ARTICLE

FDA REEXAMINATION: INCREASED COMMUNICATION BETWEEN THE FDA AND USPTO TO IMPROVE PATENT QUALITY*

*S. Sean Tu***

ABSTRACT

Communication between the United States Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA) is sorely lacking. This lack of communication has created issues when firms make significantly different statements to the FDA that directly conflict with statements made to the USPTO. This problem has not gone unnoticed by President Biden, who has signed an executive order asking the FDA and USPTO to enhance collaborative efforts. Similarly, Senators Leahy and Tillis have noted this conflict and asked the USPTO to take action.

The current solution to this problem is to invalidate the patent by using the inequitable conduct doctrine. However, this doctrine does not work well when it comes to FDA information.

** Corresponding Author. Professor, West Virginia University College of Law. Scholar, O'Neill Institute for National and Global Health Law, Georgetown Law, and Visiting Professor Program on Regulation, Therapeutics and Law (PORTAL) Brigham and Women's Hospital/Harvard Medical School. The Author would like to thank Sarah Burstein, Jorge Contreras, Jonathan Darrow, Yaniv Heled, Aaron Kesselheim, Jake Linford, Gregory Reilly, Andres Sawicki, the M3 Intellectual Property Scholars Workshop, and the participants of the 2022 University of Houston Law Center Institute for Intellectual Property & Information Law symposium for their thoughtful comments. This work was funded in part by the generous support of the West Virginia University College of Law Hodges Research Fund.

Specifically, FDA information is usually confidential and not easily available to the public, thus hidden to interested parties. Additionally, FDA information is usually generated long after the patent has issued. Finally, the USPTO is not staffed with examiners who know how to gather, interpret, and analyze FDA information with an eye towards patentability.

Increased communication between the FDA and USPTO could result in stronger patents, even absent active deception by the patent applicant. There is usually a significant lag period between patent issuance and FDA approval. More information is learned during this lag period through clinical trials and additional experiments. Communication between the FDA and USPTO could help bring this information to the USPTO's attention to help tailor claim scope by removing those embodiments that were later shown to be nonfunctional.

Creation of a new FDA Reexamination would address some of the issues associated with the lack of FDA and USPTO communication. FDA Reexamination could mirror aspects of both the ex parte reexamination procedure as well as supplemental examination. Specifically, FDA Reexamination would automatically occur after approval of a related FDA drug application. Information from the FDA would automatically be sent to the USPTO in regard to any related patents covered by the FDA drug approval. At the USPTO, the FDA information would be reviewed by a team of three senior examiners to determine if a substantial new question of patentability exists. At least one of these examiners would have the ability to analyze and interpret the FDA clinical data with an eye towards patentability. If a substantial new question of patentability is found, then the typical Director-requested reexamination procedure would ensue.

TABLE OF CONTENTS

I. INTRODUCTION

Patients, doctors, and insurers have all felt the distress of rising drug prices over the past decade. Underlying much of these cost increases are the exclusive rights granted by patents. Many firms recognize that patents play a key role in their ability to charge supracompetitive pricing and thus have been filing many more patents in order to prevent competition and extend the life of their patents. President Biden recently acknowledged this issue, stating that "patent[s] . . . have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs."[1] To address some of these issues, President Biden requested that the Food & Drug Administration (FDA) and the United States Patent & Trademark Office (USPTO) communicate and enumerate the relative concerns facing both agencies when dealing with drug patents.[2]

The USPTO and the FDA play two important but different roles in regulating pharmaceuticals.[3] The USPTO promotes the

1. Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36988 (July 14, 2021).

2. Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 14, 2021).

3. *In re* Brana, 51 F.3d 1560, 1567 (Fed. Cir. 1995) (delineating between "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption"); *see also* Scott

progress of science and the useful arts by granting patent rights to inventors. For the pharmaceutical industry, patents play a crucial role in incentivizing manufacturers to take on costly up-front risks associated with bringing a new drug to market.[4] In contrast, the FDA's mission is to protect public health by ensuring safety, efficacy, and security of human drugs, biological products, and medical devices.[5] Although the USPTO and FDA have different missions, they both rely on similar scientific and technical information provided by the applicant/drug sponsor (hereinafter applicant).[6]

A problem occurs, however, when an applicant makes separate but contradictory statements to each agency.[7] On one hand, an applicant might make statements to the FDA that a particular element of the invention was known and well established to avoid safety and efficacy questions. On the other hand, that same applicant might make statements to the USPTO about that same element arguing that the element was unexpected and novel to avoid an obviousness rejection, which would prevent patenting. A similar situation occurs when a drug or device sponsor withholds a material reference from the USPTO while submitting that same reference to the FDA.[8]

---

v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994) ("Testing for the full safety and effectiveness of a prosthetic device is more properly left to the Food and Drug Administration (FDA). Title 35 does not demand that such human testing occur within the confines of Patent and Trademark Office (PTO) proceedings.").

4. Olivier J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009–2018*, 323 JAMA 844, 849 (2020) (showing that the median capitalized research and development investment needed to bring a new drug to market was estimated at $985.3 million).

5. *What We Do*, FDA, https://www.fda.gov/about-fda/what-we-do [https://perma.cc/X6ZS-ZAMA] (Mar. 28, 2018).

6. *See* Letter from Patrick Leahy, U.S. Sen., & Thom Tillis, U.S. Sen., to Andrew Hirshfeld, USPTO Interim Dir. (Sept. 9, 2021) [hereinafter Leahy & Tillis Letter].

7. This problem also arises when applicants make conflicting statements during litigation versus during prosecution. For example, patentees might argue for a narrow claim construction during patent prosecution to avoid prior art but then argue for a broad claim construction during infringement proceedings. *See generally, e.g.*, Belcher Pharms., LLC v. Hospira, Inc., 11 F.4th 1345 (Fed. Cir. 2021) (invalidating a drug patent because the patentee made representations to the USPTO that directly conflicted with statements made in a prior FDA submission as well as hid references from the USPTO that were disclosed to the FDA).

8. *See generally, e.g.*, Baxter Int'l, Inc. v. CareFusion Corp., No. 15-CV-9986, 2017 WL 1049840 (N.D. Ill. Mar. 20, 2017) (holding that the patentee identified three devices that the FDA has approved as "substantially equivalent" to patentee's pump but did not disclose these prior art references to the USPTO); Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348 (Fed. Cir. 2005) (affirming the district court holding that the patentee had failed to disclose to the USPTO information on several invalidating

This is not a theoretical problem. In a recent letter to USPTO Interim Director Hirshfeld, Senators Leahy and Tillis stated that "it has come to our attention that some patent applicants may, in certain circumstances, make significantly different statements in submissions to other federal agencies that conflict directly with those made at the [USPTO]."[9] I note that of all of the patents that the Federal Circuit invalidated due to inequitable conduct from 2005–2018, a staggering 56% of these cases dealt with FDA drug and device related products (small molecule compounds, biologics, or medical devices).[10]

Recently, on September 1, 2021, the Federal Circuit in *Belcher* affirmed a decision to invalidate a patent based on inequitable conduct because a drug sponsor: (1) disclosed conflicting information to FDA and the USPTO; and (2) concealed relevant prior art references used at the FDA from the USPTO.[11] In *Belcher*, the drug sponsor described a new composition as having a pH range of 2.8 to 3.3.[12] In communicating to the FDA, Belcher stated that the "pH change to [the drug product was] . . . a *very minor change* not requiring additional stability studies" and cited two references to support these statements.[13] The FDA then approved the New Drug Application (NDA) on July 29, 2015, based, in part, on moving the pH to the 2.8 to 3.3 range.[14] In a patent application filed on August 15, 2014, Belcher argued that raising the pH above 2.2 to 2.6 "was *contradictory* to one skilled in the art" and that increasing the pH "*unexpectedly* reduced" the negative effects associated with the drug, "which was a nonobvious solution to the problem."[15] Belcher went further and even stated

---

prior art references that the patentee had submitted to the FDA in seeking approval to sell a medical device covered by the patent); Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418 (Fed. Cir. 1989) (holding that the patentee withheld prior art from the USPTO while submitting the same prior art to the FDA)

9. Leahy & Tillis Letter, *supra* note 6.

10. The Federal Circuit invalidated patents in thirty-one cases from 2005–2018. However, eighteen of those thirty-two cases dealt with FDA drug and device regulated products. Three additional cases covered food products. *See* Caroline Leadmon et al., *Inequitable Conduct and the Pharmaceutical Industry* (forthcoming) (data on file with the *Houston Law Review*).

11. *Belcher Pharms.*, 11 F.4th at 1354.

12. *Id.* at 1347.

13. *Id.* at 1348 (emphasis added).

14. *Id.* at 1349.

15. *Id.* (emphasis added); U.S. Patent. No. 9,283,197 col. 4 l. 55–59 (filed Mar. 15, 2016).

that the idea of using the higher pH range "seemed impossible" and "had never been accomplished before."[16]

Belcher made statements to the FDA arguing that the changes in pH were "very minor" to avoid additional studies.[17] In order to obtain a patent, however, Belcher made statements to the USPTO stating that those same pH changes were unexpected, novel, and nonobvious.[18] In addition to making conflicting statements to the USPTO, Belcher did not disclose the two key references that were disclosed to the FDA.[19] Thus, the Federal Circuit upheld the district court's patent invalidation based on inequitable conduct.[20]

As shown in the *Belcher* case, the typical way to prevent submission of conflicting information is to invalidate the patent through the doctrine of inequitable conduct. One problem, however, is the fact that the rules for inequitable conduct were heightened post-*Therasense*. Specifically, after *Therasense*, alleged infringers must plead inequitable conduct with particularity, and the material reference must be withheld with intent to deceive the USPTO.[21] There are several problems with using inequitable conduct as a stop-gap measure to prevent conflicting statements made by the applicant to the FDA and USPTO.

The first problem with FDA information under the post-*Therasense* inequitable conduct standard is that FDA information is, for the most part, held confidential and thus cannot be pled with particularity without discovery. Accordingly, many inequitable conduct allegations will be dismissed at an early stage. The second problem is that this information must be material. At the USPTO, this materiality analysis is normally achieved through the use of an expert patent examiner.[22] In court, however, this analysis is done by a judge or a jury who typically does not have the type of training needed to evaluate materiality of prior

16. '197 Patent col. 4 l. 31–35.

17. *Belcher Pharms.*, 11 F.4th at 1348.

18. *Id.* at 1349–50.

19. *Id.* at 1351.

20. *Id.* at 1354.

21. David Hricik, Exergen, Therasense*, and the Amended Rules of Civil Procedure*, PATENTLY-O (Aug. 2, 2017), https://patentlyo.com/hricik/2017/08/exergen-therasense-procedure.html [https://perma.cc/JL46-WYRD].

22. *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291–92 (Fed. Cir. 2011) (en banc); Sean Tu et al., *Overqualified and Underrepresented: Gender Inequality in Pharmaceutical Patent Law*, BYU L. REV. (forthcoming 2022) (manuscript at 3, 38–39) (on file with the *Houston Law Review*).

art. Finally, inequitable conduct must be undertaken with the intent to deceive the USPTO. No intent requirement is necessary when analyzing a patent application at the USPTO.

Even absent inequitable conduct, information learned as a result of the lag time between patent prosecution and FDA approval should be used to verify and authenticate the associated patent claims. Clinical trials are performed to verify and enable prophetic examples (theoretical examples that were not actually performed) disclosed in the patent. This new information could help substantiate and validate the scope of the claimed invention. Therefore, enhanced post-FDA approval communication between the FDA and USPTO could lead to stronger patents.

For these reasons, I suggest that Congress create a new FDA Reexamination procedure by which information from the FDA can be automatically passed along and analyzed by the USPTO. This would be easily accomplished if FDA approval precedes USPTO approval, as may be the case for most secondary patents.[23] However, a new process must be created in the more common scenario in which FDA approval comes after the USPTO grants a patent.[24]

A new FDA Reexamination process could be created where FDA information is passed back to the USPTO, even after the patent issues, for a team of examiners to determine if the USPTO should reopen prosecution. This FDA Reexamination process could be confidential until the USPTO determines if reexamination is warranted. The process could mirror aspects of ex parte reexamination and supplemental examination.

This new FDA Reexamination process would not suffer from the problems associated with the current inequitable conduct rules. First, this process would occur automatically after the FDA approves or denies a drug application, which would mean that no "pleading with particularity" is necessary. Second, the patent and the FDA information would be examined by experts in both the law and scientific evidence associated with drug patents. Finally,

23. Secondary patents are usually patents directed to minor alterations to an existing drug rather than a new chemical entity. *See* S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. L. REV. 1673, 1682, 1709 (2022).

24. Jonathan J. Darrow et al., Post-NDA Drug Patents: Prevalence, Characteristics and Relationship to Generic Approval 2 (unpublished manuscript) (on file with the *Houston Law Review*).

there would be no "intent to deceive" requirement because the process would happen sua sponte at the USPTO with a lower burden of proof. The burden of proof requirements are important because a *clear and convincing evidence standard* is applied to an *issued patent*, while a *preponderance of the evidence standard* is applied to a *patent application*.[25]

Alternatively, Congress could reverse the *Therasense* rules when it comes to drug patents. This would allow challengers to avoid pleading inequitable conduct with particularity, so that they could gain access to the relevant documents during discovery and avoid summary judgment. Additionally, Congress could lower the scienter requirement needed to show inequitable conduct for drug patents. This Article, however, focuses only on the proposed FDA Reexamination procedure.

Part II of this Article describes the differences between USPTO and FDA examination, which can lead to conflicting information sent to each agency. Part III describes the current legal solution to conflicting information, namely the doctrine of inequitable conduct, and explains why this doctrine is not ideal for solving this type of conflicting information problem. Part IV details a new FDA Reexamination procedure to help create stronger patents. Part V details another solution to prevent applicants from disclosing conflicting information to the FDA and USPTO by lowering the standard necessary to show inequitable conduct.

II. THE DIFFERENCES BETWEEN USPTO PATENT EXAMINATION AND FDA DRUG APPROVAL

As an initial matter, the goals of these two institutions are very different. The USPTO's goal is to work with "inventors and entrepreneurs [to] bring forth their ideas to create American economic development and growth . . . by granting predictable, reliable, and high-quality intellectual property . . . rights."[26] In contrast, the mission of the FDA is to "protect[] the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices."[27] Because the missions of these two agencies are different,

25. *See* MPEP § 2286(IV) (9th ed. Rev. 10, June 2020).

26. USPTO, 2018–2022 STRATEGIC PLAN 1 (2018), https://www.uspto.gov/sites/default/files/documents/USPTO_2018-2022_Strategic_Plan.pdf [https://perma.cc/NZ9U-KR8A].

27. *What We Do*, *supra* note 5.

applicants will necessarily submit different types of information and make different types of arguments between these two agencies. These arguments, however, should be consistent.

There are many differences between the USPTO patent examination procedure and the FDA drug approval procedure that can make it tempting for applicants and sponsors to either intentionally or unintentionally miscommunicate information to each agency. Table 1 summarizes some of these key differences.

Table 1

	USPTO	**FDA**
Goal	To increase innovation through grants of exclusive rights.	To ensure safety and efficacy of drugs.
Defaults	"A person shall be entitled to a patent unless . . . ." Thus, the default is to allow a patent.	No presumption of safety or efficacy. The default position is to reject a drug application. Default is rejection unless applicant shows otherwise. This is an important difference because you might get more information in the FDA process compared to the USPTO process.
Burden of Proof	The USPTO examiner has the burden to show that the application is not patentable. The examiner must locate and analyze the most relevant prior art references.	The applicant has the burden to show that the new drug is safe and effective. The applicant must submit references and data (clinical trials) to show safety and efficacy.
Access to Agency to Applicant Exchanges	Information is open, available, and easily accessible to the public. Conversations between the patent examiner and applicant are made of record and placed on a publicly available website, Public Patent Application Information Retrieval (PAIR).	Most information is confidential, difficult to obtain, and not readily available to the public.
Reviewer	Only one or two examiners. (Two examiners if the primary	Multiple reviewers from an array of specialties.

	examiner does not have signatory authority).	
Who Reviews	Usually a Ph.D. scientist in TC1600. (Not an M.D.).	A host of Ph.D.s and M.D.s, often including e.g., statisticians, microbiologists, pharmacologists, and therapeutic subject matter experts.
Timing	Patent prosecution usually 1–2 years after first office action.	Approval process can take several years. But then you still have follow-up involvement throughout marketing and post-approval monitoring.
Hours in Review	Usually less than forty hours.	Thousands of man hours.
Costs	Usually less than $30,000.	Average of $985.3 million.
Post Grant Review	IPR/ex parte reexamination/supplemental examination	Automatic-continuous monitor of safety/efficacy.
Involvement After Agency Grant	Very little involvement—most examiners don't even know if their granted patents underwent litigation.	Long-term involvement.
Consequences of Agency Error	Higher drug prices. Patent thickets might deter market entry. Lack of improvements by others. Unavailability to certain populations.	Large negative costs, including health and economic consequences. Nonadherence to drug regimen due to high drug costs.

A. Application Defaults/Burden of Proof

The first key difference is the default position for examiners in the USPTO versus the FDA. Patent law's default position is to *allow* the patent to grant unless the patent examiner shows that the applicant does not meet the patentability requirements.[28] In contrast, under the 1962 Kefauver-Harris Drug Amendments, the FDA will *reject* the New Drug Application (NDA) unless the

28. 35 U.S.C. § 102(a).

applicant shows that the drug is safe and effective.[29] This default position has important consequences as to who and what needs to be shown for agency approval.

Patent law establishes allowance as a default position, with the relevant statute stating: "A person shall be entitled to a patent unless . . . ."[30] Accordingly, the burden of proof is on the patent examiner to bring evidence to prevent an applicant from obtaining a patent. The patent applicant need only disclose her invention in a manner that meets the written description and enablement standards. The patent examiner then needs to look for and analyze the prior references to determine if the application is novel and nonobvious over the prior art. Thus, in general, the patent applicant will get a patent unless the patent examiner can find reason to reject the application.

In contrast, the Kefauver-Harris Amendments to the 1938 Food, Drug, and Cosmetic Act require that applicants show that their new drug is both safe and effective *before* they can go to market.[31] Thus, the default position at the FDA is to reject the application. The burden of proof requires the applicant to show safety and effectiveness, which typically requires manufacturers to conduct clinical investigations of drugs. Thus, the FDA applicant is required bring evidence to the FDA to show that the drug is safe and effective or else the NDA fails. This means that, in general, the FDA applicant is required to disclose more outside information to the FDA to justify their position and arguments. In contrast, at the USPTO, the burden is on the USPTO examiner to show that the claimed invention is not novel or obvious over the prior art. Accordingly, the patent examiner needs to search the literature to determine if the patentability standards are met. Thus, the patent applicant is not required to disclose any outside references to obtain a patent but is required to disclose known prior art.

These default burdens are important especially in light of the fact that: (1) the USPTO examiner is given only nineteen hours on

29. *Drug Development and Review Definitions*, FDA, https://www.fda.gov/drugs/investigational-new-drug-ind-application/drug-development-and-review-definitions [https://perma.cc/8C2F-RCHY] (Aug. 20, 2015).

30. 35 U.S.C. § 102(a).

31. *Drug Development and Review Definitions*, *supra* note 29.

average to review each application;[32] (2) most of the FDA information is confidential;[33] and (3) much of the FDA information is generated well after the patent has issued.[34] These default positions are exacerbated by the fact that once a patent has issued, it is much more difficult to invalidate in a court of law.[35] Specifically, before a patent issues the patent examiner looks at the evidence using a preponderance of the evidence standard (to grant the patent), while after a patent issues the judge/jury examines the patent using a clear and convincing evidence standard (to invalidate the patent).[36]

B. Type of Information Produced

FDA review of drug efficacy is based on a "substantial evidence" standard. The evidence needed to satisfy this requirement is usually two or more "adequate and well controlled investigations."[37] These investigations usually involve extensive and expensive clinical trials.[38] A large number of physicians, statisticians, and scientists generate, assemble, and analyze the data before submission to the FDA. This application will contain thousands of pages of drug chemistry, quality, and manufacturing data, as well as safety information from in vitro and animal studies, clinical pharmacological data (e.g., drug-interaction studies), and clinical trial data.[39] Accordingly, information generated by the applicant for FDA approval will dwarf the information submitted to the USPTO. FDA-generated submissions are much more detailed and contain much more

32. Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Including Examiners to Grant Invalid Patents? Evidence from Microlevel Application Data*, 99 REV. ECON. STAT. 550, 552 ("On average, a U.S. patent examiner spends only nineteen hours reviewing an application."); *see also infra* Section II.E.

33. *See infra* Section II.C.

34. *See infra* Section II.B.

35. Mark Stepanyuk, *So You Want to Invalidate a Patent? The PTAB May Be Your Friend!*, WASH. J.L. TECH. & ARTS (Jan. 10, 2022), https://wjlta.com/2022/01/10/so-you-want-to-invalidate-a-patent-the-ptab-may-be-your-friend/ [https://perma.cc/K55T-AXZZ] ("[I]n Federal District Court, challengers need to overcome the much higher standard of 'clear and convincing evidence' to invalidate the patent, due to the jurisdictional presumption that the patent is valid.").

36. *Id.*

37. *See* Federal Food, Drug, and Cosmetic Act (FDA Act) § 505(b), 21 U.S.C. § 355; *see also* 21 C.F.R. § 314.126 (2022).

38. Wouters et al., *supra* note 4, at 849.

39. Audry L. Gassman, et al., *FDA Regulation of Prescription Drugs*, 376 NEW ENG. J. MED. 674, 675 (2017).

information than a typical USPTO patent application. This data generated for the FDA, however, could also be useful for the USPTO to establish (or confirm) patentability.

In contrast, patent applications usually are only 14,000–15,000 words.[40] The patent specification focuses on describing how the invention is new and useful.[41] Additionally, the patent applicant must explain how to make and use the invention in clear and exact terms.[42] Importantly, previous studies have shown that biological and chemical patents contain a high number of fictional experiments called "prophetic examples,"[43] and 99% of scientific articles that cite to these prophetic examples incorrectly cite to them as if they contained factual information from actual experiments.[44] It is common, however, to use these prophetic examples in the pharmaceutical industry because it can take years and hundreds of millions of dollars to obtain permission from the FDA to run human experiments.[45]

Patent claims are also reviewed by giving the claims their broadest reasonable interpretation in light of the specification[46] and by the "preponderance of the evidence" standard.[47] Although patent specifications continue to rise in size and complexity,[48] they

40. Peter Glaser & William Goth, *Changes in Patent Language to Ensure Eligibility Under* Alice, IPWATCHDOG (Dec. 6, 2017), https://www.ipwatchdog.com/2017/12/06/changes-patent-language-ensure-eligibility-alice/id=90721/ [https://perma.cc/DH2X-TBSM] (showing that the average word count of a patent specification increased from 12,219 in 2010 to 14,780 in 2017).

41. 35 U.S.C. §§ 101–103.

42. *Id.* § 112.

43. Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 697 (2019) (showing in Table 1 that almost 17% of biology and chemistry patents contain fictional experiments).

44. *Id.* at 698–99 (showing in Table 2 that 99 out of 100 randomly chosen patents cited by scientific articles were not cited in a manner that made it clear that the cited information was prophetic).

45. *Id.* at 685–87 (arguing that without prophetic examples, "we might see reduced innovation from small companies or those in the pharmaceutical space," because prophetic examples allow the applicant to confidently invest in expensive clinical trials).

46. MPEP § 2111 (9th ed. Rev. 10, June 2020) ("[T]he pending claims must be 'given their broadest reasonable interpretation consistent with the specification.'" (quoting Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005))).

47. *Id.* § 706(I) ("The standard to be applied in all cases is the 'preponderance of the evidence' test. In other words, an examiner should reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable.").

48. Dennis Crouch, *Patent Specifications Continue to Rise in Size*, PATENTLY-O (Apr. 23, 2012), https://patentlyo.com/patent/2012/04/patent-specifications-continue-to-rise-in-size.html [https://perma.cc/D5GZ-YLK2]; *see also* Dennis Crouch, *The Rising Size and*

are dwarfed by the voluminous number of documents generated for FDA approval. In fact, the USPTO does not verify any experiments submitted by the applicants, as it would change the nature of patent examination.[49] The fact that the USPTO does not verify any experiments also compounds the problems caused by prophetic examples, as it can be difficult for those not familiar with patent law to determine if an example is a prophetic (fictitious) example or a working example that was actually completed by the applicant.

C. Access to Information

Information at the USPTO is almost entirely open to the public and free of charge. Almost all of the conversations between the applicant and examiner are open to the public through the PAIR system.[50] Additionally, most of this information is updated on a daily basis. Non-patent literature (NPL) is one big exception to the general rule. NPL is not publicly available through the PAIR website. However, the full contents of the patent application files including NPLs are available from the USPTO Public Records Division.[51] NPL usually consists of copyrighted material such as scientific articles, conference proceedings, clinical trials, books, manuals, technical or research reports, or any other material that might not be freely available to the public.[52]

Complexity of the Patent Document 3 (Univ. Mo. Sch. L. Legal Stud., Rsch. Paper No. 2008-04, 2014) (showing that the average number of words in a patent specification in 2007 was approximately 7,000).

49. The enablement requirement requires an analysis of the degree of experimentation necessary to implement an invention; "an examiner, who has no access to experts or laboratories, is not in a position to test each piece of prior art for enablement in citing it, and requiring him to do so would be onerous, if not impossible." *In re* Antor, 689 F.3d 1282, 1289 (Fed. Cir. 2012).

50. *PAIR Announcements*, USPTO, https://www.uspto.gov/patents/apply/checking-application-status/pair-announcements [https://perma.cc/LBC4-V6EC] (last visited Sept. 10, 2022) (noting that Public PAIR was phased out as of July 31, 2022, but the Patent Center provides the same information that was available on Public PAIR).

51. *PAIR FAQs*, USPTO, https://www.uspto.gov/patents/apply/checking-application-status/pair-faqs [https://perma.cc/Q22A-NTHF] (last visited Sept. 10, 2022) ("Images of non-patent literature (NPL) cited in public patent application files are not available for either viewing or downloading through Public PAIR. Certified copies of the full contents of the patent application files, including NPL are available from the USPTO Public Records Division.").

52. Gema Velayos-Ortega & Rosana Lopez-Carreno, *Non-Patent Literature*, 1 ENCYCLOPEDIA 198, 200 (2021), https://www.mdpi.com/2673-8392/1/1/19/htm [https://perma.cc/TCF3-G5ZA]. *See generally, e.g.*, Complaint at 4–5, Am. Inst. of Physics v. Hovey Williams LLP, No. 12-40410-RDR-KGS (D. Kan. Apr. 20, 2012); Am. Inst. of Physics v. Schwegman Lundberg & Woessner, P.A., No. 12-528, 2013 WL 12329050 (D. Minn. Dec. 16,

In contrast to the USPTO, most of the data from clinical trials are kept at the FDA as confidential, and the conversations between the drug sponsor and the FDA are difficult to obtain.[53] Thus, even though patent examiners are experts at searching for prior art, they will not be able to find confidential FDA information. Even if a USPTO examiner was adept at finding this information, much of this information is generated long after patent examination has concluded.

This clinical data is important for the USPTO because it may result in rebutting an "unexpected or surprising results" argument and also help with written description and enablement issues. Additionally, this data could present inconsistent results with the prophetic examples given in the patent application. Finally, this data could present inequitable conduct issues if the drug sponsor makes statements that directly contradict those statements made during patent prosecution.

It can also be difficult for a patent examiner to find FDA references such as relevant drug labels or drug package insert information. This is because the patent examiner may not know which product databases are most relevant to search. This problem is compounded by the fact that many applicants could bury the most important references by submitting hundreds (sometimes thousands) of references without disclosing the most important references to the examiner.[54]

This data is also clearly known to the applicant because they are the ones who are generating this data. The main issue with

2013); Am. Inst. of Physics v. Winstead PC, No. 3:12-CV-1230, 2013 WL 6242843, at *1–2 (N.D. Tex. Dec. 3, 2013); John Wiley & Sons, Ltd. v. McDonnell Boehnen Hubert & Berghoff LLP, No. 12 C 1446, 2013 WL 5230636, at *1 (N.D. Ill. Sept. 16, 2013).

53. 21 C.F.R. § 314.430(b), (d) (2022); *see also How to Make a FOIA Request*, FDA, https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request [https://perma.cc/M92F-VCE3] (Mar. 12, 2022) ("[R]equests for 510K, PMA, and De novo records are complex requests and take approximately 18-24 months to process.").

54. *See, e.g.*, U.S. Patent No. 8,293,728 (filed Jan. 12, 2012) (showing that the applicant submitted a total of 574 references: thirty-two patents, twenty-eight patent applications, thirty-four foreign patent documents, and 480 printed publications (mainly journal articles)); *see also* Robert B. Taylor, *Burying*, 19 MICH. TELECOMM. & TECH. L. REV. 99, 114–15 (2012); S. Sean Tu et al., *Reference Check: A Simple Strategy to Improve Drug Patent Quality*, HEALTH AFFS. FOREFRONT (June 21, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220615.404330 [https://perma.cc/9W7P-KKUM] (showing that Orange Book and Purple Book patents have an average of 218 and 378 references, respectively, whereas, in contrast, the typical biotechnology patent only has seventy-seven references and the most egregious patents have over 1,000 references).

this data is that normally "printed publication" or "otherwise accessible to the public" type prior art is considered only when it is publicly available and publicly accessible.[55] Because most FDA information is held in confidence, most of this information is neither publicly available nor publicly accessible. However, as discussed in Part IV below, there are some compelling reasons why we might want to include this type of information as art that should be considered for patentability purposes. Specifically, we should not allow applicants to submit contradictory information to two different agencies. But FDA information can also help frame how the applicant views both his invention as well as the prior art.

D. Interpretation of Information

The safety and effectiveness data submitted by the applicant is usually based on clinical trials and can contain comparisons to competitor products and prior studies. Although most patent examiners in Technology Center 1600 (TC 1600) have advanced degrees in biological sciences, none of them have medical degrees.[56] Thus, even if the USPTO examiner is able to find this information, it may not be the type of information that a USPTO examiner would be able to interpret without a medical degree. Accordingly, as further discussed in Part IV, I suggest that the application be examined by a team of examiners, which should include at least one member from the FDA with a medical degree.

Finally, the timing of these FDA clinical trials presents a significant issue. Specifically, FDA information is usually generated only after the patent is granted.[57] Accordingly, this type of information may not be available at the time of patenting. Ideally, information generated for FDA approval should simply substantiate that which was disclosed in the patent. However, this is not always the case. Accordingly, as discussed in Part IV, I suggest that a new FDA Reexamination process be created that could reopen prosecution even after the patent grants.

Statements made to the FDA that contradict arguments made by the patent applicant during prosecution should be used against the patent, even though this information is generated and

---

55. 35 U.S.C. § 102(a)(1) (stating that prior art comprises "patent[s], described in a printed publication, or in public use, on sale, or otherwise available to the public").

56. Tu et al., *supra* note 22 (manuscript at 3, 38–39) (showing that over 70% of the patent examiners in TC 1600 have advanced degrees, but no current examiner in TC 1600 has disclosed that they have a medical degree).

57. Darrow et al., *supra* note 24 (unpublished manuscript at 8).

available only after the patent issues. It is true that Congress would have to create a new type of "prior" art for this type of information. However, if a patent claim is not enabled based on statements made by the applicant, or if previous nonobviousness arguments fail based on newly generated information by the applicant, those patent claims should fall.

E. The Review Process—Examiners / Time for Review / Costs

Another big difference between FDA and USPTO review is: (1) who reviews the application; (2) how much time is given to review the application; and (3) the costs associated with the review. In sum, USPTO review is usually performed by one Ph.D. scientist, who is given no more than forty hours to review the application.[58] The cost for USPTO review is approximately $10,000–$15,000 for the original application and takes about 1–2 years after the first substantive USPTO action (first office action).[59] In contrast, the FDA review procedure is executed by a legion of scientists, clinicians, statisticians, and other medical professionals.[60] There are thousands of man hours needed to get FDA approval, and it takes 6–7 years before approval[61] and costs approximately $985 million to move a drug from lab to market.[62]

USPTO review is performed by one or two examiners, and they are usually given, in total, no more than forty hours to review each application.[63] In contrast, the FDA review team consists of:

---

58. Frakes & Wasserman, *supra* note 32, at 552 ("On average, a U.S. patent examiner spends only nineteen hours reviewing an application.").

59. AM. INTELL. PROP. L. ASS'N, REPORT OF THE ECONOMIC SURVEY 2021 48 (2021) [hereinafter AIPLA 2021 REPORT] (showing that the median cost for a U.S. utility patent is $10,000).

60. *Step 4: FDA Drug Review*, FDA, https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review [https://perma.cc/CYK6-ZPCV] (Jan. 4, 2018).

61. Molly Adams, *5 Things to Know About the FDA Approval Process*, MD ANDERSON CANCER CTR. (Aug. 12, 2021), https://www.mdanderson.org/cancerwise/5-things-to-know-about-the-fda-approval-process-.h00-159463212.html [https://perma.cc/FV3Q-SYSM] (noting that this figure does not include applications undergoing an accelerated approval process).

62. Wouters et al., *supra* note 4, at 849. The fees associated with just filing an application that requires clinical data are about $1,958,800. PETER B. HUTT ET AL., FOOD AND DRUG LAW 710, 716 (4th ed. 2014).

63. Patent applications are usually reviewed by either: (1) a "primary patent examiner" with signatory authority; or (2) a primary examiner who is supervising a junior examiner that does not have full signatory authority. *See* S. Sean Tu, *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, 38 CARDOZO ARTS & ENT. L.J. 391, 398 (2020);

medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts.[64] Evaluations are prepared by each reviewer and then considered by team leaders, division directors, and/or office directors.[65] The FDA can even call on an independent advisory committee with independent opinions and recommendations from outside experts.[66]

Both the USPTO and the FDA are user-fee funded; however, the user fees are immensely different. The USPTO charges for prosecuting a patent can range from $5,000–$20,000, including legal fees for a private practitioner to help prosecute the patent.[67] In contrast, the FDA charges are $3,117,218 for reviewing an NDA requiring clinical data and $1,558,609 for applications that do not require clinical data.[68] These FDA charges do not include attorney fees or costs associated with running clinical trials, which can also cost hundreds of millions of dollars. These numbers simply show that the agency costs associated with examination of a patent application are much less than the agency costs associated with examination of a drug application. Accordingly, applicants who are submitting information to the FDA may be more careful than applicants submitting information to the USPTO simply because of the higher stakes associated with failure at the FDA.

On the other side of the coin, the attorney who prosecutes the patent is likely not going to be the same person as the team of attorneys who submits the FDA drug application. Patent prosecution is a specialized practice that requires a separate

---

Michael A. Leonard II, *USPTO Examiner Expectancies*, FOUND PERSUASIVE, www.foundpersuasive.com/examiner_expectancies.aspx [https://perma.cc/B2PU-PTP9] (last visited Oct. 9, 2022).

64. *FDA's Drug Review Process: Continued*, FDA, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-continued [https://perma.cc/GK7C-C39Z] (Aug. 24, 2015).

65. *Id.*

66. 5 U.S.C. app. 2 § 9(b); 41 C.F.R. §§ 101-6.1001, 102-3.30 (2021); FDA, Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees; Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff; Availability (June 2016), https://www.fda.gov/media/98852/download [https://perma.cc/29R3-F5S4]; *see also Advisory Committee Laws, Regulations and Guidance*, FDA, https://www.fda.gov/advisory-committees/about-advisory-committees/advisory-committee-laws-regulations-and-guidance [https://perma.cc/EDF2-L542] (Mar. 27, 2018).

67. These fees will vary depending on the complexity of the invention. *See* AIPLA 2021 REPORT, *supra* note 59, at I-109 (showing an average cost of $11,657 for prosecution of a complex biotechnology/chemistry patent application, with prices ranging from $9,095 to $15,924 corresponding to the size of the law firm); *see also Patent Application Cost*, BITLAW GUIDANCE, https://www.bitlaw.com/guidance/patent/what-does-a-patent-application-cost.html [https://perma.cc/247W-FF5H] (last visited Sept. 1, 2022).

68. Prescription Drug User Fee Rates for Fiscal Year 2022, 86 Fed. Reg. 45732, 45737 (Aug. 16, 2021) (showing the FDA's Fee Schedule for FY 2022 in Table 13).

licensure procedure that is not required for FDA practice.[69] Unlike patent law, there is no attorney licensure requirements to submit documents to the FDA. FDA law regulatory practice, however, is a specialized practice area that requires years of training. Accordingly, the attorney who prosecutes the patent will likely not be the same attorney who helps submit the FDA approval documents.

Because there is little to no overlap between FDA and USPTO practices, the FDA attorneys might not know what arguments were made or what was even discussed during patent prosecution. As noted above, the information submitted and the arguments made to these two agencies may be very different due to their institutional goals. Accordingly, it may be easy for FDA lawyers to intentionally or unintentionally make arguments that contradict what was previously stated at the other agency. Compounding this problem is the fact that statements made to the FDA are in large part confidential or difficult to obtain; thus, lawyers may feel more emboldened to make conflicting statements, as attorneys may feel that there are little to no consequences unless the patent is litigated in the future. Litigation is less likely if the patent is not granted FDA approval because the patent may be of little value if the FDA prevents the drug from entering the market.

F. Post Grant Review

Once a patent application matures into a patent, the USPTO does little to monitor the validity of the patent. Although the USPTO has the ability to sua sponte issue a reexamination, this is rarely done.[70] For example, only forty-nine of the more than 1,700 reexaminations during 1996–2000 were instituted by the USPTO.[71] However, most of those patents where reexamination

69. *See Becoming a Patent Practitioner*, USPTO, https://www.uspto.gov/learning-and-resources/patent-and-trademark-practitioners/becoming-patent-practitioner [https://perma.cc/4RF6-LWPM] (Dec. 8, 2022, 12:40 PM).

70. 35 U.S.C. § 303 ("*On his own initiative*, and any time, the Director may determine whether a substantial new question of patentability is raised." (emphasis added)); *see also* Standard Havens Prods. Inc. v. Gencor Indus. Inc., 897 F.2d 511, 514 n.2 (Fed. Cir. 1990) ("The Commissioner initiated less than 1% of all reexaminations over the past eight years.").

71. USPTO, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2000 114 (2000) (Table 13).

was instituted by the USPTO resulted in cancellation or amendment of claims.[72]

Usually, post-grant quality control is achieved through litigation by competitors.[73] Specifically, competitors may attempt to invalidate those patents that may be infringed by the competitor's product(s).[74] Similarly, competitors may attempt to invalidate those same patents using the USPTO's administrative inter partes review (IPR) procedure.[75] In both cases, it is third parties who bring these cases and not the USPTO.[76] Additionally, both procedures are expensive, with patent litigation cost ranging from $2.6 million[77] to $6.2 million[78] and an IPR costing approximately $774,000.[79]

In contrast, the FDA continues to monitor the safety and efficacy of products even after the FDA approves the application. For example, after the Vioxx debacle,[80] the FDA launched the Sentinel Initiative, which monitors the safety of its regulated products.[81] Sentinel seeks to "develop methods to obtain access to disparate data sources" to implement a "postmarket risk

72. *Standard Havens Prods. Inc.*, 897 F.2d at 514 n.2 ("The Commissioner initiated less than 1% of all reexaminations over the past eight years, and 93% of those he did institute resulted in cancellation or amendment of the claims."); *see also* Terri Suzette Hughes, *Patent Reexamination and the PTO: Compton's Patent Invalidated at the Commissioner's Request*, 14 JOHN MARSHALL J. COMPUT. & INFO. L. 379, 381 n.19 (1996) ("The Commissioner initiated less than 1% of all reexaminations over [1982–1990] and 93% of those he did initiate resulted in cancellation or amendment of the claims.").

73. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500–02 (2001).

74. *See id.*

75. Jonathan J. Darrow et al., *Will* Inter Partes *Review Speed US Generic Drug Entry?*, 35 NATURE BIOTECHNOLOGY 1139, 1139 (2017).

76. *Standard Havens Prods. Inc.*, 897 F.2d at 514 n.2 ("The Commissioner initiated less than 1% of all reexaminations over the past eight years, and 93% of those he did institute resulted in cancellation or amendment of the claims.").

77. AIPLA 2021 REPORT, *supra* note 59, at 67, I-158 (showing an average cost of $2.608 million when $1–10 million is at risk).

78. *Id.* (showing an average cost of $6.219 million when more than $25 million is at risk).

79. *Id.* at 71, I-182–I-183 (showing an average cost of $774,000 for filing or defending a PGR/IPR in the life sciences).

80. *FDA, Merck, and Vioxx: Putting Patient Safety First: Hearing Before the S. Comm. on Fin.*, 108th Cong. 50, 52 (2004) (statement of Sandra L. Kweder, Acting Director, Office of New Drugs). *See generally* Sarah McCauley Mancinelli, Student Paper, *Placing Blame for the Vioxx Debacle* (2006) (discussing the Vioxx debacle), https://dash.harvard.edu/handle/1/9453694 [https://perma.cc/BC3X-647D].

81. *FDA's Sentinel Initiative*, FDA, https://www.fda.gov/safety/fdas-sentinel-initiative [https://perma.cc/E95Q-67CL] (Aug. 26, 2022).

identification and analysis system," which can link and analyze safety data from aggregate sources.[82]

III. THE CURRENT SOLUTIONS

There are currently three flawed solutions to the problem where patent applicants are making inconsistent statements to the FDA and USPTO. First, Congress has already authorized the USPTO to request access to FDA documents.[83] Second, the doctrine of inequitable conduct will invalidate patents that were obtained by fraud upon the USPTO.[84] Third, there are three post-grant procedures (ex parte reexamination, supplemental examination, and IPR) that can help remedy inconsistent statements.[85]

A. Enhanced Communication Between the FDA and USPTO/Timing of Information Transfer

Under the 1962 Drug Amendments, patent examiners are able to request access to "full and complete information" that the FDA may have relating to patentability determinations, such as evidence that a new drug is unexpectedly superior to an old one. Specifically, 21 U.S.C. § 372(d) provides that:

> The Secretary [of the Department of Health and Human Services] is authorized and directed, upon request from the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.[86]

The legislative history of 21 U.S.C. § 372(d) explains the purpose of this provision: "Presumably, if the Patent Office, which has no physicians or pharmacologists on its staff, is able to secure

82. 21 U.S.C. § 355(K)(3).
83. *Id.* § 372(d).
84. MPEP § 2016 (9th ed. Rev. 10, June 2020).
85. *Id.* §§ 2209, 2609, 2802; *see also* 35 U.S.C. §§ 257, 302, 311.
86. 21 U.S.C. § 372(d).

information from HEW on the therapeutic properties of drugs–which it is now able to obtain only with the consent of the patent applicant–fewer patents may be issued."[87] Accordingly, the USPTO has the ability to request information from the FDA to help in its patentability analysis.

There are two significant issues that arise from this statute. First, even if there is enhanced communication between the USPTO and FDA, the USPTO does not have the expertise to analyze the data in a meaningful fashion. Second, patenting usually occurs well before FDA approval is granted. Accordingly, much of the data and relevant information would be generated after the patent is granted and thus would not have an impact on patent prosecution.

First, the USPTO is not in a position to evaluate questions of efficacy when it comes to the complex clinical trials required by the FDA.[88] Many patent examiners have Master's and Ph.D.'s in relevant majors such as biology, biochemistry, microbiology, and biomedical engineering.[89] However, no current biotechnology examiner has a medical degree.[90] Thus, the assistance that the FDA would be able to provide the USPTO at the time of patenting would be limited.

Second, even if the FDA gives the USPTO confidential drug information and the USPTO had the resources to analyze the data, the data that the FDA would be able to provide the USPTO at the time of patenting would be limited.[91] This is because patenting occurs far before the FDA approval process. In fact, most drugs have already received patents well before the FDA process is completed.[92] Accordingly, much of the information that the FDA

87. S. REP. NO. 87-1744, at 35 (1962). "HEW" is the Department of Health Education and Welfare, the predecessor to the Department of Health and Human Services, which is the department to which the FDA belongs. *HHS Historical Highlights*, U.S. DEP'T HEALTH HUM. SERVS., https://www.hhs.gov/about/historical-highlights [https://perma.cc/9UVE-YN6U] (Jan. 21, 2021); *FDA Organization*, FDA, https://www.fda.gov/about-fda/fda-organization [https://perma.cc/53M7-LB4P] (Jan. 17, 2020).

88. Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363, 402–03 (2014).

89. Tu et al., *supra* note 22 (manuscript at 32 n.133, 38–39) (showing that over 70% of the patent examiners in TC 1600 have advanced degrees, but no current examiner in TC 1600 has a medical degree).

90. *Id.* (manuscript at 39).

91. Dmitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1143–44 (2019) (suggesting that the FDA should play a more prominent role in requesting and analyzing the data).

92. Darrow et al., *supra* note 24 (unpublished manuscript at 2).

would be able to pass along to the USPTO would not be complete and may not be relevant for the patentability analysis.

Accordingly, simply increasing the communication between the USPTO and FDA in its current form may not yield positive results. The USPTO lacks the expertise necessary to interpret the data the FDA might provide and the information that the FDA could provide at the time of patenting would be too far upstream in the drug development process. Accordingly, this Article suggests creation of an FDA Reexamination process.[93]

B. Invalidation by Inequitable Conduct

Another solution to the conflicting information problem is to invalidate the patent by using the doctrine of "inequitable conduct." Inequitable conduct is an important mechanism to invalidate erroneously granted chemical and biological patents.[94] In fact, in an analysis of all patents invalidated via inequitable conduct from 2005–2021 by the Federal Circuit, a whopping 56% of them were directed towards drugs or medical devices.[95]

A patent applicant has a duty to act with candor, good faith, and honesty when making representations to the USPTO.[96] When an applicant does not act lawfully, the patent could be invalidated via inequitable conduct.[97] Thus, inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.[98]

To prevail on a claim of inequitable conduct, an accused infringer must prove by clear and convincing evidence that the patentee: (1) made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material to the USPTO; and (2) did so with the intent to deceive the USPTO.[99] The doctrine of inequitable conduct is applied when an applicant makes affirmative misrepresentations of a material

93. *See infra* Part IV; *see also* Darrow, *supra* note 88, at 403.

94. *See* Leadmon et al., *supra* note 10.

95. *See id.*

96. 37 C.F.R. § 1.56(a) (2021); *see also* Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 999 (Fed. Cir. 2007).

97. Lee Petherbridge et al., *Unenforceability*, 70 WASH. & LEE L. REV. 1751, 1753–54 (2013).

98. *Id.*

99. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995).

fact, fails to disclose material information, or submits false material information coupled with an intent to deceive.[100] Inequitable conduct is considered "the atomic bomb of patent law" because it renders the entire patent unenforceable and not just specific claims of the patent.[101]

In the past, there was a glut of inequitable conduct charges to the point where almost every major patent case alleged inequitable conduct.[102] The Federal Circuit recognized the defense as an "absolute plague" and a "scourge" to patent litigation.[103] Accordingly, in 2011, the Federal Circuit augmented the requirements for inequitable conduct to make it more difficult for accused infringers to harass patentees.[104] An unintended consequence of the current enhanced standard for inequitable conduct is that it is much more difficult to use this defense because most of this information can only be gleaned after discovery.

Inequitable conduct, however, is not an ideal way to prevent conflicting statements made to the USPTO and FDA. There are four main problems that come with inequitable conduct: (1) courts require inequitable conduct to be "pleaded with particularity"; (2) the withheld information must be material; (3) challengers need to show an intent to deceive by clear and convincing evidence; and (4) the standard of proof is a "clear and convincing" standard.[105]

The first problem lies with the fact that many representations made by the applicant to the FDA are held confidential. Inequitable conduct needs to be "pleaded with particularity," which requires the challenger to identify the who, what, when, where, and how of the material misrepresentation or omission

100. FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987).

101. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc).

102. Jason Rantanen, *Recalibrating Our Empirical Understanding of Inequitable Conduct*, 3 IP THEORY 98, 106–07 (2013) (Tables 1 and 2); *Therasense*, *Inc.*, 649 F.3d at 1289.

103. Burlington Indus., Inc. v. Dayco Corp. 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[I]nequitable conduct in almost every major patent case has become an absolute plague."); Christian E. Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 BERKELEY TECH. L.J. 1329, 1339, 1345, 1347 (2009); *see also* Dennis Crouch, *Measuring The Plague of Inequitable Conduct*, PATENTLY-O (June 2, 2010), https://patentlyo.com/patent/2010/06/measuring-the-plague-of-inequitable-conduct.html [https://perma.cc/VF5V-KFSC].

104. *Therasense, Inc.*, 649 F.3d at 1290–92.

105. *Id.* at 1290; Exergen Corp. v Wal-Mart Stores, Inc., 575 F.3d 1312, 1318, 1326–27, 1329 (Fed. Cir. 2009).

committed before the USPTO.[106] This heightened pleading standard is almost impossible to meet without discovery because the FDA information is kept confidential and not publicly available.[107] The patent challenger, therefore, will not know of these conflicting statements until after costly discovery is completed. Accordingly, inequitable conduct allegations are usually made only in the middle of a trial and may not come up if a court grants a summary judgment or a motion to dismiss, or if parties wish to settle early.

The second problem is that the withheld information must be material. The materiality requirement is a "but-for" test and requires a court to run an interesting thought experiment.[108] Specifically, the court has to determine if a hypothetical examiner would have rejected the patent application had the examiner been aware of the undisclosed information.[109] "Materiality" is determined by "apply[ing] the preponderance of the evidence standard and giv[ing the] claims their broadest reasonable interpretation."[110] The problem with allowing courts to make this decision is the fact that most judges are not trained in the sciences. In contrast, pharmaceutical patent examiners are among the most educated at the patent office, with the majority having a Ph.D.[111] Thus, it might be difficult for a judge, who likely is not a person of ordinary skill in the art and is not trained in chemistry or biology, to determine if the FDA information might have made a difference to a hypothetical examiner. This inquiry is best suited for a patent examiner (or team of patent examiners) who is familiar with the science behind the invention.

Finally, an "accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it."[112] Direct evidence of deceptive intent is rare, so a court usually must infer intent from indirect and circumstantial

106. Hricik, *supra* note 21; *Exergen Corp.*, 575 F.3d at 1318, 1327.

107. *See generally* 21 C.F.R. § 601.51 (2021) (discussing the confidentiality of data and information in applications for biologics licenses).

108. *Therasense, Inc.*, 649 F.3d at 1291–92, 1296.

109. *Id.*

110. *Id.*

111. Tu et al., *supra* note 22 (manuscript at 37, 39) (showing that over 70% of the patent examiners in TC 1600 have advanced degrees).

112. *Therasense, Inc.*, 649 F.3d at 1290.

evidence.[113] Additionally, when there are multiple possible reasonable reasons for withholding a reference or conflicting statements, intent to deceive cannot be found.[114] This standard is difficult to meet because it requires the court to get into the mind of the applicant. Without deceptive intent, the inequitable conduct defense fails. In contrast, if the USPTO is able to find the relevant reference on its own during prosecution, the state of mind of the applicant is irrelevant.[115] Thus, the scienter element necessary for inequitable conduct is not an element needed during patent prosecution if the reference is disclosed to the examiner.

C. Post Grant Review

Ex parte reexamination, IPR, and supplemental examination are three post-grant procedures where a third party or an applicant may get the Patent Office to consider prior art references or to correct errors made during prosecution.[116] However, there are significant issues with all three procedures when it comes to FDA-generated information.

1. Ex Parte Reexamination. Ex parte reexamination is governed under 35 U.S.C. § 302.[117] Ex parte reexamination allows "any person at any time" (including the USPTO Director) to file a request that the USPTO reopen prosecution to consider new information.[118] There are, however, some significant restrictions to this process.

The first and most significant restriction to ex parte reexamination is that it can only be based on: (1) "patents or printed publications";[119] or (2) "statements of the patent owner filed in a proceeding before a Federal Court or the Office in which the patent owner took a position on the scope of any claim of a

113. *Id.* at 1290–91.

114. *Id.*

115. MPEP § 2141 (9th ed. Rev. 10, June 2020) (stating guidelines for determining obviousness).

116. 35 U.S.C. §§ 302–303 (permits any person to consider prior art patents or printed publications that may create a substantial new question of patentability); MPEP § 2209 (9th ed. Rev. 10, June 2020); 35 U.S.C. § 257 (stating that a request for supplemental examination may be lodged to "consider, reconsider, or *correct* information believed to be relevant to the patent" (emphasis added)).

117. *See also* MPEP § 2209 (9th ed. Rev. 10, June 2020).

118. *See* 35 U.S.C. § 302 (request for reexamination) and § 303 (determination of issue by Director) ("On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 or 302.").

119. 35 U.S.C. § 301(a)(1).

particular patent."[120] The rationale behind limiting ex parte reexamination to patents and printed publication is based on the idea that these types of prior art do not present difficult issues of fact that are better resolved by courts. The rationale behind the use of statements of the patent owner before a federal court or the USPTO is to prevent the patentee from making conflicting statements about the scope of the claims or prior art during litigation.

Second, the reexamination will only be granted if there is a "substantial new question of patentability."[121] The rationale behind the "substantial" and "new" requirement is to "bar reconsideration of any argument already decided by the Office."[122] The "new" requirement also helps to prevent vexatious filings by third parties that wish to harass the patent owner. The "new" reference, however, can be a reference that was already considered by the office but "presented in a new light or a different way that escaped review during earlier examination."[123] The "substantial" requirement is a fairly low bar, as most reexaminations are granted by the USPTO.[124]

The USPTO has three months to determine if they will institute the reexamination.[125] This determination is made by the "Central Reexamination Unit" (CRU).[126] If the USPTO determines that there is a substantial new question of patentability, then prosecution of the patent will reopen. All ex parte reexaminations are conducted with "special dispatch."[127]

Once prosecution is reopened, the claims will be considered anew in light of the new references. The patent is not given the presumption of validity.[128] During reexamination, the patentee

120. *Id.* § 301(a)(2).

121. *Id.* § 303.

122. H.R. REP. NO. 1037, at 7 (1980).

123. MPEP § 2216 (9th ed. Rev. 10, June 2020).

124. 265/284 (93%), 146/197 (74%), and 163/167 (98%) of ex parte reexamination requests were granted in 2021, 2020, and 2019, respectively. *Reexamination Operational Statistics*, USPTO, https://www.uspto.gov/sites/default/files/documents/reexamination-op-stats-FY22Q1.pdf [https://perma.cc/ADS2-BZ9S] (Mar. 2022).

125. 35 U.S.C. § 303(a). If the USPTO denies the reexamination request, the requesting party may appeal this decision to the Director of the USPTO, but the Director's decision is final and non-appealable. *Id.* § 303(c).

126. MPEP § 2236 (9th ed. Rev. 10, June 2020).

127. 35 U.S.C. § 305.

128. *In re* Etter, 756 F.2d 852, 856–58 (Fed. Cir. 1985).

may make narrowing claim amendments; however, the scope of the claims cannot be enlarged.[129] Examination is usually performed by a senior experienced examiner from the CRU who did not originally review the patent.[130]

Ex parte reexamination concludes when the Director issues a "certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable."[131] A canceled claim is void, and it is as if the patent never issued with that canceled claim. If the reexamination confirms the validity of the claim, that claim retains the same legal status that it had before the reexamination. Finally, if a claim is amended, then the new claim has "the same effect as that specified [for new claims in] reissued patents."[132]

As discussed in Part IV below, FDA information does not fit well with ex parte reexamination because FDA information is not a patent or printed publication. Ex parte reexamination would, however, allow the Director to throw the patent back into prosecution at any time during the life of the patent.

2. Inter Partes Review. IPR is a trial proceeding conducted by the Patent Trial and Appeal Board (PTAB), an Article I court.[133] The IPR process allows a third party who is not the patent owner

129. MPEP §§ 2209, 2249 (9th ed. Rev. 10, June 2020).

130. *See* John Cottingham, Director, Central Reexamination Unit, Patent Public Advisory Committee Quarterly Meeting: Central Reexamination Unit (CRU) (May 5, 2016), https://www.uspto.gov/sites/default/files/documents/20160505_PPAC_Operations_Update.pdf [https://perma.cc/G5TZ-CQ62] (showing in Slide 19 that the CRU consists of eighty-four GS-15 Primary Patent Examiners "with an average of 15-20 years of examining experience"); *see also* MPEP § 2255 (9th ed. Rev. 10, June 2020) (stating that the "examination will ordinarily be conducted by the same patent examiner who made the decision on whether the reexamination request should be granted"); *id.* § 2236 (stating that the CRU Supervisory Patent Examiner "will assign the reexamination request to a primary examiner, other than the examiner who originally examined the patent application.").

131. 35 U.S.C. § 307(a).

132. *Id.* § 307(b); *see* Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 977 (Fed. Cir. 1986). There are also issues of res judicata and collateral estoppel in reexamination proceedings, which are beyond the scope of this Article. *See* MPEP §§ 2242, 2259, 2286 (9th ed. Rev. 10, June 2020).

133. Janet Gongola, T*he Patent Trial and Appeal Board: Who Are They and What Do They Do?*, USPTO (2019), https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/patent-trial-and-appeal-board-who-are-they-and-what [https://perma.cc/CU9S-DB3D]; KEVIN J. HICKEY & VICTORIA L. KILLION, CONG. RSCH. SERV., SUPREME COURT PRESERVES PATENT TRIAL AND APPEAL BOARD, BUT WITH GREATER EXECUTIVE OVERSIGHT 1 (2021), https://crsreports.congress.gov/product/pdf/LSB/LSB10615 [https://perma.cc/S3XB-SH42].

to challenge the patentability of one or more claims.[134] The basis for the challenge can only be based under 35 U.S.C. § 102 (anticipation) or § 103 (obviousness) and "only on the basis of prior art consisting of patents or printed publications."[135] The USPTO fees associated with an IPR are $19,000 for the IPR request and $22,500 for post-institution fees.[136] However, with attorney fees included, the average life science IPR is $774,000.[137]

The decision to *institute* the IPR is up to the Director and that decision is final and non-appealable.[138] IPRs are ex parte proceedings that typically terminate within one year if the IPR is instituted.[139] The institution decision is based upon a showing that "there is a reasonable likelihood that the petitioner would prevail with respect to at least one claim challenged."[140]

Limited discovery is authorized during an IPR. Discovery can include cited documents, cross-examination of declaration testimony, and information inconsistent with positions advanced during the IPR and is open to "what is . . . necessary in the interests of justice."[141]

During the IPR, the patentee can cancel the claim, propose substitute claims, or amend the claims so long as the amended claims do not enlarge the scope of the patent or introduce new matter.[142] The patentee can also file a response after the

134. 35 U.S.C. § 311(a).

135. *Id.* § 311(b); MPEP § 2131 (9th ed. Rev. 10, June 2020); *see also* 35 U.S.C. § 103.

136. *USPTO Fee Schedule*, USPTO, https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule [https://perma.cc/L9PL-TKDC] (Oct. 1, 2022) (showing that fees listed are for IPRs with up to twenty claims). These fees are not reduced for small or micro entities.

137. Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, J.L. & BIOSCIENCES, July—Dec., 2022, at 1, 19, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9439849/ [https://perma.cc/3S4L-MEJW].

138. 35 U.S.C. § 314(d).

139. *Id.* § 316(a)(11). However, the Director "may, for good cause shown, extend the 1-year period by not more than 6 months." *Id.*

140. *Id.* § 314(a); *see also Inter Partes Review*, USPTO, https://www.uspto.gov/patents/ptab/trials/inter-partes-review [https://perma.cc/T9EK-MNKH] (last visited Sept. 1, 2022).

141. Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 48612, 48622 (Aug. 14, 2012) (discussing the "interest of justice" standard); *see* Garmin Int'l, Inc. v. Cuozzo Speed Tech. LLC, IPR2012-00001, Paper No. 26 (P.T.A.B. Mar. 5, 2013) (explaining the Board's decision, which discusses factors to consider when moving for additional discovery); *see also Archive of Representative Orders, Decisions, and Notices,* USPTO, https://www.uspto.gov/patents/ptab/decisions/representative-orders-decisions-notices [https://perma.cc/7W37-4XAS] (last visited Aug. 8, 2022).

142. 35 U.S.C. § 316(d).

institution of an IPR.[143] Additionally, the petitioner may supplement information in the petition for IPR within one month of the institution date.[144] The IPR is open to the public, but a party may seek to keep confidential information sealed by filing a motion to seal.[145]

If the PTAB decides to institute the IPR, there are three ways that the proceeding can end. Most commonly, the IPR will terminate with a final written decision by the PTAB. The PTAB can find all claims patentable, unpatentable, or a mix of the two. Alternatively, the parties could settle the case, which would terminate the IPR.[146] Finally, the patentee could make a "request for adverse judgment," which allows the board to enter judgment against the patent owner, and the claims at issue are canceled.[147]

Estoppel also applies to IPRs. Specifically, a petitioner in an IPR "may not request or maintain" a subsequent proceeding before the USPTO with respect to any challenged patent claims "on any ground that the petitioner raised or reasonably could have been raised" in the IPR.[148] Additionally, an IPR petitioner cannot assert in a subsequent district court or International Trade Commission (ITC) action that a "claim is invalid on any ground that the petitioner raised or reasonably could have raised" in the IPR.[149] On the other side of the coin, the patent owner is estopped from taking action inconsistent with any adverse IPR judgment.[150]

143. See MPEP § 2601.01 (9th ed. Rev. 10, June 2020) for a flowchart of the various stages of an inter partes reexamination proceeding (showing a patent owner response (1.945) after reexamination is ordered (1.931) and the initial office action is issued (1.935)).

144. 37 C.F.R. § 42.123(a)(1) (2021).

145. 35 U.S.C. § 316(a)(1) and 37 C.F.R. § 42.14 (2021) show that the default rules are that all papers filed in an IPR are open and available for access by the public; a party, however, may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion. It is, however, only "confidential information" that is protected from disclosure. 35 U.S.C. § 316(a)(7).

146. 35 U.S.C. §§ 317, 318(a); *Inter Partes Review—Parties Favor Settlement over Board Decisions*, FOLEY & LARDNER: PHARMAPATENTS (Sept. 25, 2014), https://www.foley.com/en/insights/publications/2014/09/inter-partes-review--parties-favor-settlement-over [https://perma.cc/3R9V-W6QH].

147. There are strategic reasons why a patentee may request adverse judgment. *See* Matthew Bultman, *4 Times Patent Owners May Want Adverse Judgment at PTAB*, LAW360 (Nov. 14, 2016, 3:23 PM), https://www.law360.com/articles/861675/4-times-patent-owners-may-want-adverse-judgment-at-ptab [https://perma.cc/GG68-WBR3].

148. 35 U.S.C. § 315(e)(1).

149. *Id.* § 315(e)(2).

150. 37 C.F.R. § 42.73(d)(3) (2021).

Finally, either party, if dissatisfied with the PTAB's final written decision, can appeal to the Federal Circuit.[151]

3. Supplemental Examination. Supplemental examination is governed under 35 U.S.C. § 257.[152] The procedures used in supplemental examination mirror many of the procedures of ex parte reexamination.[153]

Similar to ex parte reexamination, supplemental examination can be requested "at any time during the period of enforceability of the patent."[154] "A patent owner may request supplemental examination . . . to consider, reconsider, or correct information believed to be relevant to the patent."[155] Thus, in contrast to ex parte reexamination, supplemental examination is "not limited to patents and printed publications."[156] Furthermore, "supplemental examination may involve any ground[s] of patentability, such as . . . patent eligible subject matter, anticipation, public use or sale, obviousness, written description, enablement, indefiniteness, and double-patenting."[157]

Once a patent owner files the request for supplemental examination, the USPTO has three months to determine if there is a "substantial new question" affecting any claim of the patent raised by the patent owner's submitted information.[158] Similar to ex parte reexamination, the substantial new question determination is made by a primary examiner from the CRU who did not originally examine the patent application.[159] If the USPTO determines that there is a substantial new question of patentability based on this new information, then it will commence

151. 35 U.S.C. §§ 141(a), 319. In contrast, under 35 U.S.C. § 314(d), a party is statutorily precluded from appealing the Board's decision whether to *institute* an IPR.

152. *See* MPEP § 2209 (9th ed. Rev. 10, June 2020).

153. See *id.* § 2823 for the specific differences between ex parte reexamination (35 U.S.C. § 302) and supplemental examination (35 U.S.C. § 257).

154. 37 C.F.R. § 1.601(c) (2020); *see also* MPEP § 2808 (9th ed. Rev. 10, June 2020).

155. 35 U.S.C. § 257(a); *see also* MPEP § 2801 (9th ed. Rev. 10, June 2020) (stating that the information may include "a sales invoice, or a transcript of an audio or video recording").

156. MPEP § 2801 (9th ed. Rev. 10, June 2020).

157. *Id.*

158. 35 U.S.C. § 257; *see also* MPEP § 2816 (9th ed. Rev. 10, June 2020) (stating that the standard for a substantial new question "will be the same as the standard set forth in the MPEP § 2242 for *ex parte* reexaminations filed under 35 U.S.C. § 302").

159. MPEP § 2822 (9th ed. Rev. 10, June 2020).

a traditional ex parte reexamination.[160] Alternatively, the USPTO could determine that there is no substantial new question of patentability and issue a certificate to this effect.[161]

If, during supplemental examination, the office finds that there may have been material fraud committed on the Office, the supplemental examination will continue.[162] The Director then has a number of options available, including invalidating all claims or specific claims in the patent.[163] Additionally, the matter will be referred to the U.S. Attorney General.[164]

If the USPTO considers the new information and still finds the claims valid, then it bars federal courts from holding that patent unenforceable "on the basis of conduct relating to information" considered during supplemental examination.[165] Thus, supplemental examination acts to inoculate patents against challenges of inequitable conduct.

As discussed in Part IV below, FDA information also does not fit well with supplemental reexamination because only *the patent owner* may request supplemental examination.[166] Accordingly, the Director cannot, sua sponte, order supplemental examination.

This Article offers two solutions to the problem of conflicting submissions. The first solution relies on creation of a new FDA Reexamination process. This new FDA Reexamination process would be a hybrid between ex parte reexamination and supplemental examination. FDA Reexamination would allow the Director to order Reexamination based on FDA information submitted by the drug sponsor. The second solution calls for a return to a pre-*Therasense* world when examining information was sent to the FDA and USPTO.

IV. CREATION OF AN FDA REEXAMINATION PROCESS

This Article attempts to outline the areas of synergy where the FDA could help the USPTO with the examination and issuance of both small-molecule and biologic drugs. Specifically, the FDA

160. 35 U.S.C. § 257(b); *see also* MPEP § 2817 (9th ed. Rev. 10, June 2020).

161. 35 U.S.C. § 257(a); *see also* MPEP § 2817 (9th ed. Rev. 10, June 2020).

162. 35 U.S.C. § 257(e); MPEP § 2819 (9th ed. Rev. 10, June 2020).

163. 35 U.S.C. § 257(e).

164. *Id.*

165. *See id.* § 257.

166. *Id.* § 257(a); *see also* MPEP § 2803 (9th ed. Rev. 10, June 2020) ("Only a patent owner may file a request for supplemental examination of a patent. The statute does not authorize the Office to accept a request for supplemental examination from a party who is not the patent owner." (citation omitted)).

could help provide information to the USPTO regarding drug sponsor statements about drug safety and efficacy, which are also used during patent prosecution in a time frame that would allow for relevant analysis. Increased collaboration between the two agencies could help prevent inconsistent statements made by firms when trying to obtain drug approval versus patent protection over their drug products.

As detailed in Part II above, there is currently a statute that allows the USPTO to request information from the FDA. However, the main limitations are that: (1) the USPTO does not have the expertise to analyze this information; and (2) the patents are usually already issued when the relevant FDA information is produced. Drug sponsors further have incentives to present conflicting information or hide key references from the USPTO because they know that the FDA review process is kept confidential and that there is currently little collaboration between the FDA and USPTO. Furthermore, the doctrine of inequitable conduct and the current post grant review processes are tools that are ill-suited to deal with the problems associated with FDA-generated information.

To address these problems, I propose the creation of a new "FDA Reexamination" process. This new procedure would mirror many aspects of the current ex parte reexamination procedure under 35 U.S.C. § 302 and supplemental examination under 35 U.S.C. § 257 but will also have some significant deviations from both frameworks. Currently, both ex parte reexamination and supplemental examination are rarely used procedures compared to IPR.[167]

FDA Reexamination has several benefits. First, and most important, FDA Reexamination would be initiated automatically after FDA approval. This is key because FDA Reexamination would: (1) not need to be "plead with particularity"; and (2) act as a deterrent.[168]

---

167. Both ex parte reexamination and supplemental examination are not used often. There have only been 284, 197, and 163 ex parte reexaminations and twenty-six, thirty-nine, and twenty-three supplemental examinations in fiscal years 2021, 2020, and 2019, respectively. In contrast there were 1,308, 1,429, and 1,394 inter partes review petitions in fiscal years 2021, 2020, and 2019, respectively. *See Statistics*, USPTO, https://www.uspto.gov/patents/ptab/statistics [https://perma.cc/6AQE-RVTP] (last visited Oct. 25, 2022); *Reexamination Operational Statistics*, *supra* note 124.

168. *See supra* notes 21–23 and accompanying text.

If applicants know *ex ante* that their application will receive additional review by the USPTO after FDA approval, they might be less inclined to make conflicting statements to the FDA or USPTO. Second, the review will be done by experts in the field and not by judges or juries who may not have the scientific or medical background needed to analyze these data. Third, there would be no "intent to deceive" requirement, which is present in inequitable conduct.[169] The merits of the information would be reviewed and analyzed by those who know the field and could determine the relevance of the reference for patentability determinations.

FDA Reexamination would be a hybrid procedure that combines elements of both ex parte reexamination and supplemental examination. Similar to ex parte reexamination, FDA Reexamination would allow the Director to consider new information at any time during the patent's lifetime.[170]Also similar to use of the patentee's statements during litigation, FDA Reexamination would allow the Director to use patentees' statements to the FDA.[171] Unlike ex parte reexamination, but similar to supplemental examination, this new information would not be limited to patents and printed publications and could be based on arguments other than anticipation and obviousness.[172]

In summary, FDA Reexamination would require the FDA to send relevant drug approval information to the USPTO automatically after drug approval. This information would then be reviewed by a panel of three senior examiners with pharmaceutical patent experience. One of these three senior examiners would be an FDA expert who has a medical degree and could analyze the complex drug application information with an eye towards patentability. This team of examiners would then *confidentially* review the FDA information to determine if the FDA information creates a substantial new question of patentability and determine if it is necessary to reopen prosecution.

169. *See supra* note 21 and accompanying text.

170. *See supra* note 118 and accompanying text.

171. *See supra* notes 117–120.

172. *See* Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and to Revise Reexamination Fees, 77 Fed. Reg. 48828 (Aug. 14, 2012) (to be codified at 37 C.F.R. pt. 1) ("The information that may be presented in a request for supplemental examination is not limited to patents and printed publication, and may include, for example, issues of patentability under 35 U.S.C. 101 and 112."). This is in contrast to ex parte reexamination, which can only be based on patents and printed publications. *See supra* Section III.C.1.

FDA Reexamination would be under a "reexamination" type procedure because the patent most likely has already been granted.[173] Similar to ex parte reexamination, FDA Reexamination would allow the USPTO Director to sua sponte reopen prosecution on an already granted patent if there was a substantial issue of patentability.[174] Additionally, similar to ex parte reexamination, FDA Reexamination could occur any time during the period of enforceability of a patent.[175] Unlike ex parte reexamination, this procedure could also be used before the patent grant (if FDA approval occurs before the patent issues).[176] Allowing the USPTO to automatically reopen prosecution even after a patent is granted solves the timing issue created by the fact that FDA approval usually occurs long after the patent grant but also allows the USPTO to consider FDA information if FDA approval occurs before the patent grant.

Similar to supplemental examination, FDA Reexamination could be based on any type of information. This is important because ex parte reexamination is usually limited to "patents or printed publications."[177] The information used in an FDA Reexamination would be significantly different from normal "prior" art and cannot be considered the same as the "patents or printed publications" required by ex parte reexamination.[178]

Table 2 summarizes the similarities and differences between ex parte reexamination, supplemental examination, and the proposed new FDA Reexamination procedure. Accordingly, to create an FDA Reexamination procedure, Congress could either: (1) amend the current ex parte reexamination process to allow for information and arguments usually included in supplemental examination; or (2) allow the Director to sua sponte order a supplemental examination.

---

173. Similar to the decision in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1370, 1374–75 (2018), FDA Reexamination would simply be a reconsideration of the patent grant, and the USPTO should have authority to conduct that reconsideration.

174. 35 U.S.C. § 304.

175. *Id.* § 303(a). ("*On his own initiative, and any time*, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 or 302." (emphasis added)).

176. *See infra* notes 198–200.

177. 35 U.S.C. §§ 301, 302; *see also* MPEP § 2202 (9th ed. Rev. 10, June 2020).

178. 35 U.S.C. § 301.

Table 2

	Ex Parte Reexamination	**Inter Partes Review**	**Supplemental Examination**	**FDA Reexamination**
Who Requests	Anyone (patentee, third party, or USPTO Director).	Not the patent owner.	Patent owner only.	USPTO Director.
When Can You Request?	Anytime during enforcement.	Most commonly nine months after the grant of a patent.	Anytime.	Automatically when FDA approval concludes.
Information Considered	Patents, printed publications, and statements made by the patent owner in federal court or the USPTO.	Patents and printed publications.	Anything.	FDA-submitted information.
Grounds for Institution	35 U.S.C. §§ 102 and 103 (novelty and obviousness only).	35 U.S.C. §§ 102 and 103 (novelty and obviousness only).	Any (including 35 U.S.C. §§ 101, 102, 103, and 112).	Any (including 35 U.S.C. §§ 101, 102, 103, and 112).
Who Examines	Usually, three patent examiners from CRU who did not examine the original patent application.	PTAB (a panel of three administrative law judges).	Patent examiner from CRU who did not examine the original patent application.	Three senior patent examiners. One of those examiners is familiar with clinical trials and how to interpret FDA information.
Time to Determine If There Is a Substantial New Question of Patentability	Three months.	Three months (to determine if there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged).	Three months.	One year.
Speed of Prosecution	Special dispatch.	Decision is made twelve months after institution of IPR.	Special dispatch.	Not special.
Public Proceedings	Open to public via Public PAIR.	Open to public via PTAB E2E (PTAB end-to-end system).	Open to public via Public PAIR.	Confidential until final certificate issued.

There are several hurdles to creating a new FDA Reexamination procedure. First, the type of information that the USPTO could consider would need to be broadened to include

FDA-generated information. Second, the timing of the review process would need to be altered to allow for reexamination not only after the patent grants but also before the patent grants. Third, the personnel used in FDA Reexamination should be amended to require an FDA member who is familiar with clinical trials and interpretation and analysis of FDA-generated information. Fourth, substantive rejections should be based not only on anticipation and obviousness but also written description, enablement, and inequitable conduct. Finally, FDA Reexamination would not occur with special dispatch due to the high volume of documents that would need to be considered by the examiners. To address the cloud on title issues that could be presented due to a long FDA Reexamination period, the FDA Reexamination could be kept confidential until the substantial question of patentability determination was made.

A. Who Institutes FDA Reexamination

FDA Reexamination would be instituted by the USPTO Director automatically after drug approval by the FDA. The information would be sent directly to the USPTO to be reviewed by a team of experienced examiners. This protocol would be different from supplemental examination and IPRs but similar to ex parte reexamination.

Unlike supplemental examination[179] or IPRs[180], the Director would sua sponte institute FDA Reexamination after FDA drug approval. The ability for the Director to initiate reexamination is not novel, because ex parte reexamination can already be initiated by the Director.[181]

Interestingly, the Director may not be able to file an IPR sua sponte. Unlike ex parte reexamination, which can be filed by "[a]ny person at any time,"[182] IPRs can be filed by "a person who is not

179. Only the patent owner can initiate supplemental examination. *See supra* Section III.C.3.

180. Anyone who is not the patent owner can initiate an IPR. *See supra* Section III.C.2.

181. *See supra* Section III.C.1.

182. 35 U.S.C. § 302; *see* MPEP § 2239 (9th ed. Rev. 10, June 2020); *America Invents Act (AIA) Frequently Asked Questions*, USPTO, https://www.uspto.gov/patents/laws/america-invents-act-aia/america-invents-act-aia-frequently-asked [https://perma.cc/84AX-FGP5] (last visited Sept. 14, 2022) ("A person who is not the patent owner and has not previously filed a civil action challenging the validity of a claim of the patent may petition for an inter partes review of the patent.").

the owner of a patent."[183] Although "a person who is not the owner of a patent" is expansive enough to include the Director, the Manual of Patent Examining Procedure (MPEP) does not seem to contain any rules that allow the Director to initiate an IPR.[184] In contrast, ex parte reexamination contains specific rules outlining how the Director can initiate an ex parte reexamination proceeding.[185]

B. Type of Information Used for FDA Reexamination

FDA Reexamination would be based on both public and confidential information submitted by the drug sponsor to the FDA. Use of this type of information is fair because it was known to the applicant and is relevant to the invention in question. Some of this information would also be available to the public via Freedom of Information Act (FOIA) requests. However, some information is kept in confidence at the FDA and thus could not be considered a "printed publication."[186] Accordingly, as discussed below, Congress would likely have to act to include this type of information as prior art.[187]

The largest hurdle to overcome with a new FDA Reexamination procedure is the type of references that would be used. Currently, ex parte reexamination can only be based on: (1) "patents or printed publications";[188] or (2) "statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent."[189] In contrast, the supplemental examination procedure allows the USPTO to consider any "item of information" that the patent owner believes to be relevant to the patentability of the claimed invention.[190] To solve this reference problem, I propose that Congress create a new FDA Reexamination procedure that is a hybrid between the current ex parte reexamination and supplemental examination procedure.

183. 35 U.S.C. § 311.

184. MPEP § 2609 (9th ed. Rev. 10, June 2020).

185. See *id.* § 2239 and 37 C.F.R. § 1.520 (2021), which specifically allow ex parte reexamination at the initiative of the Director.

186. 21 C.F.R. § 20.61 (2021).

187. *See infra* Section IV.B.6.

188. 35 U.S.C. § 301(a)(1).

189. *Id.* § 301(a)(2).

190. MPEP § 2809.01 (9th ed. Rev. 10, June 2020).

1. Use of Patents and Printed Publication—Ex Parte Reexamination. Usually, ex parte reexamination is granted on the basis of prior art patents or printed publications. The statutory phrase "printed publications" is defined as references that have been "sufficiently accessible to the public interested in the art" before the critical date of the invention.[191] "[D]issemination and public accessibility are . . . keys to the legal determination whether a prior art reference [is considered] published."[192] Although extensive review documents are made available at the FDA's Drugs@FDA website, and additional information is available via FOIA request, the types of information needed to invalidate patents (such as the conversations between the drug sponsor and the FDA) may not be included in the publicly disclosed information.[193] The difficulty with FDA information is that it is usually not disseminated and not everything is publicly accessible. Most information generated for the FDA is kept confidential.[194]

The scope of information available for Director-initiated ex parte reexamination may be broader than IPR. In *Lonardo*, the Federal Circuit determined that obviousness-type double patenting based on a non-prior art patent was available as a challenge in ex parte reexamination.[195] *Lonardo* held that it was permissible for the challenger to use a non-prior art patent in ex parte reexamination under § 303(a), and not § 301(a), because § 303(a) permits the Director to institute a reexamination after "consideration of *other* patents or printed publications."[196] Accordingly, when the Director initiates ex parte reexamination, she may consider other non-prior art patents.[197]

191. *In re* Klopfenstein, 380 F.3d 1345, 1348–52 (Fed. Cir. 2004) (quoting *In re* Cronyn, 890 F.2d 1158, 1160 (Fed. Cir. 1988)).

192. *Id.* at 1348.

193. *See Drugs@FDA: FDA-Approved Drugs*, FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm [https://perma.cc/W2TL-S4AF] (last visited Sept. 14, 2022).

194. *See* FDA, REGULATORY PROCEDURES MANUAL ch. 3 § 3–7 (2022); *see also* 21 C.F.R. § 20.88 (2021) (state); 21 C.F.R. § 20.85 (2021) (federal); 21 C.F.R. § 20.61 (2021) (national defense and foreign policy).

195. *In re* Lonardo, 119 F.3d 960, 966, 968 (Fed. Cir. 1997).

196. *Id.* at 966 (emphasis added) (quoting 35 U.S.C. § 303(a) (1994)).

197. 35 U.S.C. § 303(a); *In re* Lonardo, 119 F.3d at 966.

2. Statements Used in a Federal Court or at the USPTO—Ex Parte Reexamination. In addition to patents and printed publications, ex parte reexamination can be granted based on "statements of the patent owner filed in a proceeding before a Federal court or the [Patent] Office."[198] Similar to § 301(d), the legislative history of this section makes clear that this information can only be used "to determin[e] the meaning of a patent claim in ex parte reexamination proceedings that have already been ordered and in inter partes review and post grant review proceedings that have already been instituted."[199]

35 U.S.C. § 301(d) provides that the USPTO may consider a submitted claim scope statement "to determine the proper meaning of a patent claim" in ex parte reexamination (§ 304), IPR (§ 314), or post grant review (§ 324).[200] The legislative history states that "[t]his addition will *counteract the ability of patent owners to offer differing interpretations of prior art in different proceedings*."[201]

However, the legislative history goes on to state:

> These written statements, which include documents, pleadings or evidence from proceedings that address the patent owner's statements, shall not be considered for any purpose other than to determine the proper meaning of the claims that are the subject of the request in a proceeding. Specifically, the Committee does not intend these statements to be a basis for the institution of a reexamination proceeding. Reexaminations will continue to be available only on the basis of "patents or printed publications."[202]

198. 35 U.S.C. § 301(a)(2).

199. Changes to Implement Miscellaneous Post Patent Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 46616 (Aug. 6, 2012) (to be codified at 37 C.F.R. pts. 1, 5, 10, 11, 41) [hereinafter Changes to Implement].

200. *Id.*

201. H.R. REP. NO. 112-98, pt. 1, at 19, 20, 46 (2011) (emphasis added); *see also* Changes to Implement, *supra* note 199, at 46617 ("Permitting submission of these claim scope statements is intended to limit a patent owner's ability to put forward different positions with respect to the prior art in different proceedings on the same patent.").

202. H.R. REP. NO. 112-98, at 46; *see also* Changes to Implement, *supra* note 199, at 46616 ("Section 6(g) of the AIA amends 35 U.S.C. 301 to expand the information that may be submitted in the file of an issued patent to include written statements of a patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of the patent. This amendment limits the Office's use of such written statements to determining the meaning of a patent claim in *ex parte* reexamination proceedings that have already been ordered and in *inter partes* review and post grant review proceedings that have already been instituted.").

The problem with FDA information is that it is not a patent, may not be considered a "printed publication," and is information that is neither made before a federal court or the Patent Office. It is also clear, however, that Congress has allowed this type of information to be used to prevent patentees from proffering conflicting statements about claim scope or the prior art during litigation.[203]

Conflicting statements made by the applicant, whether it be to a federal judge during litigation or the USPTO or any other regulatory agency, pose the same issues. FDA information sent to the USPTO likely could not be considered a "printed publication." Additionally, these statements to the FDA are not made "before a Federal Court or the Office." Accordingly, Congress would likely need to amend 35 U.S.C. § 301(a) to include information that is submitted to any other regulatory body to prevent conflicting statements made by the patentee.

3. Use of Patents and Printed Publications—Inter Partes Review. IPR also fails to capture FDA-submitted information for many of the same reasons that ex parte reexamination fails. IPR fails when it comes to FDA information because (1) it is not a patent or printed publication; and (2) the Director may not be able to initiate an IPR sua sponte.[204]

An IPR can only be based on "a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications."[205] A recent Federal Circuit decision reaffirmed the basis of an IPR to be limited to prior art and printed publications.[206]

Thus, the scope of an IPR is slightly narrower than ex parte reexamination, which can be based on patents or printed publications in addition to "statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent."[207]

---

203. Changes to Implement, *supra* note 199, at 46617.

204. 35 U.S.C. § 311(b) (requiring that an IPR be based on 35 U.S.C. §§ 102 or 103 prior art).

205. *Id.*

206. Qualcomm Inc. v. Apple Inc., 24 F.4th 1367, 1369, 1373–74 (Fed. Cir. 2022) (holding that prior art for IPR purposes does not include "applicant admitted prior art").

207. 35 U.S.C. § 301(a).

4. Use of Applicant Admitted Prior Art—Ex Parte Reexamination and Inter Partes Review.

Applicant admitted prior art (AAPA) is defined by the USPTO as:

> A statement by an applicant in the specification or made during prosecution identifying the work of another as "prior art" is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. Where the admitted prior art anticipates the claim but does not qualify as prior art under any of the paragraphs of 35 U.S.C. 102, the claim may be rejected as being anticipated by the admitted prior art without citing to 35 U.S.C. 102.[208]

In sum, this means that anything the applicant classifies as prior art can be used against him as prior art, even if that work would not have been classified as prior art by the USPTO.

Four common types of AAPA include: (1) "admitting that a reference is prior art"; (2) "[c]haracterizing a reference as prior art" (even if it is not technically prior art); (3) "non-reference admitted prior art," where there is "no source for the prior art" except for the admission; and (4) admission of obviousness, which includes "acknowledging a source as analogous art . . . or admitting that a modification . . . is obvious."[209]

One significant exception to AAPA is work created by the same inventive entity. Work created by the "same inventive entity may not be considered prior art against the claims unless it falls under one of the statutory categories."[210] Courts exclude this type of information because when an inventor improves his own work, his foundational work should not be considered prior art.

In a recent Federal Circuit decision, the court stated that AAPA cannot be the *basis* of a ground in an IPR or ex parte

208. MPEP § 2129 (9th ed. Rev. 10, June 2020) (citations omitted).

209. *See* Michael K. Henry, *How to Avoid Applicant Admitted Prior Art in Your Patent Applications*, HENRY PAT. L. FIRM (July 17, 2019), https://henry.law/blog/applicant-admitted-prior-art/ [https://perma.cc/7TA3-QYXY].

210. MPEP § 2129 (9th ed. Rev. 10, June 2020); *see also* Reading & Bates Constr. Co. v. Baker Energy Res. Corp., 748 F.2d 645, 650 (Fed. Cir. 1984) ("[W]here the inventor continues to improve upon his own work product, his foundational work product should not, without a statutory basis, be treated as prior art solely because he admits knowledge of *his own work*. It is common sense that an inventor, regardless of an admission, has knowledge of his own work.").

reexamination under § 302.[211] Accordingly, it is impermissible for a petition to challenge a patent relying solely on AAPA without also relying on a prior art patent or printed publication for IPR under § 311 or ex parte reexamination under § 302.

Both § 311(b) and § 301(a)(1) use identical language, stating "prior art consisting of patents or printed publications." It would be difficult to argue this identical phrase should be interpreted differently for third party-initiated ex parte reexamination under § 302.[212] Accordingly, "§ 311(b) does not permit AAPA . . . to be the basis of a ground in . . . *inter partes* review, because it is not contained in a document that is a prior art patent or prior art printed publication."[213]

In contrast, the courts have not directly addressed the use of AAPA when it comes to Director-initiated ex parte reexamination under § 303. The most relevant case, *Lonardo*, did not directly address AAPA, which could include admissions or conflicting statements made to the FDA. However, *Lonardo* did distinguish § 303(a) from § 301(a) by noting that § 303(a) "is not specifically limited to prior art patents or printed publications" and referred to printed publications as describing "*prior art* submitted by a third party."[214] Accordingly, FDA information might be considered fair game for Director-initiated ex parte reexamination.

5. Use of "Relevant Information"—Supplemental Reexamination. The use of non-patent/non-printed publication material for ex parte reexamination is not completely foreign to the USPTO. As discussed in Section III.C.3, "supplemental examination" under 35 U.S.C. § 257 allows the office to "consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish."[215] The "information" that forms the basis "for supplemental examination is not limited to patents and printed publications, and may include" other issues such as written

211. *See Qualcomm Inc.*, 24 F.4th at 1369.

212. *Id.* at 1374–75.

213. *Id.* at 1375.

214. *In re* Lonardo, 119 F.3d 960, 966 (Fed. Cir. 1997) (emphasis added); *see Qualcomm Inc.*, 24 F.4th at 1374.

215. 35 U.S.C. § 257.

description and enablement.[216] Similar to ex parte reexamination, if a "substantial new question of patentability is raised" by the new information, then reexamination is ordered and conducted according to the ex parte reexamination procedures (except the patent owner will not have the right to file a statement pursuant to 35 U.S.C. § 304).[217] The problem with supplemental examination is that only the patent owner can request supplemental examination, and the Director cannot sua sponte order supplemental examination.[218]

6. Confidential Information. Unless an application is publicly disclosed or acknowledged by the sponsor, the FDA must keep the drug application confidential until the agency sends an approval letter.[219] Some FDA information is publicly available after drug approval; however, there are many exemptions.[220] Accordingly, FDA Reexamination would be based, at least in part, on confidential information submitted to the FDA. This information may contain trade secrets as well as other confidential information. Thus, it is important to keep FDA information confidential, at least until a substantial question of patentability is found.

The use of confidential unpublished information, however, is not completely foreign to patent law. Pre-America Invents Act (AIA) § 102(e) included "secret prior art," which was prior art not immediately available to the public. Section 102(e) type of prior art is "secret" because the effective date of the references is the date on which the reference application was filed, and the USPTO usually holds the patent application in secrecy for at least eighteen months after filing.[221] The rationale for the USPTO's ability to use

216. MPEP § 2802 (9th ed. Rev. 10, June 2020) ("[S]upplemental examination is not limited to patents and printed publications, and may include, for example, issues of patentability under 35 U.S.C. 101 and 112.").

217. 35 U.S.C. § 257(b).

218. *Id.* § 257(a) ("A *patent owner* may request supplemental examination of a patent." (emphasis added)).

219. 21 C.F.R. § 314.430(b), (d) (2021) (explaining if, however, the application has been publicly acknowledged, the FDA may "disclose a summary of selected portions of . . . safety and effectiveness data that are appropriate for public consideration . . . ," such as, for example, data considered at an open session of an advisory committee that is evaluating the drug could be released in summary form).

220. 21 C.F.R. § 314.430(e)(2)–(7) (2021).

221. 35 U.S.C. § 122; MPEP § 2136 (9th ed. Rev. 10, June 2020); Dennis Crouch, *Did the AIA Eliminate Secret Prior Art?*, PATENTLY-O (Oct. 10, 2012), https://patentlyo.com/patent/2012/10/did-the-aia-eliminate-secret-prior-art.html [https://perma.cc/WRN8-KWAX].

secret prior art under § 102(e), however, is different from the rationale for using FDA information.[222]

Use of confidential information in this situation is fair because applicants should not be allowed to hide behind the veil of confidentiality to disclose contradictory statements to FDA and USPTO. Furthermore, if confidential information is necessary to practice and use the claimed invention, it should also be disclosed to enable the invention.[223] However, if certain pieces of FDA information are truly unnecessary to practice the invention and do not help define the scope of the invention, then that information should be redacted from the prosecution history that is placed on Public PAIR.

Although some FDA information might be confidential, this information is likely to be both relevant and material for anticipation, obviousness, as well as written description and enablement reasons. Additionally, Congress has already allowed similar court proceeding information to be used in the context of claim construction or prior art interpretation.[224] Furthermore, use of FDA information for patent prosecution purposes would save litigants time and money because it would help prevent invalid patents from ever issuing or prevent competitors from ever having to bring an invalidity suit. This is especially important for this subset of patents because they are known to be valuable[225] and suffer from a higher inequitable conduct invalidation rate.[226]

7. Post-Grant Information. Some information provided to the FDA may be generated after prosecution and issuance of the

222. Use of 35 U.S.C. § 102(e) art is based on the idea that "but for" the delays at the PTO, "the patent would have been prior art known to the public as of the filing date." Paul W. Leuzzi, *A Re-Evaluation of the Use of 35 U.S.C. 102(e), Secret Prior Art, in Obviousness Determinations*, 29 IDEA 167, 170 (1988).

223. Gregory N. Mandel, *The Generic Biologics Debate: Industry's Unintended Admission that Biotech Patents Fail Enablement*, VA. J.L. & TECH., Fall 2006, at 1, 25.

224. H.R. REP. NO. 112-98, pt. 1, at 12–14, 16–17, 46 (2011); *see also* Changes to Implement, *supra* note 199, at 46615, 46617 ("Permitting submission of these claim scope statements is intended to limit a patent owner's ability to put forward different positions with respect to the prior art in different proceedings on the same patent.").

225. *See generally* David Miller et al., *The Costs of Delayed Generic Drug Entry: Evidence from a Controversial Prostate Cancer Drug Patent*, 37 J. GEN. INTERNAL MED. 668 (2022) (showing that an inappropriately awarded secondary patent costs consumers $2 billion); Tu & Lemley, *supra* note 23.

226. *See* Leadmon et. al, *supra* note 10 (showing that FDA-regulated products account for 56% of Federal Circuit cases that uphold an inequitable conduct finding).

patent. Specifically, information gathered from Phase II and Phase III clinical trials may occur after the patent has already been granted. This timing is logical because many firms are unwilling to invest the hundreds of millions of dollars necessary to undergo clinical trials without a guarantee that they can recoup these costs through the exclusive rights granted by a patent.

Because some FDA information would be gathered only after the patent grants, some FDA information might not be considered "prior" art. I suggest that this information might still be used in an FDA Reexamination procedure. This may seem unfair to the patentee because some of these data might present hindsight bias issues. This may be true when it comes to issues of obviousness.

However, enablement and written description issues do not suffer from this same hindsight bias. Post-grant information may verify or contradict prophetic examples in the patent. Patentees should not be able to rely on prophetic examples to overcome rejections when it is later shown that those prophetic examples do not actually work. Section IV.E.2 has a deeper discussion of how this information might be used.

Accordingly, FDA Reexamination would be a hybrid between ex parte reexamination and supplemental reexamination. Similar to ex parte reexamination, FDA Reexamination would allow the Director to sua sponte reopen prosecution anytime during the life of the patent. Additionally, similar to supplemental examination, the Director could base FDA Reexamination on any new information that could raise a substantial new question of patentability and not just anticipation and obviousness.

C. Timing of FDA Review Process

The two relevant time frames where the USPTO could consider FDA information are: (1) if FDA review of the drug application is completed before the patent issues; and (2) if FDA review of the drug application is completed after the patent issues.

The easier situation is when the FDA review process is completed before the patent issues, because then the information only needs to be transferred from the FDA to the USPTO. Under 21 U.S.C. § 372(d), it is clear that the USPTO can request this confidential information from the FDA "to conduct or cause to be conducted, such research as may be required."[227] Accordingly, there are no significant roadblocks for the USPTO to obtain

227. 21 U.S.C. § 372(d).

information from the FDA if the FDA approval process has completed before the patent issues.

A more complex situation arises when the FDA review process is completed only after the patent issues. Unfortunately, it is far more common that the patent issues before the FDA review process is completed.[228] I suggest allowing the FDA to reopen patent prosecution even after the patent issues. Under 35 U.S.C. § 303, "[o]n his own initiative, and *any time*, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 or 302."[229] Accordingly, FDA Reexamination would borrow from 35 U.S.C. § 303, which would allow the USPTO Director to reopen prosecution any time during the life of the patent.

Thus, the FDA would automatically send its information to the USPTO, whether FDA approval occurs before or after the patent issues. The FDA drug sponsor would be required to list all patents that are associated with the FDA approval information. Failure to list the patents would constitute inequitable conduct, which should invalidate the claims of any nondisclosed patents. The USPTO would then determine if it should institute an FDA Reexamination.[230]

D. Who Reviews the FDA Information at the USPTO

Similar to current reexamination protocol, FDA Reexamination should be conducted by a team of examiners and not just one single examiner.[231] Current reexamination practice already operates through a team of three senior primary examiners at the CRU.[232] Additionally, this team should be comprised of senior examiners with at least ten years of patent examination experience. At least one of these examiners should

228. Darrow et al., *supra* note 24 (unpublished manuscript at 2).

229. 35 U.S.C. § 303(a) (emphasis added).

230. *See infra* Section IV.E.

231. Tu & Lemley, *supra* note 23, at 1710.

232. See *Central Reexamination Unit*, USPTO, https://www.uspto.gov/about-us/organizational-offices/office-commissioner-patents/office-deputy-commissioner-patent-37 [https://perma.cc/WJG2-94XK] (last visited Oct. 26, 2022) for details on the CRU; MPEP § 2271.01 (9th ed. Rev. 10, June 2020).

also be from the FDA and have the background necessary to evaluate medical information and clinical trial data.

Coordinating reexamination by senior examiners at the USPTO in conjunction with the FDA is important for at least two reasons: (1) data gathering and interpretation of medical data and clinical trials can be difficult without deep knowledge of the FDA approval process; and (2) analysis and comparison of prophetic examples in conjunction with clinical data can be challenging. I suggest that these senior examiners have a graduate degree in some Abbreviated New Drug Application (ANDA) related field and at least ten years of patent examination experience.

Additionally, at least one member of the three-member team should be from the FDA or have a deep understanding of FDA protocol and procedure. Currently, no patent examiner in TC 1600 has a medical degree.[233] This FDA member should have experience gathering, evaluating, and interpreting clinical data with an eye towards understanding how this information might affect patentability requirements. Thus, the FDA member should have a medical degree and/or have the ability to critically analyze clinical data. This team member should have knowledge of databases that are not typically searched by USPTO examiners, such as historical drug labels, correspondence between the FDA and the drug sponsor, risk evaluation and mitigation strategy (REMS) data, drug promotional materials, and other documents submitted to the FDA by the drug sponsor.[234]

E. Substantive Analysis of FDA Information by the USPTO

Similar to ex parte reexamination, the USPTO would only reopen prosecution if there was a "substantial new question of patentability."[235] This decision would be made based on FDA information gathered after approval or denial of the drug application.

Similar to ex parte reexamination, a substantial new question of patentability would be based on: (1) an obviousness or anticipation; (2) a written description or enablement (by

233. *See* Tu et al., *supra* note 22, at 27–28, 39 (showing that over 70% of the patent examiners in TC 1600 have advanced degrees, but no current examiner in TC 1600 has a medical degree). TC 1600 provides examination for patent applications in biotechnology and organic fields. Most Orange Book and Purple Book patents come from this technology center. *Id.* at 27–28.

234. Tu & Lemley, *supra* note 23, at 1679.

235. 35 U.S.C. § 303(a).

describing or explaining key components and/or limitations of the invention); and/or (3) definiteness (clarifying the scope of the claim). Conventional information necessary to obtain FDA regulatory approval includes: analysis of the target condition and available treatments, assessment of benefits and risks from clinical data, and strategies for managing risks.[236] Although FDA information is used for different purposes (safety and efficacy), some of the information disclosed by the drug sponsor will likely overlap with patentability requirements and/or help define the scope of the patent. Currently, there is little interaction between the FDA and USPTO.[237]

1. Novelty and Obviousness. FDA information would most likely be used to help determine if an anticipation and/or obviousness issue creates a substantial new question of patentability. Obviousness arguments are the basis for most pharmaceutical patent invalidations.[238] Specifically, drug applicants may submit information to the FDA arguing that changes in a drug would result in known predictable effects or were simply minor changes over prior formulations. These statements are made to the FDA in an effort to avoid additional laboratory experiments and expensive clinical studies.

However, these statements could go directly against obviousness arguments made to the USPTO. Specifically, these FDA statements might conflict with statements made to the USPTO (to overcome an obviousness rejection) arguing that a result was "unexpected" or yielded surprising benefits.[239]

Additionally, FDA communications could help uncover new prior art or actually create prior art that may be relevant to the patentability question. For example, in the IPRs for U.S. Patent Nos. 7,765,106, 7,765,107, 7,895,059, 8,457,988, 8,589,182, and 8,731,963, the FDA disclosures were used as § 103 art as well as

236. *Drug Development and Review Definitions*, *supra* note 29.

237. Darrow, *supra* note 88, at 401–03.

238. Tu & Lemley, *supra* note 23, at 1692–93 (showing in Figure 6 that obviousness arguments are the basis of almost 60% of pharmaceutical patent invalidations).

239. *See* Belcher Pharms., LLC. v. Hospira, Inc., 11 F.4th 1345, 1353–54 (Fed. Cir. 2021). In *Belcher*, the patentee argued to the FDA that a pH change was "a very minor change not requiring additional stability studies." Patentee then argued to the USPTO that those same pH changes were unexpected and "seemed impossible" to overcome an obviousness rejection. *Id.* at 1348–49.

uncovered new prior art references that eventually invalidated the patent.[240]

Similarly, FDA disclosures could result in disclosure of relevant prior art references.[241] For example, in *Belcher*, the patentee disclosed two key references to the FDA arguing that the new drug characteristic was "a well-known process."[242] However, the patentee failed to disclose these two references during the patent prosecution process. In invalidating the patent, the court found that the patentee's "alleged critical improvement over the prior art was therefore already within the public domain, just not before the examiner."[243]

2. Written Description and Enablement. FDA information could also be used to help determine if the written description and enablement requirements are met. Specifically, if the patent was granted based on prophetic examples or the patentee made arguments to rejections that were not yet completely verified, then it seems that the patentee should not benefit from using flawed or even fictional data.[244] These later-generated data could be used to show that the invention was not enabled at the time of the filing date.[245]

For example, if later-generated clinical data show that the drug is not effective at a specific concentration, then the USPTO should be able to reopen prosecution and use that data to show

240. Jazz Pharms., Inc. v. Amneal Pharms., LLC, 895 F.3d 1347, 1362–63 (Fed. Cir. 2018).

241. *Belcher Pharms.*, 11 F.4th at 1348. *See generally* Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348 (Fed. Cir. 2005) (showing that the patentee engaged in inequitable conduct because they submitted the prior art to the FDA to show similarity to a similar device to gain approval).

242. *Belcher Pharms.*, 11 F.4th at 1348, 1351 (showing that the patentee did not disclose two key references, Stepensky and Fylligen, to the USPTO that were used at the FDA to avoid additional stability studies).

243. *Id.* at 1351–53.

244. Apotex Inc. v. UCB, Inc., 763 F.3d 1354, 1362–63 (Fed. Cir. 2014) (showing that prophetic examples written in past tense are the basis for inequitable conduct invalidation); Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1359–60 (Fed. Cir. 2005); Hoffman-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1359, 1363–64 (Fed. Cir. 2003) (showing that writing prophetic examples in the past tense can lay the foundation for a case of inequitable conduct). Prophetic examples written in the present tense do not create inequitable conduct issues. Eli Lilly & Co. v. Actavis Elizabeth LLC, 676 F. Supp. 2d 352, 363–64 (D.N.J. 2009), *rev'd on other grounds*, 435 F. App'x 917 (Fed. Cir. 2011); Energy Absorption Sys., Inc. v. Roadway Safety Servs., Inc., No. 96-1264, 1997 WL 368379, at *5 (Fed. Cir. July 3, 1997).

245. *Novo Nordisk Pharms.*, 424 F.3d at 1357, 1359–63 (finding a patent that used an example written in past tense, but was really a prophetic example, was invalid due to inequitable conduct).

that the claims for that concentration range are not enabled. Competitors could make these same arguments during litigation. However, because it is difficult for competitors to obtain these data, FDA Reexamination makes this process more efficient. Additionally, this might increase generic competition by lowering the barriers necessary to enter the market. This is especially important considering the Federal Circuit's recent cases on written description.[246]

For example, the Federal Circuit's recent *Biogen* case upheld a ruling holding a patent invalid for lack of written description, pointing to later-generated FDA Phase III data.[247] The patent in this case was directed towards the use of DMF (dimethyl fumarate) at a specific dose of 480 mg/day (DMF480) for the treatment of multiple sclerosis (MS). The patent, however, contained only one prophetic example of the 480 mg/day dose used to treat MS. However, between FDA Phase II and III trials, the FDA recommended that Biogen add a 480 mg/day dose.[248]

In invalidating the Biogen patent, the court stated that "[w]hat matters for purposes of the [written description] inquiry in this case is whether, at the time of filing the disclosure—well before the Phase III study even commenced—a skilled artisan could deduce simply from reading the specification that [480 mg/day] would be a therapeutically effective treatment for MS."[249] The court went further and stated "[r]egardless of whether [the inventors] had in fact hypothesized or even conceived the idea of treating MS with a [480 mg/day] dose as early as 2003, the law is clear that a patent cannot be awarded for mere theoretical research without more."[250] Accordingly, the court found that the patentee only knew that the 480 mg/day was effective based upon *post-filing* research that cannot be added back into the written

246. S. Sean Tu & Christopher M. Holman, *Antibody Claims and the Evolution of the Written Description/Enablement Requirement*, IDEA L. REV. (forthcoming) (on file with the *Houston Law Review*); *see* Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. (forthcoming 2023) (manuscript at 24–25).

247. Biogen Int'l GMBH v. Mylan Pharms., Inc., 18 F.4th 1333, 1339, 1343–44, 1346 (Fed. Cir. 2021).

248. *Id.* at 1339 ("[T]he FDA recommended that Biogen add a DMF480 dosing regimen in the Phase III study because the lower dose 'might improve patient compliance and/or minimize dropouts from adverse effects during the study.'").

249. *Id.* at 1343–44.

250. *Id.* at 1344 (citation omitted).

description.[251] Thus, analysis of Phase II and III trials in relation to what was originally disclosed in the patent application can be crucial in determining patentability.

Similar to the data used in the *Biogen* case, I suggest that FDA Reexamination can be based on post-grant information. This is not classically considered "prior" art because it is information that is generated after the patent was filed. However, if the patent was based on prophetic examples or examples that did not have written description/enablement support, then it seems fair to use these later-generated data to rebut the conclusions implied from the prophetic examples or limit the scope to what was actually described/enabled by the patentee.

F. Criteria for Instituting FDA Reexamination

The USPTO will not automatically institute an FDA Reexamination based on FDA information. Similar to the ex parte reexamination and supplemental examination procedure, the USPTO would only institute an FDA Reexamination if there were a substantial new question of patentability. Accordingly, the USPTO would review the information sent by the FDA to decide if there is a substantial new question of patentability based on this new FDA information. The proposed standard for instituting FDA Reexamination would follow the same guidelines as detailed by 35 U.S.C. § 303.[252]

The cost of the initial review to determine if there is a substantial new question of patentability would be borne indirectly by the Patent Office. I previously suggested that all patents listed on the Orange Book should be flagged *ex ante* by the applicant.[253] The application fees associated with these patents could be increased to reflect the costs of possible FDA Reexamination if the drug becomes FDA approved. This initial fee should not be substantial because the fee would apply to all possible Orange Book-listed patent applications, even if the

---

251. *Id.* at 1343–44. Note that Judge Lourie wrote a dissent in the en banc denial that argues that the patent should not have been invalidated based on written description. Specifically, Judge Lourie states: "By focusing on whether the patentee ***proved*** that 480 mg per day is an effective amount to treat multiple sclerosis—as distinct from whether the '514 patent specification ***discloses*** that 480 mg per day is an effective amount to treat multiple sclerosis—the panel majority and the district court erroneously imported operability considerations into the written description analysis." Biogen Int'l, GMBH v. Mylan Pharms., 28 F.4th 1194, 1195, 1198, 1201 (Fed. Cir. 2022) (Lourie, J., dissenting).

252. *See* 35 U.S.C. § 303; *supra* Section IV.C.

253. Tu & Lemley, *supra* note 23, at 1708.

application does not mature into a patent and even if the drug does not garner FDA approval. In contrast, if the USPTO determines that there is a substantial new question of patentability based on FDA information, the costs associated with examination after this determination should be borne by the patentee.

The rationale for using the substantial new question review would also mirror the ex parte reexamination rationale. Specifically, institution based on FDA information should only occur if the FDA information raises "a new, non-cumulative technological teaching that was not previously considered and discussed on the record during . . . prosecution."[254] Thus, if the new FDA information simply verifies the information in the patent application then reopening prosecution is unnecessary.

A substantial new question of patentability, however, could be raised about a previously considered reference if that reference is presented in a new light based on the FDA information. For example, if the applicant presents an interpretation of the prior art at the FDA in a way that contradicts a previous interpretation made during patent prosecution at the USPTO, then this would present a substantial new question of patentability.

Finally, FDA Reexamination does not suffer from "sham reexamination" (where competitors file serial reexaminations to harass the patentee). The FDA information reviewed is provided by the drug sponsor and thus should not contain material designed to harass the patentee.[255] Accordingly, unlike ex parte reexamination information submitted and framed by a third party, FDA information should not suffer from fabricated or grossly misrepresented evidence.

G. FDA Reexamination—Inequitable Conduct and Abbreviated New Drug Application (ANDA) Litigation

Supplemental examination was created, in part, to permit patentees to inoculate themselves against charges of inequitable

254. *See* MPEP § 2216 (9th ed. Rev. 10, June 2020).

255. *See generally* Raymond A. Mercado, *The Use and Abuse of Patent Reexamination: Sham Petitioning Before the USPTO*, 12 COLUM. SCI. & TECH. L. REV. 92 (2011); Raymond A. Mercado, *Ensuring the Integrity of Administrative Challenges to Patents: Lessons from Reexamination*, 14 COLUM. SCI. & TECH. L. REV. 558 (2013).

conduct.[256] Specifically, under § 257(c)(1), "[a] patent shall not be held unenforceable on the basis of conduct relating to information" considered during supplemental examination.[257] Although FDA Reexamination would allow the patentee to explain possible conflicting statements made to the FDA and USPTO, it should not inoculate the patentee against charges of inequitable conduct.

FDA Reexamination should not inoculate against inequitable conduct because, unlike supplemental examination, which is initiated by the applicant by providing the relevant references/information, FDA Reexamination is initiated by the USPTO Director. Because the patentee is not presenting this new information and did not bring this new information to the USPTO, they should not receive the benefit of inoculation.

Furthermore, supplemental examination specifically deals with two situations that mirror issues that may commonly come up in FDA Reexamination. These two situations deal with fraud and ANDA litigation.[258] Specifically, FDA Reexamination would also include two provisions that would deal with fraud and ANDA litigation.

1. Fraud on the USPTO. If the new FDA information presents a picture of manipulation or outright fraud by the patentee, then the Director may take action.[259] Similar to § 257(e) in supplemental examination, FDA Reexamination would include a provision that would allow the Director to take action if material fraud may have been committed.

Unlike inequitable conduct, which invalidates the entire patent, FDA Reexamination would allow the Director to cancel one or more claims of the patent. This remedy would allow the Director to excise those claims that were tainted by inequitable conduct while leaving those claims which were not obtained by inequitable conduct intact. Thus, FDA Reexamination could act more like a

256. *See* H.R. REP. NO. 112-98, pt. 1, at 50 (2011) ("The Act addresses the inequitable conduct doctrine by authorizing supplemental examination of a patent to correct errors or omissions in proceedings before the Office. Under this new procedure, information that was not considered or was inadequately considered or was incorrect can be presented to the Office. If the Office determines that the information does not present a substantial new question of patentability or that the patent is still valid, that information cannot later be used to hold the patent unenforceable or invalid on the basis for an inequitable-conduct attack in civil litigation.").

257. 35 U.S.C. § 257(c)(1).

258. *Id.* § 257(c)(2)(A), (e).

259. *See generally* Lisa A. Dolak, *America Invents the Supplemental Examination, but Retains the Duty of Candor: Questions and Implications*, 6 AKRON INTELL. PROP. J. 147, 156 (2012).

scalpel to remove the offending claims and less like an "atomic bomb" indiscriminately invalidating all claims in the entire patent.[260]

Additionally, similar to supplemental examination, the Director would also be able to refer inequitable conduct issues to the Attorney General for appropriate action.[261] Actions should also be taken against those parties involved in committing fraud upon the USPTO. The Office of Enrollment and Discipline (OED) could fashion remedies such as suspension or debarment.

2. ANDA Litigation. FDA Reexamination could also work in concert with ANDA litigation. ANDA litigation can occur as a civil action under § 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv)(II)), before the date of an FDA Reexamination.[262] If the patent is already undergoing litigation, and the alleged infringer has already pleaded inequitable conduct with particularity using FDA information, then the USPTO could review that same information in an FDA Reexamination proceeding.[263] This situation, however, is likely to have very limited application because, as mentioned in Section III.B, evidence of inequitable conduct is frequently unavailable until discovery occurs.[264]

There are several benefits of analyzing inequitable conduct-type information via FDA Reexamination instead of a judge or jury. Specifically, the patent is not given the presumption of validity, the analysis is done by both medical/patent experts, and there is no intent to deceive requirement.[265] Accordingly, FDA

260. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc).

261. *See* Dolak, *supra* note 259, at 174.

262. 35 U.S.C. § 257(c)(2)(A).

263. This would be pursuant to portions of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1598, 1603 (codified at 35 U.S.C. §§ 156, 271, 282). A generic drug manufacturer can market a drug using the FDA's "Abbreviated New Drug Application[]" process but must certify that: "(I) such [Orange Book] information has not been filed, (II) that such [Orange Book] patent has expired, (III) [that the ANDA applicant will wait until] the date on which [the Orange Book] patent will expire, or (IV) such [Orange Book] patent is invalid or will not be infringed . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV).

264. *See* Formax Inc. v. Alkar-Rapidpak-MP Equip., Inc., No. 11–C–0298, 2013 WL 2368824, at *6 (E.D. Wis. May 29, 2013) ("Allegations of inequitable conduct are often based on information uniquely within the possession of the patentee, and often cannot be brought until after significant discovery has been completed.").

265. *See supra* Sections III.B, III.C.1.

Reexamination is a solution that could deal with many of the issues that make inequitable conduct ill-suited to deal with conflicting statements made by the applicant to the FDA and USPTO.

H. Miscellaneous Issues with FDA Reexamination—Time for Review / Costs

Some minor procedural issues would also likely present small hurdles for an FDA Reexamination process. Specifically, due to the voluminous amounts of information generated by the FDA, the USPTO timetables for review would have to differ from ex parte reexamination. Additionally, public access to some of the information used in FDA Reexamination would likely have to be redacted due to confidential and trade secret issues.

1. Time to Determine Substantial New Question of Patentability. Both supplemental examination and ex parte reexamination require the Director to determine if there is a substantial new question of patentability within three months of the request.[266] However, the data that is reviewed for both supplemental and ex parte reexamination is not as voluminous as FDA-generated information. For example, supplemental examination can only be based on a maximum of twelve references.[267]

FDA-generated information usually consists of thousands of pages of material.[268] Thus, FDA information will be considerably more voluminous than what is submitted during a typical ex parte reexamination.[269] Accordingly, the FDA Reexamination procedure

266. 35 U.S.C. §§ 257, 303(a).

267. 37 C.F.R. § 1.605(a) (2021) ("Each request for supplemental examination may include no more than twelve items of information believed to be relevant to the patent."). However, an applicant can submit more than one request for supplemental application. *See* MPEP § 2809 (9th ed. Rev. 10, June 2020) ("[T]he patent owner may file one or more additional requests for supplemental examination of the same patent sequentially or at the same time, each of which may include up to twelve additional items of information.").

268. *FDA Drug Approval Process*, DRUGS.COM (May 28, 2022), https://www.drugs.com/fda-approval-process.html [https://perma.cc/6D2V-E89U].

269. One FDA insider stated that each new drug application created at least two semi-trucks full of paperwork. Joel F. Studebaker, *Computers in the New Drug Application Process*, 33 J. CHEM. INFO. & COMPUT. SCI. 86, 86 (1993) (stating that the NDA "may consist of over 100,000 pages"); *see also* FRANCISCO NOGUEIRA, WELCOME TO ACCUMULUS SYNERGY 1 (2022), https://www.accumulus.org/wp-content/uploads/2021/06/Accumulus_Synergy_White_Paper.pdf [https://perma.cc/5CTJ-5MWA] ("Filing a New Drug Application may have shifted from driving a truckload of paper to the relevant regulatory authority, to FedEx-ing a CD-ROM, to uploading a set of PDFs through the Electronic Submissions Gateway, but the documents themselves, and the underlying processes, remain little changed.").

will necessarily take a longer amount of time. I suggest allowing this team of three examiners a longer period of time to review the colossal amount of FDA information.

2. Speed of FDA Reexamination. FDA Reexamination would not proceed with "special dispatch." This is in contrast to ex parte reexamination, where the proceedings are conducted "with special dispatch."[270] The USPTO attempts to quickly move the ex parte reexamination procedure forward.

FDA Reexamination would not proceed with special dispatch because FDA information would contain many more references than the typical ex parte reexamination or supplemental examination. It will take much longer for examiners to filter, inspect, and then assess thousands of pages of FDA information. This lack of speed, however, should not affect the patentee because FDA Reexamination could proceed confidentially until a final judgment is made by the USPTO.

Normally, reexamination may throw a veil of uncertainty upon the patent because patent prosecution is reopened, the patent is no longer presumed valid, and competitors may not know if the patent claims are valid or not until after the reexamination proceeding is concluded. Accordingly, it is reasonable for the USPTO to attempt to move through prosecution as quickly as possible. However, these issues would not be as pronounced for FDA Reexamination because it could be kept confidential until concluded.

Thus, the USPTO could review the thousands of pages of FDA information, which may also contain valuable trade secrets, in confidence and use a timetable that is reasonable for examiners. Additionally, it would allow the USPTO to censor and redact any confidential information when the FDA Reexamination concludes. This information would be treated similar to non-patent literature and would be available to the public in redacted form only upon request.

3. Public Access to FDA Reexamination Information. Public access to information discussed in either ex parte reexamination or supplemental examination is usually made public after grant of

270. 37 C.F.R. § 1.550 (2021); 35 U.S.C. § 305; MPEP § 2209 (9th ed. Rev. 10, June 2020). See MPEP § 2254 for timetables set up for ex parte reexamination proceedings.

the request.[271] One exception, however, is non-patent literature (NPL), which is not generally made available to the public via Public PAIR.[272] However, certified copies of those documents could be accessed by request from the USPTO Public Records Division.[273] These requests should be honored, but private information and information protected by trade secret should be redacted.

As an initial matter, similar to ex parte reexamination, FDA Reexamination materials should not be made public before the grant of the request. Additionally, FDA information should be available to the public only if a substantial question of patentability is found. Confidential information as well as trade secrets could be present in FDA information passed to the USPTO. Confidential information and trade secrets should be kept confidential if possible. However, if this information is necessary to practice the invention, then it should be disclosed as part of the enablement requirement.[274]

I. Gold Plating Drug Patents

Patents that survive FDA Reexamination should receive a benefit because of this additional review. Similar to the "gold-plat[ed]" patents, these patents should be accorded greater deference when it comes to the information already considered by the USPTO.[275] This is consistent with the larger literature suggesting that additional review is warranted for those patents that are important.[276]

An additional benefit that applicants could receive is a higher presumption of validity for the FDA information considered by the examiners.[277] The presumption of validity might even be

271. MPEP § 2803.02 (9th ed. Rev. 10, June 2020).

272. *PAIR FAQs*, *supra* note 51 ("Images of non-patent literature (NPL) cited in public patent application files are not available for either viewing or downloading through Public PAIR. Certified copies of the full contents of the patent application files, including NPL are available from the USPTO Public Records Division.").

273. *Id.*

274. Mandel, *supra* note 223, at 1, 21–23, 25.

275. Mark Lemley et al., *What to Do About Bad Patents?*, REGULATION, Winter 2005–2006, at 10, 12–13.

276. *See* Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 47–51, 56 (2007) (discussing how the USPTO cannot complete a "rigorous or accurate initial patent review"); *see also* Lemley et al., *supra* note 275, at 12; Tu & Lemley, *supra* note 23, at 1707.

277. Lichtman & Lemley, *supra* note 276, at 62; *see also* Lemley et al., *supra* note 275, at 12; Tu & Lemley, *supra* note 23, at 1711.

conclusive as to the FDA information considered. Furthermore, we could import the current clear and convincing evidence presumption from litigation to IPR proceedings for FDA-considered information.[278] This would also help encourage applicants to disclose the most relevant prior art references during patent prosecution as well as for FDA approval.

J. Other Possible Solutions

There are a host of other possible ways to address the information imbalance between the FDA and USPTO. Two additional solutions include: (1) creating a new post grant review (PGR) period after FDA approval; and (2) embed a patent examiner at the FDA to help review information with an eye towards patenting.

1. Creation of a New Post Grant Review Period. First, instead of creating an FDA Reexamination process, you could trigger a new PGR period after NDA approval with mandatory disclosure of the FDA submissions. This solution has the advantage of being adversarial and speedy. Allowing third parties to bring a PGR would allow competitors to use FDA information to challenge key patents.

Lack of adversariness may be problematic because examiners may not have the added incentives necessary to push back on patent owner arguments. Additionally, patent examiners lack the ability to confirm statements made by the patent owner. The USPTO does not have its own laboratory or the resources to conduct experiments to verify patent owner statements. Accordingly, others have argued for allowing interested third parties to participate in the pharmaceutical patent examination process.[279]

This solution also has the added benefit of speed. As noted in Section III.B above, one problem with FDA information is that it is voluminous. Allowing interested third parties to participate might speed this process up by allowing them to spend the resources necessary to quickly identify and analyze the relevant

278. There is currently no such presumption. *See* 35 U.S.C. § 314(a).

279. *See generally* Dmitry Karshtedt, *Pharmaceutical Patents and Adversarial Examination*, 91 GEO. WASH. L. REV. (forthcoming 2023) (on file with the *Houston Law Review*).

documents. This would allow generics to get to market faster and diminish the problems associated with the cloud on title associated with FDA Reexamination.

One problem with this solution is that IPRs do not trigger the 180-day exclusivity given to the first ANDA filer.[280] To give an incentive to generic manufacturers to use this information to challenge these patents, Congress should broaden the 180-day exclusivity right to include invalidation of patents via IPR or PGR.

A second problem with this solution is that some FDA information is confidential and not available to third parties. The FDA would have to spend the time to redact information that was related to trade secrets. It is possible that the patent owner would try to redact as much information as possible, which may diminish the value of PGR because the patent owner would attempt to redact the key references or any conflicting statements made to the FDA.

2. Embed a USPTO Examiner in the FDA. Another possible solution would be for the USPTO to embed a patent examiner at the FDA to help review documents with an eye towards patentability. This solution has the benefit of forcing the NDA applicant to deal head on with safety and efficacy concerns that may contradict the patent claims.

The problems with this solution deal mainly with cost and efficiency. Many drugs do not make it through FDA approval. Embedding a patent examiner for all drugs before FDA approval would be costly, inefficient, and unnecessary for those drugs that do not make it through FDA approval. Focusing on only those patents that correspond to drugs that *actually* make it through FDA approval is more efficient and cost-effective rather than focusing on all patents that *could* make it through FDA approval.

V. CONCLUSION

Creation of a new FDA Reexamination procedure would help create stronger and higher quality patents. FDA Reexamination avoids the problems associated with the current inequitable conduct doctrine as well as the lack of communication between the FDA and USPTO. As mentioned in Section III.A, the current communication between the FDA and USPTO is problematic

280. Brian T. Apel, *An Administrative Meter Maid: Using Inter Partes Review and Post-Grant Review to Curb Exclusivity Parking via the "Failure to Market" Provision of the Hatch-Waxman Act*, 114 MICH. L. REV. 107, 113, 127–28 (2015).

because (1) the USPTO lacks the expertise needed to analyze FDA information; and (2) FDA information is usually generated long after the patent has issued and thus not available during patent prosecution.

If statements made to the FDA conflict with statements previously made to the USPTO, FDA Reexamination should allow for analysis of the claims by reopening prosecution. FDA Reexamination also allows the applicant to clarify any possible misleading statements to the USPTO. Furthermore, FDA Reexamination allows the applicant to narrow claims by amendment to limit the scope of the invention to those ranges that are supported by the FDA data (and not prophetic examples).

Allowing a team of examiners to determine if the conflicting statements were material places the materiality analysis in the hands of those who understand the technology and the relevance (or irrelevance) of statements made by the applicant. It is likely that only the most egregious examples of inequitable conduct are currently caught by the court simply because judges and juries may not have the expertise necessary to analyze the nuanced and complex FDA information. Thus, FDA Reexamination allows for a more nuanced determination of materiality made by experts in the field.

Furthermore, automatically sending FDA information to the USPTO so that examiners can determine if there is a substantial new question of patentability will help avoid the *Therasense* requirements to show inequitable conduct. This is especially important in light of the fact that many FDA products face invalidation by inequitable conduct at the Federal Circuit.[281] Additionally, with the current *Therasense* pleading requirements, it is more difficult to survive a summary judgment or motion to dismiss without specific evidence of inequitable conduct, which would only be available through discovery. If drug applicants knew that their patents were automatically going to be reviewed by the USPTO, it might act as a deterrent against submitting for conflicting statements. At a minimum, automatic FDA Reexamination would require attorneys to review the patent prosecution history before submitting potentially conflicting information to the FDA.

281. *See* Leadmon et al., *supra* note 10.

Thus, competitors would no longer need to rely on litigation to make these important factual determinations. There would be no need to plead inequitable conduct with specificity as required by *Therasense*, because this information would automatically be sent to the USPTO for review. Similarly, there would be no intent requirement needed because prosecution would simply be reopened if a substantial new question of patentability was found based on the new FDA information.

Furthermore, the FDA Reexamination process would be an administrative reopening of patent prosecution. Accordingly, unlike litigation, the patent would no longer receive the presumption of validity. Removing this presumption is reasonable because the information considered is statements and submissions made by the applicant (or assignees) themselves.

Overall, this FDA Reexamination process should improve drug patent quality while preventing costly litigation. The purpose of FDA Reexamination would be to improve patent quality as well as patient safety by applying the patentee's own disclosures as part of the examination process. This type of reexamination is important because there is currently little collaboration between the USPTO and FDA. This is especially important in light of the fact that most patents that are held unenforceable due to inequitable conduct by the Federal Circuit are associated with FDA-regulated products.