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July 8, 2024

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property
Director, United States Patent and Trademark Office
Docket Number: PTO-P-2024-0003

Submitted electronically via www.regulations.gov

Re: ***Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting*** **[PTO-P-2024-0003]**

Dear Director Vidal:

Kaiser Permanente appreciates the opportunity to comment on the above-captioned proposed rule issued by the United States Patent and Trademark Office (USPTO).[1]

Kaiser Permanente is the largest private integrated healthcare delivery system in the U.S., delivering health care to 12.6 million members in eight states and the District of Columbia.[2] Within our footprint, we maintain a primarily internalized pharmacy system, including 537 outpatient, hospital, infusion, specialty and mail order pharmacy sites staffed by over 14,800 pharmacy personnel. Kaiser Permanente spends approximately $11.7 billion annually on pharmaceuticals. Our Permanente Medical Group (PMG) physicians and other authorized practitioners prescribe, and our pharmacies dispense, over 100 million outpatient prescriptions, 60 million inpatient prescriptions and 60 million clinic infusions annually. Our mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

We strongly support this proposed rule to amend the terminal disclaimer practice such that if one patent is found invalid or unenforceable, other patents tied to it through a terminal disclaimer are also invalid or unenforceable. This is an important step toward dismantling pharmaceutical manufacturers' use of patent thickets, which will promote innovation and competition while reducing the amount of litigation related to patents that are subject to a terminal disclaimer.

Unsustainable Drug Spending

In 2023, United States pharmaceutical expenditures reached $722.5 billion,[3] with spending on brand drugs growing by $54 billion.[4] According to a recent Reuters analysis, the median annual list price for a new drug

[1] 89 Fed. Reg. 40439 (May 10, 2024).
[2] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plans, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 40 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.
[3] Tichy EM, Hoffman JM, et. al., *National trends in prescription drug expenditures and projections for 2024*, Am J Health Syst Pharm., (Apr. 24, 2024), available at: https://pubmed.ncbi.nlm.nih.gov/38656319/.
[4] IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2024*, (Apr. 2024), available at https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024.

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was $300,000, up from $222,000 in 2022.[5] Prescription drug prices and spending continue to rise at unsustainable levels, fueled in large part by a patent system for pharmaceuticals that is broken. Pharmaceutical manufacturers are exploiting the patent system through several tactics, including patent thickets, through which manufacturers file or accumulate hundreds of patents—many after product approval—to delay or prevent competition and maintain their monopoly power. This abuse of the patent system drives up health care spending and delays the arrival of lower-cost medicines.

The Problem with Patent Thickets

The U.S. patent system must incentivize and protect the research and development investment needed to bring innovative therapies to market. The current system, however, is no longer meeting these objectives, and instead is rewarding pharmaceutical manufacturers that maneuver within the legal system to protect old inventions, while delaying generic and biosimilar competition.

Manufacturers are using patent thickets to extend their monopoly power on products with expiring patents by amassing additional continuation patents with terminal disclaimers that cover incremental changes, rather than meaningful improvements to those drugs. This complex web of patents makes it difficult for generic and biosimilar manufacturers to navigate and challenge patents as they try to launch lower-cost versions of drugs and biologics. As researchers have noted, by using such patent thickets, manufacturers "are not relying on the quality of their patents to prevent market entry" but instead relying on "the sheer number of patents in the thicket" to prevent competitors from entering the market.[6]

A recent examination of four of the leading biologic drugs that had biosimilar competition introduced since 2019—Humira, Avastin, Rituxan and Lantus—found that manufacturers used patent thickets to add an additional 6.2 years of extended patent protection.[7] Over these additional years manufacturers averaged $70 billion in U.S. sales, with all four drugs earning significantly more per year after the primary patent protection expired.[8] The drugs averaged $6.2 billion per year in the extended period versus $2.4 billion in the primary period,[9] exemplifying how the use of patent thickets drives up health care spending.

Unfortunately, most patents filed by pharmaceutical manufacturers protect existing, rather than new, products. Reports highlight that for the 10 top-selling drugs in the United States, roughly 66 percent of patent applications were filed after the FDA approved the drug to be on the market.[10] In the case of Humira, for example, over half of its patents in the Purple Book are subject to a terminal disclaimer.[11] Manufacturers' use of continuation patents and terminal disclaimers, the latter of which is not permitted in other countries,[12] creates a daunting legal barrier for any competitor looking to enter the market.

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[5] Deena Beasley, *Prices for new US drugs rose 35% in 2023, more than the previous year*, Reuters, (Feb. 23, 2024), available at https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/.

[6] Goode R, Chao B., *Biological patent thickets and delayed access to biosimilars, an American problem*, J Law Biosci., (Sep. 1, 2022), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9439849/#fn7.

[7] Initiative for Medicines, Access, and Knowledge (I-MAK), *The Burden of Patent Thickets*, (2023), available at https://www.i-mak.org/wp-content/uploads/2023/09/The-Burden-of-Patent-Thickets-FINAL.pdf.

[8] *Id*.

[9] *Id*.

[10] I-MAK, *Overpatented, Overpriced, Curbing patent abuse: Tackling the root of the drug pricing crisis*, (Sept. 2022), available at https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf.

[11] Letter from I-MAK in response to *Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (USPTO Docket No. PTO-P-2022-0025)*, (Feb. 1, 2023).

[12] Tu SS, Goode R, et. al., *Biologic Patent Thickets and Terminal Disclaimers,* JAMA, (Dec. 14, 2023), available at

When comparing patent portfolios of biologic products across different countries, the evidence demonstrates that these drugs are protected by far more patents in the U.S. than other countries.[13] In the case of the United Kingdom and Canada, biosimilars are entering those markets far more quickly than they are in the U.S.[14] Patent thickets are clearly contributing to delayed market entry of generic and biosimilar products, burdening patients and other health care stakeholders with avoidable costs.

Supporting the Proposed Rule

The proposed rule would establish a vital requirement that patent holders filing a terminal disclaimer must include an agreement that if the primary patent upon which the terminal disclaimer is based is invalidated or found unpatentable, those other patents subject to the terminal disclaimer are also invalidated. This will ensure that several patents tied via terminal disclaimers need not be separately litigated by competitors seeking to bring their product to market. As the USPTO notes, "in a litigation in which a patent owner is enforcing a patent along with several other patents that are tied by one or more terminal disclaimers to that patent, a competitor could seek to have the court narrow any validity disputes to address only that patent."[15]

We agree with the USPTO that "[n]arrowing validity disputes in litigation to only one such patent could result in more focused claim construction hearings, lower litigation costs, and faster resolution."[16] Importantly, this policy will combat anti-competitive patent thicket practices and help bring lower cost generics and biosimilars to market sooner.

Kaiser Permanente believes this proposed rule is a positive step toward restoring a framework for pharmaceutical patents that appropriately rewards innovation and discovery while preserving competition. Our patent system must ensure access to medicines at prices that patients and the health care system can afford.

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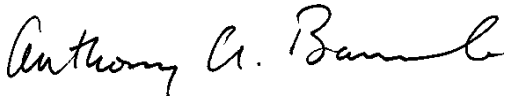
We appreciate the USPTO's consideration of our comments. Please feel free to contact me at (510) 271-6835 or anthony.barrueta@kp.org or Simon Vismantas at (425) 677-1267 or simon.p.vismantas@kp.org with any questions or concerns.

Sincerely,



Anthony A. Barrueta
Senior Vice President, Government Relations

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https://jamanetwork.com/journals/jama/fullarticle/2813272.
[13] Goode R., *supra* note 6.
[14] *Id*.
[15] 89 Fed. Reg. at 40440.
[16] *Id*.