Public Interest
Patent Law Institute

December 19, 2022

The Honorable Patrick Leahy
Chair, Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable Thom Tillis
Ranking Member, Subcommittee on Intellectual Property
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

RE: Duty of Candor Enforceability in Patent Applications

Dear Chairman Leahy, Ranking Member Tillis, and Director Vidal:

I write regarding your recent correspondence about patent applicants' obligations of disclosure and candor to the United States Patent and Trademark Office (USPTO or Office).

The Public Interest Patent Law Institute (PIPLI) is a non-profit organization dedicated to ensuring the patent system promotes innovation and access for all. Millions of Americans depend on patented technology to earn a living, get an education, and access medical care, but do not acquire, own, or assert patents. Because they do not actively participate in the patent system, their needs are often inadequately represented. This lack of representation makes it difficult for the patent system to promote innovation and access effectively and equitably. PIPLI's mission is to enhance representation of the public's interest so that the patent system can promote scientific advancement, economic growth, and a higher standard of living for all Americans.

Thank you for recognizing the importance of applicants' compliance with their obligations of disclosure and candor to patent quality, technological innovation, and public health. These obligations require patent applicants to disclose all information material to patentability to the USPTO in patent prosecution or review proceedings, and to do so with both candor and good faith, as the Director and USPTO's Federal Register Notice have emphasized.[1]

[1] *Director's Blog: the latest from USPTO leadership*, USPTO (July 28, 2022), https://www.uspto.gov/blog/director/entry/duty-of-disclosure-and-duty; Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45764 (July 29, 2022), https://www.federalregister.gov/documents/2022/07/29/2022-16299/duties-of-disclosure-and-reasonable-inquiry-during-examination-reexamination-and-reissue-and-for.

Unfortunately, as the Senators have pointed out,[2] patent applicants, in certain circumstances, violate these obligations, including by submitting conflicting information to the USPTO and other federal agencies, particularly the United States Food and Drug Administration (FDA). While the USPTO's recent efforts to remind applicants of their duties is commendable, we agree with the Senators that steps must be taken to reduce the extent, frequency, and harmful effects of false or conflicting submissions.

We write to express our support for action on this issue, to underscore the ways in which the conduct of the sort you identified in your letter contributes to the inflated prices of drugs in the United States, and to offer proposals for consideration as Congress, the USPTO, and federal agencies consider a path forward on this important issue.

BACKGROUND

1. The Duty of Candor

As noted in your correspondence, patent applicants have a duty of candor when submitting applications to the PTO.[3] This means that applicants have a legal (and ethical) obligation to include only truthful information in their applications and to update that information if subsequent developments undermine its truthfulness.

But there are no oversight or enforcement mechanisms to ensure that applicants respect this duty. Indeed, the regulation setting forth the duty of candor explicitly says patent examiners cannot investigate potential violations of the duty of candor or reject patent applications based on such violations: "Because of the lack of tools in the Office . . . , the examiner does not investigate and reject original or reissue applications under 37 CFR 1.56."[4] Because examiners do not investigate or address duty of candor violations, they cannot prevent patents from issuing based on false submissions, or deter applicants from making them. Nor is there any other mechanism or process through which the USPTO investigates potential violations of candor or holds applicants accountable for them.[5]

2. Consequences of Violating the Duty of Candor

Duty of candor violations must not be taken lightly given the gravity of the harm they cause. When a patent unduly confers or extends an applicant's exclusive rights over pharmaceutical treatments, no competition is possible, as generic providers are barred from entering the market.

The lack of competition with generic manufacturers allows brand-name providers to inflate and maintain inflated drug prices. Studies show that generic competition reduces drug prices by 80%

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[2] Letter from Senators Leahy and Tillis to Andrew Hirshfeld (Sept. 29, 2021), https://www.leahy.senate.gov/imo/media/doc/20210909%20Letter%20to%20PTO%20on%20FDA%20submissions.pdf.

[3] *See* 37 C.F.R. § 1.56(a).

[4] *Id.*; *see also* Manual of Patent Examining Procedure (M.P.E.P.) § 2010 (prohibiting examiners from commenting on duty of disclosure issues except to say: "such issues are not considered by the examiner during examination of patent applications").

[5] The USPTO has mechanisms for disciplinary action against patent agents and attorneys, but not applicants.

on average.[6] Patents that prevent or delay the marketing of generic products force individual Americans and the U.S. government (through Medicare and Medicaid) to pay billions of dollars more than our international counterparts for the same medical treatments.[7]

While monopoly pricing may be appropriate to ensure the costs of inventing novel treatments are recoverable, monopoly pricing is inimical to the patent system when applied to trivial or obvious variations of existing treatments. Without a new and non-obvious invention, there is no scientific advancement to reward.

3. Incentives for Violating the Duty of Candor

Because monopoly prices are so profitable, drug companies face powerful incentives to extend their ability to impose them. To extend their ability to charge monopoly prices beyond the twenty-year patent term, pharmaceutical companies often apply for patents on trivial variations of patented drugs. These secondary pharmaceutical patents allow companies to charge monopoly prices for new drug products incorporating these trivial variations rather than compete with generic manufacturers.

One example of a false submission to the USPTO extending a drug monopoly beyond the original patent term was the basis for a recent lawsuit under the False Claims Act.[8] That case, *Silbersher v. Allergan*, involves a patent claiming a particular (extended) dosage of a drug for dementia, Namenda, whose active ingredient was the subject of an earlier patent.[9] The patent applicant, Adamas, emphatically claimed to the USPTO that the efficacy and safety of the dosage were unexpected results—and therefore worthy of a patent. But those claims contradicted its own clinical tests, which demonstrated both the efficacy and safety of the same dose years earlier. The USPTO did not know about this contradiction because Adamas submitted declarations (mis)characterizing its earlier test results instead of the actual test data.[10] These declarations convinced the USPTO to abandon its initial rejection and grant the patent. That patent entitled Allergan (which commercialized the drug) to delay generic competition and charge inflated prices for 10 years after its patent on the original version of Namenda expired.

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[6] Robin Feldman, *May Your Drug Price Be Evergreen*, J. Of L. And The Biosciences, 590, 601 (2018).
[7] *See, e.g.,* Kathleen Doheny, *U.S. Drug Prices Much Higher Than in Other Nations*, WEB MD (Jan. 29, 2021), https://www.webmd.com/health-insurance/news/20210129/us-drug-prices-much-higher-than-in-other-nations ("Prescription drug prices in the U.S. are more than *250% times higher* overall than those in 32 other countries") (emphasis added); STAFF OF H.R. WAYS AND MEANS COMM., *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices* (Sep. 2019), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf ("Americans pay on average nearly *four times more* for drugs than other countries – in some cases, 67 times more for the same drug") (emphasis added). *See generally, Overpatented, Overpriced: Curbing Patent Abuse: Tackling the Root of the Drug Pricing Crisis*, I-MAK (Sep. 2022), https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf.
[8] *See infra* at page 6, § 3.
[9] *Silbersher v. Allergan Inc.,* 506 F. Supp. 3d 780 (N.D. Cal. 2020; *See also* Alex Moss, *PIPLI to Ninth Circuit: Hold Companies Accountable when their Fraud Leads to Invalid Patents that Harm the Public*, PUBLIC INTEREST PATENT LAW INSTITUTE (Sep. 9, 2019), https://www.piplius.org/news/pipli-to-ninth-circuit-dont-let-patent-owners-get-away-with-fraud-5xKjv (Containing a link to the full amicus brief submitted by PIPLI in connection with *Allergan*).
[10] In an earlier patent application, Adamas had submitted the actual test data; that application was rejected.

4. Contradictory Representations to the USPTO and FDA

There are particularly strong incentives for companies to make contradictory representations to the USPTO and FDA. To obtain a patent, a company must tell the USPTO that the drug qualifies as a novel and non-obvious invention. To obtain permission to market a new drug without new rounds of clinical testing, companies must tell the FDA the drug is sufficiently similar to an approved drug already on the market. The USPTO's requirement of novelty and the FDA's requirement of similarity are difficult and, in certain circumstances, impossible to reconcile. The same is true of representations companies make to the two agencies regarding the same drug product.

Unfortunately, conflicting submissions often go unnoticed. In most cases, the FDA and USPTO do not know that they are both considering statements about the same product from the same company. This lack of knowledge, combined with the absence of oversight, means pharmaceutical companies have practically nothing to lose from using false submissions to patent minor variations of existing drugs—and billions of dollars to gain.

One example of a patent obtained through fraud of this kind is Belcher Pharmaceuticals' patent on an injectable liquid formulation of epinephrine with a pH (a measure of acidity) within a particular range. The USPTO initially rejected the application as obvious, but Belcher overcame that rejection by arguing the pH range was a critical part of the invention that unexpectedly increased the formulation's efficacy. However, in its application for FDA approval, Belcher argued that the same epinephrine formulation was the result of such an old and well-known process that additional safety and efficacy tests were unnecessary. These facts were not revealed until Belcher sued Hospira to prevent it from marketing a competing product.[11] After four years of litigation, the patent was ultimately invalidated due to Belcher's inequitable conduct, but that finding did not disturb Belcher's years of ill-gotten gains.

5. Benefits of Greater Compliance with the Duty of Candor

The American public and our government have a powerful interest in ensuring patent applicants comply with their duty of candor. Increasing compliance will prevent pharmaceutical companies from obtaining patents on old or obvious variations of existing drugs that unduly provide or extend patent monopolies that block generic competition, increase drug prices, and impede access to medicine. But compliance will increase only if mechanisms are put in place to identify, punish, and deter duty of candor violations.

PROPOSALS

Described below are proposed mechanisms for (1) encouraging applicants to comply with their duty of candor, (2) identifying duty of candor violations during patent examination, and (3) addressing violations after patent issuance. These mechanisms can be implemented without new legislation or regulations. Together, they would contribute substantially to improved patent quality, reduced health care costs, and more equitable access to medical care.

[11] *Belcher Pharm., LLC v. Hospira, Inc*., 11 F.4th 1345 (Fed. Cir. 2021).

1. Prior to Submission of Patent Applications: Clarify Requirements.

Clarifying the requirements for compliance with the duty of candor will help applicants acting in good faith to comply, thus preventing inadvertent violations, while also making it easier to identify violations so that action may be taken.[12]

As the Senators' letter suggests, one way to provide clarity would be to state explicitly that applicants must disclose to the USPTO all statements and representations they have made, particularly to other agencies, relating to inventions claimed in their patent applications. Because conflicting statements are frequently made regarding the significance of clinical or laboratory tests, applicants could be directed specifically to disclose to the USPTO all statements made to other government agencies (e.g., state and federal) or in other public settings (e.g., in printed publications and conference presentations) about any tests referenced in a patent application.

These specific disclosure requirements can be added, for example, to the Manual of Patent Examining Procedure (MPEP) along with specific examples of violative behavior, such as those discussed above.

2. During Patent Examination: Requests for Information Pursuant to 37 CFR § 1.105.

Existing regulations allow patent examiners to request further information from applicants during the patent investigation process.[13] Such requests could be used to obtain information that reveals inaccuracies, inconsistencies, or other misrepresentations in USPTO submissions. This could help identify duty of candor violations, deter applicants from making them, and prevent patents from being erroneously granted.

At present, this regulation, codified at 37 C.F.R. § 1.105, is not widely used. Several barriers discourage its use: **First**, supervisory review and approval is often required before such requests are sent to applicants.[14] This requirement makes sending such a request more administratively burdensome and professionally costly for examiners. **Second,** the MPEP makes the threshold for making such requests unreasonably high, stating that they are "only warranted where the benefit from the information exceeds the burden in obtaining information."[15] Because examiners cannot know how beneficial information will be in advance, but applicants can claim its disclosure is burdensome, this requirement puts a heavy thumb on the scale against such requests. **Third**, the

[12] *See infra* at page 6, § 3 for an explanation of "legal action by third parties".
[13] *See* 37 CFR § 1.105.
[14] Note that this requirement is not codified in the MPEP, but has been spoken of in interviews with patent examiners, and is included in informational materials regarding § 1.105 requests. *See, e.g.,* Thurman K. Page, *§ 1.105 Request for Information Informational Ppt*, *https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiC7Lbo5ML7AhXHMlkFHaMrD3QQFnoECBYQAQ&url=https%3A%2F%2Fwww.uspto.gov%2Fsites%2Fdefault%2Ffiles%2Fweb%2Fpatents%2Fbiochempharm%2Fdocuments%2Frequest.pps&usg=AOvVaw3t3DfyyWatLMq6kDDSDwb4*, slide 8 ("Each Technology Center will provide supervisory review and authorization over all rule § 1.105 requirements prior to mailing."). The lack of clarity regarding this procedural requirement may itself be a deterrent to examiners' use of § 1.105 requests.
[15] MPEP § 704.14.

MPEP prohibits examiners from issuing final rejections based on information provided in response to such a request, ensuring that the request can only prolong examination.[16]

To reduce these barriers and encourage requests for information, we suggest the following:

(1) Remove the requirement of supervisory approval and review, at least for Section 1.105 requests seeking disclosures of an applicant's own prior statements, particularly those relating to an applicants' statements to the USPTO regarding patentability;

(2) Reduce the threshold for making a request to require only a reasonable likelihood that the benefit of the additional information will outweigh the burden of its disclosure;

(3) Permit examiners to make final rejections based on the contents of an applicant's own statements;

(4) Provide form paragraphs for examiners to use to request information about an applicant's statements to other government entities as well as in printed publications and conference presentations, at least in connection with applications claiming inventions embodied in pharmaceutical products; and

(5) Identify situations in which such requests should be required or encouraged, such as when applicants attempt to overcome obviousness rejections, particularly on the basis of unexpected results.

The MPEP already provides examiners with form paragraphs for use in Section 1.105 requests. Adding a form paragraph for pharmaceutical patents would provide examiners with the ability to easily submit a Section 1.105 request for further information in this context. For example, the paragraph could specifically request statements, publications, and reports relating to tests referenced in the application or other submissions to the USPTO during examination.

3. After Patent Issuance: Permission for Private Enforcement Actions.

Given the number of patent applications filed and granted each year, it is not reasonable to expect USPTO personnel to search systematically for evidence of duty of candor violations in the files of granted patents. Fortunately, existing statutes incentivize members of the public to search for such evidence and bring private enforcement actions in federal courts. The government can and should do more to encourage and support the public's use of such mechanisms.

For example, the False Claims Act (FCA)[17] has enormous potential to help penalize and deter false submissions affecting pharmaceutical prices. The FCA authorizes members of the public to bring "*qui tam"* lawsuits against those who make fraudulent claims for payment to the federal government. When successful, those who bring these claims (called "relators") can recover three times the amount the government wrongly paid, with 70% going to the government and 30% to

[16] *Id.*
[17] 31 U.S.C. § 3730.

the relator.[18] Because brand name drug companies are known to make false statements to the USPTO to obtain patents, and then rely on those patents to charge the government (through Medicare and Medicaid) monopoly prices for drugs that would otherwise cost approximately 80% less, relators should be able to use the FCA to hold those companies accountable, recover costs wrongly imposed on the government, and deter such practices in the future.

While the FCA has great promise, its viability is in peril. In the previously mentioned[19] case, *US v. Allergan*, the Ninth Circuit recently held that relators cannot use the FCA to hold companies liable for false statements to the USPTO unless the government supports the lawsuit.[20] Following the Ninth Circuit's decision, statements to the USPTO qualify as public disclosures for which recovery is unavailable unless the government files a statement opposing a defendant's motion to dismiss.[21] As a result, relators will now only be able to use the FCA in connection with statements to the USPTO if the government either participates in the lawsuit or informs the court that it opposes a defendant's effort to dismiss the case.

The Ninth Circuit's decision can be an opportunity instead of an obstacle if the DOJ responds by taking a more active role in supporting FCA cases involving pharmaceutical patents. It can do so by carefully evaluating such cases and deciding what action to take in consultation with agencies such as the USPTO, FDA, and Department of Health and Human Services, including the Centers for Medicare and Medicaid Services, which directly bear the economic burden of fraudulently obtained patents. Alternatively, the DOJ can implement a policy of opposing all motions to dismiss in FCA cases seeking recovery of overcharges due to fraudulently obtained pharmaceutical patents. That would minimize the burden on government personnel and let courts decide the merits of individual cases, giving both sides a full and fair opportunity to be heard.

This opportunity is not theoretical: the DOJ can and should act now in the case against Allergan (discussed above). The Ninth Circuit has sent the case back to the district court, where a motion to dismiss is still pending. If the DOJ remains silent, the court will have to dismiss the case regardless of whether Allergan obtained a patent through fraud on the USPTO. That will prevent the federal government from recovering millions, if not billions, of dollars while allowing Allergan to hold onto its ill-gotten gains. Moreover, the government's silence will embolden pharmaceutical companies by signaling that the government will not hold them accountable for fraudulent submissions to the USPTO or help members of the public do so. That may benefit pharmaceutical companies, but the American public will pay the price with our tax dollars and our health.

Conclusion

We are grateful for the efforts you have already put into these important issues, and hope that these efforts will continue. Mechanisms that ensure patent applicants fulfill their duty of candor to the USPTO are essential for the patent system to promote the advancement of science and access to scientific advances on which public health depends.

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[18] *Id.*
[19] *See supra* page 3.
[20] *See United States v. Allergan, Inc.,* 46 F.4th 991 (9th Cir. 2022).
[21] 31 U.S.C. § 3730(e)(4).

Sincerely,

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