U.S. Chamber of Commerce

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July 2, 2024

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property
Director, United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Re: Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, Docket No. PTO-P-2024-0003

Dear Director Vidal:

The U.S. Chamber of Commerce ("Chamber") Global Innovation Policy Center ("GIPC") appreciates the opportunity to comment on the U.S. Patent and Trademark Office's ("USPTO") proposed changes to the rules on the use of terminal disclaimers.

The USPTO's examination of patent applications is critical to American innovation. The timely issuance of high quality rigorously examined patents provide the legal protection needed for new, innovative products to be brought to market faster and with the confidence that the massive investment that made those innovations possible can be recouped. However, as a threshold matter, the Chamber notes that while this proposal[1] is being broadly framed and, in theory, technologically neutral, the reality is the questions raised and agency actions contemplated by this proposal appear to be targeted primarily towards the use of continuation practice by the life sciences technology sectors.[2]

As the Chamber has consistently made clear[3], it is unwise as a matter of public policy to consider changes to examination practices, which will, under well-established US and international law, apply to all art units and technology sectors, simply to address a perceived problem in one technology sector.

With these threshold issues addressed, the Chamber's views on this proposal can be summarized in three main points:

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[1] These comments do not take a position on whether the agency possesses the authority to change terminal disclaimer and continuation practice.
[2] *See* Ltr. from Senators Patrick Leahy (D-VT), John Cornyn (R-TX), Richard Blumenthal (D-CT), Susan Collins (R-ME), Amy Klobuchar (D-MN) and Mike Braun (R-IL), to USPTO Director Kathi Vidal, June 2022.
[3] *See* US Chamber of Commerce Statement for the Record for a Senate Committee on the Judiciary Hearing entitled *Ensuring Affordable & Accessible Medications: Examining Competition in the Prescription Drug Market,* May 20, 2024.

I. This proposal is predicated on faulty evidence about life-science patenting activity, evidence that was discredited recently by USPTO itself, and therefore should be abandoned if that is in fact the motivation for the proposal.

II. In the context of life science innovation, continuations and terminal disclaimers are incredibly beneficial to society and enable the development of new, lifesaving, and life-altering medications.

III. To the extent that more robust patent examination practices are needed in other technology sectors, the Chamber supports providing increased resources for USPTO to carry out its missions as America's innovation agency.

The Chamber's concerns are outlined in more detail below.

I. The proposed changes to continuation and terminal disclaimer practices are based on debunked claims by anti-patent activists about the life science industry, claims that were thoroughly disproven and discredited by USPTO's own objective analysis.

All federal policy making should be evidence-based and premised on the best available data. Effective and empirical research is the best metric to decide if any policy should be undertaken. In contrast, the current proposals come in response to activists who have equated not only the number but also the mere existence of patents as indications of barriers to access to medicines. While advocates for weakened patent rights for life-saving treatments routinely cite studies that parrot false narratives regarding so-called "patent thickets" and "evergreening,"[4] these studies have been rightly criticized for their inaccurate use of underlying data, lack of transparency, and flawed methodology.[5]

Indeed, as recently as last month the USPTO itself released its own empirical study that thoroughly disproves and debunks the myths made by anti-patent activists.[6] In that study, the agency noted multiple discrepancies between the claims made by certain anti-patent activists regarding the number of patents on specific products and

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[4] *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, The Initiative for Medicines, Access & Knowledge; *See also* Evergreen Drug Patent Search Database, University of California College of Law.

[5] Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, The Hudson Institute, January 2022; Erika Lietzan & Kristina M.L. Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations,* Fordham Intellectual Property, Media & Entertainment Law Journal, Vol. 33, Sep. 26, 2022; *Ltr. from Senator Thom Tillis, Ranking Member, Senate Judiciary Committee Subcommittee on Intellectual Property to Tahir Amin*, January 31, 2022; Professor Kristen Osenga, *Are "patent thickets" to blame for high drug prices,* Richmond-Times Dispatch, Nov. 30, 2022.

[6] https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf

the actual number of patents on those products.[7] Moreover, the agency found that multiple patents associated with a single marketed product are not unique to life-sciences and instead are common in many innovative industries. Finally, and perhaps most interestingly, the agency also found that the expiration date of a patent has little to no impact on the actual launch timing of competing products.

Given the USPTO's own findings, the Chamber does not believe this proposal is supported in any way by independent, objective data or facts pertaining to the life sciences industry. Substantive rulemaking should not be predicated on faulty data. The USPTO should give great weight to this objective third party study. Accordingly, the proposed changes to terminal disclaimer practice should be abandoned until accurate data about life science industry practices is available to justify any modification to current practice.

II. Terminal disclaimers are used productively in the field of life sciences, and the changes contemplated by USPTO would hinder the development of new medications, vaccines, cures, and treatments for American patients.

The Chamber's broad and diverse membership includes many companies which have legitimate concerns around patent examination quality in their art areas. This is why, as will be discussed more fulsomely in section three, the Chamber has supported increased funding for USPTO to hire and train more patent examiners and facilitate information technology improvements at the Office. Nevertheless, the comments below reflect the Chamber's strong impression that current proposed changes to continuation and terminal disclaimer practice are politically and practically directed at the life sciences industry only[8], and the views expressed here reflect that context.

In the context of the life-sciences industry, continuations and terminal disclaimers can provide tremendous benefits to society. Continuation practice in the life sciences industries is essential for ensuring that patent applicants obtain protection on the full scope and variations of their inventions.[9] Without continuation

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[7] For example, despite claims to the contrary the agency found no drugs with 200 patents and 40-year monopolies, contrary to IMAK's claims. Additionally, the agency found only 3 patents for Eliquis, whereas IMAK counted 27. For Revlimid, the agency found only 27 patents and 16 years of exclusivity, not 96 patents and 40 years as claimed by IMAK. Finally, Lyrica was found to have only 3 patents and less than 15 years of monopoly, not 68 patents and 32 years as claimed by IMAK.

[8] It is not difficult to see the raw partisan politics behind this proposal. This is hardly the first time the Biden Administration has targeted the life sciences sector, and especially the patent rights of innovative companies that produce new treatments and cures. Perhaps most notably, the Administration has proposed a scheme to confiscate the patents of some of the most innovative American companies.

[9] The Chamber's understanding is that within life sciences It is common for an invention disclosed in an application to have various features that can be included in the patent claims, and an applicant may believe that a first set of allowed claims may not capture the full scope of his or her invention. When an applicant files a continuation application, the applicant and the examiner continue to work incrementally to best define the claims that adequately protect the inventions disclosed in the application whilst meeting the requirements of patentability. Continuation applications permit an applicant to agree to one set of claims and then continue to pursue claims of different wording, scope, and variation that were either not presented or were not agreed upon in

practice, innovative life-science companies would not be able to invest in the research and development necessary to bring new life saving and life enhancing inventions to consumers, while ensuring the patents that arise from that research expire at the appropriate time and thereby become usable by the public and competitors. Inventors, follow-on users, courts, and USPTO have relied on the terminal disclaimer and continuation system for decades without any problem and the only reason it is perceived to be a problem in the life sciences industry today is because of the debunked data referenced section one.

USPTO is intimately familiar with the terms and conditions of the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act ("BPCIA"). These twin pieces of legislation represent the product of intense and detailed negotiations in which Congress, the branch of government actually responsible for making substantive patent law, set forth a balance of the interests. This balance of interest ensures that the patent rights of life science innovators are protected, while promoting the ability of companies seeking to offer generic and biosimilar equivalents to access the market once the relevant patent rights expire. Working together, this framework promotes the interest of innovative life science companies and patients in the development and equitable access of new treatments to treat disease and improve lives.

This balance is appropriately struck when life science innovators are afforded the ability to patent the full scope of their inventions, without improperly extending the patent term. Life science innovations, whether a first of its kind groundbreaking invention or inventions in a crowded field, continue to improve as they are refined and perfected over years, if not decades, due to additional research and development. This refinement includes new engineering to allow production to scale, possible improvements to safety, and most importantly, increased efficacy of the product.

The BPCIA and Hatch-Waxman frameworks have worked well for decades and produced tremendous, life-saving results for American patients. Now, the USPTO is proposing changes that would upset that balance. The proposed changes to terminal disclaimer practice in the life-science sector would limit the patents that life science companies can acquire and assert, thus potentially inhibiting bringing new medical treatments to market.[10] Instead, in the absence of the full scope of protection that can exist today, the proposed rules would encourage some actors to game the system and ultimately undermine the ability of American patients to access new cures and

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the initial examination. Additionally, for r start-ups and other small biopharma companies, investors often require companies to establish patent protections early enough to be the first company to file a patent, in order to establish the necessary priority under the U.S. first-to-file system.

[10] This proposal also appears to be in direct contradiction of USPTO's stated goals in "*Request for Comments: Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace*," PTO-C-2024-0004, 89 F.R. 18907 (March 15, 2024); *See also* U.S. Chamber of Commerce comments in response to the IP Commercialization RFC, May 14, 2024.

treatments. Surely that result isn't one that America's innovation agency should be advocating for.

III. To improve the reliability of granted patents, the proper solution is to improve the examination process by providing the agency with more resources, technology, and personnel.

The Chamber has consistently supported full funding of the USPTO at levels that would improve the patent examination process and would lead to higher patent quality and stronger patent rights, and, which in turn, would reduce excessive, costly litigation. GIPC continues to support common-sense steps including hiring more examiners, increasing coordination between art units, enhancing training, and providing new and updated prior art search technology.[11] These improvements would also promote more robust enforcement of the patentability requirements.[12]

In support of these goals, we reiterate here the objectives which we have consistently urged Congress to pursue: appropriate the previously diverted funds from the USPTO budget so that they can be channeled back to the agency to improve the entire patent examination processes. Additionally, we reiterate our support for reasonable fee increases necessary to support that goal.[13] This approach—more resources, more technology, and an increase in better trained personnel— is the appropriate way to improve patent examination and ensure robust, reliable, and high-quality patents, particularly in art and technology areas outside of the life-sciences.

The Chamber and its member companies stand ready and willing to work with the USPTO to secure these appropriations and any other additional resources needed to effectively achieve its mission.

IV. Conclusion

The Chamber appreciates the opportunity to submit these comments for the record. The Chamber is happy to work with USPTO and Congress on common sense solutions that improve patent quality, particularly in art sectors that have traditionally had less rigorous examination, but also that support innovation. However, the heavy-handed approach being promoted in this proposal is unsupported by facts and evidence and will only lead to less life-science innovation, ultimately harming the American public.

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[11] *See* Chamber response to USPTO Request for Comments on Initiatives to Ensure the Robustness and Reliability of Patent Rights, February 1, 2023; *see also* Chamber Comments for House Judiciary Committee, Subcommittee on Courts, Intellectual Property, and the Internet, for a hearing entitled *Oversight of the Patent and Trademark Office,* April 26, 2023; *See also* Chamber response to USPTO Request for Comments on FY 2025 Patent Fee Increases, May 30, 2024.

[12] Chamber members in the high-tech sector believe that ensuring continuation patents find support in the priority filing under Section 112 is particularly important and critical to ensuring robust examination in their art area.

[13] *Id.*

Sincerely,

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U.S. Chamber of Commerce