

Subject Matter Eligibility Examples: Life Sciences

amplifying using Cool-Melt PCR yields a claim as a whole that is significantly more than the judicial exception itself (*Step 2B: YES*). The claim recites patent eligible subject matter.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that the claim recites the abstract idea of comparing sequence information. However, the claim is eligible because it recites additional limitations that when considered as a combination are more than a mere instruction to “apply” the abstract idea using well-understood, routine or conventional techniques in the field.

Claim 85: Eligible

Claim 85 recites at least one step or act, *e.g.*, amplifying nucleic acids using Cool-Melt PCR. Thus, the claim is directed to a statutory category of invention (a process; *Step 1: YES*).

The claim is then analyzed to determine whether it is directed to any judicial exception. The claim recites a step of amplifying nucleic acids (all or part of a human subject’s BRCA1 gene) using Cool-Melt PCR and a step of sequencing the amplified nucleic acids. These steps do not recite or describe any recognized exception. *See, e.g., Mayo Collaborative Svcs. v. Prometheus Labs.*, 566 U.S. __, 132 S. Ct. 1289, 1297 (2012) (recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient “are not themselves natural laws”). Accordingly, the claim is not directed to an exception (*Step 2A: NO*), and is eligible.

Note that although nature-based product limitations are recited in the claim (*e.g.*, the primers and BRCA1 gene), analysis of the claim as a whole indicates that the claim is focused on a process of amplifying and sequencing a BRCA1 gene, and is not focused on the products *per se*. Thus, there is no need to perform the markedly different characteristics analysis on the recited nature-based product limitations. In addition, note that because the analysis of this claim ends with eligibility at Step 2A, the Step 2B analysis does not need to be performed. Thus, the examiner would not need to evaluate the significantly more considerations for this claim.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance, indicating that the claim is not directed to any judicial exception.

32. Paper-Making Machine

This hypothetical example demonstrates the use of the streamlined analysis. The claim below is based on the technology from U.S. Patent 845,224, which was upheld by the Supreme Court in Eibel Process Co. v. Minnesota & Ontario Paper Co., 261 U.S. 45 (1923). As a streamlined analysis would not result in a written rejection, the discussion sets forth exemplary reasoning an examiner might use in drawing a conclusion of eligibility.

Background

Fourdrinier machines are used to make paper from a slurry of wood pulp mixed with water (called “stock”). The paper-forming section of the machines typically comprises a headbox that feeds the stock onto one end of a conveyor belt called a “paper-making wire”, which is passed over a series of rolls at a constant speed. The belt carries the stock from the headbox end of the machine (called the “breast-roll end”) to the other end (called the “couch-roll end”), while simultaneously draining and shaking the stock to form a continuous paper web. The paper web is then passed into the press section of the machine for further processing.

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At the time applicant made the invention and filed the application, it was routine and conventional to arrange the paper-making wire so that the breast-roll end was at the same or a lower height than the couch-roll end, and to feed the stock from the headbox onto the paper-making wire at a speed substantially slower than the wire speed. However, this arrangement necessitated running the machine at an overall slow speed (less than 500 feet/minute) in order to avoid undesirable effects (*e.g.*, waves, wrinkles and ripples) on the quality of the paper web.

Applicant's invention is a Fourdrinier machine that solves the problem of running the process at a slow speed by raising the breast-roll end of the paper-making wire to a height substantially above the couch-roll end, and by using gravity to feed the stock into the machine at a speed approximately equal to the wire speed. This gravity-fed arrangement permits applicant's machine to be run at an overall speed that is much higher (*e.g.*, more than 700 feet/minute) than conventional machines, without producing undesirable effects on the quality of the paper web.

Hypothetical Claim

1. A Fourdrinier machine having a breast-roll end of a paper-making wire maintained at a substantial elevation above level, whereby stock is caused to travel by gravity, rapidly, in the direction of movement of the paper-making wire, and at a speed approximately equal to the speed of the paper-making wire.

Analysis

Claim 1: Eligible.

The claim recites a Fourdrinier machine with a paper-making wire (conveyor belt) that is passed over a breast-roll. The claim is directed to a machine (a combination of mechanical parts), which is one of the statutory categories of invention (*Step 1: YES*).

Next, the claim must be evaluated to determine if the claim is directed to a judicial exception. But when the claim is reviewed, it is immediately evident that although the claimed machine operates using gravity, which is a law of nature, the claim clearly does not seek to tie up this law of nature so that others cannot utilize it. In particular, the claim's recitation of a Fourdrinier machine (which is understood in the art to have a specific structure comprising a headbox, a paper-making wire, and a series of rolls) that is arranged in a particular way to optimize the speed of the machine while maintaining quality of the formed paper web makes it clear that the claim as a whole would clearly amount to significantly more than any recited exception. The claim as a whole adds meaningful limitations to the use of the law of nature (gravity). Additionally, use of the law of nature improves paper-making technology. Thus, eligibility of the claim is self-evident for these reasons, and there is no need to perform the full eligibility analysis (*e.g.*, Steps 2A and 2B). The claim is patent eligible.

If the examiner believes that the record would benefit from clarification, remarks could be added to an Office action or reasons for allowance indicating that while the claim recites gravity - a law of nature - the claim clearly amounts to significantly more than the mere use of gravity by providing meaningful limitations to the law of nature and additionally improving paper-making technology.

It is noted that although Eibel Process Co. was decided prior to the 1952 Patent Act, the Supreme Court has subsequently described the decision as upholding the eligibility of process claims containing a law of nature. *See, e.g., Diamond v. Diehr*, 450 U.S. 175, 187-88 (1981); Parker v. Flook, 437 U.S. 584, 590-91 and n.12 (1978).