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Fact Sheet on the Medication Affordability and Patent Integrity Act

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The Medication Affordability and Patent Integrity Act (S. 2658, "MAPIA") is a proposed amendment not only to the Food, Drug, and Cosmetic Act but also to the Patent Act[1] that would require biopharmaceutical companies to certify that any information that they submit to the Food & Drug Administration (FDA) and to the US Patent & Trademark Office (PTO) is consistent in its representations.

This bill addresses the claim that drug companies make contradictory statements to the two agencies, but evidence does not support that premise. MAPIA is not only unnecessary but also contrary to clear federal court precedent and would lead to abuse of defenses to patent infringement and increased administrative costs. The net effect would be to weaken biopharmaceutical innovation in the United States.

MAPIA Is Unnecessary.

- Courts have repeatedly recognized that the PTO and the FDA ask for fundamentally different information under fundamentally different legal standards.
    - The FDA focuses on safety and efficacy from the viewpoint of clinicians, using clinical trials data and other information pertaining to the drug's medicinal properties to determine whether that drug product should be approved for human use.[2]
    - By contrast, the PTO focuses not on human consumption but on whether individual drug-related inventions are new, nonobvious, and useful by a purely technological

[1] Some have even challenged the Health, Education, Labor, and Pensions (HELP) Committee's authority to amend the Patent Act. *See, e.g.*, Letter from Frank Cullen, Council for Innovation Promotion, to Bill Cassidy, Chairman, and Bernie Sanders, Ranking Member, S. Comm. On Health, Educ., Labor & Pensions (June 15, 2026), https://c4ip.org/wp-content/uploads/2026/06/C4IP-Letter-to-Senate-HELP-Committee-RE_-Medication-Affordability-and-Patent-Integrity-Act.pdf.

[2] 21 U.S.C. § 393(b); *see also aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002) "[T]he FDA focuses on its primary task of ensuring that drugs are safe and effective . . . because the FDA has no expertise in making patent law judgments."

standard.[3] In other words, the PTO examines whether a given drug-related invention meets the basic requirements necessary to obtain a patent, not whether it can eventually be approved by the FDA as part of a drug product.

- Courts have repeatedly recognized that statements to the PTO and the FDA are made at two different times and, consequently, from two different perspectives. Companies typically obtain patents on pharmaceuticals long before they test them in clinical trials. As one court put it, while "a patent owner's own disclosures to the FDA may be considered in assessing the state of the prior art … a fact finder must not allow its analysis to be distorted by hind-sight bias."[4] Information about patentability has little relevance to determinations of the safety and efficacy of a drug, and safety and efficacy have little relevance to the patentability of its various components.

- The law already offers multiple mechanisms to ensure disclosure of relevant information.
  - Applicants already bear parallel but distinct legal obligations of disclosure to both agencies.[5] They are obligated to disclose to both the PTO and FDA everything that is relevant to each agency's determinations.
  - The USPTO already has a statutory mechanism to request relevant information from the FDA.[6]
  - A patent applicant's duty of candor to the PTO likewise already includes a duty to ensure that statements made to the PTO are consistent with those made to other agencies. This duty applies not only when originally filing a patent application but also during any later reexamination, reissue, or proceedings before the Patent Trial and Appeal Board at the PTO. In fact, the PTO clarified this duty in 2022 specifically in response to allegations that patent applicants were making inconsistent statements to the PTO and the FDA.[7]
  - The inequitable conduct doctrine already renders patents unenforceable for intentional concealment of material information.[8] When a patent applicant

[3] *See, e.g., Manual of Patent Examining Procedure (MPEP) § 2107.03*.
[4] *Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1377 (Fed. Cir. 2019), accord *Chiesi USA, Inc. v. Aurobindo Pharma USA, Inc.*, No. CV1918756ZNQLHG, 2022 WL 3703207, at 13 (D.N.J. 2022); *Cephalon, Inc. v. Slayback Pharma LLC*, 456 F. Supp. 3d 594, 619 (D. Del. 2020).
[5] 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 (July 29, 2022), https://www.govinfo.gov/content/pkg/FR-2022-07-29/pdf/2022-16299.pdf; see also MPEP § 2001.06(e).
[6] 21 U.S.C. § 372(d), permitting the Director of the PTO to ask the FDA "to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application."
[7] Duties of Disclosure, 87 Fed. Reg. 45,764, at 45,765.
[8] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc).

deliberately deceives the PTO about some aspect of their invention that, but for that deception, would have led the PTO to deny their patent application, the court will refuse to enforce that patent even if the patent is otherwise valid. This law applies to both pharmaceutical and nonpharmaceutical inventions alike.

- Generic and biosimilar manufacturers thus already have every incentive to uncover genuine misconduct, given that the inequitable conduct doctrine can cause a patent to become unenforceable. This means that any manufacturer at risk of patent infringement is highly likely to scour any representation, written or otherwise, a biopharmaceutical company has made to the FDA, which by federal regulation are all available for public disclosure.[9]

- More importantly, there is no evidence that biopharmaceutical companies routinely make fraudulent or materially inconsistent representations to the USPTO or the FDA. This is significant, given that, as noted above, generic and biosimilar manufacturers have both opportunity and incentive to ferret out any such misrepresentations.

MAPIA Would Lead to Wasteful Patent Unenforceability Claims.

- MAPIA would lead exactly to the practice the Federal Circuit sought to preclude in its 2011 decision in *Therasense, Inc. v. Becton, Dickinson, and Co*.

  - In *Therasense*, the Federal Circuit pointedly tightened the standard for inequitable conduct to require clear and convincing evidence that a patent applicant made a deliberate decision to deceive the PTO by withholding information that the applicant knew would have prevented the patent from being granted.[10]

  - This heightened standard was necessary because patent infringement defendants were habitually claiming inequitable conduct on "the slenderest grounds."[11] This led to abuse of the inequitable conduct defense that caused what the *Therasense* court called a "plague."[12]

  - Because the original, lower standard imposed liability on honest mistakes in disclosure, applicants were incentivized to disclose everything that might conceivably be relevant to the application. As a result, the PTO and its patent

[9] 21 C.F.R. §§ 20.103(a), 20.104(a), and 314.430(e)(7) (exempting only trade secrets, confidential business information, and unapproved drug applications).
[10] *Therasense*, 649 F.3d at 1290 (requiring clear and convincing evidence of a specific intent to deceive and rejecting negligence and gross negligence as sufficient to prove inequitable conduct).
[11] *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988).
[12] *Therasense*, 649 F.3d at 1289–90 (citing *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), describing the "plague" of inequitable conduct and its costs to the courts, to settlement, and to the USPTO).

examiners were inundated with excess documents that were not actually material to examination, significantly clogging the process.[13]

- By effectively undoing the Federal Circuit's well-considered opinion on the matter, MAPIA would reopen the floodgates to excessive disclosure and impose undue burden on patent examiners.
    - MAPIA would lower the standard to merely negligent omission of *any* inconsistent statements relevant to patentability, regardless of whether they would have actually changed the PTO's decision.[14] This would return us to the excessive disclosure problem that the court attempted to solve in *Therasense*.
    - As a result, the PTO would be flooded with marginally relevant disclosures, wasting administrative resources and time and obscuring important information.[15] MAPIA would return us to the pre-*Therasense* period of redundant disclosures and significant administrative inefficiencies.

MAPIA Would Undermine Other Intellectual Property Laws.

- While MAPIA has a limit on confidentiality protections for FDA information sent to the PTO, this exception permits the PTO to decide that information disclosed to the FDA is "necessary for the public to understand the scope of patent claims granted."[16]
- This provision requires the PTO to create procedures as necessary to ensure confidentiality on that information, but MAPIA does not provide any guidance or deadlines for these procedures.[17]

In the end, MAPIA would flood the PTO with over-disclosure and flood the courts with wasteful claims.

[13] *Therasense*, 649 F.3d at 1288–90 (citing *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), describing the "plague" of inequitable conduct and its costs to the courts, to settlement, and to the USPTO).
[14] S. 2658, 119th Cong. (as reported July 28, 2026), https://www.congress.gov/bill/119th-congress/senate-bill/2658/text.
[15] *Therasense*, 649 F.3d at 1289 (anticipating that the threat of unenforceability would lead applicants to over-disclose). Scholarship affirms the risk of overloading examiners through over-disclosure. See Christopher A. Cotropia, *Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 Berkeley Tech. L.J. 723, 771 (2009).
[16] S. 2658, § 2(a)(1) (adding FDCA § 505(b)(8)(E)).
[17] S. 2658, § 2(a)(1) (adding FDCA § 505(b)(8)(E)).