the MPS instrument, wherein each of the selected first plurality of text strings represent a nucleotide sequence that-corresponds to a first target locus in the amplified sample; comparing the selected first plurality of text strings to one another to determine an abundance count for each unique text string included in the selected first plurality of text strings; identifying a first number of unique text strings included in the selected first plurality of text strings as representing noise responses; anddetermining a method detection limit (MDL) as a function of the abundance counts for the first number of unique text strings identified as representing noise responses.	**The Board**[197] **found the claim eligible for patenting** because even if the judges were to agree with the Examiner that the rejected claims involve an abstract idea (i.e. manipulation of nucleic acid sequence data), they were not persuaded that the preponderance of evidence on the record supported a factual finding that other features of the claims, MPS in particular, were well-understood, routine conventional activities.

[197] *Ex parte* Young, Appeal No. 2017-007443 (P.T.A.B. July 18, 2018).

Nagy's Application Ser. No. 14/223,113 claim 2. A method of assessing the risk of AD progression in a human subject suspected of having AD, which method comprises: (i) obtaining lymphocytes from said human subject suspected of having AD and from an age-matched healthy subject with normal cognitive ability; (ii) inducing cell division in the lymphocytes taken from the human subject suspected of having AD; (iii) separating the dividing lymphocytes of (ii) into two pools and treating one pool of lymphocytes with rapamycin; (iv) assaying the level of protein of at least one interleukin selected of interleukin ("IL") 1 beta (IL1B), IL-2, IL-6 or IL-10 in the pool of lymphocytes treated with rapamycin and in the untreated pool; (v) comparing the level of protein of the at least one interleukin obtained in (iv) for the pool of rapamycin-treated lymphocytes and the untreated lymphocyte pool to quantify the change in protein levels in response to rapamycin; (vi) repeating steps (ii)-(iv) using control lymphocytes taken from the age-matched healthy subject with normal cognitive ability; and (vii) determining that said human subject suspected of having AD is at increased risk of AD progression when (a) the reduction of IL1B or IL10 protein levels in response to rapamycin is higher in control lymphocytes as compared to lymphocytes taken from the human subject suspected of having AD [and/or] (b) the reduction of IL-2 or IL-6 protein levels in response to rapamycin is lower in control lymphocytes as compared to lymphocytes taken from the human subject suspected of having AD	**The Board**[198] **found the claim ineligible for patenting** because as in *Mayo*, the claims were not directed to a method of treating a disease and to the contrary, Nagy's claims were similar to those in *Mayo*, which "were directed to a diagnostic method based on the 'relationships between concentrations of certain metabolites [of the administered thiopurine drug] in the blood and the likelihood that a dosage of the thiopurine drug will prove ineffective or cause harm.'"

[198] *Ex parte* Nagy, Appeal No. 2017-008793 (P.T.A.B. July 30, 2018).

Schwartz' Application claim 21. A method [of] selectively modulating expression of a target gene in the genome of a human cell determined to be in need thereof comprising: determining the presence of an encoded antisense transcript overlapping a promoter of the target gene; contacting the antisense transcript with an exogenous gapmer or double-stranded ag["antigene"]RNA; and detecting a resultant modulation of expression of the target gene, the gapmer comprising a DNA insert complementary to a sequence in the antisense transcript upstream relative to the transcription start site of the gene, and the agRNA being 18-28 bases and complementary to a portion of the antisense transcript upstream to a portion of the antisense transcript upstream relative to the transcription start site of the gene.	**The Board**[199] **found the claim eligible for patenting** because they disagreed with the Examiner's finding that the claims were directed to the abstract idea of determining the presence of an encoded antisense transcript that overlapped a promoter of a target gene, and because the Examiner had not identified another applicable judicially recognized exception. Hence, the Board reversed the Examiner's rejection of the claims.
Ho's Application claim 133. An isolated cell population of human bone marrow-derived cells, wherein said cell population has been cultured in vitro at cell seeding densities of about 30 cells/cm2 under about 5% oxygen conditions for more than 30 population doublings, wherein said cell population continues to maintain a population doubling time of about 30 hours per doubling and wherein greater than 91% of the cells in said cell population continue to co-express cell surface markers CD49c and CD90, and wherein said cell population does not express cell surface markers CD34 or CD45, and wherein said cell population expresses telomerase at a relative expression of between about 1 transcript of telomerase per 106 transcripts of an 18s rRNA and about 10 transcripts of telomerase per 106 transcripts of an 18s rRNA.	**The Board**[200] **found the claim eligible for patenting** because Appellants provided information showing that the characteristics of the claimed cells were the direct result of the inventor's experimentation with low oxygen and low-density culture conditions. The Board found that the Examiner had not persuasively identified any inadequacy in Appellants' rebuttal evidence, and that the Examiner had not provided scientific reasoning or evidence sufficient to support a finding that the claimed isolated cell population was a product of nature, lacking markedly different characteristics from a naturally occurring counterpart. Hence, the Board reversed the rejection under section 101.

[199] *Ex parte* Schwartz, Appeal No. 2017-004975 (P.T.A.B. August 2, 2018).
[200] *Ex parte* Ho, Appeal No. 2016-007472 (P.T.A.B. Aug. 7, 2018).

Parenteau's Application claim 17. An isolated tumor C-RC cell population prepared by (a) obtaining a tumor sample from an individual; (b) cultivating the tumor sample under conditions that induce a stress response in non-C-RC differentiating and differentiated cells leading to apoptosis and necrosis but permit C-RC cells to propagate through the activation of a regenerative response; (c) isolating the dominant actively expanding, most rapidly dividing population of cells from step (b); and (d) culturing the cells to obtain a population of 51 % to 100% C-RC, in a serum-free, defined cell culture medium containing agents selected from the group consisting of agents inducing the apoptosis and/or necrosis of the cells, cAMP elevating agents, agents inhibiting cell-cell adhesion, nitric oxide, tumor necrosis factor-alpha (TNF-α), interleukin I-beta (ILI-α), interferon-gamma (IFN-γ), agents disrupting cell adhesion, agents interfering with survival of more differentiated cells, and calcium in a concentration of less than about 1 mM calcium, wherein 80-100% of the C-RC population consists of actively expanding and dividing VSEC, SDEC and SCEC cells and abnormal transit amplifying cells.	**The Board**[201] **found the claim eligible for patenting** because the Examiner failed to establish an evidentiary basis to support a finding that that such culture media was well known, routine and conventionally used in the art at the time of Appellants' claimed invention. Hence, the Board reversed the rejection under section 101 and found that the tumor C-RC cell population prepared as recited in the claim was eligible for patenting.

[201] *Ex parte* Parenteau, Appeal No. 2017-002191 (P.T.A.B. August 22, 2018).

Roche's U.S. Patent 5,643,723 claim 1:	**The Federal Circuit[202] found the claims ineligible for patenting** because despite Roche's arguments that such primers are not found in nature, for example, because *M. tuberculosis* has a circular genome so there is no "end" to the natural *M. tuberculosis* DNA, and hence from a chemical perspective no 3'-hydroxyl groups naturally present in *M. tuberculosis* DNA, the Federal Circuit found that such primers "are not chemically or structurally different" from the primer that they held patent ineligible in *Based Hereditary Cancer Test Patent Lit.*, 774 F.3d 755 (Fed. Cir. 2014)(referred to by the Federal Circuit as *BRCA1*). Similarly, the Federal Circuit held that the diagnostic claims were ineligible for patenting as a naturally occurring phenomenon. The Federal Circuit characterized the method claims as a diagnostic test containing two steps: the amplification step and the determination of the presence of *M. tuberculosis* based on the presence or absence of the PCR amplification product. Following step 2 of the Mayo/Alice analysis, the court found nothing inventive about the amplification step and that the "detecting step is similarly devoid of an inventive concept because it involves a simple mental determination of the presence of *M. tuberculosis* based on the presence of absence of a PCR amplification product."
1. A method for detecting *Mycobacterium tuberculosis* in a biological sample suspected of containing M. tuberculosis comprising: (a) subjecting DNA from the biological sample to polymerase chain reaction using a plurality of primers under reaction conditions sufficient to simplify a portion of a *M. tuberculosis* rpoB gone to produce an amplification product, wherein the plurality of primers comprises at least one primer that hybridizes under hybridizing conditions to the amplified portion of the gone at a site comprising at least one position-specific M. tuberculosis signature nucleotide selected, with reference to FIG. 3 (SEQ D NO:1), from the group consisting a G at nucleotide position 2312, a T at nucleotide position 2313, an A at nucleotide position 2373, a G at nucleotide position 2374, an A at nucleotide position 2378, a G at nucleotide position 2408, a T at nucleotide position 2409, an A at nucleotide position 2426, a G at nucleotide position 2441,an A at nucleotide position 2456, and a T at nucleotide position 2465; and (b) detecting the presenceAppeal no. 2017-2508 or absence of an amplification product, wherein the presence of an amplification product is indicative of the presence of *M. tuberculosis* in the biological sample and wherein the absence of the amplification product is indicative of the absence of *M. tuberculosis* in the biological sample.	

[202] Roche Molecular Systems, Inc. v. Cepheid, 905 F.3d 1363 (Fed. Cir. 2018).

Athena's U.S. Patent 7,267,820 claims 1 and 7: 1. A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of MuSK. 7. A method according to claim 1, comprising contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid, immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex, wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to muscle specific tyrosine kinase (MuSK).	The Federal Circuit[203] held the claims ineligible for patenting because the claimed advance was only in the discovery of a natural law, and the additional recited steps only apply conventional techniques to detect that natural law.

[203] Athena Diagnostics, Inc. v. Mayo Collababorative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019).

manent improvement in quality and character of the work can be perceived to be possible.

A panic in the business world would temporarily alleviate the situation in the Office, but it is hoped that other eventualities more pleasant to contemplate and more permanent in nature may arise to provide the desired remedy.

The Detroit News Articles on the Patent Office.

Mr. Cyril A. Player of the staff of the Detroit News, has written a series of notable articles on the Patent Office which appeared in that paper during April. He made a personal investigation of the situation, coming to Washington for that purpose; searched every available record and interviewed authorities both here and in Detroit who could give him any information on the subject.

Considering the ramifications of his inquiry, the vast amount of material handled, and the rapidity with which the review was whipped into shape, it was a most remarkably informative and comprehensive piece of work. It uncovered, as no previous attempt succeeded in disclosing, the critical condition in which public neglect has left this institution. No detail has been lacking in its presentation, and illustrations of the nature of the work in the Patent Office, its unique relation to industry, and its identity with the most prized of our national characteristics are told with telling effect. The need for immediate relief is strikingly exhibited and the whole presentation bears every evidence of study and sincerity.

The articles have been quoted extensively from one end of the country to the other, and comprise by far the best presentation of the critical condition of the Office and the need for immediate remedial action that we have seen. Every friend of the Patent Office should be grateful to the Detroit News and its brilliant correspondent for the fine effort exerted in its behalf and for the undoubtedly favorable results that must come therefrom.

A Manual of Instruction.

"The young recruit is 'aughty—'e draf's from Gawd knows where," and the statement might apply with equal

truth to the newly appointed assistant examiner. He comes from the college, the machine shop, the office, the school room. He has his own ideas of what constitutes invention. The word "inventor" suggests to him such names as Fulton, Eli Whitney, Bell, Edison, Marconi. Then he comes into the Patent Office and finds among the recent art a patent for a toy which he and other boys whittled out and played with twenty years ago, and he forthwith begins to wonder whether the patent may not have issued through inadvertance, accident or mistake.

The progress of the young examiner in acquiring knowledge on patent matters depends partly upon his own adaptibility but also upon the men with whom his lot is cast and especially upon the kindly guidance of the primary examiner under whom he serves. The good of the office demands that he shall rapidly gain skill in office procedure and shall acquire a general point of view on patent matters which shall approach the normal view of the office. But we have in the Patent Office 46 distinct divisions each presided over by a primary examiner whose duty it is to direct the work of his assistants. These men have different methods of directing the work of their respective divisions. Some supervise very closely and insist on directing every action, while others leave the preliminary actions largely to their assistants. All are governed by the Rules of Practice, but the Rules do not reach to all details and allow much to the individual examiner. The finer points of the Rules are only acquired with time and close study. The young examiner must depend for many things on the personal instruction of his chief and his associates.

Furthermore, most people do not get a matter fixed in their minds and settled on the first telling . Hence the young examiner must question and discuss before he can get a point fixed in its proper relation to other matters. The writer in his own experience as a raw recruit found that many things had to be explained to him again and again and much time was lost in repetition.

It seems that anything that will aid the examiner in adjusting himself to his surroundings and adjusting his mind to think rightly on patent matters will increase the efficiency of the office. To this end a properly prepared manual would be of inestimable benefit. Such a manual

should contain well worded explanations of the things which the young examiner should know—the steps in filing and recording the complete application from the time it is received in the mail until it is laid upon his desk; the meaning of the different marks and stamps which are placed upon the file and drawing; just what he must do in examining an application and what errors to watch for, etc.

With such a manual before him, containing directions and explanations to which he may turn for ready reference, the young examiner should make more rapid progress than he can hope to make when he has to depend on the personal explanations given by an overworked chief.

It is further felt that with such a manual placed in the hands of the examiners as soon as they enter the office all will be instructed alike and there will be a much greater tendency toward uniformity in the methods and practice throughout the office.

It seems equally certain that such a manual would prove of great value in an attorney's office for the instruction of assistants whose first duty is to become thoroughly acquainted with the details of the course an application takes in its passage through the Patent Office.

In 1912 some thousands of dollars were spent in investigating the Patent Office. The Commission reported at length its findings together with many excellent recommendations.

In this same report on page 39 we find—"It is believed that a manual of instructions ought to be prepared, and amended and revised from time to time. Such a manual would be useful not only in fixing the responsibility upon the examining force for following the instructions of the Commissioner, but would be useful in the education of the examiner upon his first entrance to the office." If this was true in 1912 when there were 43 examining divisions it is even more true today with an increased personnel and a greatly increased volume of work and with a force which is being daily depleted by the resignation of experienced examiners and the substitution in their places of raw recruits.

The Patent Office can not with its present equipment do many things which need to be done, but the Patent Office can escape some blame if it does what it can from

within to increase its own efficiency and the effectiveness of the patent system. No one should be blamed for what he does not know and has never had opportunity to learn, but Squeers of Dotheboys Hall has laid down a maxim which may well serve as a rule for all ages,—

"When a man knows it he goes and does it."

It is desired to announce that in view of the need for a manual of instruction as above set forth such a manual has been compiled by Examiner E. S. Glascock and former Assistant Examiner H. B. Wilcox; it is the purpose of the Editorial Board to print the same in the Journal as soon as possible.

A MONTHLY APPLICATION CURVE.

(Applications for Mechanical Patents)

AARON L. APPLEBAUM, Assistant Examiner.

It ought to be an interesting study to inventors, manufacturers and patent attorneys, particularly the latter, to observe the monthly "application curve" with its relation to business, both before and after the World War. Commencing with January 1913 and continuing up to date, it has been found that the low water mark was reached in September, 1918, when but 3900 applications, in round numbers, were filed. Accordingly, on the scale, 4000 has been taken as the minimum and 8000 as the maximum number of applications for any one month.

It will be observed that during the five years preceding our entry in the war, the total number of applications filed in the Patent Office during the successive years, did not vary to any marked appreciable extent. The maximum number of cases filed during the year appears to be in the month of March, while the month of September generally shows the least number.

As was expected, there was a marked decrease in the number of applications filed during the war period, 1918 being the poorest year in every respect, the maximum being reached again in March when 5800 applications were filed and then decreasing to 3900 for the month of September.

Entrance Examinations.

225 applicants took the August examination, but the papers have not yet been corrected. The result of the three preceding examinations is given below.

Examination	Total no. examined.	Passed	Appointed.	Accepted to come later.	Undetermined.	Declined
April	211	59	36	4	11	8
May	154	30	20	0	1	9
June	157	20	16	1	2	1
Total	522	109	72	5	14	18

There are also 92 men on a supplemental register made up of those who attained an average of 60% or more in certain major subjects and are available for temporary appointment subject to their passing the examination at a later date in the subjects on which they failed. No appointments have yet been made from this list but it is expected that some will be in the next few months.

As soon as the assistants are sworn in, they are given a memorandum to read containing information concerning the work of the Office. They are also directed to study the circular of general information and certain portions of the Service Monograph on the Patent Office by the Institute of Government Research.

A CORRECTION.

The article entitled "The Law of Functional Claims" in the August Journal, should have been credited to Mr. Hugh Keneipp.

EUSTACE S. GLASCOCK.

Eustace S. Glascock was born in Gloucester County, Virginia, March 16, 1863. He was educated at McDonogh School, Maryland, and the United States Naval Academy, graduating from the latter in 1883.

He resigned from the Navy in 1885 and soon after engaged in teaching in Texas.

In 1899 he resigned the principalship of Waco High School to accept an appointment as Fourth Assistant Examiner in the Patent Office.

Glascock was assigned to Division 30, and remained in that division until promoted to Principal Examiner February 11, 1913. He was placed in charge of Division 40, and later organized Divisions 44, 46 and 47. Since January 1, 1921, he has been in charge of Division 19.

WALTER D. GROESBECK.

Walter D. Groesbeck was born at Cazenovia, N. Y., his parents removing to southern Michigan during his sixth year.

Reared on a farm, he attended, and later taught in the district, graded and high schools at Union City, Michigan, entering the mechanical engineering course of the Michigan Agricultural College with the class of 1889. At the end of the freshman year, he again taught school, and later did land-surveying, irrigation-development work and drafting in and about Los Angeles, Calif., returning to college and receiving the degree of B. S. in mechanical engineering in 1892, and serving one year thereafter as instructor in machine-shop practice, at the same college.

He was appointed a fourth assistant examiner in the Patent Office in July 1894, being assigned to Div. 13 and later to the Classification Division; also obtaining the degrees LL.B., LL.M. and M.P.L. in Washington lay schools and being admitted to the bar of the Supreme Court and Court of Appeals of the District of Columbia.

Resigning in 1903, he became local representative of a Pittsburgh firm of attorneys and also practiced patent law until July 1, 1908, when he re-entered the examining corps, being again assigned to Div. 13 and later to Div. 30.

He was assigned to Div. 23 as Primary Examiner Dec. 12, 1913, where he has since remained.

the assignment fees increasing from $98,896 to $111,805, or 13%.

The Patent Office "ten cent store" also did a phenomenal business, since the number of printed copies disposed of during the year increased from 6,405,000 to 7,453,000, or 17%. In fact, the number of printed copies disposed of increased from 5,595,000 two years ago to 7,163,000 last year. This means that *each* day the Patent Office disposed of 5,000 copies more than it did two years ago.

The number of photostats made by the Patent Office increased during the year from 713,000 to 978,000, or 37%, bringing in a profit of over $40,000.

The total receipts for the year were over $4,000,000 or $300,000 greater than the previous "peak" year, 1929.

424,574 patents were granted during the last ten years —more than were granted in the 100 years from Washington's inauguration in 1789 to Harrison's inauguration in 1889.

THE BOARD OF SUPERVISORY EXAMINERS

Harry C. Armstrong

Harry C. Armstrong, formerly Chief of Division 11, was detailed last November as Assistant to the Commissioner to make a survey of the problem of coordinating the administrative procedure in the sixty-two examining divisions of the Patent Office, and was on May 1, 1930 appointed to the position of Supervisory Examiner.

Mr. Armstrong, a native of Indiana, and a graduate in Mechanical Engineering from Worcester Polytechnic Institute entered the Patent Office in 1894, served 18 years in Division 3 and 17 years as Principal Examiner of Division 11.

Eustace S. Glascock

Eustace S. Glascock was transferred from his position as Principal Examiner of Division 19, and on May 1, 1930, appointed a Supervisory Examiner.

Mr. Glascock is a native of Virginia and graduated from the United States Naval Academy in 1883. He entered the Patent Office in 1899, serving in Division 30 until he was promoted to Principal Examiner in 1913 and assigned to Division 40, later organizing Divisions 44, 46 and 47. He is the author of Glascock's *Manual of Office Procedure.*

James H. Lightfoot

James H. Lightfoot was transferred from the position of Principal Examiner of Division 25, and appointed a Supervisory Examiner on May 1, 1930.

Mr. Lightfoot, a native of Virginia, was appointed Fourth Assistant Examiner in 1887 and, having been promoted up through the grades under the established examination system, was appointed Principal Examiner in 1909 in charge of Division 25.

Mr. Lightfoot is a graduate of Columbian, now George Washington, University in law, having received the degrees of Bachelor and Master of Law in the classes of 1891-92, and is a member of the Bar of the District of Columbia and of the U. S. Supreme Court.

Clinton L. Wolcott

Clinton L. Wolcott was transferred from Principal Examiner of Division 46 and appointed a Supervisory Examiner May 1, 1930.

Mr. Wolcott was born in Ohio and graduated from the National Normal University of Lebanon, Ohio, with the degrees of B. S. A. B. and A. M. He entered the Patent Office July 1, 1905 and was promoted to Principal Examiner July 1, 1920, having served as the head of Division 46 for the past ten years.

All of the members of the Supervisory Board have had long experience as successful heads of examining divisions and by reason of this essential training and their natural qualities and personality are eminently fitted for the duties and problems of this new and pioneer work.

Retirements in Patent Office

Frank C. Skinner

With 50 years' service in the Patent Office, Frank C. Skinner, examiner in chief, was retired on April 1, 1933 after having received three extensions over the retirement limit. Mr. Skinner was born in Lawrence, Mass., March 28, 1857, and was educated there, graduating from Lawrence High School. After attending M. I. T. a year he was appointed to the Naval Academy in 1874, from which he resigned in 1877 because he thought a naval officer's future prospects were poor. He moved to Lewiston, Me., studied law and was graduated from the Albany (N. Y.) Law School in 1879. He practiced law in Nebraska a short time and then was employed by several industrial concerns in St. Louis.

Appointed to the Patent Office in 1883, Mr. Skinner became principal examiner in August, 1888, and organized the classification division Patent Office in 1898. Theodore Roosevelt signed the appointment advancing Mr. Skinner to examiner in chief in December, 1908, which office he has occupied to the present time. He became a member of the Board of Appeals in January, 1909, and has been a member for nearly 25 years. In August, 1932, Mr. Skinner was exempted from the rules of the economy act by President Hoover that he might continue in office. He has no immediate plans, but to rest. Later he may open a patent law office.

Eustace S. Glascock

Eustace S. Glascock, supervisory examiner, Patent Office, retired on April 1, 1933. Mr. Glascock entered service in the Patent Office as fourth assistant examiner October 21, 1899. Length of service in the office was 33 years 5 months and 10 days.

He was born in Gloucester County, Va. March 16, 1863. He graduated from the U. S. Naval Academy in 1883, and resigned from the Navy in 1885 and thereupon en-

gaged in teaching in Texas. In 1899 he resigned as principal of Waco High School and entered the Patent Office as Fourth Assistant Examiner in Div. 30. In 1913 he was promoted to Principal Examiner. He was later in charge of Div. 40 and also organized Divisions 44, 46 and 47. On Jan. 1, 1921 he was placed in charge of Div. 19. Since May 1, 1930 he has been a Supervisory Examiner until his retirement.

Upon Mr. Glascock's retirement the Patent Office Society presented Mr. Glascock with an easy chair and the following testimonial was handed him by Mr. Lewis W. Worrell, the President of the Society:

As you have retired from the Patent Office the Patent Office Society takes this means of expressing its regret at losing the direct and active interest you have always manifested in it.

You have served the Patent Office in a large number of positions. You discharged your duties in all of them with high ability, friendliness, and common sense. Your career in it may well be taken as the model.

Not content with merely doing well the work to which you were assigned, you assumed the task of preparing the Manual of Patent Office Procedure which bears your name. Since its initial publication you have painstakingly followed the changes in practice and revised the text wherever necessary. Because of this volunteer work, it can be truthfully said that you have done at least as much as any other one person to bring about unification of the practice in the many divisions of the Patent Office. For this work you have received no remuneration.

In keeping with your generous disposition and your constant friendship for the Patent Office Society, you gave the Society the manuscript of the Manual together with all your later notes relating to changes to be made in the next edition. In emulation of your generosity, the Society has published the Manual through six editions and it will publish a new one probably before the year is over. The aim of the Society, in publishing the next edition, will be, as it has been with past editions, to distribute it at as near cost of publication as practical. Because you have thus permitted the Society to join with you in the work of unifying the practice in the Patent Office, you have placed it under a debt it can never repay.

You have the friendship and respect of the members of the Society. That organization can add nothing of importance to these. Yet, as an organization, it wishes to give you some

memento as a symbol of this friendship and respect. It is therefore sending you a Chair which it hopes you will find comfortable and in which, now and then, you may think of your many friends in the Patent Office and in the Patent Office Society.

The Society extends to you its sincere wishes for the greatest possible happiness for you.

Ballard N. Morris

On July 1, 1875 Mr. Morris was appointed as a messenger at $300 per year. Seven years later he was appointed as assistant examiner. In 1891 he became Principal Examiner of Div. 29, where he remained until his retirement on May 1, 1933. A complete biographical sketch of Mr. Morris was published in this JOURNAL, Vol. VI, Pages 55-57.

Upon his retirement the assistants presented Mr. Ballard with personal gifts and the following testimonial:

Your assistants in Division 29 taking cognizance of your approaching separation from the service take this means of expressing their appreciation of the opportunity of having been associated with you and of the pleasure and education that such association has meant.

To all of us, as well as to the many other examiners, who have had the good fortune to come under your tutelage, your wisdom gleaned from your long experience, your patient training and your unfailing courtesy, have served as an inspiration throughout the years of practice in their chosen profession.

While it is to be regretted that the government loses a very valuable official in the height of his mental powers, you have at least the satisfaction of being able to use the leisure thus acquired in full vigor and integrity.

As the senior primary Examiner of the Patent Office, with a record of unblemished service to the government, and of a character universally acknowledged to be of the highest efficiency, we wish to acknowledge the indebtedness that is your due, and to express our personal wishes for a long, useful and happy future.

colophon

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