International Patent Reviews Releases Study on Acadia Pharmaceuticals' DAYBUE® Patents

International Patent Reviews, LLC
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DALLAS, August 7, 2024 -- Today, International Patent Reviews, LLC (IPR) released a study on Acadia Pharmaceuticals' U.S. Patent No. 11,370,755 entitled “Compositions of Trofinetide” directed to their drug, DAYBUE® for treating Rett Syndrome. A copy of the study can be found at IPR's website[1].

Trofinetide is an analog of the tripeptide Glypromate® (GPE, glycine-L-proline-L-glutamate). GPE was first identified around 1989 and quickly became a target of intense research since it was shown to impart neuroprotective effects in the brain. GPE analogs began turning up in the patent office soon after that in late 2002[2] and the first disclosures of trofinetide by Neuren Pharmaceuticals were seen by about mid-2005[3]. The ‘755 patent to Neuren was issued in June 2022.

Dr. R. L. Smith of IPR commented that "the 775 is one of the strangest patents we have ever examined. Since trofinetide had been discovered so long ago, the inventors had to try to distinguish this patent from the original, well-known compound. They did this by claiming an actual *impurity* commonly found during the synthesis of the analog." Dr. Smith went on to say that “the chemistry used in the ‘775, benzyloxycarbonyl-based protection for peptide synthesis, was first described way back in 1932 and was very well known and widely utilized for peptide synthesis for *years* before the discovery of trofinetide itself.” He went on to

[1] https://patent-reviews.com/
[2] See, e.g. WO 02/094856 A2 entitled “GPE Analogs and Peptidomimetics” published Nov 28, 2002.
[3] Harris et al., “Synthesis of proline-modified analogues of the neuroprotective agent glycyl-L-prolyl-glutamic acid (GPE)” Tetrahedron 2005; 61: 10018–10035; Alonso De Diego et al., “New Gly–Pro–Glu (GPE) analogues: expedite solid-phase synthesis and biological activity” Bioorg Med Chem 2006;16:1392–6.

emphasize that the ‘755 “is not a breakthrough in the treatment of a disease by a new (or old) compound; it is not a new method of synthesis or making the compound. It is simply a mixture of a known compound and a small amount of a precursor of that compound leftover from the synthetic process used to make it. That is all. This patent probably should have never been issued.”

IPR's primary focus is to identify patents filed by pharmaceutical companies that do not qualify as novel inventions deserving protection. IPR has implemented a comprehensive and diverse approach to identify pharmaceutical patent filings that exploit loopholes in the patent system. Once identified, IPR strives to demonstrate that these patents lack uniqueness and utility. Dr. Smith emphasized, "Our team produces some of the industry's most thorough and rigorous analyses. However, we believe that further public scrutiny and collective intelligence can only enhance our efforts to help control runaway drug costs. That is why we release these studies to the public. We hope that this information will be utilized to invalidate weak patents by interested parties and other stakeholders, thereby contributing to the containment of escalating costs associated with branded pharmaceuticals."

IPR indicated that the price for treatment for Rett syndrome with Daybue® is estimated to have an annual list price ranging from $575,000 to $595,000 according to Market Watch[4]. IPR hopes that allowing generic competition for this patented composition will result in significant saving to reduce the drug's costs for patients, hospitals, and caregivers.

SOURCE: International Patent Reviews, LLC

[4] “Acadia’s rare-disease drug to cost $575,000 to $595,000”, March 13, 2023. https://www.marketwatch.com/story/acadias-rare-disease-drug-to-cost-575-000-to-595-000-5e883843?mod=search_headline