Your Generics & Biosimilars Industry

Association for Accessible Medicines Statement
Senate Judiciary Committee Hearing on "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition."
May 7, 2019

Chairman Graham, Ranking Member Feinstein, and members of the Committee:

Thank you for holding this important hearing and for the opportunity to submit this written statement on behalf of the Association for Accessible Medicines ("AAM"). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Our members provide more than 36,700 jobs at nearly 150 facilities and manufacture more than 61 billion doses in the United States every year. AAM's core mission is to improve lives by advancing timely access to affordable generic and biosimilar medications.

Over the years, AAM has worked extensively with this Committee to ensure that the patent system strikes the appropriate balance. We are especially grateful for this Committee's work on addressing anticompetitive gaming of the regulatory system and in advancing the bipartisan Creating and Restoring Equal Access to Equivalent Samples CREATES Act (S. 340) out of committee last year. Under the leadership of Senators Leahy, Grassley, Lee, and Klobuchar, the CREATES Act is now supported by more than 90 organizations and would reduce federal spending on prescription drugs—including for seniors with Medicare coverage—by $3.9 billion, according to the Congressional Budget Office.

Importantly, AAM and our member companies support a patent system that rewards true innovation ***and*** serves the public interest by allowing true inventions to be patented for a single, limited time. After that time expires, the door should be opened to free competition—competition that naturally leads to lower prescription drug prices.

We are pleased that the Committee is holding this hearing. The current patent system has fallen out of balance, and the cost is ultimately being borne by patients, taxpayers, health plans, and everyone who pays for medicine. Take the biologic medicine Humira®, for example. It has become a more lucrative franchise than ***the entire National Football League***.[1] The high price of this much-in-

[1] Anna Rose Welch, *AbbVie's Humira Can Tackle the NFL – But Can It Handle Biosimilars*, *available at* https://www.outsourcedpharma.com/doc/abbvie-s-humira-can-tackle-the-nfl-but-can-it-handle-biosimilars-0001.

demand medicine is a direct function of the U.S. patent system, which has allowed AbbVie to obtain approximately 136 patents and more than 30 years of market exclusivity on Humira®—far more than the exclusivity period contemplated by Congress.[2] As AbbVie has itself admitted, its 136-patent estate on Humira® is "designed to make it more difficult for . . . biosimilar[s]."[3] The intent is to accumulate patents—not because they are innovative—but rather to increase the litigation and development costs for potential would-be generic and biosimilar competitors.

Something must change. In this submission, we propose five areas for reform:

- strengthening *inter partes* review to weed out bad patents faster and more efficiently;
- improving the process of patent examination so that fewer bad patents are issued;
- maintaining high standards for patent eligibility;
- preserving procompetitive patent settlements; and
- improving the rules governing biologic medicines to provide a date certain for biosimilar entry.

I. Strengthening *Inter Partes* Review

This Committee has pride of authorship over one of the most important mechanisms for ensuring patent quality: *inter partes* review (IPR) and the other post-grant review procedures that allow the Patent Office to reconsider the mistaken grant of patents that never should have issued. As a strong majority of the Supreme Court held in upholding the committee's work, IPR "protects 'the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope.'"[4]

The examination process is not by itself sufficient to serve that "paramount" public interest. The process is one-sided and limited, and provides no meaningful opportunity for interested third parties to participate. Significantly, the examiner must accomplish a number of distinct tasks during the examination process—all of which must be completed in a mere ***19 hours***.[5] In particular, the

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[2] *Humira Patent Fortress at Center Stage During Pharma Execs' D.C. Showdown*, *available at* https://www.chicagobusiness.com/ health-care/humira-patent-fortress-center-stage-during-pharma-execs-dc-showdown.

[3] Statement of William Chase, AbbVie 6.11.2014 Goldman Sachs Healthcare Conference Transcript.

[4] *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) (citation omitted).

examiner must consider whether the claimed invention satisfies all of the provisions that Congress has included into the Patent Act, including whether the claimed invention is new and not obvious. Novelty and non-obviousness are measured against the prior art—but much of the prior art that comes before the examiner is submitted by the applicant. And the examiner's ability to search for additional prior art—much less to apply its teachings to the application—is highly constrained. That dearth of information is magnified by the Patent Office's "count" system—a system set up to reward productivity, not care.[6]

Litigation in federal district court is not an adequate forum by itself to weed out invalid patents. District court cases are slow-moving and costly. The parties generally litigate infringement as well as the invalidity of the patents. That means months or even years of fact and expert discovery. Significantly, the District of Delaware and the District of the New Jersey—two of the most popular forums for Hatch-Waxman litigation—have a median time to trial of 731 and 795 days, respectively.[7]

That is why Congress adopted legislation allowing the Patent Office to fix its own mistakes with the benefit of more time and more information. IPR allows interested parties to supply the Patent Office with important pieces of prior art that the examiner may have missed during examination. It allows invalidity issues to go before experts from within the Patent Office, rather than lay jurors or generalist federal trial judges. It also allows certain grounds of invalidity to be tested in a speedy, time-limited, and streamlined proceeding without the distraction of other issues such as infringement. And it allows a patent owner's arguments to be tested through cross-examination and the submissions of opposing experts in a way that examination does not allow.

Unfortunately, the careful and comprehensive IPR system that this Committee created has been substantially diluted since its establishment. For the generic industry, studies report a lower success rate for generics at the PTAB compared to district courts—a particularly jarring statistic given that the PTAB is applying a lower standard of proof than district courts.[8] According to Bloomberg, Orange Book patents are upheld about 77% of the time at the PTAB.[9]

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[5] Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat'l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), http://www.nber.org/papers/w20337.pdf.

[6] Eric Blatt & Lian Huang, *USPTO Incentive Policies Influence Patentability Decisions*, *available at* https://www.law360.com/articles/1052622/uspto-incentive-policies-influence-patentability-decisions.

[7] *Pharmaceutical Patent Litigation Increases Nearly 30 Percent in 2017: Lex Machina Releases Fourth Hatch-Waxman/ANDA Litigation Report*, available at https://lexmachina.com/media/press/lex-machina-releases-fourth-hatch-waxman-anda-litigation-report/.

[8] Scott McKeown, Filko Prugo, and Jon Tanaka, *Insight: Orange, Purple Book Patentees Hone PTAB Survival Skills*, Bloomberg Law, 2 (Jun. 13, 2018).

[9] *Id.*

Rather than addressing this downward trend, the Patent Office has been actively revising the IPR system in a way that compounds the problem. Most notably, Director Iancu recently abolished the longstanding practice of interpreting a patent the same way in IPR as in examination.[10] Under that longstanding practice (known as giving patent language its "broadest reasonable interpretation"), a patent should not survive IPR if it should not have survived examination. Applying the same standards in IPR and examination makes sense, as the Supreme Court concluded, especially given that claims can be amended in IPR just as they can in examination—but unlike litigation.[11] The recent change instead interprets a patent more narrowly, as a court would in litigation. In other words, some patents that should not have survived examination *will* survive IPR. And even though the art submitted to the PTAB would have caused the examiner to reject the patent, the patent will survive.

The Federal Circuit has also struggled with the implementation of IPR. For example, the full Federal Circuit was unable to reach a majority decision on an important question of procedure for amending a claim during an IPR—who bears the burden of proving that a substitute claim is or is not patentable.[12]

The Committee should preserve and strengthen IPR and resist changes that would weaken it. *First*, it should make clear in the statute that a patent should be interpreted in IPR the same way that it would be interpreted in examination. *Second*, it should resolve the question that splintered the Federal Circuit and make clear that because amended claims in IPR do not get examined by the Patent Office, a patent owner must affirmatively prove that they are patentable. *Third*, it should make clear that the statutory provisions restricting the Patent Office from instituting duplicative IPRs are sufficient—the Patent Office should not exercise its discretion to create ***new*** limitations on instituting an IPR.

II. Improving Examination

Improving IPR is important, because it provides an immediate way to address the consequences of inadequate patent examination. The Committee should also address the examination problem directly. That would produce long-term benefits for every stakeholder in the patent system.

As detailed above, patent examiners do not have enough time to devote to each patent application—to learning the prior art, to ensuring that the claim language is definite and unambiguous, and to rejecting any claim that does not satisfy the standards Congress has set. And relying solely

[10] 83 Fed. Reg. 51340.

[11] *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016).

[12] *Aqua Products, Inc. v. Matal*, 872 F. 3d 1290 (Fed. Cir. 2017) (*en banc*).

on the patent applicant to bring forward prior art creates further problems.

The consequences are tangible: branded pharmaceutical companies file application after application with the Patent Office because the odds are good that each one will eventually be granted. And by using so-called "continuation applications," companies can take shot after shot at getting more and more claims from the same original application. For example, 89% of the total U.S. patent applications on Humira® were filed *after* the product was first approved.[13]

Contrast that with the experience in Europe. According to the Initiative for Medicines, Access and Knowledge (I-MAK), AbbVie filed 247 patent applications in the United States but only 76 in Europe and 63 in Japan. As a result, Humira is now off patent in Europe, and the patent applications that could have gotten AbbVie a longer monopoly were refused or withdrawn (or the patents successfully challenged).[14]

We propose three concrete steps that the Committee could take to improve examination on the front-end so that there is less need for IPR and similar challenges at the back-end.

First, we want examiners to have the best possible information. When a product has already come to market, there is no excuse for a patentee not to disclose everything "available to the public" about that product to the Patent Office. For too long, patent owners have gotten away with claiming that ***their own labeling*** was not part of the prior art—even for patent applications that they filed after the product hit the market.[15] And as a backstop, third parties should be able to provide information directly to patent examiners and see that information meaningfully considered during prosecution.

Second, the experience with Humira® shows that the phenomenon of multiple patenting must be brought under control. The Patent Office and the courts currently will allow many patents and sequential term extensions on the same invention so long as the second patent is not an "obvious" variant of the first. The standard for proving obviousness is the same one used in challenges to an issued patent—whether any person of ordinary skill in the art would have thought the second patent obvious in light of the first. That is too high a standard when the ***patent owner*** intends to claim the second variant all along, but strategically holds it back in an attempt to claim a longer patent term. Especially when a patent is not the second but the fifty-second, or the 132nd, covering the same product, the Patent Office should impose a more rigorous standard for claims that could and should have been included in an earlier application. We recognize that sometimes the Patent Office will

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[13] I-MAK, *Overpatented, Overpriced: Special Humira Edition*, at 5, http://www.i-mak.org/wp-content/uploads/2018/09/i-mak.humira.report.final_.0917.pdf.

[14] *Id.*

[15] *See, e.g.*, *Celltrion, Inc. v. Biogen, Inc.*, No. IPR2016–01614, 2018 WL 1037223, at *6 (PTAB Feb. 21, 2018).

direct an applicant to divide its application in two and proceed on them separately. But where the multiplicity results from the applicant's choice and not the Patent Office's, there should be a limit.

Finally, Congress should use its control over user fees to reorder the incentives. Currently, the Patent Office takes in more money when it issues a patent than when it examines a patent.[16] But the cost to the system comes from examination, not issuance. Filing a blizzard of applications should come at a cost. And under no circumstances should the Patent Office face a financial incentive—even a subliminal one—to issue patent applications rather than reject them. That decision must be made on the merits.

III. Patentability Criteria

As the Supreme Court has recently confirmed, Congress sets the criteria for issuance of a patent. The Patent Office does not. And rightly, Congress has never given the Patent Office the legislative authority that it would need to change those criteria through rulemaking.[17]

We are concerned that the Patent Office is using the informal guidance it issues to the examiner corps as a way of trying to assume a broader role—deciding not what the criteria for patent eligibility *are*, but what they *should be*. That is properly for Congress, including this Committee. For example, Senators Tillis and Coons have held several stakeholder roundtables on the issue of patent eligible subject matter under Section 101. We think the Committee should continue those efforts, and that the Patent Office should not try to get out in front of these legislative efforts. The Patent Office's focus should be on faithfully applying patent eligibility as it currently stands.

Whatever issues may have arisen in applying Section 101, they do not call into question the basic point of Section 101's limitation on eligible subject-matter. As the Supreme Court has emphasized, allowing patents on "the basic tools of scientific and technological work" would stand in the way of future innovation using those basic tools.[18] A person who uncovers a fundamental truth about the natural world is not, in the constitutional sense, an "inventor" who is entitled to patent a discovery and prevent others from exploiting it for up to twenty years.

Fundamental truths should remain free for any innovator to apply, and the patent system properly focuses on protecting innovations *applying* those fundamental truths. That is just as true in the life sciences—if not more so. If scientific principles like $E=mc^2$ are to remain ineligible for patent

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

[17] *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 628 (2019) (rejecting the PTO's interpretation of the on-sale bar in 35 U.S.C. § 102).

[18] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (citations omitted).

protection, the same should be true of similar principles in the life sciences, such as the existence of a particular gene, a particular species, or a particular combination of naturally occurring species.

Advocates for more and longer patents often claim that current law is too restrictive and prevents them from getting patents on genuine innovations. The evidence shows that is not true. If anything, lower courts have erred on the side of *upholding* patents in the face of strong Section 101 challenges. As of today, we are not aware of any method-of-treatment claims that were finally invalidated in court after appeals were exhausted. The Supreme Court held that the type of patent that will be invalidated under Section 101 is different from "a typical patent on a new drug or a new way of using an existing drug."[19] And in multiple cases over the last year, the Federal Circuit has specifically held that methods for treating disease by administering a drug were patent-eligible even where they incorporated diagnostic steps relying on (for example) genetic information.[20] Although we disagree with the application of the law to the facts in those cases, the results do not warrant any sea change in the law. Meaningful patent eligibility standards, such as those under Section 101, must be maintained if we are to avoid even higher drug prices due to abuses of the patent system by some brand-name drug companies.

IV. Procompetitive Settlement Agreements

We urge the Committee to focus its attention on the areas where the patent system has gotten out of balance and undermined competition. Some proposals that have been introduced in Congress, by contrast, are concerning because they would actually serve to ***reduce*** opportunities for competition in this critical area.

As the Committee is well aware, generic pharmaceuticals come to market only after the brand-name drug company has an opportunity to litigate any remaining patents it may have. And under the Hatch-Waxman Amendments, if the brand-name drug company wins, the generic will be kept off the market until after the last patent expires.[21] A generic that litigates all the way through trial and appeal, only to end up with that outcome, is actually in a worse position than if it had never challenged the patent in the first place—because of uncertainty about the outcome and the possible launch date, it has sunk money into both litigation and launch preparations.

In the vast majority of cases and particularly since the Supreme Court's decision in *FTC v. Actavis*, settlement of Hatch-Waxman litigation enables competition and benefits the public in a very tangible way: it can allow the public access to more affordable generic alternatives considerably

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[19] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 566 U.S. 66, 87 (2012).

[20] *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018), *petition for cert. pending*, No. 18-817; *Endo Pharms Inc. v. Teva Pharms. USA, Inc.*, __ F.3d __, 2019 WL 1387988 (Fed. Cir. Mar. 28, 2019).

[21] 35 U.S.C. § 271(e)(4)(A).

sooner than the patents would otherwise allow. At least one analysis has found that patent settlements lead to generic entry, on average, ***81 months*** before patent expiry.[22] This option is becoming all the more important as branded companies amass larger and larger patent portfolios on each product: if ***every*** patent had to be litigated all the way to final judgment—with no possibility of settlement—that would create a barrier to entry and deter generic manufacturers from even trying to launch a competing product before the patent expires.

Recent legislative proposals substantially threaten these pro-consumer settlements.[23] The Supreme Court's 2013 decision in *FTC v. Actavis* significantly changed the landscape for how patent settlement litigation is resolved. Settlement agreements with "large, unjustified reverse payments" were determined to be potentially anticompetitive when combined with a market entry date well-beyond patent expiry. AAM supports the Supreme Court's decision. But the current legislative proposals are not targeted at just pay-for-delay; many pro-competitive patent settlements between brands and generic companies would potentially be impacted. By deeming virtually all settlements presumptively anticompetitive, those proposals—if enacted—would severely chill the ability of generic and biosimilar manufacturers to obtain a settlement and disincentivize their ability to challenge patents in the first place. The legislative proposals go well beyond the Supreme Court's opinion that "traditional settlement considerations, such as avoided litigation costs," do not pose the same risks as a pay-for-delay payment.[24]

As the FTC has itself conceded, "the number of settlements potentially involving "pay for delay" decreased significantly in the wake of the *Actavis* decision." And FTC's own data confirm as much—potential "pay-for-delay" deals dropped from 33 immediately prior to *Actavis* to 5 in 2015 to, reportedly, just one in 2016.[25]

In other words, the vast majority, if not all, patent litigation settlements that occur today benefit consumers. They ensure early generic and biosimilar competition before the patents have all expired. And they provide manufacturers with certainty about their entry date, which allows manufacturers to fulfill the promise of early entry ***on*** that date. As the Committee takes action on the topic of today's hearing—"Balancing Innovation and Competition"—it should not ***undermine*** one of the ways in which our current system enables generic drug and biosimilar competition to expensive brand-name drugs.

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[22] Patent Docs, *IMS Study Shows Pro-Competitive Effects of Reverse Payment Settlement Agreements in ANDA Litigation*, July 2013.

[23] S. 64; H.R. 1499; H.R. 2375.

[24] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013).

[25] FTC, *Overview of Agreements Filed in FY2015*, *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/ overview_of_fy_2015_mma_agreements_0.pdf.

V. Ensuring a Date Certain for Biosimilar Competition

The high cost of pharmaceuticals is an immediate problem, and we are certain the Committee is focused on current solutions. As noted above, AbbVie has managed to build an enormous patent thicket around Humira®. We urge the Committee to consider longer-term solutions as well, especially in the area of biologic medicines, where patent thickets are creating an extraordinary obstacle to biosimilar competition.

One option to consider would be to provide biosimilar applicants with a date certain for market entry. During consideration of the BPCIA, Eli Lilly expressly proposed this concept: if regulatory exclusivity were granted for a long enough period, Lilly would be willing to give up its ability to use its patents to keep biosimilars off the market longer.[26] Yet in the final BPCIA, brand manufacturers got 12 years of exclusivity—almost as long as the 14 years Lilly proposed, and much longer than any other form of exclusivity on the books—but gave up ***none*** of their ability to stave off competition through patents.

AAM recognizes the value of true innovation and wants to see the owners of properly issued patents receive compensation for the use of their invention. But in the context of today's patent thickets, each patent potentially becomes a weapon far out of proportion to the innovation it embodies. Each patent can be used to keep biosimilar competition off the market, either through a court order enforcing the patent through an injunction or by a company-crippling award of lost profits for the entire biologic franchise. The patent laws do not have to give such disproportionate power to incremental advancements in knowledge—say, to the 132nd patent in the thicket covering a single product, even assuming the other 131 are valid.

After a suitable monopoly period, Congress could choose to refocus any remaining patents on providing compensation to the inventor, perhaps through royalties, rather than block competition. Working out the details of such a system would involve work and discussion by both the Committee and stakeholders. But if the Committee wants to have a lasting impact on the high prices that the current patent environment makes possible, it is time to begin such a discussion.

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Thank you again for the opportunity to provide AAM's views. We would be happy to answer any questions about the issues covered in this statement or the hearing.

[26] John Wilkerson, *Lilly Proposed Forfeiting Biologics Patents if Exclusivity Sufficient*, Inside Health Pol'y (Dec. 4, 2008).