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

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Submitted Electronically via: www.regulations.gov

The Honorable Kathi Vidal
Director
U.S. Patent and Trademark Office
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

Re: Request for Public Comment to Proposed Rule: Terminal Disclaimer Practice to Obviate Non-statutory Double Patenting

Docket No. PTO-P-2024-0003

Dear Director Vidal,

The ERISA Industry Committee (ERIC) is pleased to submit the following comments in response to the Request for Public Comment on the United States Patent and Trademark Office (USPTO) Proposed Rule on terminal disclaimer practices.

ERIC is a national advocacy 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. ERIC member companies offer benefits to tens of millions of employees and their families, located in every state, city, and Congressional district.

ERIC has a significant interest in the patent system generally due to the ever-increasing cost of prescription drugs. ERIC's member companies sponsor health benefit plans for workers and their families, and these benefits are governed by the Employee Retirement Income Security Act (ERISA). Their health benefits are self-insured, meaning that the employer is ultimately at risk for the costs of the plan. Employer plan sponsors have a fiduciary duty under ERISA 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. This challenge is apparent as plan sponsors struggle to ensure access to prescription drugs, despite ever-increasing costs, and the resulting pressures of these costs raise health insurance premiums for workers and families. As health care costs continue to rise, plan sponsors have a keen interest in reining in these costs, and employers are especially supportive of promoting the development and approval of, and access to, biosimilars and generics. One commonsense way to encourage access to these affordable alternative therapies is to ensure a fair patent system exists where innovation is rewarded but a robust, competitive drug market is promoted.

Because of our interest in lowering the rising cost of prescription drugs, ERIC commissioned independent studies from Johns Hopkins Bloomberg School of Public Health, Fidelity Investments, and Segal to learn how employer plans provide for the use of biosimilars, and the role employers and government have in realizing greater benefits from biosimilar options compared to brand drugs.[1] Analyzing health plan data, researchers found that biosimilars saved employers, employees, and their families significant amounts of money. However, they also identified many barriers to the availability of biosimilars in the marketplace, including barriers and loopholes in the current patent system such as "obviousness-type double patenting" (OTDP) and the use of terminal disclaimers, which keep costs higher.

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 by using secondary-structure patents or OTDP.

Such practices are in direct conflict with the standards established by the 1984 *Drug Price Competition and Patent Term Restoration Act* (Public Law 98-417), commonly referred to as the *Hatch Waxman Act,* as well as the *Biologics Price Competition and Innovation Act of 2009* (BPCIA). The *Hatch Waxman Act* rewards innovator companies with market monopolies for a limited and defined duration of time. This reward system has been abused by drug manufacturers who submit patent requests multiple times on virtually the same drug, effectively creating what experts call "patent thickets" to protect the drug's long-standing exclusivity. *BPCIA* is similar in concept to *Hatch Waxman* as it creates abbreviated pathways for biological products that are demonstrated to be "highly similar" to or "interchangeable" with an FDA-approved biological product, but again have experienced delays due to current gaming of the patent system.

Patent thickets allow drug manufacturers to delay generic and biosimilar market entry by relying on the significant cost associated with challenging numerous patents through litigation. 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. It can also force any generic companies that had cleared a path to launch to possibly exit the market. Patent thickets allow 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.

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

Terminal disclaimers have prevented competition and contributed to fewer biosimilars coming to the U.S. market. According to a 2023 study, 48 percent of patents involved in litigation against biosimilars had terminal disclaimers.[2] The number of patents issued with terminal disclaimers spiked 12 years after branded drug approval, coinciding with the end of the U.S. Food and Drug Administration-granted statutory biologic exclusivity.[3] This reflects the behavior of branded drug companies to amass many terminally disclaimed patents at the expected time of biosimilar market entry to cause disruption and uncertainty to prospective biosimilar launches. This practice also blocks or delays a lower-cost alternative to patients and health care payers like ERISA self-insured health plans.

The USPTO's proposed rule is a balanced solution that would increase patent quality and allow more biosimilars and generics to more quickly come to the U.S. market. ERIC sees this proposed rule as effective in balancing competition and innovation with the patent holder's right to a limited, defined period of exclusivity. The proposed rule allows 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. Therefore, if a particular patent is invalidated, the patents linked to it by a terminal disclaimer should be held unenforceable. This will make challenging a patent family effective and efficient, clearing a path to earlier generic and biosimilar entry, and reducing the extensive legal costs involved in resolving the same patent issue multiple times.

Importantly, the proposed rule rightly captures the spirit of *Hatch Waxman* and *BPCIA* by striking the balance between rewarding innovation and promoting competition. Under the proposed rule, drug manufacturers can still use continuations to protect innovation, traversing OTDP rejections and using the reissuance procedure. Moreover, the proposed rule will change the incentive for branded drug manufacturers, from focusing on amassing a high number of patents, instead to focusing on amassing high quality patents and claim construction, just as Congress intended by establishing the 30-month stay under *Hatch Waxman* and *BPCIA*.

Thank you in advance for considering our comments. Updating and refreshing regulations in this space is essential to address anticompetitive practices that in the end hurt patients, employees, retirees, and their families by limiting access to prescription drugs. Please do not hesitate to contact me at 202-789-1400 or mbartlett@eric.org with any questions or if ERIC can serve as a resource on these very important issues.

Sincerely,

Melissa Bartlett

Senior Vice President, Health Policy

[2] Tu SS, Goode R, Feldman WB. Biologic Patent Thickets and Terminal Disclaimers. JAMA. 2024 Jan 23;331(4):355-357. doi: 10.1001/jama.2023.25389. PMID: 38095894; PMCID: PMC10722383.
[3] *Id*