

# DRUGS, DECEPTION, AND DISCLOSURE

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## I. INTRODUCTION

How can we address the problem of pharmaceutical companies making inconsistent representations to the United States Patent and Trademark Office (USPTO or PTO) and the United States Food and Drug Administration (FDA)? Pharmaceutical innovators seeking both patent protection and regulatory approval of their drug products experience fundamentally misaligned incentives when they engage with the USPTO and FDA. On the one hand, FDA approval is often faster and cheaper for pharmaceuticals that bear significant similarities to already-approved drugs. On the other, successfully patenting a new small molecule requires an inventor to distinguish their product from the existing prior art—which often includes those very same drugs. As a consequence, pharmaceutical innovators are at once motivated to disclose to the FDA information about existing drug products and to hide that same information from the USPTO, even (or perhaps especially) when that information may be material to patentability. And, if innovators submit to that temptation, they can end up with patents that, in reality, should never have been issued in the first place.

Permitting pharmaceutical companies to make inconsistent representations to the USPTO and FDA is harmful both to the integrity of the patent system and to the public good. President Biden recognized as much in a July 2021 Executive Order, calling on the USPTO and FDA to work together “to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition.”<sup>1</sup> Since President Biden issued his Executive Order, the heads of the USPTO and FDA have reiterated time and again that meaningful change is needed in the pharmaceutical industry both to uphold foundational patent-law doctrines and to provide public access to affordable drug products. But, to date, the agencies have provided very little indication of what that change will look like in practice.

This Note proposes two solutions to the problem of inconsistent representation at the USPTO and FDA. Part II outlines the nature of the problem, as well as the growing demand for reform. Part III proposes a first solution: a new system of USPTO-FDA interaction during patent prosecution. Because the overall effectiveness of such a system could be somewhat limited by issues of confidentiality, timing, and noncompliance, Part IV offers a complementary post-patent-issuance solution to the problem of inconsistent representation. Specifically, Part IV argues that the Federal Circuit should revise its inequitable conduct doctrine to create a “pharma exception” to the

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1. See Exec. Order No. 14306, 86 Fed. Reg. 36,987, 36,997 (July 9, 2021).

otherwise exceedingly high legal standards outlined in *Therasense*.<sup>2</sup> Finally, Part V summarizes the key takeaways from Parts II, III, and IV.

## II. INCONSISTENT REPRESENTATIONS AT THE USPTO AND FDA

This Part begins by providing a basic overview of (1) patent exclusivity, which is granted by the USPTO; and (2) regulatory approval, which is required in the pharmaceutical context by the FDA.<sup>3</sup> Though these two systems often work in tandem, they are separate and distinct. Unique hurdles to patentability and regulatory approval create misaligned information-disclosure (or information-nondisclosure) incentives for pharmaceutical innovators seeking to both patent their new drug products and sell those products in interstate commerce. Thus, this Part argues, pharmaceutical innovators are at once motivated to disclose to the FDA information that may be material to patentability and to hide (or at least recharacterize) that same information when prosecuting a patent application at the USPTO.<sup>4</sup> Finally, this Part summarizes the growing demand for meaningful change to the patenting and regulatory systems—both from within the USPTO and FDA as well as further afield.

### A. PATENT EXCLUSIVITY, REGULATORY APPROVAL, AND MISALIGNED INCENTIVES

A fundamental—but often misunderstood—characteristic of any patent issued by the USPTO is that it does not grant its owner any affirmative rights.<sup>5</sup>

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

3. *Compare* 35 U.S.C. § 101 (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, *may* obtain a patent therefor.”) (emphasis added), *with* 21 U.S.C. § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [this section] is effective with respect to such drug.”).

4. *See* Letter from Patrick Leahy, U.S. Senator, and Thom Tillis, U.S. Senator, to Andrew Hirshfeld, Performing Functions & Duties Under Sec’y Com. for Intell. Prop. & Dir. USPTO 1 (Sept. 9, 2021) (<https://www.leahy.senate.gov/imo/media/doc/20210909%20Letter%20to%20PTO%20on%20FDA%20submissions.pdf>) [hereinafter Leahy & Tillis Letter] (“[I]nconsistent statements submitted to the Food and Drug Administration (FDA) to secure approval of a product—asserting that the product is the same as a prior product that is already on the market—can then be directly contradicted by statements made to the PTO to secure a patent on the product.”).

5. *See Patentability Versus Freedom-To-Operate*, BUCKINGHAM, DOOLITTLE & BURROUGHS, LLC (May 10, 2021), <https://www.bdblaw.com/patentability-versus-freedom-to-operate/> (“Most often people mistakenly believe that a patent gives them the right to make,

In reality, patent rights are negative rights.<sup>6</sup> The patent owner has the ability to exclude another from making, using, selling, offering for sale, or importing the claimed invention for twenty years from the filing date of the earliest nonprovisional application to which priority is claimed.<sup>7</sup> However, the patent does not automatically confer to its owner the right to make, use, sell, offer for sale, or import that same invention.<sup>8</sup> In fact, in many instances where the patent owner wishes to take any of those affirmative steps, they first need to obtain some sort of regulatory approval from an administrative body.<sup>9</sup>

In the pharmaceutical context, regulatory approval for new small-molecule drug products—patented or otherwise—must be obtained from the FDA before the drug can be sold in interstate commerce.<sup>10</sup> Obtaining patent protection from the USPTO and market approval from the FDA are separate endeavors. But the incentive to obtain patent exclusivity from the USPTO is sustained in part by the FDA’s informationally demanding regulatory approval standards.<sup>11</sup> In fact, there are two distinct FDA-created informational costs

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use, and sell an invention. Not so. A patent does not confer the right to do anything but sue others for patent infringement. This is perhaps the single most misunderstood feature of patents, and at the same time one of the most expensive mistakes an innovator can make.”).

6. See PETER S. MENELL, MARK A. LEMLEY, ROBERT P. MERGES & SHYAMKRISHNA BALGANESH, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2022* 177 (2022) (“The exclusionary right is in a sense a negative right . . . [A] patent does not automatically grant an affirmative right to do anything.”); *Patterson v. Kentucky*, 97 U.S. 501, 506 (1879) (“All which [patents] primarily secure is the *exclusive* right in the discovery.”) (emphasis added).

7. 35 U.S.C. § 154(a)(1) (“Every patent shall . . . grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”); 35 U.S.C. § 154(a)(2) (“Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.”).

8. See *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1559 (Fed. Cir. 1996) (“[T]he existence of one’s own patent does not constitute a defense to infringement of someone else’s patent. It is elementary that a patent grants only the right to *exclude others* and confers no right on its holder to make, use, or sell.”) (citation omitted); *Herman v. Youngstown Car Mfg. Co.*, 191 F. 579, 584 (6th Cir. 1911) (“A patent is not the grant of a right to make or use or sell. It does not, directly or indirectly, imply any such right. It grants only the right to exclude others.”).

9. For example, before entering interstate commerce, an insecticide manufacturer likely needs to obtain regulatory approval from the Environmental Protection Agency (EPA), and a radio broadcaster likely needs to obtain regulatory approval from the Federal Communications Commission (FCC).

10. See 21 U.S.C. § 355(a).

11. See *id.* §§ 355(b), (j) (describing the statutory requirements for obtaining FDA approval for new drugs).

that encourage patenting.<sup>12</sup> First, FDA approval standards vastly increase the cost of pharmaceutical innovation by requiring innovators to generate significant quantities of clinical (safety and effectiveness) data.<sup>13</sup> Second, FDA approval standards massively decrease the cost of pharmaceutical imitation by permitting imitators (primarily, generics manufacturers) to reap the benefits of those same clinical data without having to generate them *de novo*.<sup>14</sup> To make generating costly clinical data worthwhile, pharmaceutical innovators thus need market exclusivity—and patents help them get it.<sup>15</sup>

For a pharmaceutical innovator, then, patents are incredibly important—so long as the financial benefits of exclusivity are unlocked by FDA approval. Without approval, the innovator cannot produce, market, or sell their patented drug—and, as a result, they lose out on the highly supramarginal profits that are commonplace in the pharmaceutical industry.<sup>16</sup> Of course, the exclusionary property rights that attach to drug patents can help delay the entry of generic competitors into markets for which FDA approval is part of the price of admission.<sup>17</sup> But without FDA approval, the innovator company is *also* barred

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12. See Talha Syed, *Should a Prize System for Pharmaceuticals Require Patent Protection for Eligibility?*, INCENTIVES FOR GLOB. HEALTH DISCUSSION PAPER NO. 2, at 14 (2009), [https://healthimpactfund.org/pdf/DP2\\_Syed.pdf](https://healthimpactfund.org/pdf/DP2_Syed.pdf) (suggesting that “the case for strong patent protection for pharmaceuticals may be largely based on the combination of regulatorily-mandated clinical trials for innovators and regulatorily-enabled piggybacking for imitators”).

13. See 21 U.S.C. § 355(b) (describing the statutory requirements for obtaining FDA approval for new drugs); Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 24 (2016) (showing, in Table 2, the average out-of-pocket clinical period costs for investigational compounds in Phases I, II, and III of regulatory approval).

14. See 21 U.S.C. § 355(j) (describing the statutory requirements for Abbreviated New Drug Applications or ANDAs).

15. See 35 U.S.C. § 154(a)(1) (“Every patent shall . . . grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.”); 35 U.S.C. § 154(a)(2) (“Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.”).

16. See 21 U.S.C. § 355(a); Angus Liu, Eric Sagonowsky, Kevin Dunleavy, Fraiser Kansteiner & Zoey Becker, *The Top 10 Most Profitable Pharma Companies in 2021*, FIERCE PHARMA (June 14, 2022), <https://www.fiercepharma.com/special-reports/top-10-most-profitable-pharma-companies-2021> (ranking the top ten pharmaceutical companies by 2021 net income); ERIN H. WARD, KEVIN J. HICKEY & KEVIN T. RICHARDS, CONG. RESEARCH SERV., R46679, DRUG PRICING AND PHARMACEUTICAL PATENT PRACTICES 2 (2021), <https://crsreports.congress.gov/product/pdf/R/R46679> (“IP rights can deter or delay the market entry of generic drug or biosimilar competition, and thus may allow the rights holder to charge higher-than-competitive prices.”).

17. Rachel Sachs, *Drug Innovation: When Patents Work (And When They Don't)*, MILKEN INST. REV. (Oct. 23, 2020), <https://www.milkenreview.org/articles/drug-innovation-when->

from that same market.<sup>18</sup> In other words, as much as patent exclusivity can help safeguard an innovator's market share once it is established, the innovator needs FDA approval to amass that market share in the first place.<sup>19</sup>

Few industries—if any—value patents as much as the pharmaceutical sector.<sup>20</sup> For proponents of strong patent rights, that can only be a good thing.<sup>21</sup> Patent rights provide financial incentives to innovate—including, as noted above, compensation for the high cost of satisfying informationally demanding FDA approval standards.<sup>22</sup> Patent rights also encourage early public disclosure of new inventions, which reduces duplicative research and development efforts between different inventors.<sup>23</sup> Since innovation and disclosure ultimately serve the public good, it is fair to reward the makers of new and useful drugs with patent exclusivity.<sup>24</sup> But what if our current system of granting patent exclusivity is not actually up to the task? What if pharmaceutical “inventors” are able to gain patent exclusivity for drug “inventions” that are, in reality, not inventive at all—is that still fair?

patents-work (“[R]egulatory exclusivities and patents function similarly, enabling innovators to block generic competitors from the market.”).

18. See 21 U.S.C. § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.”).

19. See Sachs, *supra* note 17 (“[R]egulatory exclusivities and patents function similarly, enabling innovators to block generic competitors from the market.”); 21 U.S.C. § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.”).

20. Sachs, *supra* note 17 (“[P]harmaceutical executives rate patents as far more important to innovation than do representatives of any other tech-driven business.”).

21. See generally MENELL ET AL., *supra* note 6, at 18–22 (describing the utilitarian justification for intellectual property rights).

22. See *id.* at 36 (“The public benefits directly [from patents] through the spur to innovation and disclosure of new technology.”); Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1908 (2013) (“Conventional economic actors will only produce a good when they can appropriate sufficient returns to recoup the capitalized costs of providing the good.”).

23. See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 871 (1990) (noting that granting patent rights after invention but before commercialization “allows the inventor to coordinate her activities with those of potential imitators to reduce ineffective duplication of inventive effort”).

24. See generally U.S. CONST. art. 1, § 8, cl. 8 (“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”); MENELL ET AL., *supra* note 6, at 19 (“The economic philosophy behind the [constitutional] clause empowering Congress to grant patents and copyrights is the conviction that it is the best way to advance public welfare through the talents of authors and inventors in ‘Science and useful Arts.’ Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered.”).

### 1. *Patenting*

Patent applicants have several major hurdles to clear between filing a patent application and obtaining a valid patent. Chief among them is the need to show that their invention is both novel and nonobvious in view of any prior art. The novelty requirement<sup>25</sup> is relatively easy to understand. If a single prior art reference discloses each and every feature of the claimed invention, the reference anticipates the invention and renders it unpatentable.<sup>26</sup> The nonobviousness requirement<sup>27</sup> can seem somewhat less intuitive. However, at bottom, a patent applicant needs to demonstrate that their invention would not be obvious to a skilled artisan in view of the totality of the prior art's teachings (even if no single reference anticipates the invention).<sup>28</sup>

### 2. *Obtaining Regulatory Approval*

To better understand how the FDA grants regulatory approval for new pharmaceutical products, consider one particular scenario: the approval of a small-molecule New Drug Application (NDA) under § 505 of the Federal Food, Drug, and Cosmetic Act.<sup>29</sup> Section 505 broadly describes the application process for legally marketing all new drugs in the United States.<sup>30</sup> If a drug product is entirely novel, in that it contains an active ingredient that has never been approved by the FDA, then the pharmaceutical innovator (known as “the sponsor”) will follow the regulatory pathway outlined in § 505(b)(1).<sup>31</sup> To that end, the sponsor itself will generate (often from scratch) all the safety and efficacy data that are needed to support its case for regulatory approval.<sup>32</sup>

If, however, the sponsor's new product is best described as a modification of a previously approved drug (e.g., a liquid formulation of an earlier-approved solid tablet), then the sponsor may be able to seek expedited approval under § 505(b)(2).<sup>33</sup> Even though, under a § 505(b)(2) framework, the sponsor still needs to provide full assurance of the drug's safety and efficacy to the FDA, they can satisfy some of those requirements by pointing to data that were

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25. 35 U.S.C. § 102.

26. MPEP § 2131 (9th ed. Rev. 10.2019, June 2020).

27. 35 U.S.C. § 103.

28. MPEP § 2141 (9th ed. Rev. 10.2019, June 2020).

29. *See* 21 U.S.C. § 355.

30. *Id.*

31. *See* 21 U.S.C. § 355(b)(1).

32. *See* 21 U.S.C. § 355(b)(1)(A)(i).

33. *See* 21 U.S.C. § 355(b)(2).

submitted with the earlier-approved analog.<sup>34</sup> In practice, then, a § 505(b)(2) sponsor needs to first define the informational “bridge” between the already-approved product and their new formulation.<sup>35</sup> Then, they must provide whatever new data are needed to cross that bridge.<sup>36</sup> But because the informational bridge will, by its nature, always be shorter than the full regulatory pathway under § 505(b)(1), there are temporal and financial incentives for the sponsor to obtain approval under § 505(b)(2).<sup>37</sup>

### 3. *Misaligned Incentives*

Briefly comparing these two processes—patenting and FDA approval via § 505(b)(2)—reveals parallel, though oppositely aligned, incentives.<sup>38</sup> Because of patent law’s novelty and nonobviousness requirements, a patent applicant will naturally want to create as much distance as possible between their invention and the prior art, which may include FDA-approved drug products that are already on the market. However, when that same inventor approaches the FDA to seek regulatory approval under § 505(b)(2), their prerogative is to emphasize the similarities between their new formulation and one or more of those same earlier-approved drug products. The more a sponsor can

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34. FDA, DETERMINING WHETHER TO SUBMIT AN ANDA OR A 505(B)(2) APPLICATION 7–13 (May 2019), <https://www.fda.gov/media/124848/download> (outlining “Scientific Considerations for ANDAs and 505(b)(2) Applications”).

35. Ingrid Freije, Stéphane Lamouche & Mario Tanguay, *Review of Drugs Approved via the 505(b)(2) Pathway: Uncovering Drug Development Trends and Regulatory Requirements*, 54 THERAPEUTIC INNOVATION & REGUL. SCI. 128, 128 (2020) (“A drug submitted via 505(b)(2) can be approved based on data from studies not conducted by the sponsor, by relying on (1) Agency’s previous findings of safety and effectiveness (AFSE) of an approved drug; and/or (2) clinical and preclinical studies’ data from published literature without the right of reference. This requires not only a successful bridging to an RLD (reference listed drug), by the means of relative bioavailability (BA) or bioequivalence (BE) studies, but also some potential additional studies that may be needed to fully support efficacy and/or safety of the new product.”).

36. *Id.*

37. See Mitchell Katz, *Why Are 505(b)(2)s Gaining Increased Interest Among Midsize Biopharma Companies?*, LIFE SCI. LEADER (Feb. 7, 2018), <https://www.lifescienceleader.com/doc/why-are-b-s-gaining-increased-interest-among-midsize-biopharma-companies-0001> (explaining that approval under § 505(b)(2) “takes less time, cost, and risk to get product[s] onto the market because the active ingredient has been previously approved with data from a prior submission package”).

38. This misalignment of incentives could also occur, for example, when a pharmaceutical innovator submits a patent application with the USPTO and (1) an Investigational New Drug (IND) application, or (2) an NDA via § 505(b)(1) with the FDA in relation to the same small-molecule drug. Like § 505(b)(2) applications, IND applications and § 505(b)(1) applications may include information that is material to patentability. But the misalignment of incentives is particularly strong for § 505(b)(2) drug products because of the inherently comparative nature of the § 505(b)(2) pathway.



demonstrate a sameness between their formulation and its already-approved analogs, the shorter the § 505(b)(2) “bridge” to approval will be—and the cheaper and faster it will be for the sponsor to cross it.<sup>39</sup>

Thus, there is a (potentially big) problem. The innovator is at once incentivized to share information about analogous competitor products with the FDA and to hide (or at least reframe) that same information when seeking patent exclusivity at the USPTO—even if the innovator suspects that the information speaks to the novelty or nonobviousness of their invention.<sup>40</sup> If they give into that temptation, they may well end up with a patent that does not meet the statutory requirements for patentability. Not only does such a patent offend the integrity of the patent system by undermining foundational principles of novelty and nonobviousness, but it also denies the public access to generics that are unfairly blocked by invalid patents.<sup>41</sup>

Unfortunately, it seems that at least some patent applicants do give into that temptation. In a 2021 decision, *Belcher Pharmaceuticals, LLC v. Hospira, Inc.* (“*Belcher IP*”), the Federal Circuit affirmed the District Court for the District of Delaware’s holding that a pharmaceutical patent assigned to Belcher Pharmaceuticals, LLC (“Belcher”) was unenforceable over a range of inconsistent representations that Belcher made when interacting with the USPTO and FDA.<sup>42</sup> First, Belcher disclosed to the FDA information about similar third-party products that it later withheld from the USPTO.<sup>43</sup> Second, Belcher, when corresponding with the FDA, referred to the pH range of a competitor product as “old,” later asserting that that same pH range was “unexpectedly found to be critical” to its own invention when contesting an obviousness rejection at the USPTO.<sup>44</sup> As a result, the district court found—and the Federal Circuit agreed—that Belcher “did not merely withhold . . .

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39. See Katz, *supra* note 37 (explaining why approval under § 505(b)(2) is faster, cheaper, and less risky).

40. See The Editorial Board, *Save America’s Patent System*, N.Y. TIMES (Apr. 16, 2022), <https://www.nytimes.com/2022/04/16/opinion/patents-reform-drug-prices.html> (“In 2014, for example, the E.P.A. discovered that some pesticide makers were routinely amplifying the novel effects of their latest products in patent applications, only to downplay the same effects to federal regulators. ‘They would tell the patent office that their pesticide deserved a patent because it was different than what was already out there,’ said Charles Duan, a public interest attorney and a member of the patent office’s public advisory committee . . . ‘Then they’d tell the E.P.A. that the same pesticide didn’t need extra regulatory clearance because it was no different than what was already out there.’ Experts have long warned that the same thing could easily be happening at the F.D.A.”).

41. See Sachs, *supra* note 17 (“[R]egulatory exclusivities and patents function similarly, enabling innovators to block generic competitors from the market.”).

42. 11 F.4th 1345 (Fed. Cir. 2021).

43. *Id.* at 1354.

44. *Id.* at 1350–51.

information but also used emphatic language” to make inconsistent statements to the USPTO and FDA.<sup>45</sup>

*Belcher II* is, of course, just one case.<sup>46</sup> But it represents an important tipping point in the wider recognition of the inconsistent-representation problem that is besmirching the pharmaceutical industry.<sup>47</sup> Within a week of the *Belcher II* decision, U.S. Senator Patrick Leahy of Vermont and U.S. Senator Thom Tillis of North Carolina penned a bipartisan letter to the USPTO requesting that it “take steps to reduce patent applicants’ [sic] making inappropriate conflicting statements in submissions to the PTO and other federal agencies,” including the FDA.<sup>48</sup> The senators’ letter echoed the demands for meaningful reform that nonprofit organizations, such as I-MAK, had been making for years.<sup>49</sup> After *Belcher II*, it seems like the USPTO and FDA are finally starting to listen.<sup>50</sup>

## B. THE NEED FOR REFORM

On July 9, 2021, President Biden issued Executive Order No. 14306, entitled “Executive Order on Promoting Competition in the American Economy.”<sup>51</sup> Section 5(p)(vi) of the Executive Order stated that, “to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition,” the FDA should send a letter to the USPTO “enumerating and describing any relevant concerns.”<sup>52</sup> Biden’s Executive Order set in motion a series of communications between the FDA and the USPTO. Though the various communications differ in substance and scope, they all share a common message: There is an urgent need for change.

On September 10, 2021, Janet Woodcock, then-Acting Commissioner of Food and Drugs, sent a letter to the USPTO in accordance with Executive

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45. *Id.* at 1352.

46. That said, there are relatively few cases that make it to the courts. *See infra* Section IV.C.

47. *See* The Editorial Board, *supra* note 40 (describing the problem of inconsistent representation at the USPTO and FDA).

48. *See* Leahy & Tillis Letter, *supra* note 4, at 1.

49. *See* I-MAK, STRENGTHENING COMPETITION FOR PRESCRIPTION DRUGS THROUGH PATENT AND DRUG REGULATORY REFORM 6 (2022), <https://www.i-mak.org/strengthening-competition-blueprint/> (describing proposals to “expand interagency collaboration, starting with partnership between the PTO and the FDA”).

50. USPTO Director Vidal later acknowledged the senators’ letter in a post on the USPTO “Director’s Blog.” *See* Kathi Vidal, *Duty of Disclosure and Duty of Reasonable Inquiry Promote Robust and Reliable Patents, Drive Competition and Economic Growth, and Bring Life-Saving Drugs to the American People*, DIRECTOR’S BLOG (July 28, 2022, 5:34 AM), <https://www.uspto.gov/blog/director/entry/duty-of-disclosure-and-duty>.

51. Exec. Order No. 14306, 86 Fed. Reg. 36,987, 36,997 (July 9, 2021).

52. *Id.*

Order No. 14306.<sup>53</sup> Woodcock wrote generally of her desire to increase “engagement between FDA and USPTO,” including, for example, offering USPTO Examiners “training on FDA’s public information and databases that may help USPTO locate pertinent references.”<sup>54</sup>

Then, on July 6, 2022, USPTO Director Kathi Vidal, in response to Woodcock’s letter, asserted her desire to work with the FDA on “[e]xplor[ing] consistency in representations made to the USPTO and FDA,” such as “initiatives to require patent applicants to provide relevant information to the USPTO that has been submitted to other agencies.”<sup>55</sup> Further, on July 29, 2022, Director Vidal published a Notice in the Federal Register that broadly discussed the duties of disclosure and reasonable inquiry during patent prosecution.<sup>56</sup> Most notably, in Section V of the Notice, Director Vidal explained that:

“Each individual with a duty to disclose, or party with a duty of reasonable inquiry, should ensure that the statements made to the USPTO and other Government agencies, or any statements made on their behalf to other Government agencies regarding the claimed subject matter, are consistent . . . . Providing material information to other Government agencies, including the FDA, while simultaneously withholding the same information from the USPTO undermines both the intent and spirit of the duty of disclosure and violates those duties.”<sup>57</sup>

Director Vidal specifically outlined several instances in which it may be incumbent upon patent applicants (or any other party involved in patent prosecution who has a duty to disclose) to share information with the USPTO that has arisen through dealings with other government agencies.<sup>58</sup> For example, a party with a duty to disclose should always review information they receive from other government agencies in relation to their invention to determine whether that information should be shared with the USPTO.<sup>59</sup> To

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53. Letter from Janet Woodcock, Acting Comm’r Food & Drugs, to Andrew Hirshfeld, Performing Functions & Duties Under Sec’y Com. for Intell. Prop. & Dir. USPTO 4 (Sept. 10, 2021), <https://www.fda.gov/media/152086/download>.

54. *Id.*

55. Letter from Katherine K. Vidal, Under Sec’y Com. for Intell. Prop. & Dir. USPTO, to Robert M. Califf, Comm’r Food & Drugs 3–4 (July 6, 2022), <https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf>.

56. Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board, 87 Fed. Reg. 45,764, 45,764–67 (July 29, 2022) [hereinafter July 2022 Notice].

57. *Id.* at 45,766.

58. *Id.* at 45,766–67.

59. *Id.*

illustrate this point, Director Vidal noted that pharmaceutical patentees who receive Paragraph IV certifications should review the certification to determine whether the factual and legal bases of the Paragraph IV challenge contain information that is material to the patentability of matters still pending before the USPTO (e.g., in a continuation application within the same family).<sup>60</sup> Likewise, patent practitioners violate their duty of good faith and candor under 37 C.F.R. § 1.56(a) when they devise deliberate schemes to prevent individuals with a duty to disclose from obtaining relevant information in the first place.<sup>61</sup> As a consequence, the duty to disclose cannot be circumvented by “walling off the patent prosecution practitioners from the attorneys seeking FDA approval.”<sup>62</sup>

On October 4, 2022, Director Vidal published a second Notice in the Federal Register requesting public comments on “proposed initiatives directed at bolstering the robustness and reliability of patents.”<sup>63</sup> The Notice described the letters previously exchanged between the USPTO and FDA, reiterating that the “USPTO could work with the FDA to ensure that our patent system properly and adequately protects innovation while not unnecessarily delaying generic and biosimilar competition.”<sup>64</sup> However, neither the specific USPTO initiatives described in the Notice nor the questions ultimately submitted for public comment referred to increased USPTO-FDA collaboration.<sup>65</sup>

On November 7, 2022, Director Vidal published a third Notice in the Federal Register, in which she outlined a “Public Listening Session” to be jointly hosted by the USPTO and FDA on January 19, 2023.<sup>66</sup> In preparation

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60. *Id.* Pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), a “Paragraph IV” submission is made when a generic applicant includes “in its application a ‘certification’ that a patent submitted to FDA by the brand-name drug’s sponsor and listed in FDA’s [Orange Book] is, in the generic applicant’s opinion and to the best of its knowledge, invalid, unenforceable, or will not be infringed by the generic product.” FDA, PATENT CERTIFICATIONS AND SUITABILITY PETITIONS (2022), <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions>. Examples of “continuing applications” include continuation, divisional, and continuation-in-part applications. *See* MPEP § 201.02 (9th ed. Rev. 10.2019, June 2020); *see generally* Chen Chen, *Using Continuation Applications Strategically*, COOLEYGO, <https://www.cooleygo.com/using-continuation-applications-strategically/> (last visited Dec. 13, 2023) (describing continuation applications in the context of patent portfolio development).

61. July 2022 Notice, *supra* note 56, at 45,767.

62. *Id.*

63. Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, 87 Fed. Reg. 60,130, 60,130–34 (Oct. 4, 2022).

64. *Id.* at 60,130.

65. *See id.*

66. Joint USPTO–FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments, 87 Fed. Reg. 67,019, 67,019–20 (Nov. 7, 2022) [hereinafter November

for the session, Director Vidal specifically requested written comments in response to the following question: “What mechanisms could assist patent examiners in determining whether patent applicants have submitted inconsistent statements to the USPTO and the FDA?”<sup>67</sup> Part III of this Note responds directly to Director Vidal’s request.

### III. TACKLING INCONSISTENT REPRESENTATIONS DURING PATENT PROSECUTION

Director Vidal has, as outlined above, spoken repeatedly of her desire to increase USPTO-FDA interaction in ways that would help ensure the robustness of the patent system. However, the USPTO and FDA have yet to provide any detail on what this increased interaction would look like in practice. This Part, in response, proposes a new system of USPTO-FDA interaction that, to the extent possible, undercuts inconsistent representation before a patent issues—that is, during examination of a nonprovisional patent application.

#### A. A NEW SYSTEM OF USPTO-FDA INTERACTION

This Section argues that the USPTO should require that, when a patent applicant files an NDA relating to the same subject matter, they must provide the NDA application number to the USPTO. Then, USPTO Examiners must (1) search for the NDA in the FDA’s public databases, (2) review the information contained within the NDA submission, and (3) factor any relevant information into their patentability (in particular, novelty and nonobviousness) assessments during examination. The NDA information will then become part of the prosecution file for each patent application.

As an initial matter, the burden of creating and maintaining this (or any) new interagency system should lie primarily with the USPTO rather than the FDA. The FDA has made it clear that it is not—and has no desire to become—a patenting body.<sup>68</sup> In addition, the responsibility of overseeing interagency conduct that serves to reinforce duties of disclosure, good faith, and candor should fall on the agency that creates and perpetuates those

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2022 Notice]; *see also* Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments, 87 Fed. Reg. 11,902, 11,902–03 (Feb. 24, 2023) (explaining that the deadline for comment had been extended through March 10, 2023).

67. *Id.* at 67,021–22.

68. *See* Woodcock, *supra* note 53, at 2 (“FDA has an important but ministerial role with respect to patents.”).

duties—namely, the USPTO.<sup>69</sup> Because any new system of USPTO-FDA interaction will ultimately be intended to help the USPTO properly assess (or, as the case may be, reassess) patentability, it makes sense that USPTO Examiners will bear the burden of collecting and using FDA submissions to facilitate such assessments.<sup>70</sup>

What will the new system of USPTO-FDA interaction look like in practice? When a patent applicant files a nonprovisional application, they will also be required to submit to the USPTO the application numbers of any relevant NDAs pending at or approved by the FDA.<sup>71</sup> Then, during patent prosecution, the Examiner will use that NDA information to access and review publicly available FDA records—for example, using the Drugs@FDA database and the FDA's Orange Book.<sup>72</sup> The Drugs@FDA database, in particular, contains (often redacted) correspondence between the FDA and the pharmaceutical sponsor, including approval letters, review letters, and general correspondence.<sup>73</sup> As a result, the Examiner will likely be able to note, for example, whether the sponsor claimed that their product was comparable to an already-approved Reference Listed Drug (RLD) as part of a § 505(b)(2) application.<sup>74</sup> Thus, even if substantive comments about the already-approved product are redacted, the Examiner may still gain baseline knowledge about

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69. See MPEP § 2001 (9th ed. Rev. 10.2019, June 2020) (describing the Duty of Disclosure, Candor, and Good Faith).

70. Arguably, NDA information should still be submitted to the relevant prosecution files of relevant *issued* patents. In those cases, the Examiner can review the publicly available NDA records and, if they find information that raises new questions of patentability, the Examiner should be permitted to re-open prosecution. This process could, in many ways, mimic existing post-issuance proceedings such as *ex parte* reexamination. See 35 U.S.C. § 302.

71. To understand the differences between provisional and nonprovisional patent applications in the United States, see MPEP § 201 (9th ed. Rev. 10.2019, June 2020).

72. See Woodcock, *supra* note 53, at 4; *Drugs@FDA: FDA-Approved Drugs*, FDA, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>; FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS | ORANGE BOOK (Oct. 17, 2022), <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book> (“The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.”).

73. See *Drugs@FDA: FDA-Approved Drugs*, FDA, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>.

74. See FDA, *supra* note 34, at 2 n.7 (“The RLD ‘is the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.’ 21 CFR 314.3(b). Because an ANDA applicant is relying upon FDA’s finding that the RLD is safe and effective, FDA’s practice is to designate as RLDs drug products that have been approved for safety and effectiveness.”).

the existence of a comparable, already-approved product, which may well qualify as prior art that is material to patentability.

B. WHAT THIS NEW SYSTEM ACHIEVES—AND WHAT IT DOES NOT

Revisiting the *Belcher II* decision provides a helpful example of the potential usefulness of the new system of USPTO-FDA interaction proposed in this Part.<sup>75</sup> In that case, Belcher first submitted a § 505(b)(2) NDA for its epinephrine formulation in November 2012, which the FDA ultimately approved in July 2014.<sup>76</sup> The Drugs@FDA entry for Belcher’s formulation then became publicly accessible in March 2015.<sup>77</sup> Meanwhile, Belcher filed a nonprovisional patent application (claiming the same formulation) with the USPTO in August 2014.<sup>78</sup> The application later issued as a U.S. Patent in March 2016.<sup>79</sup> Thus, a full year lapsed between Belcher’s NDA being released on publicly available FDA databases (March 2015) and Belcher’s patent being issued by the USPTO (March 2016).

If the USPTO-FDA system proposed in this Part had been in place at that time, the USPTO Examiner would have had a full twelve months to review the publicly available components of Belcher’s NDA submissions on Drugs@FDA.<sup>80</sup> Had the Examiner undertaken such a review, they would have been made aware, for example, that Belcher listed Twinject, an already-approved epinephrine formulation, as an RLD in its § 505(b)(2) application.<sup>81</sup> As explained by the district court in *Belcher I*, Twinject used the “old” pH range that Belcher later described as “critical” when trying to patent its own formulation at the USPTO.<sup>82</sup> At minimum, then, notice of Belcher’s NDA would have made the Examiner aware of a patently material third-party product that Belcher did not disclose to the USPTO, despite Belcher’s belief

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75. See *supra* Section II.A.3.

76. NDA NO. 205029, DRUGS@FDA: FDA-APPROVED DRUGS (Mar. 31, 2015), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2014/205029Orig1s000TOC.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205029Orig1s000TOC.cfm).

77. *Id.*

78. U.S. Patent Application No. 14/460,845 (filed Aug. 15, 2014).

79. U.S. Patent No. 9,283,197; *Belcher Pharms., LLC v. Hospira, Inc. (Belcher II)*, 11 F.4th 1345, 1349–50 (Fed. Cir. 2021).

80. Assuming, of course, that the patenting timeline remained otherwise unaltered.

81. See, e.g., FDA, PHARMACOLOGY REVIEW 46 (Jan. 30, 2013), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2014/205029Orig1s000PharmR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205029Orig1s000PharmR.pdf) (“This submission is primarily based on published literature as a 505(b)(2) application and safety information from Twinject (NDA 020800, an approved drug) as the listed reference drug.”).

82. *Belcher Pharms., LLC v. Hospira, Inc. (Belcher I)*, 450 F. Supp. 3d 512, 522–23 (D. Del. 2020). Note that, while Belcher specifically described the pH range of another third-party formulation—that of Sintetica SA—as “old,” the *Belcher I* court explained that the Twinject and Sintetica SA formulations “had approximately the same pH.” *Id.*

that such a product was similar enough to its own to be listed as an RLD in its NDA.

But a new system of USPTO-FDA interaction is not just useful—it is necessary. First, creating a system of dual requirements—that patent applicants disclose NDA information and that USPTO Examiners review publicly available FDA records—increases the likelihood that the relevant information will be provided to and considered by the Examiner. To be sure, the duty of disclosure already encompasses the requirement to share with the USPTO material information submitted to other government agencies.<sup>83</sup> And USPTO Examiners have always been able to access FDA’s public databases without a formal system of USPTO-FDA interaction. But the status quo is clearly not working, at least with the effectiveness needed to tackle the problem of inconsistent representation.<sup>84</sup> Establishing a system of explicit disclosure and review requirements for patent applicants and Examiners, respectively, is thus necessary to uphold “both the intent and spirit of the duty of disclosure.”<sup>85</sup>

Second, the FDA Orange Book—the closest existing analog of the proposed new system—only lists issued patents for approved drugs.<sup>86</sup> Consequently, by the time an Examiner is able to use the Orange Book to link patents and FDA records, prosecution is long over.<sup>87</sup> A system that instead connects FDA submissions to pending patent applications (at least some of the time) will help tackle inconsistent representation in the most effective way possible: *before* an invalid patent actually issues.<sup>88</sup> This will save critical USPTO resources in the long run by shortening the time spent by Examiners prosecuting ultimately unpatentable inventions.

The new system proposed herein will also have beneficial outcomes both for generics manufacturers and the general public. As things stand, an accused infringer has to wait for (in reality, invalid) patents to issue and appear in the

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83. See July 2022 Notice, *supra* note 56, at 45,766.

84. See November 2022 Notice, *supra* note 66, at 67,021–22 (requesting public comment on possible mechanisms for tackling the inconsistent representation problem); Woodcock, *supra* note 53, at 4 (suggesting that USPTO Examiners could benefit from “training on FDA’s public information and databases that may help USPTO locate pertinent references”).

85. See July 2022 Notice, *supra* note 56, at 45,766.

86. See FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS | ORANGE BOOK (Oct. 17, 2022), <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book> (describing the Orange Book).

87. Of course, prosecution may be ongoing for other applications in the patent family. But there is currently no straightforward way for an Examiner to know that the patent application she is assessing is part of a family with issued patents listed in the Orange Book.

88. Again, that is not to say that patentees should not also be required to submit NDA information for *issued* patents. See *supra* note 70.



Orange Book before they can submit Paragraph IV unenforceability certifications based on inconsistent representation.<sup>89</sup> This delay has significant financial costs for generics manufacturers while they are frozen out of the market.<sup>90</sup> More importantly, it denies the public access to generic medicines that are unfairly blocked by invalid patents.<sup>91</sup> It is thus imperative that the USPTO devise a system, such as the one proposed in this Part, that allows patent Examiners to access FDA submissions as early as possible in the patent prosecution timeline.

Admittedly, the proposed new system of USPTO-FDA interaction would be far from perfect. One significant problem is that our current patent prosecution and FDA approval processes suffer from a fundamental—if not fatal—incompatibility. Patent prosecution, unlike the FDA approval process, is inherently public.<sup>92</sup> Indeed, USPTO Director Vidal, writing in her November 2022 Notice in the Federal Register, seemed to anticipate the problematic nature of this private-public dichotomy: As part of her request for mechanisms to tackle inconsistent representation, Director Vidal asked commenters to “explain whether such mechanisms present confidentiality concerns and, if so, how those concerns could be addressed.”<sup>93</sup>

Likewise, the public-private problem has not gone unnoticed by nonagency advocates of greater USPTO-FDA interaction. For instance, I-MAK, a nonprofit organization, has suggested that pharmaceutical patent applicants should be required to submit copies of all FDA filings with the USPTO during prosecution.<sup>94</sup> Acknowledging the need to “avoid any issues relating to trade secrets,” I-MAK suggested that “[t]he sharing of information on drug products between FDA and PTO could be made through a

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89. See FDA, *supra* note 60 (describing Paragraph IV certifications as governed by 21 U.S.C. § 355(b)(2)(A)(iv)).

90. See Sachs, *supra* note 17 (“Lower-priced generic versions of these drugs may not appear for decades—and may be delayed beyond the expected date by patent holders’ arcane strategies for extending their legal monopolies. In the meantime, patent holders may have no qualms about raising their prices year after year, putting their products even further out of reach.”).

91. See *id.*

92. Compare 37 C.F.R. § 1.11 (2012) (explaining the public components of patent prosecution), with 21 C.F.R. § 314.430 (2008) (discussing the “[a]vailability for public disclosure of data and information in an [NDA] or abbreviated application”). For this reason, this Part suggests that patent applicants should only be required to submit *NDA* information to the USPTO since those applications (or at least parts of them) eventually become accessible to the public. Other types of FDA submissions, e.g., INDs, generally do *not* become public. See 21 C.F.R. § 312.130 (2003) (discussing the “[a]vailability for public disclosure of data and information in an IND”).

93. See November 2022 Notice, *supra* note 66, at 67,022.

94. I-MAK, *supra* note 49, at 6.

memorandum of understanding.”<sup>95</sup> The problem with I-MAK’s recommendation is that the Examiner cannot keep confidential a patent applicant’s statements from an NDA and also use them as the basis of a novelty or obviousness rejection that becomes part of an entirely public patent prosecution record.<sup>96</sup> To be sure, the *Belcher II* timeline outlined at the beginning of this Section does demonstrate that even publicly accessible NDA information could, under the system proposed in this Part, prove useful to patentability assessments. But as long as patent prosecution and FDA approval continue to operate in inherently incompatible public and private spheres, USPTO Examiners can only ever be required to access publicly available information in FDA databases.

A second issue is that pharmaceutical companies typically file patent applications long before they submit corresponding NDAs.<sup>97</sup> To compound the problem, the FDA adds information about drug products to its publicly accessible databases only after the drug has been approved, which typically occurs six to ten months after NDA submission.<sup>98</sup> As a consequence, it is entirely possible that one or more patents will have already issued in a patent family covering the product for which the pharmaceutical entity later obtains regulatory approval.<sup>99</sup> For these patents, the new system of USPTO-FDA interaction and the existing FDA Orange Book would, in essence, become mirror images of each other: The USPTO’s file wrapper would contain NDA

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95. *Id.*

96. See 37 C.F.R. § 1.11 (describing the public components of patent prosecution).

97. Consider the following sample timelines. According to data from 2000 to 2010, the time interval between filing a provisional patent application with the USPTO and receiving an IND effective date (which typically occurs up to 30 days after filing the initial IND application) for a New Chemical Entity at the FDA can be as long as 4.7 years without sacrificing market exclusivity. Michael K. Dunn, *Timing of Patent Filing and Market Exclusivity*, 10 NATURE REVS. DRUG DISCOVERY 487, 488 (2011). In contrast, in January 2023, the mean time between filing a nonprovisional application and receiving a final disposition (patent issuance or abandonment of the application) in the 1600 Technology Center was 2.3 years. *Patents Pendency Data October 2023*, USPTO, <https://www.uspto.gov/dashboard/patents/total-pendency-by-tc.html> (last visited Dec. 13, 2023). Thus, as a very rough estimate (assuming consistency over time, etc.), a typical pharmaceutical patentee will obtain a patent for their drug product more than one year before they file an IND application at the FDA. Note that pharmaceutical sponsors tend to submit an IND approximately 5–7 years before filing the corresponding NDA. See Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BD. FAMILY PRAC. 362, 365 (2001).

98. See FDA, STEP 4: FDA DRUG REVIEW (Jan. 4, 2018), <https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review#>.

99. See *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348, 376 (D.N.J. 2010) (“Indeed, most drugs are patented long before their commercial use is approved by the FDA.”).

information for approved drugs and the FDA Orange Book would provide relevant patent information for those same approved drugs.

Arguably, then, the real value of this new USPTO-FDA system lies in its potential for circumventing patent “evergreening.”<sup>100</sup> Because most drugs are covered by multiple patents, it is likely that a significant number of continuing applications<sup>101</sup> will remain pending after initial FDA approval.<sup>102</sup> For example, many pharmaceutical companies, when patenting a small-molecule drug product, will first patent the chemical entity, and then subsequently patent specific formulations, methods of treatment, and dosing.<sup>103</sup> NDA submissions often contain therapeutically specific safety and efficacy information that is more relevant to these later-issued patents.<sup>104</sup> It is therefore possible that later-filed patent applications covering these aspects of the invention will still be undergoing prosecution when the corresponding NDAs are submitted. Should that be the case, any information that is material to patentability—assuming it

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100. See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 354 (2007) (describing “evergreening” as the practice by which patentees seek “to prolong their effective periods of patent protection through . . . strategies that add new patents to their quivers as old ones expire”); see also WARD, HICKEY & RICHARDS, *supra* note 16, at 41–45 (providing more information about common “evergreening” practices).

101. Examples of “continuing applications” include continuation, divisional, and continuation-in-part applications. See MPEP § 201.02 (9th ed. Rev. 10.2019, June 2020); see generally Chen Chen, *Using Continuation Applications Strategically*, COOLEYGO, <https://www.cooleygo.com/using-continuation-applications-strategically/> (last visited Dec. 13, 2023) (describing continuation applications in the context of patent portfolio development).

102. See Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 601–02 (2018) (“Simple techniques can involve obtaining new protections on existing drugs by filing additional patents, sometimes on methods of producing or manufacturing the drugs . . . . More complex evergreening strategies involve developing new formulations, dosage schedules, or combinations that can be used to obtain new patents”); Uri Y. Hachoen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 486 (2020) (“In [the pharmaceutical] industry, patents of negligible market value are sometimes disproportionately rewarded by allowing brand-name manufacturers to artificially extend their monopolies over existing drugs when their current legal protections are about to expire.”).

103. See M. David Weingarten & Shana K. Cyr, *Securing and Maintaining a Strong Patent Portfolio for Pharmaceuticals*, 10 ACS MEDICINAL CHEMISTRY LETTERS 838, 839 (2019) (“Once researchers begin to generate novel compounds that show relevant biological activity, patent applications may be filed on potential drug candidates, both specifically and generically, and their methods of use. As these potential drug candidates advance through preclinical and then clinical development, applications may be filed on further scientific advances such as new dosage forms, potential new uses, methods of administration, and possible novel drug combinations with other known drugs.”).

104. See FDA, BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES SUBMITTED IN NDAS OR INDs—GENERAL CONSIDERATIONS (Mar. 2014), <https://www.fda.gov/media/88254/download> (describing the types of safety and efficacy information often included in FDA submissions).

is publicly available—can be assessed during the prosecution of those applications and, if the timing is right, prevent patents from issuing.<sup>105</sup>

Lastly, this new system of USPTO-FDA interagency disclosure could suffer from noncompliance. To be sure, it would likely be more difficult for a patent applicant to offer a good-faith explanation of their decision to forgo a simple and explicit mandate—timely disclosure of FDA submission details to the USPTO—than it might be for them to excuse a failure to comply with a more amorphous duty to disclose.<sup>106</sup> But, as in any administrative system, at least some participants will default on their duties (intentionally or otherwise) and fail to provide relevant NDA information to the USPTO.

Taken together, issues of confidentiality, timing, and noncompliance would likely undermine, at least to some extent, the overall usefulness of the proposed system of USPTO-FDA interaction. This Note contends that such a system could nonetheless play an important role in undercutting inconsistent representation—especially in large, multi-generational patent families with drawn-out prosecution timelines. Further, all patent applicants would arguably be discouraged from making inconsistent representations in the first place: Because Examiners would have notice of and access to FDA records (later, if not sooner), there would be less incentive to try and game the system from the outset. But the proposed new system of USPTO-FDA interaction would certainly not be foolproof. What is needed, then, is a safety net. Accused patent infringers must have an effective means by which they can challenge the validity of a pharmaceutical patent obtained in spite of (if not because of) inconsistent representation at the USPTO and FDA.<sup>107</sup> And that, this Note proposes, is where the courts come in.

#### IV. TACKLING INCONSISTENT REPRESENTATIONS AFTER PATENT ISSUANCE

Under current law, if a court finds that a patentee engaged in inequitable conduct during patent prosecution, the whole patent is rendered

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105. Again, that is not to say that patentees should not also be required to submit NDA information for *issued* patents. See *supra* note 70.

106. It is possible (though purely speculative) that similar reasoning underscored Director Vidal's decision to recently clarify that the duty to disclose already encompasses the need to make consistent representations to government agencies. See July 2022 Notice, *supra* note 56, at 45,764–67.

107. Issues of patentee noncompliance aside, an invalid patent might also be granted if the USPTO Examiner failed to recognize the materiality of information contained in an FDA submission.

unenforceable.<sup>108</sup> In theory, then, inequitable conduct doctrine *should* provide a useful mechanism for accused patent infringers to challenge the enforceability of a patent obtained through deception—including where that deception is evidenced by inconsistent representation at the USPTO and FDA.<sup>109</sup> But in practice, it is all but impossible for defendants in patent infringement lawsuits to raise a successful inequitable conduct claim because of the exceptionally high legal standards outlined by the Federal Circuit in *Therasense*.<sup>110</sup>

This Part argues that the Federal Circuit should revise its inequitable conduct doctrine to create a “pharma exception” to *Therasense*. The court should hold that, when an accused infringer shows that a patentee (1) failed to disclose to the USPTO references it shared with the FDA to support its case for regulatory approval, or (2) made inconsistent or contradictory statements to the USPTO and the FDA, there should be a rebuttable presumption that *both* the materiality *and* the intent prongs of the *Therasense* inequitable conduct test are satisfied.<sup>111</sup> By adopting this change, the court would revitalize an important post-patent-issuance mechanism for tackling the problem of inconsistent representation.

#### A. INEQUITABLE CONDUCT DOCTRINE UNDER *THERASENSE*

The remedy for a finding of inequitable conduct—whole-patent unenforceability—is the “atomic bomb” of patent law.<sup>112</sup> Patentees—even ones who are ultimately successful—must defend their good names against accusations of bad faith.<sup>113</sup> The attorney who prosecuted the application will undoubtedly face devastating consequences to their professional reputation.<sup>114</sup> Perhaps unsurprisingly, then, courts have struggled to strike the right balance between “ensur[ing] . . . candor and truthfulness” on the part of patent

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108. *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d at 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting).

109. *See* *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc) (“As the inequitable conduct doctrine evolved . . . it came to embrace a broader scope of misconduct, including not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts but also the mere nondisclosure of information to the PTO.”).

110. *See id.* at 1290–95; Frederick Frei & Sean Wooden, *Inequitable Conduct Claims One Year After Therasense*, 221 *MANAGING INTELL. PROP.* 66, 66 (2012) (“After the holding in *Therasense*, it was widely believed that the court had sounded the death knell to the inequitable conduct defense by imposing evidentiary requirements that could rarely be met.”).

111. These two criteria mirror Director Vidal’s framing of the inconsistent representation problem. *See* July 2022 Notice, *supra* note 56, at 45,766.

112. *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting).

113. *Therasense*, 649 F.3d at 1288.

114. *Id.*

applicants and nurturing the incentive to seek patent protection in the first place.<sup>115</sup>

The origins of inequitable conduct doctrine in patent law can be traced to the unclean hands doctrine.<sup>116</sup> The Supreme Court laid the foundations of modern inequitable conduct doctrine in three germinal cases: *Keystone Driller Co. v. General Excavator Co.*,<sup>117</sup> *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*,<sup>118</sup> and *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*<sup>119</sup> Shortly thereafter, the Patent Act of 1952 triggered the advent of whole-patent unenforceability as the remedy for inequitable conduct.<sup>120</sup> The creation of the Federal Circuit in 1982 brought much-needed uniformity to inequitable conduct doctrine.<sup>121</sup> Because earlier cases had involved such flagrant misconduct, and the claims had arisen in equity, not law, the Supreme Court had been unable to articulate clear legal standards to guide lower courts.<sup>122</sup> Fortunately, the Federal Court, since its inception, has been consistent in requiring that two elements be satisfied for a showing of inequitable conduct: materiality and intent.<sup>123</sup> Unfortunately, the consistency ends there.<sup>124</sup>

The pleading and legal standards that govern inequitable conduct defenses have changed considerably and frequently over the past four decades.<sup>125</sup>

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115. See *Aventis*, 525 F.3d at 1349 (Rader, J., dissenting).

116. *Therasense*, 649 F.3d at 1285 (“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct.”).

117. 290 U.S. 240 (1933).

118. 322 U.S. 238 (1944).

119. 324 U.S. 806 (1945).

120. 35 U.S.C. § 282(b)(1).

121. For a more detailed description of the evolution of inequitable conduct doctrine in lower courts prior to the establishment of the Federal Circuit, see Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 HARV. J.L. & TECH. 37, 52–67 (1993).

122. Robert Swanson, *The Exergen and Therasense Effects*, 66 STAN. L. REV. 695, 700 (2014).

123. See *id.* at 701 (“For the entire duration of the Federal Circuit’s existence, it has been clear that inequitable conduct has two elements: materiality and intent.”).

124. See *id.* (explaining that, even after the creation of the Federal Circuit, “the elements needed to prove inequitable conduct were often vague and shifting”).

125. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287–88 (Fed. Cir. 2011) (en banc) (“[T]he standards for intent to deceive and materiality have fluctuated over time.”); see, e.g., *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir. 1984) (finding that materiality and intent exist on a sliding scale); *Hoffman-LaRoche Inc. v. Lemmon Co.*, 906 F.2d 684, 688 (Fed. Cir. 1990) (holding that gross negligence is insufficient for a finding of intent); *Ferring B.V. v. Barr Lab’s, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (finding that intent may be presumed in the absence of a credible explanation for gross negligence on the part of the patentee); *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d

*Exergen Corp. v. Wal-Mart Stores, Inc.* marked a particularly notable shift.<sup>126</sup> In that case, the Federal Circuit held that, because inequitable conduct is a type of fraud, it demands a heightened pleading standard—specifically, it must be pleaded with particularity per Rule 9(b) of the Federal Rules of Civil Procedure.<sup>127</sup> Under materiality, the *Exergen* court held, the accused infringer’s plea must “identify the specific who, what, when, where, and how of the material misrepresentation or omission.”<sup>128</sup> Under intent, the party raising the inequitable conduct defense must include sufficient factual detail for a court to “infer that a specific individual (1) knew of the withheld information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.”<sup>129</sup>

A second major change occurred after *Therasense*. In response to concerns over the perceived leniency of its inequitable conduct doctrine, the Federal Circuit heightened the legal standards for both the materiality and the intent prongs of its two-part test.<sup>130</sup> Now, under materiality, the defendant must show, by a preponderance of the evidence, that the information in question is but-for material to patentability such that the USPTO would not have allowed a claim if it had been aware of the information.<sup>131</sup> Importantly, this but-for

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1357, 1366–67 (Fed. Cir. 2008) (holding that materiality and intent must be established separately by clear and convincing evidence before the court can engage in balancing the facts and equities of unenforceability).

126. See 575 F.3d 1312 (Fed. Cir. 2009).

127. *Id.* at 1327.

128. *Id.* at 1328.

129. *Id.* at 1328–29.

130. *Therasense*, 649 F.3d at 1290 (“While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality. This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”).

131. *Id.* at 1291–92. Prior to *Therasense*, the materiality standard had been pegged to the USPTO’s own (fluctuating) materiality standard under Rule 56. But now, the standard under *Therasense* is stricter than the USPTO’s Rule 56, which currently specifies that information is only material if it (1) is non-cumulative over the information already disclosed, and (2) either establishes a prima facie case of unpatentability or is inconsistent with a position patentee adopted during prosecution. In fact, the *Therasense* “but-for material” requirement for inequitable conduct is now virtually coextensive with the materiality standard needed to invalidate a claim. The only difference in the two tests is the standard of proof: but-for materiality must be proven by a preponderance of the evidence for a finding of inequitable conduct, but by clear and convincing evidence for a finding of invalidity. *Id.* Thus, a finding of invalidity in district court based on a withheld reference implies that the reference is necessarily but-for material under *Therasense*’s materiality standard. However, a withheld reference may still be but-for material in terms of inequitable conduct doctrine even if it is not sufficient to invalidate a claim in district court.

materiality is purely objective: Under this first prong of the two-part test, it matters not whether the patentee had knowledge of the information, let alone its materiality.<sup>132</sup> The question to be answered is simply whether the information would have precluded patentability had the USPTO been aware of it.<sup>133</sup>

Under the second prong of the *Therasense* test, the defendant must show, by clear and convincing evidence, that the specific intent to deceive or mislead the USPTO is the “single most reasonable inference” to be drawn.<sup>134</sup> In fact, when there are “multiple reasonable inferences . . . intent to deceive cannot be found.”<sup>135</sup> Writing for the majority in *Therasense*, Chief Judge Rader explained that, to satisfy the intent prong of an inequitable conduct defense, an accused infringer must show three things, each by clear and convincing evidence: (1) the patentee knew of the information, (2) the patentee knew that the information was material, and (3) the patentee made a deliberate decision to withhold the information from the USPTO.<sup>136</sup>

Note that the first and second requirements under the intent prong of the inequitable conduct test create a separate and distinct materiality component.<sup>137</sup> As discussed above, the information withheld from the USPTO

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132. See *Therasense*, 649 F.3d at 1291 (“[I]n assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.”).

133. See *id.*

134. *Id.* at 1290; see *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1374–75 (Fed. Cir. 2012) (“Knowledge of the reference and knowledge of materiality alone are insufficient after *Therasense* to show an intent to deceive . . . . [I]t is not enough to argue carelessness, lack of attention, poor docketing or cross-referencing, or anything else that might be considered negligent or even grossly negligent.”); *Western Plastics, Inc. v. DuBose Strapping, Inc.*, No. 2021-1371, 2022 WL 576218, at \*1 (Fed. Cir. Feb. 25, 2022) (“[W]e agree with the district court that [the defendant] did not set forth evidence to meet the high [post-*Therasense*] standard of establishing that the patent applicant intended to deceive the Patent Office, as required to sustain an inequitable conduct defense.”).

135. *Therasense*, 649 F.3d at 1290–91.

136. *Id.* at 1290. Note that, though *Therasense* dealt with a patentee that withheld references from the PTO, the Federal Circuit has clarified that the *Therasense* standard also applies to factual misrepresentations (including representations about references that were actually submitted to the USPTO). See, e.g., *Ohio Willow Wood Co. v. Alps S., LLC*, 813 F.3d 1350, 1357 (Fed. Cir. 2016) (“A party seeking to prove inequitable conduct must show by clear and convincing evidence that the patent applicant made *misrepresentations or omissions* material to patentability, that he did so with the specific intent to mislead or deceive the PTO, and that deceptive intent was the single most reasonable inference to be drawn from the evidence.”) (emphasis added).

137. See, e.g., *Baxter Int’l, Inc. v. CareFusion Corp.*, No. 15 C 9986, 2022 WL 981115, at \*8 (N.D. Ill. Mar. 31, 2022) (“The next requirement is that the inventors must have known



must first be *objectively* but-for material to patentability.<sup>138</sup> But a showing of intent requires the accused infringer to prove that the patentee had a *subjective* knowledge both of the information's existence and of its materiality.<sup>139</sup> Note also that the third requirement of the intent prong—a showing that the patentee made a “deliberate decision to withhold” the information from the USPTO—is one of purpose, not knowledge.<sup>140</sup> In his closing remarks in *Therasense*, Chief Judge Rader ordered that, on remand, the lower court should determine whether the patentee “made the conscious decision not to disclose [the relevant information] *in order to deceive* the PTO.”<sup>141</sup> In other words, a showing that the patentee understood that their conduct would deceive the USPTO is not enough—the defendant must prove that the patentee had the express purpose of deception.

Thus, for post-*Therasense* defendants, the bar to raising an inequitable conduct defense is exceedingly high. Only a showing (under demanding evidentiary standards) that the patentee intentionally withheld or misrepresented information that would have precluded issuance of a patented claim will suffice. Indeed, it bears repeating: Not only must the accused infringer show that the information withheld from or misrepresented to the USPTO was objectively but-for material to patentability, but they must also show that the patentee had a subjective appreciation of the information's materiality and acted with the purpose of deceiving the USPTO when it withheld or misrepresented the material information. Importantly, the *Therasense* court also explicitly disavowed the sliding scale approach it had favored in the past, “where a weak showing of intent [could] be found sufficient based on a strong showing of materiality, and vice versa.”<sup>142</sup> Instead, after *Therasense*, the “court must weigh the evidence of intent to deceive independent of its analysis of materiality.”<sup>143</sup>

Some critics have suggested that the *Therasense* court was overzealous in its efforts to address the “plague” of inequitable conduct defenses that were

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the [withheld information was] material. This is a requirement of knowledge, not of the separate inquiry of but-for materiality required for an inequitable conduct showing.”)

138. See *Therasense*, 649 F.3d at 1291 (“[I]n assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.”).

139. See *id.* at 1290.

140. See *id.*

141. *Id.* at 1296 (emphasis added).

142. See *id.* at 1290.

143. *Id.*

common in patent litigation.<sup>144</sup> This view was seemingly shared by the dissent in *Therasense*, which, believing the majority's approach to be too restrictive, advocated for a more modest materiality test.<sup>145</sup> However, the data show that courts reject post-*Therasense* inequitable conduct defenses for lack of intent (87% of failed defenses) much more frequently than for lack of materiality (57% of failed defenses).<sup>146</sup> This trend may be attributable to the fact that "direct evidence of specific intent to deceive is difficult to find, so it is relatively simple for a judge to conclude that an accused infringer failed to prove intent."<sup>147</sup> As a result, even if the Federal Circuit were to now soften its materiality requirement, it is not clear that such a change, in the absence of a sliding scale, could revive the effectiveness of the inequitable conduct defense.<sup>148</sup>

#### B. THREE CASE STUDIES IN INCONSISTENT REPRESENTATION: *BRUNO*, *BELCHER*, AND *BAXTER*

To understand the impact of *Therasense*, and the changes to the legal standards of the intent prong in particular, this Section considers three case studies: (1) *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*;<sup>149</sup> (2) *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*;<sup>150</sup> and (3) *Baxter International, Inc. v. CareFusion Corp.*,<sup>151</sup> each of which is discussed in turn below. All three cases (the first two from the Federal Circuit and the third from the Northern District of Illinois) turned on issues of inconsistent representation at the USPTO and FDA. Notably, *Bruno* and *Baxter* did not involve pharmaceutical patents. But the analysis and holdings in each case are nonetheless helpful for understanding the application of pre- and post-*Therasense* inequitable conduct

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144. *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988); see Swanson, *supra* note 122, at 720–24 (outlining criticism of the Federal Circuit's rationale for *Therasense*).

145. See *Therasense*, 649 F.3d at 1304 (Bryson, J., dissenting) (arguing that materiality should be measured by the PTO's Rule 56 standard).

146. Swanson, *supra* note 122, at 708. These findings are consistent with pre-*Therasense* data generated by Petherbridge and co-workers in 2011. See Lee Petherbridge, Jason Rantanen & Ali Mojibi, *The Federal Circuit and Inequitable Conduct: An Empirical Assessment*, 84 S. CAL. L. REV. 1293, 1319–21 (2011) ("[W]hen the Federal Circuit gives a single reason for patentee success, the reason is nearly two and a half times more likely to be lack of intent to deceive than it is to be lack of materiality.").

147. Swanson, *supra* note 122, at 709.

148. See *Therasense*, 649 F.3d at 1290 ("[A] court must weigh the evidence of intent to deceive independent of its analysis of materiality.").

149. 394 F.3d 1348 (Fed. Cir. 2005).

150. 11 F.4th 1345 (Fed. Cir. 2021).

151. No. 15 C 9986, 2022 WL 981115 (N.D. Ill. Mar. 31, 2022).

doctrine by the courts to claims of inconsistent representation at the USPTO and FDA.

1. Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.

In *Bruno*, a pre-*Therasense* case, the Federal Circuit held that a stairlift manufacturer had engaged in inequitable conduct<sup>152</sup> by withholding from the USPTO material prior art they had previously disclosed to the FDA as part of a § 510(k) submission.<sup>153</sup> The analysis turned on disclosure of a competitor product, the “Wecolator.”<sup>154</sup> In seeking FDA approval to sell its stairlift, Bruno Independent Living Aids, Inc. (“Bruno”) made a claim of “substantial equivalence” between its product and the Wecolator.<sup>155</sup> However, the same information about the competitor product was never shared with the USPTO.<sup>156</sup>

Adopting a pre-*Therasense* Rule 56 materiality standard,<sup>157</sup> the Federal Circuit held that, “[h]ad the Examiner known about the Wecolator . . . Bruno could not have touted the front offset swivel as a point of novelty.”<sup>158</sup> The Wecolator disclosure was thus material to patentability under Rule 56.<sup>159</sup> In fact, the Wecolator’s materiality was also crucial to the Federal Circuit’s analysis of intent. The court acknowledged that the district court had “provided little explicit support for its finding of intent.”<sup>160</sup> However, the court relied on the pre-*Therasense* materiality-intent sliding scale, finding that “the high materiality of the Wecolator” meant there was “sufficient evidence based upon which a fair inference of deceptive intent may be drawn.”<sup>161</sup> Such a reliance would, as noted above, be impossible post-*Therasense*.<sup>162</sup>

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152. *Bruno*, 394 F.3d at 1355.

153. 510(k) NO. K921648, 510(k) PREMARKET NOTIFICATION (May 4, 1992), <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K921648>. Note that § 510(k) submissions are used by medical device manufacturers to notify the FDA of their intent to market a medical device in the United States. See *510(k) Clearances*, FDA (Nov. 6, 2023), <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances>.

154. *Bruno*, 394 F.3d at 1351–52.

155. *Id.* at 1352.

156. *Id.*

157. 37 C.F.R. § 1.56(b)(2)(ii) (2012).

158. *Bruno*, 395 F.3d at 1353.

159. *Id.* at 1354.

160. *Id.*

161. *Id.*

162. See *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc) (“[A] court must weigh the evidence of intent to deceive independent of its analysis of materiality.”).

The Federal Circuit likewise held that, because Bruno had “not proffered a credible explanation for the nondisclosure,” it was fair to make an inference of deceptive intent.<sup>163</sup> After *Therasense*, that type of inference cannot be made: Now, a “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.”<sup>164</sup> In other words, a patentee’s silence in the face of an inequitable conduct accusation leads to very different consequences pre- and post-*Therasense*. Before *Therasense*, the court was free to infer malintent from a lack of good-faith explanation; after *Therasense*, a patentee can hide behind their silence so long as the accused infringer fails to provide clear and convincing evidence of the intent to deceive the USPTO.

## 2. Belcher Pharmaceuticals, LLC v. Hospira, Inc.

In the *Belcher II* case, a post-*Therasense* Federal Circuit held a pharmaceutical patent unenforceable for inequitable conduct.<sup>165</sup> Recall that Belcher submitted a § 505(b)(2) NDA with the FDA for an injectable epinephrine formulation.<sup>166</sup> Belcher, in supporting its case for § 505(b)(2) approval, had disclosed to the FDA information about similar third-party products that it later withheld from the USPTO.<sup>167</sup> Likewise, Belcher, when corresponding with the FDA, referred to the pH range of one such competitor product as “old,” later asserting that that same pH range was “unexpectedly found to be critical” to its own invention when contesting an obviousness rejection at the USPTO.<sup>168</sup> The district court found—and the Federal Circuit agreed—that Belcher “did not merely withhold . . . information but also used emphatic language” to make inconsistent statements to the USPTO and FDA.<sup>169</sup>

Applying *Therasense*, the Federal Circuit found that Belcher had withheld multiple pieces of information, including knowledge of third-party products, that were but-for material to patentability.<sup>170</sup> The Federal Circuit rejected Belcher’s argument that it only withheld information that it believed to be cumulative over the art already on record.<sup>171</sup> In the court’s view, Belcher’s argument was unpersuasive because it was “directly at odds” with Belcher’s

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163. *Bruno*, 395 F.3d at 1354.

164. *Therasense*, 649 F.3d at 1291 (citing *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1368 (Fed. Cir. 2008)).

165. *Belcher Pharms., LLC v. Hospira, Inc. (Belcher II)*, 11 F.4th 1345, 1354 (Fed. Cir. 2021).

166. *Id.*

167. *Id.*

168. *Id.* at 1350–51.

169. *Id.* at 1352.

170. *Id.* at 1353.

171. *Id.*

assertion during patent prosecution that the claimed pH range was critical.<sup>172</sup> Likewise, the Federal Circuit affirmed the district court's finding of intent.<sup>173</sup> Recognizing that it is often difficult to find direct proof of intent, the court pointed to evidence in the record (for example, Belcher's knowledge of third-party products and its assertions relating to the criticality of the pH range) that supported a finding that "the single most reasonable inference is that [Belcher] possessed the specific intent to deceive the PTO."<sup>174</sup>

### 3. Baxter International, Inc. v. CareFusion Corp.

Most recently, in *Baxter*, a district court in Illinois found that an infusion-pump manufacturer did not engage in inequitable conduct when it failed to disclose to the USPTO information about competitor products that it had described as "substantially equivalent" to its own device as part of a § 510(k) submission to the FDA.<sup>175</sup>

The court analyzed each of the three intent components (subjective knowledge of the existence of the information, subjective knowledge of the materiality of the information, and specific intent to deceive the USPTO) for each of the three Baxter International ("Baxter") inventors in turn.<sup>176</sup> Judge Kendall acknowledged that there were genuine issues of fact as to whether certain inventors knew of the existence of the withheld information, its materiality, or both.<sup>177</sup> However, the court ultimately concluded that such factual disputes were not dispositive because CareFusion Corporation ("CareFusion") could not "set forth evidence that any Baxter Inventor made a deliberate decision to deceive the USPTO."<sup>178</sup>

In reality, the court found, "even if a factfinder were to disbelieve the Baxter Inventors, the 'single most reasonable inference' would still not be" one of deliberate deception.<sup>179</sup> Because a reasonable factfinder could equally conclude that the nondisclosure was due to, for example, gross negligence or incompetence, it would not be possible for that same factfinder to conclude that Baxter had engaged in inequitable conduct under the standards set forth in *Therasense*.<sup>180</sup> Accordingly, Judge Kendall granted Baxter's Motion for Partial

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172. *Id.*

173. *Id.* at 1354.

174. *Id.*

175. *Baxter Int'l, Inc. v. CareFusion Corp.*, No. 15 C 9986, 2022 WL 981115, at \*6 (N.D. Ill. Mar. 31, 2022).

176. *Id.* at \*6–7.

177. *Id.* at \*7.

178. *Id.*

179. *Id.*

180. *Id.*

Summary Judgment of No Inequitable Conduct, noting that, even if it were true that summary judgment motions for no inequitable conduct were rarely granted pre-*Therasense*, that “is no longer the case.”<sup>181</sup>

Judge Kendall specifically disparaged CareFusion’s attempt to analogize the factual and legal issues in *Baxter* to the Federal Circuit’s analysis in *Bruno*.<sup>182</sup> Kendall distinguished *Baxter* from *Bruno* in two key ways. First, she noted that, post-*Therasense*, use of a materiality-intent sliding scale was “improper.”<sup>183</sup> Second, she explained that *Therasense* voided the possibility of inferring deceptive intent from the absence of a good-faith explanation from the patentee for their nondisclosure.<sup>184</sup>

Taken together, *Bruno*, *Belcher II*, and *Baxter* provide a number of important insights into the development of inequitable conduct doctrine over time, especially with respect to the courts’ understanding of the intent requirement. For one thing, it is clear that, based on the evidence presented at trial, the pre-*Therasense Bruno* court would almost certainly have been unable to find that the patentee had the intent to deceive if the court had instead been operating under a *Therasense* standard that did not permit the use of a materiality-intent sliding scale.<sup>185</sup> But even in light of *Belcher II*, it is not so clear exactly how a court *can* find intent in cases of inconsistent representation at the USPTO and FDA in a post-*Therasense* world.<sup>186</sup> In fact, *Belcher II* may be most notable because it is

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181. *Id.* at \*8.

182. *See supra* Section IV.B.1.

183. *Baxter*, No. 15 C 9986, 2022 WL 981115, at \*7.

184. *Id.* at \*8.

185. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc) (“[A] court must weigh the evidence of intent to deceive independent of its analysis of materiality.”).

186. For examples of other cases in which federal courts have failed to find inequitable conduct post-*Therasense*, see *Exergen Corp. v. Kaz USA, Inc.*, 120 F. Supp. 3d 1, 7 (D. Mass. 2015) (“Because Kaz has not adduced competent evidence to establish the intent element of its inequitable conduct claim, the claim is not viable as a matter of law and must be dismissed.”); *Galderma Lab’sys, L.P. v. Tolmar, Inc.*, 891 F. Supp. 2d 588, 649–50 (D. Del. 2012) (“The alleged failure to disclose the Phase III clinical trial data [to the USPTO] was not but-for material . . . [T]he Court concludes that the [patentee’s conduct] does not rise to the level of an affirmative egregious act of misconduct . . . [I]nequitable conduct fails for the additional reason that the evidence does not persuade the Court that the inventors acted with an intent to deceive the PTO.”); *Sun Pharma Glob. Fze v. Lupid Ltd.*, No. CV 18-2213 (FLW), 2021 WL 4473411, at \*34 (D.N.J. Sept. 30, 2021) (finding that, because PTO and FDA disclosures “serve very different purposes,” intent to deceive could not be inferred from a decision to withhold a reference from the PTO when the reasons for doing so were plausible); *ProStrakan, Inc. v. Actavis Lab’sys UT, Inc.*, No. 2:16-CV-00044-RWS, 2018 WL 11363829, at \*72 (E.D. Tex. Sept. 28, 2018) (“[E]ven assuming that the data in the [patent] was material to patentability, Actavis has no evidence—either express or inferred—that anyone associated

rare. In preparing this Note, not a single other instance of a post-*Therasense* court finding inequitable conduct based on inconsistent representation at the USPTO and FDA was found at the trial or appellate level.<sup>187</sup> Thus, this Note argues, post-*Therasense* inequitable conduct doctrine—at least in its current form—is wholly inadequate for tackling the inconsistent-representation problem in the pharmaceutical industry. The Federal Circuit must revisit its inequitable conduct doctrine to uphold the integrity of the patent system and promote public access to innovation.

### C. A NEW “PHARMA EXCEPTION” TO *THERASENSE*

The Federal Circuit should revise its inequitable conduct doctrine to create a “pharma exception” to the otherwise exceedingly high legal standards outlined in *Therasense*. Specifically, the court should hold that, when an accused infringer shows that a patentee (1) failed to disclose to the USPTO references it shared with the FDA to support its case for regulatory approval, or (2) made inconsistent or contradictory statements to the USPTO and the FDA, there should be a rebuttable presumption that *both* the materiality *and* the intent prongs of the *Therasense* inequitable conduct test are satisfied.

Adopting a “pharma exception” to *Therasense* will help address the problem of inconsistent representation in at least three ways. First, creating a presumption of inequitable conduct in cases of inconsistent representation will encourage accused infringers (including generics manufacturers) to raise inequitable conduct defenses when their products are unfairly blocked by invalid patents.<sup>188</sup> Second, once such defenses are raised, the accused infringer will have a greater chance of success.<sup>189</sup> Third, the combined effect of an accused infringer being both more likely to raise and to win on a claim of

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with the prosecution of the [patent]—including the named inventors—intended to deceive the PTO.”).

187. The term (“inequitable conduct” + “patent” + “FDA”) was searched in Westlaw on October 5, 2022. The search was limited to “All Federal” cases that were decided on or after May 26, 2011 (*Therasense* was decided on May 25, 2011). The search returned 109 hits, each of which was reviewed individually for (1) factual issues of inconsistent representation, (2) a finding of inequitable conduct, (3) a finding of materiality, (4) reliance on the “egregious misconduct” exception to but-for materiality, and (5) a finding of intent. Of the 109 hits, seven cases were found to turn on issues of inconsistent representation and were ultimately decided on the merits (which, for the sake of this review, included summary judgment for no inequitable conduct but did not include, for example, Rule 12(b)(6) motions).

188. *See* Frei & Wooden, *supra* note 110, at 66 (“After the holding in *Therasense*, it was widely believed that the court had sounded the death knell to the inequitable conduct defense by imposing evidentiary requirements that could rarely be met.”).

189. *See id.*

inequitable conduct will deter pharmaceutical patentees from making inconsistent representations in the first place.<sup>190</sup>

The Federal Circuit has already shown its willingness to create exceptions to *Therasense*. Despite the court's determination to heighten the legal standards for inequitable conduct, *Therasense* preserved an "egregious misconduct" exception which, when triggered, infers per se materiality.<sup>191</sup> In the court's view, the exception "strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct."<sup>192</sup> However, the egregious misconduct exception is wholly inadequate for tackling *Belcher*-style inconsistent representation in the pharmaceutical industry for at least two reasons.

First, the *Therasense* court was clear that the "mere nondisclosure of prior art references" to the USPTO is not egregious misconduct.<sup>193</sup> Second, because the *Therasense* court specifically disavowed the "sliding scale" approach that had existed in the past, per se materiality in light of egregious misconduct infers nothing about intent: the "single most reasonable inference" standard remains unaltered.<sup>194</sup> Thus, even if a court were to find that making inconsistent representations to the USPTO and FDA denoted misconduct that was sufficiently egregious to infer materiality, the court could still conclude that the patentee lacked the intent to render such misconduct inequitable.<sup>195</sup> It follows,

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190. See Louis Kaplow, *On the Optimal Burden of Proof*, 119 J. POL. ECON. 1104, 1104 (2011) ("The optimal strength of the burden of proof . . . involves trading off deterrence and the chilling of desirable behavior.").

191. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc) ("Although but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, this court recognizes an exception in cases of affirmative egregious misconduct . . . . When the patentee has engaged in affirmative acts of egregious misconduct . . . the misconduct is material."); see also *Regeneron Pharms., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 585 (S.D.N.Y. 2015) ("The Court finds by clear and convincing evidence . . . that Regeneron made false and misleading statements. The Court finds by clear and convincing evidence that this constitutes egregious affirmative misconduct."); *Apotex, Inc. v. UCB, Inc.*, 970 F. Supp. 2d 1297, 1328 (S.D. Fla. 2013) ("I find that this case is one of those exceptional cases where, as discussed above, a finding of materiality is not necessary. Specifically, I find that [patentee] engaged in affirmative and egregious misconduct.").

192. *Therasense*, 649 F.3d at 1293.

193. See *id.* at 1292.

194. See *id.* at 1290 ("[A] court must weigh the evidence of intent to deceive independent of its analysis of materiality.").

195. See, e.g., *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012) ("Although on its face, it appears that a false declaration of small entity status would fall within the definition of an 'unmistakably false affidavit,' . . . we need not decide that question. Even if a false assertion of small entity status were per se material, the requirements of *Therasense* are not met here because there was no clear and convincing evidence of intent to deceive the PTO.").



then, that, if a revamped inequitable conduct doctrine is to be a truly useful tool for tackling inconsistent representation at the USPTO and FDA, any worthwhile proposal must alter both components of *Therasense*'s two-prong test.<sup>196</sup>

It is reasonable to presume both materiality and intent in cases of inconsistent representation at the USPTO and FDA. As outlined in Part II, patentability and regulatory approval often turn on similar issues—including novelty and nonobviousness—but to opposite ends. A patent applicant needs to convince the USPTO that their drug is both novel and nonobvious over the prior art.<sup>197</sup> But that same patent applicant may want to point to similarities between their product and existing alternatives when they seek FDA approval, e.g., through the § 505(b)(2) pathway.<sup>198</sup> Thus, it is fair to presume that information is material to patentability when it has been (1) disclosed to the FDA but not to the USPTO, or (2) characterized inconsistently (or, in some cases, contradictorily) before each entity.<sup>199</sup>

Likewise, it is reasonable to presume intent. In recognizing the need for a finding of per se materiality in cases of egregious misconduct, the Federal Circuit explained that “a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent.”<sup>200</sup> In other words, it is reasonable to presume that patentees engage in risky and deceptive tactics only with respect to information that is material to patentability. But the inverse is also true. A patentee is unlikely to withhold or misrepresent material information at the USPTO unless they wish to “deceive the PTO with a falsehood [that] will affect issuance of the patent.”<sup>201</sup> In that sense, it is fair to presume both materiality and intent when there is evidence of inconsistent representation.

Creating a new “pharma exception” in cases of inconsistent representation would also help “strike a necessary balance” between encouraging honesty before the USPTO and triggering a new “plague” of inequitable conduct defenses.<sup>202</sup> First, the exception would help nurture a culture of honesty among

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196. Recall that 87% of unsuccessful post-*Therasense* inequitable defense claims fail the intent prong. Swanson, *supra* note 122, at 708.

197. See *supra* Section II.A.

198. See *id.*

199. See July 2022 Notice, *supra* note 56, at 45,766 (discussing these two scenarios in the context of the duty to disclose).

200. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc).

201. See *id.*

202. See *id.* at 1293.

pharmaceutical patentees—somewhere it is currently known to be lacking.<sup>203</sup> There would be little point in making inconsistent representations at the USPTO and FDA if an accused infringer could then rely on such representations as the basis of an inequitable conduct defense that would now be more likely to succeed.

Second, creating a “pharma exception” is unlikely to produce an overwhelming increase in the number of inequitable conduct defenses being raised. For one thing, the exception would be limited to instances of inconsistent representation by pharmaceutical patentees at the FDA and USPTO.<sup>204</sup> That is, of course, not to say that variations of this exception could not apply elsewhere. There may well be other instances of interagency inconsistent representation for which it would be reasonable to presume inequitable conduct—for example, when a patentee withholds material information about the novelty of a medical device from the USPTO while disclosing that same information to the FDA for regulatory approval.<sup>205</sup> However, this Note focuses on tackling inconsistent representation by pharmaceutical patentees at the USPTO and FDA because (1) this particular problem is causing such notable concern across the full spectrum of parties involved in pharmaceutical patenting and regulation, including the agencies themselves; and (2) the courts may be more receptive to a narrowly tailored solution that addresses a highly specific grievance.<sup>206</sup>

Likewise, *Exergen’s* heightened pleading standards could continue to provide a gatekeeping mechanism that discourages frivolous claims of inequitable conduct.<sup>207</sup> An accused infringer invoking the “pharma exception”

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203. See *supra* Part II.

204. For a discussion of the benefits and drawbacks of sector-specific (as opposed to uniform) intellectual property regimes, compare Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1159–60 (2002) (discussing the downsides of uniform intellectual property regimes), and Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U.L. REV. 845, 849–50 (2006) (explaining that uniform intellectual property rights necessarily result in deadweight loss), with ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 203–05 (2004) (arguing for the need for uniform treatment of intellectual property), and R. Polk Wagner, *(Mostly) Against Exceptionalism* 8–17 (U. Penn. L. Sch. Inst. for L. & Econ., Rsch. Paper No. 02-18, 2002), <https://ssrn.com/abstract=321981> (advocating against “Type II Exceptionalism,” which “shifts consideration of the patent law from a general background principle of property rights to a vehicle for a particularistic, technology-specific innovation policy choices”).

205. For more information on the approval of medical devices by the FDA, see 510(k) CLEARANCES, FDA (Nov. 6, 2023), <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances>.

206. See *supra* Section II.B.

207. See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328–29 (Fed. Cir. 2009) (explaining that inequitable conduct must be pleaded with particularity under Federal Rule of

would now be required to “identify the specific who, what, when, where, and how” of the inconsistent representation at the USPTO and FDA.<sup>208</sup> As a result, only those accused infringers who are able to point to the particularities of a meaningful instance of interagency misrepresentation will be able to successfully plead a “pharma exception” to *Therasense*.

Third, rebuttable presumptions of intent and materiality are, as the name would suggest, rebuttable. If a patentee is able to show, by a preponderance of the evidence, that the information that they withheld or characterized inconsistently before the USPTO and FDA is not objectively but-for material to patentability, there will be no finding of inequitable conduct.<sup>209</sup> Likewise, if a patentee can show, by a preponderance of the evidence, that the intent to deceive the PTO is not the “single most reasonable inference,” their patent will not be unenforceable.<sup>210</sup> Consequently, a patentee acting in good faith has nothing to fear. Likewise, an accused infringer has no incentive to raise an inequitable conduct defense over matters of inconsistent representation if their claim is merely frivolous.

Note that, when the “pharma exception” is invoked, the evidentiary standard under the materiality prong stays the same, whereas the evidentiary standard under the intent prong changes. Recall that, under *Therasense*, the defendant bears the burden of proving (1) materiality by a preponderance of the evidence, and (2) intent to deceive by clear and convincing evidence.<sup>211</sup> This Note suggests that, when, under the “pharma exception,” the burden of proof flips from the infringer-defendant to the patentee-plaintiff, the evidentiary standard under intent should shift, too—specifically, to require a showing of intent by a preponderance of the evidence.<sup>212</sup> In that way, the

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Civil Procedure 9(b)). But Swanson suggests that courts should exercise caution when applying post-*Exergen* pleading standards as a means of safeguarding meritorious claims. Swanson, *supra* note 122, at 723 (“[C]ourts must permissively grant leave to amend pleadings to add inequitable conduct defenses.”).

208. *See Exergen*, 575 F.3d at 1328.

209. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (en banc) (“[I]n assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.”).

210. *See id.* at 1290.

211. *See id.* at 1290–92.

212. This Note declines to recommend a change in the evidentiary standard for the materiality prong because, as noted by the *Therasense* court, the evidentiary standard under materiality mirrors that used by the USPTO. *See id.* at 1291–92 (“[I]n assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction.”).

“pharma exception” maintains some of *Therasense*’s pro-patentee skew: Under the “pharma exception,” it is easier for the patentee-plaintiff to rebut a presumption of intent than it is for a traditional infringer-defendant to raise a viable inequitable conduct claim in the first place.

What would a successful rebuttal look like in practice? A patentee could successfully rebut a presumption of materiality by showing, by a preponderance of the evidence, that the inconsistent representation relates to information that is not objectively but-for material to patentability.<sup>213</sup> The patentee could demonstrate, for instance, that the information in question neither anticipates the claimed invention nor renders it obvious.<sup>214</sup> Likewise, a patentee could successfully rebut a presumption of intent by demonstrating, by a preponderance of the evidence, that the intent to deceive is not the “single most reasonable inference” to be drawn.<sup>215</sup> To do this, the patentee would simply show that at least one other inference is as equally reasonable as the intent to deceive.<sup>216</sup> For example, the patentee could point to internal communications between the inventors that indicate a failure to subjectively appreciate the materiality of the reference to patentability.<sup>217</sup> In that case, a court may well find it at least equally reasonable to attribute the patentee’s actions to incompetence or ignorance as opposed to purposeful deception, meaning the presumption of intent can be rebutted.<sup>218</sup>

Grounding the new “pharma exception” in rebuttable presumptions of materiality and intent (rather than, say, strict liability) and maintaining some of *Therasense*’s pro-patentee skew is likely to make the “pharma exception” more doctrinally palatable for the courts, too. As noted above, under *Therasense*, the court is already willing to infer strict liability with respect to materiality in cases of egregious misconduct—but, even in those instances, the burden of proving the intent to deceive as the “single most reasonable inference” remains with

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213. *See id.* at 1291 (“[I]n assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference.”).

214. *See supra* Section IV.A.

215. *See Therasense*, 649 F.3d at 1290.

216. *See id.* at 1290–91 (noting that, when there are “multiple reasonable inferences . . . intent to deceive cannot be found.”); *see also* Sun Pharma Glob. Fze v. Lupid Ltd., No. CV 18-2213 (FLW), 2021 WL 4473411, at \*34 (D.N.J. Sept. 30, 2021) (“FDA and PTO disclosures serve very different purposes, and Defendants have not presented evidence to suggest that they must or should overlap in this case.”).

217. *See Therasense*, 649 F.3d at 1290 (“[T]he 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.”) (emphasis added).

218. *See id.* at 1290–91 (noting that when there are “multiple reasonable inferences . . . intent to deceive cannot be found”).

the accused infringer.<sup>219</sup> The Federal Circuit thus balanced strict liability in the materiality prong against a much more patentee-friendly intent standard. Meanwhile, under the new “pharma exception,” materiality and intent are both presumed. In other words, inconsistent representation does not go so far as to trigger strict liability in either prong of the two-part test—but it does create presumptions of both materiality and intent that are relatively easy for a good-faith patentee to rebut. In that way, the new “pharma exception” maintains the balance advocated by the *Therasense* court: It encourages honesty before the USPTO without risking a deluge of inadequately robust inequitable conduct claims.

## V. CONCLUSION

This Note opened with a question: How can we address the problem of pharmaceutical companies making inconsistent representations to the USPTO and FDA? This Note, in response, offered two solutions. Part III outlined a new system of USPTO-FDA interaction that, to the extent possible, undercuts inconsistent representation before a patent issues. But because the system in Part III would likely suffer from issues of confidentiality, timing, and noncompliance, Part IV offered a post-patent-issuance safety net. Specifically, Part IV proposed that the Federal Circuit revise its inequitable conduct doctrine—by creating a new “pharma exception” to *Therasense*’s strict materiality-plus-intent test—to make it easier for accused infringers to raise claims of inequitable conduct and undermine the enforceability of pharmaceutical patents obtained through deception.

Importantly, the solutions outlined in Part III and Part IV need not be mutually exclusive. In fact, they could be synergistic. First, if a patentee failed to comply with their duty of disclosure in the new USPTO-FDA system of Part III, the patentee’s noncompliance could weigh in favor of triggering the dual presumptions under the new *Therasense* exception outlined in Part IV. Second, adopting the proposed system of Part III could help maintain the balance between encouraging honesty before the USPTO and preserving judicial resources for reviewing inequitable conduct claims. Because the new system would undercut at least some acts of inconsistent disclosure before patent issuance, fewer unenforceable patents will issue in the first place, thereby lessening the need for post-issuance judicial remedies.

Both solutions described herein can play a meaningful role in tackling the problem of inconsistent representation by pharmaceutical patentees. But whichever solutions the USPTO, the FDA, and the courts adopt, one thing is

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219. *Id.*

certain: Meaningful change is needed to uphold the integrity of the patent system and promote public access to generic drug products that are unfairly blocked by invalid patents. Reform can come from the federal agencies, or the courts, or both. But it must indeed come—and soon.