Your Generics & Biosimilars Industry

February 1, 2023

Via Federal eRulemaking Portal (https://www.regulations.gov)

The Honorable Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Madison Building
600 Dulany Street
Alexandria, VA 22314

Re: Comments from the Association for Accessible Medicines Regarding Docket No. PTO–P–2022–0025, "USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights"

Dear Director Vidal:

The Association for Accessible Medicines ("AAM") provides these comments in response to the U.S. Patent and Trademark Office's ("PTO" or "Office") Request for Comments, titled "USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights."[1]

AAM is the nation's leading trade association for manufacturers of FDA-approved generic and biosimilar prescription medicines. Our members' medicines comprise nearly 6 billion prescriptions every year.[2] We aim to improve the lives of patients by advancing timely access to safe, effective, and affordable generic and biosimilar medicines.

Generic drugs are vital to ensuring access to affordable healthcare. Generics represent greater than 90% of all prescriptions dispensed in the United States, yet account for only 18.2% of expenditures on prescription drugs.[3] Savings attributable to generic and biosimilar medicines have kept nearly $2.6 trillion in the pockets of patients and taxpayers over the past ten years.[4] This increased affordability has also expanded access to critical medications that improve patient outcomes. Experts estimate that half of patients with chronic diseases do not take their medications as prescribed and that patients' failure to adhere to prescription regimens accounts

[1] 87 Fed. Reg. 60130 (Oct. 4, 2022).

[2] Ass'n for Accessible Meds., *2022 The U.S. Generic & Biosimilar Medicines Savings Report* 3 (Sept. 2022), https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf.

[3] *Id.* at 7.

[4] *Id.*

for approximately 125,000 deaths annually.[5] Patient abandonment rates for generic medicines, however, are approximately 66% lower than for branded drugs, an unsurprising figure given that 90% of all generic medicines are available to consumers for less than $20.[6]

AAM supports a strong and robust patent system that encourages and enables innovation through the issuance of high-quality patents. Indeed, AAM's member companies frequently obtain and assert patents themselves. But we are concerned that some PTO policies and procedures have allowed brand-name pharmaceutical companies to amass low-quality patents that pose significant barriers to patients' timely access to life-saving generic and biosimilar medicines.

These low-quality patents are not worthy of protection—they discourage and disable innovation, and artificially inflate health-care costs by shutting out market alternatives and stifling the savings that generic competition brings. We applaud the PTO's recognition of this problem and its stated commitment to "ensure that our system, as a whole, does not unnecessarily delay generic and biosimilar competition."[7] Many of the changes addressed in these comments represent, what we see as, valuable steps towards achieving that goal.

Below, we summarize the harm that large patent estates comprising improvidently granted patents present for patients and the healthcare system: by amassing fortresses of overlapping patents, many of which are non-robust, of vague scope, and/or covering indistinct limitations over related patents, brands make it impossible for generic and biosimilar companies to economically challenge those patent estates, a precursor to bringing lower-cost medicines to patients. Brands have admitted to this strategy in numerous internal company documents—they play a numbers game "designed to make it more difficult for . . . [generics and] biosimilar[s]."[8] This numbers game, detailed in part (I), substantially delays the availability of these lower-cost medicines and leaves patients paying more for longer.

In part (II), we provide specific examples of the harm that these large patent estates present for patients. Then, in part (III), we provide recommendations to address patent quality issues, including specific recommendations to increase examiner time and training, to modify the PTO's fee structure, and to improve monitoring of large pharmaceutical patent estates. Finally, we answer the specific questions that the PTO has posed in part (IV).

II. THE PROLIFERATION OF LARGE PATENT ESTATES HARMS PATIENTS

Simply stated, the current patent system has fallen out of balance. Consider the biologic medicine Humira®. It became a more lucrative franchise than the entire National Football League.[9] The

---

[5] Ass'n for Accessible Meds., *Ensuring the Future of Accessible Medicines in the U.S.* 5 (2018), https://www.accessiblemeds.org/sites/default/files/2018-02/AAM-Whitepaper-Ensuring-Future-of-Generic-Medicines.pdf.

[6] *Id.*

[7] 87 Fed. Reg. at 60131.

[8] Statement of William Chase, AbbVie at Goldman Sachs Healthcare Conference Transcript (June 11, 2014).

[9] Anna Rose Welch, *AbbVie's Humira Can Tackle the NFL – But Can It Handle Biosimilars*, Outsourced Pharma (Feb. 12, 2015), https://www.outsourcedpharma.com/doc/abbvie-s-humira-can-tackle-the-nfl-but-can-it-handle-biosimilars-0001.

high price of this much-in-demand medicine is a direct function of the current U.S. patent system, which has allowed AbbVie to obtain approximately 136 patents that stack exclusivity period on top of exclusivity period—far more than the "limited" exclusivity period contemplated by the Constitution.[10] From the time the key patent on Humira® was set to expire in 2016, AbbVie's abuse of the patent system allowed it to raise the medicine's list price by 60%, generating an additional $114 billion in revenue for the company.[11] AbbVie's clear intent is to accumulate patents because they increase costs and constitute barriers for potential biosimilar competitors. Indeed, external, peer-reviewed research has found that the Humira® patent estate is comprised of 80% duplicative patents.[12] This practice is entirely allowed by PTO rules. And this is not merely a Humira® problem: numerous other large brand-name pharmaceutical companies are purportedly following this exact same strategy.[13]

These masses of duplicative patents create a numbers game for generic and biosimilar companies that ultimately harms patients. Challenging a large patent estate requires generic and biosimilar manufacturers to engage in years of slow-moving and costly litigation, yet the process of obtaining additional patents is comparatively quite simple. For example, although a "duplicative patent[] may cost as little as $25,000 to obtain," challengers will pay, on average, "$774,000 to challenge that patent" in administrative proceedings and "even more" to bring a similar challenge in district court.[14] Given these mounting costs, uncertainties, and long litigation timelines, the sheer number of "patents directed to obvious variants of an invention" often make even the easiest of legal challenges "prohibitively expensive."[15] The incentive to bring these cases is further reduced by the fact that, even after a successful challenge to "one or [] several of these patents," a generic manufacturer "do[es] not necessarily enter the market . . . [and] may simply face more patent roadblocks."[16]

The net result is delayed patient access to lower-cost generics and biosimilar medicines. Indeed, as shown in the chart below, time to entry is, unsurprisingly, directly tied to the number of asserted patents, and the United States lags behind other countries such as the United Kingdom and Canada in getting lower-cost medicines in the hands of patients:[17]

---

[10] *Humira Patent Fortress at Center Stage During Pharma Execs' D.C. Showdown*, Crains Chicago Business (Feb. 26, 2019), https://www.chicagobusiness.com/health-care/humira-patent-fortress-center-stage-during-pharma-execs-dc-showdown.

[11] Rebecca Robbins, *How a Drug Company Made $114 Billion by Gaming the U.S. Patent System*, N.Y. Times (Jan. 28, 2023), https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html.

[12] Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J.L. & Biosciences, 19 (Sept. 2022).

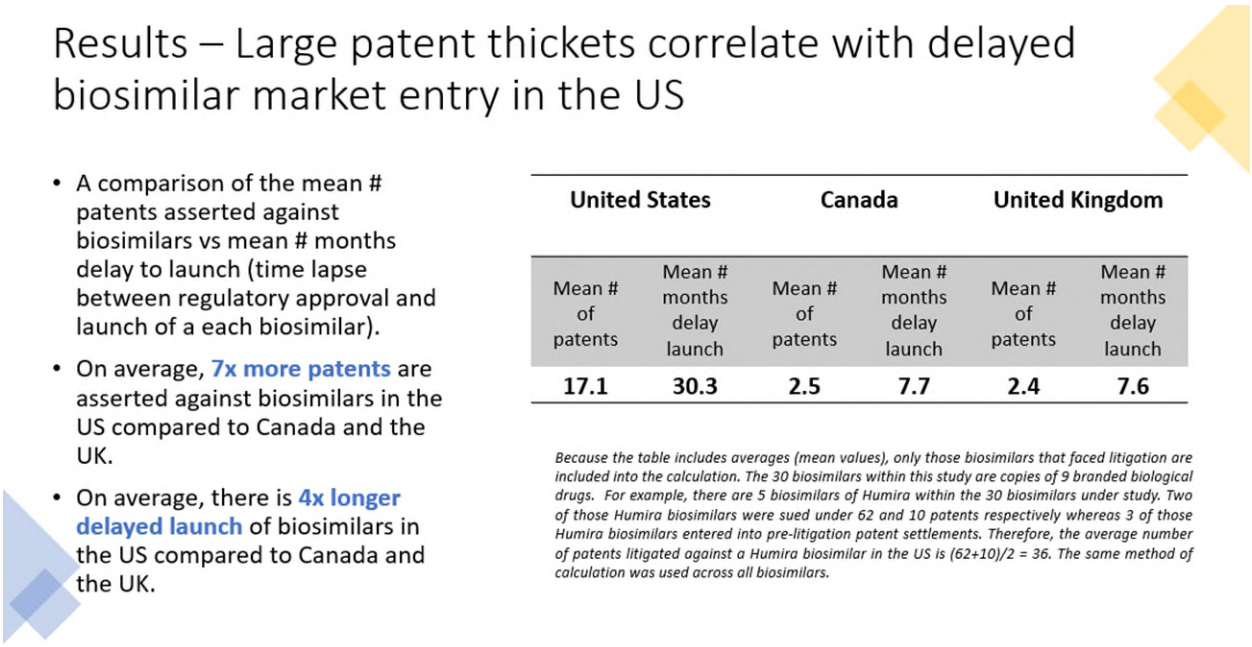
[13] Robbins, *supra* note 11; *see also* Dulan Lokuwithana, *Merck Leans on New Keytruda Formulation to Avoid Patent Cliff*, Seeking Alpha (Dec. 2, 2022), https://seekingalpha.com/news/3913649-merck-leans-on-new-keytruda-formulation-to-avoid-patent-cliff.

[14] Goode & Chao, *supra* note 12, at 19.

[15] 87 Fed. Reg. at 60131.

[16] Goode & Chao, *supra* note 12, at 3.

[17] Goode & Chao, *supra* note 12, at 3.



The time to entry in the United States for biosimilars is nearly 4 times that of Canada and the United Kingdom and the number of patents is nearly 8 times the number in these countries.

The data clearly show that the assertion of a large number of duplicative, overlapping patents results in delayed generic and biosimilar entry. Given the vast difference between the cost of applying for a patent and challenging that patent in court, we propose that the PTO address this issue on the front-end through better safeguards in the examination process and procedural tools that will stop this unwarranted proliferation of patents. Below, we detail these proposals in the specific recommendations section (part III), and then in the answers to the PTO's specific questions.

III. SPECIFIC RECOMMENDATIONS

A. The PTO Should Increase Examiner Time and Training

As an initial observation, today's proliferation of low-quality patents is unsurprising given the time-pressured conditions examiners work under. Examiners must complete numerous distinct tasks during the examination process, all of which must take place on average within a mere 19 hours.[18] These time constraints hinder examiners' ability to thoroughly vet each patent application—a complex process that requires them to identify and understand the relevant prior art, ensure that the claims are definite and unambiguous, and to confirm that those claims satisfy the statutory standards Congress has set. Examiners would also benefit from improved training, at the beginning of and during their tenure at the PTO. Experts have estimated that greater examination scrutiny would result in litigation savings.[19]

---

[18] Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 Vand. L. Rev. 975, 984 (2019).

[19] *See id.* at 994.

B. The PTO Should Modify its Count System

Patent quality issues are further exacerbated by the Office's fee system. The PTO earns more money for issuing a patent than it does for examining one, incentivizing the award of numerous overlapping patents.[20] We struggle to understand this fee structure given that the bulk of the costs to the system are derived from time spent on examination, not issuance. The PTO's "count" system is also responsible for patent quality issues, as its current design rewards productivity, not care.[21] By measuring rigid production goals in "counts," time-pressured examiners are well-aware of the fact that granting a "first-action allowance is the fastest way to receive . . . the full 2 counts" available per application.[22] Given that a first action grant represents the "biggest reward for the least amount of work," undertaking this less-rigorous review is an understandably enticing option for examiners whose performance and pay are contingent on amassing the highest possible number of "counts" to receive better performance reviews.[23]

In light of these disincentives, we would recommend that the PTO consider modifying the count system such that a final office action is equated with an allowance. In our view, this would help ensure that examiners are not incentivized to grant a quick allowance to obtain more counts and that the grounds for a rejection are fully and carefully vetted before issuing such an allowance.

C. The PTO Should Monitor the Development of Large Patent Estates

Finally, patent quality issues can be addressed through improved monitoring and public reporting of the development of large patent estates. The office should draw on additional resources to combat disproportionate patent estates. Reporting these patent estates to the public (e.g., by grant number, pre-grant publication number, or application number), also functions to put the public on notice of these abusive practices, allowing the public to take action (e.g., in the form of pre-grant proceedings, like filing protests and third party submissions, and in the form of post-grant proceedings like re-examinations, PGRs, and IPRs).

Our remaining comments relate to the Office's proposed initiatives in questions one, four, six, and seven, regarding consideration of an "applicant's submission of prior art," namely "on sale" evidence, "that is not accessible in the Patents End-to-End Search system," and regarding proposals to "limit or change . . . non-statutory double patenting practice to achieve the aims of fostering innovation, competition, and access to information through robust and reliable patents[.]"[24]

---

[20] Michael D. Frakes & Melissa F. Wasserman, *Decreasing the Patent Office's Incentive to Grant Invalid Patents*, Brookings Hamilton Project 8 (Dec. 2017).

[21] Eric Blatt & Lian Huang, *USPTO Incentive Policies Influence Patentability Decisions*, Law360 (July 23, 2018), https://www.law360.com/articles/1052622/uspto-incentive-policies-influence-patentability-decisions.

[22] Charles A.W. deGrazia et al., *Examination Incentives, Learning, and Patent Office Outcomes: The Use of Examiner's Amendments at the USPTO*, 50 Research Policy 1, 3 (Dec. 2021).

[23] Russ Krajec, *Why Patents in September Are a Bad Thing*, BlueIron (last visited Jan. 19, 2023), https://blueironip.com/why-patents-in-september-are-a-bad-thing/.

[24] 87 Fed. Reg. at 60133.

IV. ANSWERS TO SPECIFIC QUESTIONS

A. Terminal Disclaimers Should Be Considered Evidence of Obviousness Type Double Patenting (Questions 4, 6, and 7).

There is no more fundamental rule of patent law than that an inventor is entitled to only a single patent for an invention. That is because a single patent "endow[s] [its] holders with superpowers, but only for a limited time."[25] A central corollary to that rule is that a patentholder cannot obtain a patent claim on an obvious variant of an existing claim. The obviousness type double-patenting ("ODP") doctrine ensures that a patentee receives one period of exclusivity for an invention—a period that cannot be extended through subsequent claims covering obvious variations of the invention. The limits imposed by the ODP doctrine are important not only to the general health of the patent system, but they are critical as applied to drug patents. Nonetheless, when an examiner rejects a patent owner's claims under the ODP doctrine, the applicant may "revive" and receive protection for their previously-rejected claims by filing a terminal disclaimer.[26]

Unfortunately, terminal disclaimers have permitted industry patentholders to engage in gamesmanship that has kept low-cost generics and biosimilars out of the market. Pharmaceutical companies have abused the system to obtain later patents that claim small, incremental changes that are neither genuinely innovative nor beneficial to patients. Yet these non-innovative and oftentimes duplicative patents are effective at their primary goal: delaying generic competition and extending patent-supported monopolies on brand-name drugs beyond the maximum statutory limits.

As shown in the table below, the Humira patent estate discussed above is dominated by duplicative patent families, which is entirely permissible under current PTO rules. All of these patents must be separately challenged by biosimilar manufacturers:[27]

---

[25] *Kimble v. Marvel Ent., LLC.*, 576 U.S. 446, 451 (2015).

[26] 87 Fed. Reg. at 60131.

[27] Goode & Chao, *supra* note 12, at 4, 10–11.

Case study: the Humira patent thicket (USA)

- The Humira patent thicket contains 73 granted US patents that are directed to the product, formulation or method of treatments (the core thicket).
- The 73 US patents (core Humira thicket) are derived from only 8 patent families. Within each patent family, many patents are linked by terminal disclaimers and so are not patentably distinct.
- 59 of the Humira patents are non-patentably distinct from other members. **80% of the US Humira patents are duplicative.**

Core Humira Patent Thicket (USA)

	Patented subject matter and earliest granted family member	Number of granted US patents within each family	Number of granted US linked by terminal disclaimers within each family (non-patentably distinct)	% of Humira patents within each family that are non-patentably distinct
Humira patent family 1	Basic product patent US6090382	10	10	100%
Humira patent family 2	Primary indications US8889135	7	4	57%
Humira patent family 3	Formulation (single concentration) US8216583	21	21	100%
Humira patent family 4	Secondary indications US8889136	18	15	83%
Humira patent family 5	Purity level US8916153	8	8	100%
Humira patent family 6	Treatment of hidradenitis suppurativa US8747854	2	2	100%
Humira patent family 7	Treatment of juvenile diseases US8999337	3	3	100%
Humira patent family 8	Formulation (double concentration) US8420081	4	4	100%

The originator of Humira, Abbvie, also owns various platform (drug agnostic) manufacturing patents, not shown above

As shown above, two separate patent families in the Humira® patent estate comprise 36 separate patents linked by terminal disclaimers. Again, this is a numbers game. Biosimilar developers must go 36-for-36 in challenging these patents despite their overlapping nature. Yet AbbVie needs to prevail only on a single claim in a single one of those patents to enjoin the biosimilar manufacturer until patent expiration.

The system has fallen out of balance, and the phenomenon of multiple patenting is largely to blame. To address this problem and restore necessary balance to the patent system, we believe that terminal disclaimers should constitute strong evidence of obviousness-type double patenting. The Federal Circuit already recognized the value of this position in *SimpleAir, Inc. v. Google LLC*. *SimpleAir* began by explaining that an "applicant waives potentially valuable rights," when filing a terminal disclaimer.[28] Namely, "the right to alienate their patents, and in certain cases years of exclusivity."[29] The Federal Circuit specifically noted that terminal disclaimers are "typically file[d] . . . to overcome obviousness-type double patenting rejections," and held that "a terminal disclaimer is a strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the parent."[30]

Treating terminal disclaimers as strong evidence of ODP will level the playing field of a system that is currently stacked against generic and biosimilar competition. Brand-name pharmaceutical companies have options when faced with an ODP rejection during prosecution—they can choose to fight the rejection on the merits if they believe that the rejected claims are patentably distinct, or they can avoid that dispute and file a terminal disclaimer. The proposals outlined in questions

[28] *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1168 (Fed. Cir. 2018).

[29] *Id.*

[30] *Id.*

4 and 7 would merely attach consequences to an applicant's voluntary decision to choose the latter option. If the brand-name company strongly believed that the claims in a given patent were, in fact, patentably distinct, it could continue to challenge the PTO's ODP rejection.

B. The PTO Should Not Consider Additional On-Sale Bar Evidence as Part of Patent Prosecution (Question 1).

The on-sale bar prohibits applicants from obtaining a patent if "the claimed invention was . . . on sale . . . before the effective filing date of the claimed invention."[31] This assessment depends on a two-part inquiry: the first step asks whether the product was the subject of a commercial offer for sale, and the second focuses on whether the invention was ready for patenting.[32]

The question of the on-sale bar's applicability is one "of law based on underlying factual findings."[33] Consistent with that principle, the Federal Circuit has held that in determining whether an offer for a sale exists, the question must be "'analyzed under the law of contracts'" and "must focus on those activities that would be understood to be commercial sales and offers for sale 'in the commercial community.'"[34]

Encouraging examiners to consider on-sale evidence during the examination process would not, in our view, move lower-cost medicines into the hands of patients more quickly. As explained above, assessing the applicability of the on-sale bar is a fact-intensive, contract-based inquiry that the system is not equipped to handle. In its current form, the patent examination process is one-sided and very limited in its scope. PTO procedures provide no meaningful opportunity for third-party participation, and even more troubling, no opportunity for examiners to hear from relevant witnesses or to assess their credibility. Also lacking is the ability for those witnesses to be cross-examined. Nor is the patent prosecution system designed to handle the examination of confidential contracts and other sensitive business documents that are part-and-parcel of the on-sale inquiry. The task of sifting through these facts is one best left to adversarial proceedings in district court.

We similarly struggle to see how examiners—who receive no specific training on the common law of contracts or the Uniform Commercial Code—will be able to successfully interpret complex questions of contract law and apply those doctrines to complicated findings of fact. Encouraging examiners to consider on-sale evidence during the examination process will likely result in poor outcomes. If examiners are forced to undertake additional factual and legal duties during an examination process that is already pressed for time, these additional duties might detract from examiners' ability to properly assess a patent's validity, perversely leading to the issuance of a greater number of improper, yet presumptively valid patents.

V. CONCLUSION

---

[31] 35 U.S.C. § 102(a)(1).

[32] *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998).

[33] *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1371 (Fed. Cir. 2016) (en banc) (citing *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1045–46 (Fed. Cir. 2001)).

[34] *Medicines Co.*, 827 F.3d at 1373.

AAM thanks the Office for its efforts to address the quality issues currently facing our patent system. The suggestions outlined above represent meaningful steps that the Office can take to improve the quality of future patents and to combat existing, low-quality patents that burden patients' timely access to life-saving generic and biosimilar medicines.