ERIC | THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

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President

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Submitted Electronically via: ***www.regulations.gov***

United States Department of Commerce
United States Patent and Trademark Office
Attention: PTO–P–2022–0025

RE: Comments on Proposed Regulations on the United States Patent and Trademark Office Initiatives to Ensure the Robustness and Reliability of Patent Rights (PTO–P–2022–0025)

To Whom It May Concern:

The ERISA Industry Committee (ERIC) is pleased to submit the following comments in response to the Notice of Proposed Rulemaking (NPRM) on the United States Patent and Trademark Office (USPTO) Initiative to Ensure the Robustness and Reliability of Patent Rights, an initiative directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition.

ERIC is a national nonprofit organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every economic sector, ERIC is the voice of large employer plan sponsors on Federal, State, and Local public policies impacting their ability to sponsor benefit plans and to lawfully operate under national, uniform standards, rather than a patchwork of different and conflicting State and Local laws, in addition to Federal law.

Americans engage with an ERIC member company many times a day, such as when they drive a car or fill it with gas, use a cell phone or a computer, watch TV, dine out or at home, enjoy a beverage or snack, use cosmetics, fly on an airplane, visit a bank or hotel, benefit from our national defense, receive or send a package, or go shopping.

ERIC member companies provide comprehensive health care and retirement benefits to millions of active and retired workers and their families across the country. Our members offer these great benefits to attract and retain employees to be competitive for human capital, to improve health – physical, mental, and financial health – and to provide peace of mind.

More than 155 million Americans receive health care benefits through their employer, with large employers paying more than 80 percent of health care premiums for their employees.[1] As prescription drug costs rise, employers and employees are burdened with higher costs for medications and for insurance coverage.

[1] See 2021 Employer Health Benefits Survey at https://www.kff.org/report-section/ehbs-2021-summary-of-findings/

ERIC's large employer members are self-insured employers, abiding by the Employee Retirement Income Security Act of 1974 (ERISA), and these employers act as fiduciaries, ensuring that plan dollars are well spent, vendors are well managed, and patient data is protected, among many other responsibilities.

ERIC has a significant interest in the patent system generally – and patents issued to prescription drug manufacturers specifically – due to (1) the ever-increasing cost of prescription drugs and (2) a self-insured plan sponsor's fiduciary responsibility to "*act in the best interest of plan participants*" (when offering health coverage to employees and their dependents) while also "*defraying reasonable costs to the plan*" (when providing coverage for life-saving prescription drugs and treatments for the day-to-day health-and-well-being of plan participants). As health care costs continue to rise – due in large part to significant year-over-year increases in the price of prescription drugs – employer sponsors of self-insured plans have a keen interest in reining in these costs, whether that is through patent reform or through other means like value-based contracting with drug manufacturers.

As discussed more fully below, ERIC believes that the USPTO must take steps to eliminate abuse of the patent system, which is harmful to the American health care system, and patients and health care payers alike. Failure to respond to this systematic abuse will lead to a system with insufficient competition, ultimately harming innovation, access, and affordability for patients.

COMMENTS

Patent Policies Should Be Aligned with Congressional Intent to Balance Innovation with Competition

1. *The USPTO Needs to Act Now*

Patents awarded to prescription drug manufacturers are intended to protect the science, research, and resources associated with creating and developing a new drug or therapy for 20 years, beginning with the time the patent application was first submitted. However, it is well-accepted that patent applications are often filed with the intent to extend monopolies for certain prescription drugs for longer than 20 years.

Unfortunately, some manufacturers submit hundreds of questionable patent requests on the same drug, and/or seek to continue a drug's market exclusivity through using the secondary-structure patent. This has prevented competition for some products, and contributed to excessive price increases for certain patented drugs. According to some reports, prices for the 12 best-selling drugs in the United States increased by close to 150 percent between 2012 and 2018.[2] These practices also block or delay generic and biosimilar drugs from entering the market to compete with these patented drugs, which would otherwise bring down the cost of patented drugs and provide a lower-cost alternative to patients and health care payers like self-insured health employer plans.

[2] See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices at https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf.

ERIC commissioned independent studies from Johns Hopkins Bloomberg School of Public Health, Fidelity Investments, and Segal to learn how employers are currently using biosimilars and the role employers and government have in realizing greater benefits from biosimilar options.[3] Analyzing health plan data, researchers found that biosimilars saved employers, employees, and their families significant amounts of money. They identified many barriers to the availability of biosimilars in the marketplace, including those in the current patent system, which keep costs higher. **The following actions should be considered by USPTO to improve the current patent process.**

2. *Limit the Use of Secondary-Structure Patents*

An increasingly common strategy to maintain market exclusivity on certain prescription drugs is to patent the same drug using two distinct patent filings (through primary-structure and secondary-structure filings), which enables patent owners to put an early marker (using the primary-structure patent) and to inappropriately prolong market exclusivity (using the secondary-structure patent) for the same drug.

This long-tail in exclusivity prevents generic and biosimilar drugs from coming to market to compete with the patented prescription drug. The lack of competition keeps the cost of the drug high. This frustrates the purpose of the Hatch Waxman Act, in which Congress intended for innovators to recoup their investments and enjoy market exclusivity for a limited time, and then to face competition from cheaper alternatives.

Efforts should be made to limit the use of secondary-structure patents by enabling USPTO examiners to source back to the primary-structure filing and to coordinate with the Food and Drug Administration (FDA) to seek disclosures and information relating to the secondary-structure claim.

With respect to FDA coordination, FDA officials should be made available to answer questions from patent examiners regarding the technical details of a patent filing, provide relevant information from the drug regulatory dossier, and conduct research for patent examiners upon request. In addition, drug manufacturers that file patent applications should be required to stipulate to the USPTO that the drug makers have not made any statements to the FDA that are inconsistent with the statements they are making to the USPTO.

3. *Eliminate the Practice of Obviousness-Type Double Patenting and the Use of Terminal Disclaimers*

Similar to the practice of using secondary-structure patents to extend the exclusivity of a patent, some drug manufacturers may engage in a practice industry experts call "*obviousness-type double patenting*" (OTDP). Here, drug manufacturers submit patent requests multiple times on virtually the same drug, effectively creating what industry-experts call "patent thickets" to protect the drug's long-standing exclusivity.

[3] Biosimilars: Employers and Employees See Savings, More Competition Needed (2020) https://www.eric.org/wp-content/uploads/2020/03/ERIC-Biosimilars-Initiative.pdf

Patent thickets allow drug manufacturers to delay generic and biosimilar market entry by relying on the significant cost associated with challenging numerous patents. In other words, the cost associated with challenging multiple non-patentably distinct patents is prohibitive for generic and biosimilar drug makers wanting to enter the market. This allows drug manufacturers to build large patent portfolios that shield their current patents from scrutiny, requiring, for example, self-insured plan sponsors to continue paying high prices for prescription drugs that Congress intended to experience competition at an earlier date.

It is important to emphasize that OTDP is restricted in other countries around the world. In addition, the United States is the only country that allows OTPD through the use of "*terminal disclaimers*" where drug manufacturers are able to claim non-patentably distinct patents across multiple patents, so long as the drug manufacturer aligns the expiry date of each patent using a terminal disclaimer. This leads to large, duplicative patent thickets; in some cases, nearly 80 percent of a prescription drug's patents are linked together through terminal disclaimers. This discrepancy has created an imbalance in which a given patented drug will often have many more patents in the U.S. than it has in other markets such as the European Union.

Often times a manufacturer seeking to compete with a generic or biosimilar product will have to challenge extraneous patents on a reference product. In the event challenges are raised against a particular patent, the use of terminal disclaimers has a significant impact on such challenges. Specifically, generic and biosimilar drug makers must invalidate all non-patently distinct patents to have freedom to commercialize their product, meaning they cannot invalidate just one non-patently distinct patent. **To resolve this issue, the USPTO should allow patents tied together through terminal disclaimers to rise and fall together, by requiring an acknowledgement from the patent owner, that the claims are non-patentably distinct from the earlier patent(s). Meaning if a particular patent is invalidated, the patents linked to it by a terminal disclaimer should be held unenforceable.**

In conclusion, the use of terminal disclaimers is contributing to a lack of competition and unnecessarily high drug costs, and serves as a disincentive to innovation. **As an alternative to allowing non-patentably distinct patents to rise and fall together, the USPTO should take steps to eliminate terminal disclaimers so that claims that are obvious variations to claims already contained in prior granted patents should be rejected, and terminal disclaimers should not be a tool to overcome such rejections.**

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Thank you in advance for considering these comments. Please do not hesitate to contact me at 202-789-1400 or jgelfand@eric.org with any questions or if we can serve as a resource on these very important issues.

Sincerely,

James P Gelfand