SKINNY WITHOUT INTENT TO INDUCE

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For decades, the American pharmaceutical industry relied on the sturdy foundation of the Hatch-Waxman Act, legislation that prioritizes innovation, affordability, and consumer well-being. However, in 2021, the Court of Appeals for the Federal Circuit forged a new path forward, threatening the traditional understanding of "intent" in what appeared to be a straightforward induced infringement case, GlaxoSmithKline v. Teva Pharm. USA, Inc. The court indicated that it was mechanically implementing established law, but a mere hairline fracture in application reverberated across the pharmaceutical field and attracted criticism for destroying the balance defined in Hatch-Waxman.

This note explores the court's analysis of the "intent" prong of induced infringement and concludes that a flawed application of the law unjustly penalized Teva Pharmaceuticals and revised the established understanding of "intent" as an element of induced infringement. The legal guessing game that now permeates the American pharmaceutical industry begs the Supreme Court to provide clarity and direction in hopes of once again better serving the American people in need of affordable, life-changing drugs.

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I. INTRODUCTION

Carvedilol is a life-saving drug that continues to be one of the most impactful and sought-after drugs on the American pharmaceutical market more than twenty-five years after its initial use as a cardiac treatment option. Carvedilol was patented in 1985, under United States Patent Number 4,503,067 (`067), claiming a multiple action drug that blocks β-1, β-2, and α-1 adrenoceptors.[1] Carvedilol was revolutionary because it was the first beta-blocking medication to successfully treat congestive heart failure (CHF).[1] Therefore, it was not simply another drug, but a groundbreaking discovery in the medical field with the potential to change lives and to save those in desperate need of a medical miracle.[2] Upon entering the market, carvedilol replaced other classes of drugs, like ACE inhibitors, as the gold standard of cardiovascular care.[3] However, the current legal system is poised to wrest new, life-saving drugs—like carvedilol—away from patients in need based on a flawed application of the law.

The Court of Appeals for the Federal Circuit's (CAFC) holding in *GlaxoSmithKline LLC. v. Teva Pharm. USA, Inc.* rests on a flawed application of the law and jeopardizes the traditional meaning of "intent" as a prong of induced infringement. The holding permits brand pharmaceuticals, like GlaxoSmithKline (GSK), to gatekeep valuable medications like carvedilol from patients in exchange for extended patent protection and increased profit margins. Leading up to the case at issue, GSK branded carvedilol under the name Coreg®, which was a major scientific breakthrough as it emerged in an "adverse regulatory climate."[4] The third-generation beta-blocker,[5] a hybrid hypertensive drug that reduces blood pressure by beta-blocking and dilating action,[6] materialized after many people discounted it as a

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[1] Robert R. Ruffolo & Giora Z. Feuerstein, *Carvedilol Case History: The Discovery and Development of the First β-Blocker for the Treatment of Congestive Heart Failure*, NAT'L LIBR. MED., (June 2006), https://pubmed.ncbi.nlm.nih.gov/23506034/ [https://perma.cc/4YRR-EALE]; GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1346 (Fed. Cir. 2021).

[1] Ruffolo, *supra* note 1.

[2] *See id.*

[3] *Id.*; GlaxoSmithKline, 7 F.4th at 1323.

[4] Ruffolo, *supra* note 1.

[5] R.R. Ruffolo & G.Z. Feuerstein, *Carvedilol*, SCI. DIRECT, https://www.sciencedirect.com/science/article/abs/pii/B008045044X002960 (last visited Aug. 29, 2024) [https://perma.cc/PGM2-7UHA].

[6] J. Widimský, *Third Generation Beta Blockers in the Treatment of Hypertension*, NAT'L LIBR. MED. (May 1992), https://pubmed.ncbi.nlm.nih.gov/1354908/#:~:text=Beta%2Dblockers%20of%20the%20third,and%20by%20a%20dilatating%20action [https://perma.cc/49RY-GGBU].

potential cardiac treatment option.[7] During GSK's initial investigations, carvedilol was contraindicated for CHF because beta-blockers decrease heart rate and limit the heart's capacity to cycle blood, which could be fatal to patients with heart failure.[8] Many pharmaceutical companies abandoned beta-blockers as a potential solution in the quest for cardiac remedies and started searching for other treatments altogether.[9] However, despite what may have seemed to be an initially fruitless endeavor, GSK persistently invested time, money, and resources into exploring the potential advantages of beta-blockers.[10] After conducting the then-largest heart failure study, carvedilol presented marked reductions in patient morbidity and mortality.[11]

While carvedilol presented a new and drastically more effective way to manage various heart conditions, some patients have to take it for the rest of their lives to maintain low blood pressure.[12] Consequently, those patients may pose present an indefinite revenue source for pharmaceutical companies furnishing carvedilol.[13] Thus, pharmaceutical companies may have an incentive to secure extended profit periods by supplying carvedilol to long-term use patients.[14]

In 2014, GSK sued Teva for induced infringement of carvedilol.[15] In the United States District Court for the District of Delaware, the jury found for GSK, but the District Court overturned the jury's verdict by entering judgment as a matter of law (JMOL).[16] Subsequently, the CAFC reversed the decision and reinstated the jury verdict for GSK.[17] The CAFC's decision generated public uproar and incited eight amicus briefs from brands, generics, and law professors—including a statement from Congressman Waxman

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[7] *See* Ruffolo, *supra* note 1.
[8] *See* GlaxoSmithKline, 7 F.4th at 1323.
[9] *See* Ruffolo, *supra* note 1.
[10] *See id.*
[11] *Id.*
[12] *Carvedilol (Oral Route)*, MAYO CLINIC (Mar. 1, 2024), https://www.mayoclinic.org/drugs-supplements/carvedilol-oral-route/proper-use/drg-20067565#:~:text=You%20must%20continue%20to%20take,%2C%20stroke%2C%20or%20kidney%20disease [https://perma.cc/N6FV-H48T].
[13] *See id.*
[14] *See id.*
[15] GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1348 (Fed. Cir. 2021).
[16] *Id.*
[17] *Id.*

himself that criticized the CAFC's legislation and policymaking.[18] In response, Teva petitioned for a rehearing, but the CAFC held again for GSK, though Judge Prost published a dissenting opinion.[19] Left with no other options, Teva petitioned the United States Supreme Court for certiorari in 2023, but was denied.[20]

"Skinny labels," the center of controversy in *GlaxoSmithKline LLC. v. Teva Pharm. USA, Inc.*, were introduced in the Hatch-Waxman Act of 1984 (the Act).[21] Skinny labels are created when a generic markets a drug with only some of its approved indications.[22] Consequently, the label is missing one or more of the still-patented indications and is "skinnier" or "smaller" than the full label.[23] The CAFC's decision in this case crafts a murky precedent that fails to clearly define what is and what is not permissible conduct for generics before all indications of a brand's pharmaceutical have expired. The standing decision jeopardizes the Act's delicate "balance" of innovation, affordability, and consumer well-being. Without amelioration, the current decision heavily preferences innovation and the costliness of brand drugs at the expense of generic pharmaceuticals and the well-being of desperate American consumers who need carvedilol to survive.

In this note, I will discuss the critical nature and consequences of the CAFC's recent decision in *GlaxoSmithKline LLC. v. Teva Pharm. USA, Inc.* Part II provides the history and disposition of the case (up to the 2021 CAFC opinion) in context of the Act's tenets, including skinny labeling and the concept of inducement. Then, Part III argues that the majority's interpretation of "intent" as an element of induced infringement is flawed. Instead, this note supports Judge Prost's dissenting opinion that "cobbling together"[24] pieces of a label does not demonstrate intent. Finally, Part IV discusses the inevitable implications trickling down from the opinion, including increased consumer drug prices, ambiguity permeating what constitutes legal conduct, and the breakdown of the long-standing balance among

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[18] *See id.*
[19] *Id.* at 1342–43.
[20] *See Teva Pharmaceuticals USA, Inc., v. GlaxoSmithKline, LLC*, SCOTUS BLOG (May 15, 2023), https://www.scotusblog.com/case-files/cases/teva-pharmaceuticals-usa-inc-v-glaxosmithkline-llc/ [https://perma.cc/E9MS-X9VU].
[21] *See* GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1344 (Fed. Cir. 2021) (Prost, J., dissenting); 21 U.S.C. § 355(j)(2)(A)(viii).
[22] GlaxoSmithKline, 7 F.4th at 1342 (Prost, J., dissenting).
[23] *Id.*
[24] *Id.* at 1329 (majority opinion) (per curiam).

innovation, affordability, and consumer well-being as the cornerstone of the Act.

II. CASE HISTORY AND DISPOSITION

The CAFC's current decision in *GlaxoSmithKline LLC. v. Teva Pharm. USA, Inc.* penalized Teva with $235 million for induced infringement.[25] In the aftermath, generic and brand pharmaceuticals unleashed criticism arguing that mere marketing and selling under a proper skinny label should not result in liability.[26] The Act provides a comprehensive legal framework to facilitate the process more efficiently for generic pharmaceuticals to obtain drug approvals while still preserving incentives for innovation.[27] The underpinning legislative intent aimed to achieve a defined balance among brand innovation, generic affordability, and consumer well-being by generating more profits for brands in the short term but providing accessibility and affordability to consumers via generics in the long term.[28] Thus, courts should defend Congress's intent "to simplify the complicated path to market for generic drug manufacturers."[29]

A. Pertinent Facts & Procedure

Carvedilol, the active ingredient in Coreg® was initially patented in 1985 under 4,503,067 (`067) and was set to expire in March 2007.[30] Carvedilol was shown to reduce cardiovascular mortality in clinically stable patients who had survived the acute phase of myocardial infarction and had a left ventricular ejection fraction of less than or equal to 40%, with or without symptomatic heart failure (also known as post-MI LVD).[31] Up to this point, most brands had abandoned researching beta-blockers, like carvedilol, for treating cardiovascular ailments and had re-focused efforts towards pursuing

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[25] *Id.* at 1348 (Prost, J., dissenting).
[26] *Id.*
[27] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585; 21 U.S.C. § 301.
[28] Emma Murray, *Skinny Labels and Skinnier Prospects: How a Recent Federal Circuit Court Decision on Patent Infringement Places Well-Established Generic Drug Practice in Jeopardy*, 71 WASH. U. J.L. & POL'Y 131, 134 (2023).
[29] *Id.* at 131.
[30] GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1323 (Fed. Cir. 2021).
[31] *Id.* at 1328.

other treatment options.[32] Thus, this drug was a fantastic discovery that would revolutionize cardiac care and save lives across America.[33]

About a decade later, in 1997, the FDA approved carvedilol to be prescribed for two more uses in addition to post-MI LVD: congestive heart failure (CHF) and hypertension.[34] The following year, a method of administration of carvedilol to decrease CHF was patented under United States Patent Number 5,760,069 (`069).[35] The `069 patent permissibly covered the later-approved indications because a brand may not only patent a drug's active ingredient and original use, but may also patent supplemental indications that the FDA approves after a drug is already on the market.[36] Therefore, the later-approved indications covering CHF and hypertension are termed "secondary method of use patents," as the same active ingredient, carvedilol, was discovered to facilitate more uses beyond treating post-MI LVD.[37]

To effectuate the goal of balance between brands and generics, the Act created the Abbreviated New Drug Application (ANDA) process which allows generic pharmaceutical companies to obtain expedited, regulatory approval for drugs by filing an ANDA application.[38] Under this regime, a brand manufacturer submits a New Drug Application (NDA) that details a proposed drug label to be approved by the FDA.[39] Then, a generic may seek permission to enter the market by filing an ANDA.[40] The ANDA process bypasses the pre-Act generic-approval protocol which mandated independent testing and verification, often a lengthy and costly process.[41] This workaround creates a meaningful shortcut for generics looking for FDA approval,

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[32] *Id.* at 1323.
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.* at 1342 (Prost, J., dissenting).
[37] *See generally id.* at 1344–45.
[38] *Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984 – PL 98-417*, IP MALL, https://ipmall.law.unh.edu/content/legislative-history-drug-price-competition-and-patent-term-restoration-act-1984-pl-98-417 (last visited Mar. 13, 2024) [https://perma.cc/TA7F-UFRL].
[39] Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404–405 (2012).
[40] *Id.*
[41] Gregory J. Glover, *ANDA Section VIII Label Carve-Outs Explained*, PHARM. L. GRP. (Jan. 2, 2019), https://www.pharmalawgrp.com/blog/1/anda-section-viii-label-carve-outs-explained/ [https://perma.cc/5JAA-HD2W].

because they only need to demonstrate that the ANDA is "bioequivalent" to the listed drug.[42] Bioequivalence is defined as

> the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed [bioequivalence] study.[43]

When reviewing an ANDA, the FDA "cannot authorize a generic drug that would infringe a patent," so the FDA heavily relies on a brand's assurances of what its active patents cover.[44] The FDA is not an arbiter of patent issues and will not approve a generic drug if it infringes on a brand's active patent.[45] Thus, for a generic to come to market, it must "carve out," or remove, a brand's patented uses from its label and market its bioequivalent generic only under non-patented uses: a skinny label.[46] The Act allows generics to avoid patent lawsuits if a generic's label omits infringing uses of a brand-name drug

> if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.[47]

Teva filed an ANDA five years in advance of carvedilol's March 2007 patent-term expiration date and filed for all three of carvedilol's patented indications: post-MI LVD, CHF, and hypertension.[48] Teva certified, based on paragraph III of the Act, that it would not market its generic until GSK's patent expired and acknowledged that the March 2007 date was critical.[49] Additionally,

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[42] *Id.*
[43] 21 C.F.R. § 314.3(b) (2024).
[44] Caraco, 132 S.Ct. at 1676.
[45] *See* GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1344–45 (Fed. Cir. 2021).
[46] Caraco Pharm. Lab., Ltd*,* 566 U.S. at 406*;* 21 U.S.C. § 355(j)(2)(A)(viii).
[47] Hatch Waxman Act § 505(j)(2)(A)(viii).
[48] GlaxoSmithKline LLC, 7 F.4th at 1323–24.
[49] *Id.*

Teva certified under paragraph IV of the Act that GSK's `069 patent was invalid.[50] Initially, GSK did *nothing* in response to Teva's paragraph IV notice.[51] A year later in 2003, the FDA approved carvedilol for another use, post-MI LVD, "to reduce cardiovascular mortality in patients suffering from left ventricular dysfunction following a myocardial infarction."[52]

Two years after filing its ANDA, Teva received tentative approval for the hypertension and heart-failure indications for carvedilol, yet it affirmatively maintained that it would not market the drug until 2007.[53] Teva's use of the skinny label procedure under the Act's reforms allowed Teva to effectively and legally market two of the three approved indications—post-MI LVD and hypertension—but it excluded CHF because it was still patented.[54]

Finally in 2007, Teva's approval to market its carvedilol generic with its approved skinny label was supposed to be fully effective upon the expiration of the `067 patent.[55] Teva included the following language in its skinny label, which listed its usage only for the approved and no-longer-patented post-MI LVD and hypertension indications: "[c]arvedilol is indicated to reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of less than or equal to 40% (with or without symptomatic heart failure)."[56] Further, Teva *again* certified that it would not contain the CHF indication on its label and explicitly recognized carvedilol's current listing under U-233 in the Orange Book.[57]

After the debut of Teva's skinny label, Teva's press releases and marketing materials asserted that it was the "AB Rated generic of Coreg® Tablets."[58] Additional materials promoted its generic carvedilol as "indicated for treatment of heart failure and hypertension" as the "generic version of Coreg®."[59] Such statements regarding generic equivalence are not only protected by but *required*

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[50] *Id.*
[51] *Id.*
[52] *Id.* at 1323.
[53] *Id.* at 1323–24.
[54] *Id.*
[55] *Id.* at 1323.
[56] *Id.* at 1328.
[57] *Id.* at 1324.
[58] *Id.*
[59] *Id.*

by the Act to communicate to consumers that the generic is in all meaningful respects the exact same as the brand drug but comes at a sharply discounted rate.[60]

After GSK's silence in response to Teva's paragraph IV notice, ultimately Teva prevailed.[61] Based on invalidity under paragraph IV, in January 2008, the United States Patent and Trademark Office (USPTO) reissued GSK's `069 patent under RE40,000 (`000).[62] The new patent included a maintenance period of at least six months and contained the following language: "wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months."[63] The following month, GSK informed the FDA about the`000 reissue based on the former paragraph IV notice.[64] GSK reported that the new patented language included "a method of decreasing mortality caused by CHF by administering carvedilol with at least one other therapeutic agent."[65]

Three years passed uneventfully, and in 2011 GSK delisted its carvedilol patents from the Orange Book, as they were no longer patent protected.[66] Subsequently, the FDA advised Teva to revise its current skinny label, containing just the post-MI LVD and hypertension indications, to now include the CHF indication.[67]

Based on the FDA's guidance and GSK's contributions, Teva added the CHF indication to the skinny label.[68] Prior to adding CHF, Teva abided by both GSK's and the FDA's guidance to complete its label and market it with the CHF indication.[69] The FDA required Teva to amend its label for carvedilol accordingly, and Teva complied "identical in content to the approved [GSK Coreg®] labeling (including the package insert and any patient package insert and/or Medication Guide that may be required)."[70]

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[60] 21 U.S.C. § 355(j)(2)(A)(iv).
[61] GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1323–43 (Fed. Cir. 2021).
[62] *Id.*
[63] *Id.* at 1324.
[64] *Id.*
[65] *Id.*
[66] *Id.* at 1324–25.
[67] *Id.*
[68] *Id.* at 1325.
[69] *Id.*
[70] *Id.* at 1324.

Based on direct guidance from the FDA, Teva revised its label to verbatim contain the FDA's approved language that was constructed based on GSK's representations and assertions about its `000 patent.[71] Teva then confirmed that it did not need certification because it already received approval of its ANDA before `000 reissue.[72] Before launching its generic carvedilol, Teva once again certified to the FDA that its label "will not include the indication defined in use code U-233" until the corresponding patent expired.[73]

Three years passed without issue.[74] Teva continued to market and sell its approved generic carvedilol, thus alleviating consumers' physical and financial burdens.[75] Nothing was amiss.[76] Suddenly, in 2014, GSK sued Teva for induced infringement of the `000 patent in the United States District Court for the District of Delaware.[77]

B. Pertinent Patent Language

The following language quotes GSK's `069 patent claim 1 and contains additional italicized text to show the claim limitations that were added after the reissue and release of the `000 patent in 2008 under 35 U.S.C. § 251.[78]

> A method of decreasing mortality caused by congestive heart failure in a patient in need thereof which comprises administering a therapeutically acceptable amount of carvedilol in conjunction with one or more other therapeutic agents, said agents being selected from the group consisting of an angiotensin converting enzyme inhibitor (ACE), a diuretic, and digoxin,
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> *wherein the administering comprises administering to said patient daily maintenance dosages for a maintenance period to decrease a risk of mortality caused by congestive heart failure, and said maintenance period is greater than six months*.[79]

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[71] *See id.* at 1324–25.
[72] *Id.* at 1325.
[73] *Id.* at 1324.
[74] *Id.* at 1324–25.
[75] *See generally id.* at 1348 (Prost, J., dissenting).
[76] *Id.*
[77] *Id.* at 1325.
[78] *Id.* at 1324.
[79] U.S. Pat. No. RE40,000 col. 2 l. 36 (filed June 7, 1995).

C. The District Court Opinion

In 2017, the Delaware District Court jury found in favor of GSK, but Judge Stark overturned the finding via JMOL.[80] Initially, the jury determined that Teva's label, combined with its marketing, encouraged physicians to prescribe carvedilol in a way that amounted to patent infringement.[81] However, Judge Stark invoked JMOL to remedy the jury's mistaken verdict.[82]

JMOL should only be implemented if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party."[83] GSK, as the non-moving party, was entitled to "the benefit of all logical inferences that could be drawn from the evidence presented."[84] Despite the favorable inference for GSK, Judge Stark determined that the evidence confirmed that Teva's label did not infringe the `000 patent.[85] Judge Stark concluded that it would have been preposterous for a reasonable juror to surmise that doctors merely relied on Teva's label when doctors have abundant access to other sources about carvedilol's mechanisms of action, including, the American Heart Association guidelines, research studies in the *British Heart Journal* and *New England Journal of Medicine* about carvedilol, and even GSK's own Coreg® label.[86]

Teva further presented evidence that doctors continued to seamlessly prescribe carvedilol before and after the generic entered the market.[87] All three of the expert witnesses at trial, Dr. McCullough, Dr. Zusmann, and Dr. Rosendorf, concurred that even after Teva marketed carvedilol, they continued to prescribe the drug based on alternative "guidelines and research, as well as their own experience, in addition to GSK marketing."[88] None of the doctors testified that they relied on any of Teva's materials to advise or influence their prescribing practices.[89]

Despite the weight of the evidence, the jury concluded that Teva induced infringement of claims 1–3 of the `000 patent, between

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[80] GlaxoSmithKline LLC v. Teva Pharm. USA, Inc., 313 F.Supp. 3d 582, 589–90 (D. Del. 2018).
[81] *Id.* at 590.
[82] *Id.* at 589–90.
[83] Fed. R. Civ. P. 50(a)(1).
[84] Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991).
[85] GlaxoSmithKline*,* 313 F.Supp. 3d at 593.
[86] *Id.* at 594.
[87] *Id.*
[88] *Id.*
[89] *See id.*

January 2008 (the date `000 was issued) and April 2011 (right before Teva amended its label).[90] Additionally, the jury found that Teva induced infringement of claims 1–3 and 6–9 during the amended label period from May 2011 to June 2015, when the `000 patent expired.[91]

In response, Judge Stark agreed with Teva's contention that "the substantial uncontroverted evidence presented at trial showed that alternative factors caused doctors to infringe GSK's patent."[92] Despite GSK's advancement that the jury could have plausibly found that at least one prescribing doctor was influenced by Teva's actions to prescribe carvedilol in an infringing manner, that evidence is neither sufficient nor substantial.[93]

Contrarily, GSK's purported evidence, Dr. McCullough's testimony, "does not show Dr. McCullough stating what GSK seems to think he said."[94] Dr. McCullough's testimony affirms he *assumed* that carvedilol was identical to Coreg® and could be prescribed accordingly, but he did not read Teva's label prior to administration and relied on other sources.[95]

In the eyes of the district court, the jury's verdict of induced infringement caved under the weight of the contrary evidentiary landscape.[96] The jury's verdict was unreasonable and unsupportable given that doctors' prescribing decisions were not influenced by Teva, but by the amalgamation of external factors baked into their education as medical professionals.[97]

D. The First CAFC Opinion

The CAFC initially decided the case on October 2, 2020.[98] GSK sued because even though Teva's skinny label carved out CHF, it alleged Teva's label induced infringement because Teva intentionally encouraged infringing uses.[99] In support, GSK produced two "cursory, pre-patent press releases that announce[d] Teva's tentative drug

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[90] GlaxoSmithKline, 7 F.4th at 1325.
[91] *Id.*
[92] GlaxoSmithKline LLC v. Teva Pharm. USA, Inc., 313 F.Supp. 3d 582, 591 (D. Del. 2018).
[93] *Id*. at 590–91.
[94] *Id.* at 591.
[95] *Id.*
[96] *Id.* at 595.
[97] *Id.*
[98] GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., 976 F.3d 1347 (Fed. Cir. 2020).
[99] *Id.* at 1350–51.

approval" in which it stated that it was "the generic equivalent of Coreg®."[100] GSK asserted that the evidence demonstrated that Teva possessed culpable intent to encourage infringement, and its skinny label and/or press releases directed doctors' infringement via prescriptions to patients.[101] Teva asserted that it followed FDA instructions to "carve out" the patented CHF method from its label to create its skinny label, which only included post-MI LVD and hypertension.[102]

Teva claimed that induced infringement was not a viable theory for suit because cardiologists already knew about carvedilol and its uses.[103] GSK and Teva recruited doctors as witnesses who each testified that cardiologists were educated on carvedilol as a treatment, and specifically Coreg's® uses.[104] Dr. McCullough, GSK's witness, testified that Teva was "telling him, as a physician, that Teva 'was expecting to have a generic version of GlaxoSmithKline Coreg® that is AB rated, and that is indicated for the treatment of heart failure.'"[105] For reasons later scrutinized, this statement may be veracious but is not dispositive of Teva's intent.

The majority found that there was induced infringement throughout `000's patent term, including liability for the skinny and full label. [106] Ultimately, JMOL was reversed, and the case was remanded.[107] Judge Prost dissented.

The dissent, which this note will further dissect, supported JMOL as the necessary remedy to achieve the sure and just result.[108] Like many other critics of the initial and current standing decision, Judge Prost commended the district court judge's logic and judicial practice.[109]

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[100] GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1342 (Fed. Cir. 2021).
[101] GlaxoSmithKline, 976 F.3d at 1353.
[102] GlaxoSmithKline, 7 F.4th at 1325.
[103] GlaxoSmithKline, 976 F.3d at 1353–54.
[104] *Id.* at 1354.
[105] *Id.* at 1353–54.
[106] *Id.* at 1356.
[107] *Id.*
[108] *See generally* GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1342 (Prost, J., dissenting) (Fed. Cir. 2021).
[109] *Id.*

E. The Second CAFC Opinion

In 2021, the CAFC responded to public uproar and decided to reconsider its 2020 decision.[110] The majority opinion dwells on three issues: the language that remained on Teva's skinny label after carveouts, doctors who supposedly "relied" on Teva's label to infringe, and the underlying culpable intent behind a generic prescribing its product as an "equivalent" to the brand drug[111].

The CAFC concluded that Teva's partial label "instructed physicians to use its carvedilol in an infringing way."[112] Dr. McCullough stated that the partial label satisfied each claim limitation, which encouraged physicians to infringe.[113] The CAFC determined that the partial label, in conjunction with Teva's product catalogs, advertising, promotional activities, and testimony all encouraged infringement.[114] However, a drug label's instructions must *teach* the infringing mode to confer inducement liability.[115] Thus, the label itself needs to *teach* infringement via encouragement, recommendation, or promotion so that the court may appropriately *infer* an affirmative intent to infringe based on those instructions.[116]

Teva affirmed that it created its skinny label "exactly as the FDA instructed it to in accordance with the GSK-provided use code" in the Orange Book.[117] Despite Teva's affirmations, the court favored GSK's argument that Teva's section VIII heart failure carve out was not skinny enough.[118] Dr. McCullough compared claim 1 on Teva's partial label to the `000 Coreg® patent.[119] He explained that post-MI LVD is akin to heart failure because a patient with left ventricular ejection fraction of less than or equal to 40% with symptomatic heart failure would also be suffering from CHF.[120]

Further, GSK asserted that the rest of the claim limitations were satisfied by referencing Teva's label language in conjunction with its cited clinical studies. For instance, Figure 1 in Clinical Studies

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[110] *Id.* at 1320 (majority opinion).
[111] *Id*. at 1342–43 (Prost, J., dissenting).
[112] *Id.* at 1333 (majority opinion).
[113] *Id.* at 1333–34.
[114] *Id.*
[115] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1320 (Fed. Cir. 2021).
[116] *Id.* at 1333.
[117] *Id.*
[118] *Id.* at 1327.
[119] *Id.* at 1328.
[120] *Id.*

§ 14.1 displayed treatment for more than six months which satisfies the claim limitation of a "maintenance period . . . greater than six months."[121] The majority refuted criticism that they engaged in "cobbling together" disparate portions of the partial label to satisfy claim limitations.[122] Instead, the majority chose to underscore the jury's verdict in favor of GSK.[123]

The majority insisted that because doctors read drug labels to impact prescribing decisions, the drug label could incite them to prescribe carvedilol for infringing uses, like CHF.[124] The opinion relies on testimony from various medical professionals who confirm that doctors examine drug labels prior to prescribing.[125] The opinion failed to address doctors' pre-existing knowledge of additional uses prior to reading labels.[126]

The decision also dissected Teva's marketing materials, including catalogs and press releases, as well as Teva's witness testimony.[127] Teva released two product catalogs in spring 2008 and 2009, which stated that carvedilol is an "AB rated therapeutic equivalent to Coreg®," as *required* by the ANDA process.[128] The court acknowledged that an AB rating indicates therapeutic equivalence but conflates therapeutic equivalence with intent to infringe.[129] The court combined the required therapeutic equivalence with the required language in the partial label to demonstrate intent.[130]

Similarly, the majority misconstrued Teva's 2004 and 2007 press releases to encourage infringement.[131] Like the product catalogs, the 2004 press release referred to carvedilol as an "AB rated generic equivalent" of "Coreg® Tablets . . . [which] are indicated for treatment of heart failure and hypertension."[132] The majority mistook the presence of the "heart failure" language to indicate that Teva intends

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[121] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1324 (Fed. Cir. 2021).
[122] *Id.* at 1329.
[123] *Id.* at 1328–30.
[124] *Id.* at 1335.
[125] *Id.*
[126] *Id.*
[127] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1320 (Fed. Cir. 2021).
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] *Id.* at 1335–36.
[132] *See generally* GlaxoSmithKline, 7 F.4th at 1335–36.

for carvedilol to treat heart failure.[133] However, Teva is instead asserting that carvedilol is an equivalent to Coreg®, which treats heart failure.[134] In an attempt to clarify, the majority wrote that "heart failure" is not an "errant reference" but rather a pointed indication that carvedilol is a generic substitute for Coreg® to treat CHF in the same manner as the protected `000 patent. [135]

Like the 2004 press release, the majority criticized Teva's 2007 press release because Teva announced that it had final approval "to market its generic version of GlaxoSmithKline's *cardiovascular agent* Coreg® (Carvedilol) Tablets."[136] The majority took issue with the language, "cardiovascular agent," because it indicates that doctors could use carvedilol "for all indications," including the protected heart failure indication.[137] Despite acknowledging that "cardiovascular agent" is commonly known as "relating to the heart," the majority argued that one could understand the language to indicate that carvedilol "could be used for all indications including heart failure."[138]

Ultimately, the opinion concluded that Teva's partial label infringed because it was not a true skinny label;[139] it was not skinny enough. The majority opined that Teva's marketing materials directed doctors to examine the label, and doctors who referenced the label to supplement their existing knowledge of the generic were induced to infringe.[140] Finally, the majority wrote that the language in Teva's press releases also encouraged doctors to prescribe in an infringing manner.[141]

In May 2011, Teva's label omitted carveouts and was published as the full label including post-MI LVD, hypertension, and heart failure.[142] To announce its full label, Teva distributed marketing materials and catalogs to doctors.[143] This time, Dr. McCullough

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[133] *Id.*
[134] *Id.* at 1336.
[135] *Id.*
[136] *Id.* (emphasis added).
[137] *Id.* at 1336–37.
[138] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1337 (Fed. Cir. 2021).
[139] *Id.* at 1337–38.
[140] *Id.* at 1338.
[141] *Id.*
[142] *Id.*
[143] *Id.*

targeted Teva's 2012 Monthly Prescribing Reference which delineated that a doctor should be "familiar" with product labeling.[144]

Despite criticism that the court engaged in piecing together disjointed elements of a label, the majority confirmed in its second decision that Teva engaged in inducing infringement.[145] Again, the CAFC became the subject of criticism and Judge Prost's dissent.

F. Judge Prost's Dissent

Judge Prost's dissent seared the majority opinion for reasoning that is sometimes "labored, sometimes opaque . . . [and] strains to prop up a jury verdict that is unsupportable."[146] The dissent focused on the weakening of the intent prong of inducement by deconstructing the distinction between *describing* and *teaching* an infringing use in a drug label.[147] Additionally, Judge Prost found no culpable intent underlying Teva's branding of carvedilol as an "equivalent" to Coreg®.[148] Instead, she defended Teva for following the Act's protocol which requires generics to be "equivalent."[149]

Judge Prost criticized the majority for hewing together various parts of the label to manufacture a case of inducement.[150] She asserted the reality is "as though Teva had drafted a potentially infringing user manual and then, abiding by the patentee's clear guidance, deleted all the pages that might be viewed as encouraging infringement of a patented method."[151]

Teva's skinny label contained the post-MI LVD indication because GSK's sworn filings never claimed it was patented, so Dr. McCullough's efforts to combine disparate language on the label fall short of satisfying the patented claim limitations.[152] Judge Prost pointed out that Dr. McCullough "never testified that the skinny label encouraged, recommended, or promoted practicing the claimed method," but merely by piecing together language from various label

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[144] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1320 (Fed. Cir. 2021).
[145] *Id.* at 1341–42.
[146] *Id.* at 1342 (Prost, J., dissenting).
[147] *Id.* at 1343.
[148] *Id.* at 1342–43.
[149] *Id.* at 1343.
[150] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1356–57 (Fed. Cir. 2021) (Prost, J., dissenting).
[151] *Id* at 1349.
[152] *Id.* at 1351.

sections, he stated that some limitations might be "met."[153] This distinction indicates at most *description* of the claim limitations, *not teaching*.[154]

Additionally, Judge Prost found no culpable intent underlying Teva's branding of carvedilol as an "equivalent" to Coreg®.[155] The majority, insupportably, infers inducement from Teva's 2007 press release which announced its final approval to market carvedilol.[156] However, Judge Prost emphasized that a generic must demonstrate bioequivalence to the brand and that the labeling "must essentially copy the brand's drug label."[157] Congress did not intend to predicate pharmaceutical liability for marketing drugs as "equivalents," when pharmaceuticals are required to obtain that status.[158]

Judge Prost similarly found it unfathomable that describing carvedilol as a "cardiovascular agent" in Teva's 2007 press release is culpable.[159] The dissent concurred with the majority's recognition that "cardiovascular agent" means "relating to the heart."[160] Carvedilol is related to the heart because it treats heart conditions.[161] However, "cardiovascular" is a descriptive term and cannot "*reasonably* be viewed as evidencing culpable intent to encourage practicing the specific claimed CHF method."[162]

Prior to addressing the 2004 press release, Judge Prost cemented its factual disposition: the press release issued years before the `000's issue.[163] At that point, Teva affirmatively indicated CHF on the label, but it ultimately elected to follow a section VIII, skinny label route.[164] She dissected the precise legal language of "tentative approval," which indicates that "a patent or regulatory exclusivity stands in the way of final approval," and thus, it is conditional approval.[165]

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[153] *Id.*
[154] *Id.*
[155] *Id.* at 1353.
[156] *Id.*
[157] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1344 (Fed. Cir. 2021) (Prost, J., dissenting). *See also* 21 U.S.C. § 355(j)(2)(A)(i), (j)(2)(A)(iv), (j)(2)(A)(v), (j)(4)(G).
[158] GlaxoSmithKline, 7 F.4th at 1353.
[159] *Id.*
[160] *Id.*
[161] *Id.*
[162] *Id.*
[163] *Id.* at 1354.
[164] *Id.*
[165] *Id.*; 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.3(b).

The dissent also notes the majority's criticism of the "AB-rated generic equivalent" language.[166] For the same reasons discussed above, Prost argued that the 2004 press release, like the 2007 release, lacks evidence of culpability.[167] Though the majority seemed to think that the "heart failure" language is condemning, the press release was produced "under materially different regulatory circumstances" and stated that the approval was *tentative*.[168] This alone should preclude liability.[169] The 2004 press release should have absolved, not punished, Teva.[170]

Judge Prost disputed the majority's additional evidence of intent: "extensive expert testimony," and Teva's "Monthly Prescribing References," among others.[171] She noted that the issues in the "Monthly Prescribing References" are rooted in the skinny label's language, which she previously resolved.[172] Regarding the "product catalogs" and "advertising and promotional activities," they only demonstrated that Teva *described* carvedilol as the "AB-rated equivalent" to Coreg®."[173] This should result in the same outcome as the discussion of Teva's press releases with identical language.[174] Finally, "testimony from Teva's own company witnesses" is unproblematic because all of that information harkens back to the press releases or the language on the skinny label.[175] All liability is contingent upon the language in the press releases and the skinny label, neither of which are culpable based on the FDA's equivalence requirement.[176] Thus, there is no liability.[177] The full label should also be precluded from liability[178] because "nothing about doctors' prescribing practices changed when Teva amended its label to the full

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[166] *G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1354 (Fed. Cir. 2021) (Prost, J., dissenting).
[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] *See id.* at 1355.
[171] *Id.*
[172] *Id.*
[173] *Id.* at 1355–56.
[174] *Id.*
[175] *Id.* at 1356.
[176] *Id.*
[177] *Id.*
[178] *Id.*

version."[179] Neither GSK nor the majority present contrary evidence.[180]

Crucially, the majority refrained from discussing the differences between encouragement and description.[181] Judge Prost warned that if a jury can be directed to "infer culpable intent from a mere description, the legal distinction is meaningless."[182] This poses a unique danger that is contrary to the existing law in the Act.[183] The current ruling dictates that "description would *always* suffice to infer inducement," which decimates Congress's intent.[184]

Finally, Judge Prost expressed concern about what constitutes legal and illegal conduct going forward.[185] The majority provided zero guidance for how Teva should have executed its skinny label.[186] Though the majority attempted to console amici that the Act remains untouched, "as a matter of law, this is a skinny label case about skinny label provisions."[187]

This second majority opinion also fails to clarify what predicates liability and how to protect future pharmaceuticals from also incurring liability. Judge Prost succinctly noted that she is unsure whether the skinny label itself, press releases, or some other circumstantial evidence was the nail in Teva's coffin.[188] Even though the majority attempted to provide consolation that the ruling is "case-specific," this should serve as a red flag for other pharmaceuticals to be wary of the unknown.[189]

III. THE FLAWED INTERPRETATION OF INTENT

The majority's analysis of intent as a prong of induced infringement is misguided and incongruous with existing law. The current ruling presents a tumultuous path forward for generic pharmaceuticals in direct opposition to the Act's purpose: to accelerate

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[179] *Id.*
[180] *Id.*
[181] *Id.* at 1357.
[182] *Id.*
[183] *Id.*
[184] *Id.*
[185] *Id.* at 1359–60.
[186] *Id.* at 1360.
[187] *Id.*
[188] *See id.* at 1360–61.
[189] *See generally id.*

the availability of low-cost alternatives to the market via generics,[190] rooted in a balance between brand innovation and generic affordability.[191] This conclusion rests upon statutory law, case law, and Judge Prost's dissent. The proper application of intent would have precluded Teva's liability and continued to promote the seamless production of generics despite secondary method of use patents. The majority opinion conflated the distinction between *encouraging, recommending,* or *promoting* an infringing use and merely *describing* it, penalized generics for following the law, and failed to provide guidance regarding compliance with the law.

A. Description Versus Inducement

The majority opinion essentially reinterprets 35 U.S.C. § 271(b), which doles out liability for "actively and knowingly aiding and abetting another's direct infringement,"[192] to square with its conclusion that Teva induced infringement of Coreg®. The pillars of induced infringement are active encouragement coupled with knowledge that such conduct constitutes infringement.[193] There is a legal distinction between the conduct the statute penalizes and the conduct it does not.[194] Encouragement, recommendation, and promotion of an infringing use are culpable and indicate intent to infringe.[195] However, mere description of an infringing use is not culpable.[196] The court ignores this delicate delineation and penalizes Teva for the former despite conduct that falls under the latter.

The intent prong of induced infringement hinges liability upon whether the defendant had a "specific intent to encourage infringement."[197] Like the knowledge prong, (35 U.S.C. § 271(b) lacks explicit language regarding intent), case law underscores the notion that intent is necessary to find culpability and to effectuate

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[190] *See* Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404–405 (2012).
[191] *See generally* Murray, *supra* note 28, at 134.
[192] C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc. 911 F.2d 670, 675 (Fed. Cir. 1990).
[193] *See* 35 U.S.C.§ 271(b); *see also* Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 760 (2011); *see also* Water Tech. Corp. v. Calco, Ltd., 850 F.2d 660, 668–69 (Fed. Cir. 1988).
[194] *See generally G*laxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1357 (Fed. Cir. 2021) (Prost, J., dissenting).
[195] *See* 35 U.S.C. § 271(b).
[196] *See generally id.*
[197] Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990).

congressional intent.[198] The Federal Circuit affirmatively discarded any doubts that intent may not be integral to an induced infringement analysis.[199] The CAFC previously addressed this matter and wrote, "we are of the opinion that proof of *actual intent to cause the acts* which constitute infringement is a necessary prerequisite to finding active inducement."[200] Simply possessing the awareness that one might somehow cause another to infringe the patent without the requisite desire or intent to cause such infringement falls short of the legal standard for induced infringement.[201]

If a generic drug produces a label that encourages, recommends, or promotes infringement, then the generic is liable for induced infringement if a doctor prescribes the medication to patients.[202] In contrast, if a generic drug label does not explicitly contain infringing language and instead merely *describes a use that could constitute infringement*, the generic is not liable for induced infringement.[203] There is no induced infringement because there is no intent to cause another to infringe.[204] Yet, if the drug label explicitly contained specific infringing language, not just pieces of the language that could be hewn together to construct the infringing use, then there may be induced infringement.[205] Accordingly, the intent prong of induced infringement works to ensure that a potential infringer is well-aware of their actions and then desires to take them in efforts to infringe prior to imparting liability.

It is straining to imagine that Teva schemed to induce infringement by hiding infringing language in various portions of its ANDA materials. Teva's label omitted infringing uses, notably the protected CHF indication.[206] The standing opinion relies on a collage

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[198] *See* Robert A. Matthews, *§ 10.54. Intent to Cause the Acts of Infringement is a Prerequisite*, 2 ANN. PAT. DIG. § 10.54 (2024).
[199] *See id.*
[200] Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990) (emphasis added).
[201] *See generally* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363-65 (Fed. Cir. 2003).
[202] *See* Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015).
[203] HZNP Meds. LLC v. Actavis Labs. UT, Inc., 940 F.3d 680, 702 (Fed. Cir. 2019) (citing Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 632 (Fed. Cir. 2015)).
[204] *Id.*
[205] *Id.*
[206] GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1329 (Fed. Cir. 2021).

of data pulled from disparate sources to construct a canvas of infringement. However, not one source has been identified to contain all the infringing language.[207] Instead, Teva was found liable based on a string of discordant evidence including everything outside of the label's language. If infringement can be garnered from pulling potentially infringing language from one source and then combining it with other potentially infringing language from two or three other sources, that fails to demonstrate intent.

The law examines a drug's label to parse what the drug *teaches* and *encourages*.[208] If the condemning language is not on the label, the search for infringement is over. If it takes the combination of various disparate sources to manufacture something that looked like intent to infringe, that hardly meets the standard of "actual intent to cause the acts which constitute infringement."[209] That is not infringement, but manufactured intent designed to target otherwise legal conduct. If Teva had the requisite desire to infringe, then likely all the suspect language would be found on the label, or at least in one place, not scattered about just to be pieced together by those seeking the infringing use.

Therefore, the critical inquiry is whether a drug's label explicitly teaches an infringing use so that it can be properly read from the instructions that there was an actual, specific intent to infringe the brand's patent.[210] Merely "describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use should be performed."[211] Case law solidifies the definition of intent, as the defendant must have an "affirmative intent to cause direct infringement."[212]

B. Medical Inferences About a Generic Do Not Prove Intent

A doctor's common-sense knowledge about the nature of a generic drug and its prescriptive benefits cannot confer liability onto the generic if the generic did not explicitly induce infringement

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[207] *Id.*
[208] *Id.* at 1334.
[209] Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990).
[210] LAWRENCE M. SUNG & JEFF E. SCHWARTZ, PATENT LAW HANDBOOK § 3.4, § 3.:4 ACTIVITY—35 U.S.C.A. § 271(B) (2023).
[211] *Id.*
[212] MATTHEWS, *supra* note 198; Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 915 (2005).

through the label's language.[213] For example, in *Takeda*, Hikma, a generic pharmaceutical, attempted to make a generic version of Mitigare via a section VIII carveout.[214] Accordingly, Hikma did not apply for FDA approval to market its generic medication for "acute gout flares" which were actively patented by Takeda.[215] Hikma's label did not contain any language regarding the treatment of gout flares.[216] The label stated that "[i]f you have a gout flare while taking [Mitigare], tell your healthcare provider."[217] Unsuccessfully, Takeda alleged that Hikma's label induced infringement because if patients experienced a gout flare while taking Mitigare and consulted a healthcare provider, as the label instructed, that doctors "would likely tell the patient to use the Mitigare product to treat the acute flare."[218] Takeda was concerned that doctors' instructions to prescribe Mitigare for acute gout flares, despite the lack of explicit label language, would induce infringement.[219] The CAFC confirmed that such practice does not amount to induced infringement because the doctor's instructions are not connected to the label language; accordingly, Hikma should not be punished.[220]

Pointedly, the court noted that while infringement may have existed in this case, Hikma escaped liability for inducement.[221] To incur liability, the label language would have had to possess an affirmative intent to infringe and not just *describe* how the process could be infringed (in theory, by going to a healthcare provider who subsequently prescribes the generic for an infringing use based on requisite knowledge about generic equivalence).[222] Ultimately, the CAFC concluded that "mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement."[223] Similarly, just because a generic may have knowledge that healthcare providers might infringe, this is not akin to inducement.[224] Congress understood that section VIII

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[213] Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 630 (Fed. Cir. 2015).
[214] *Id.*
[215] *Id.*
[216] *Id.*
[217] *Id.*
[218] *Id.*
[219] *Id.* at 633.
[220] *Id.* at 630.
[221] *Id.* at 632.
[222] *Id.* at 630–31.
[223] *Id.* at 631.
[224] *Id.*

carveouts could lead to some off-label infringing uses, but these uses are not automatically indicative of inducement.[225]

Teva, like Hikma, created a skinny label with carveouts under fire for not being skinny enough because doctors have requisite knowledge to piece together how the generic might be used for patented purposes. Hikma's label did not print language about gout flares, and Teva's label contained no CHF language. Still, GSK attacked Teva because doctors had pre-existing knowledge to prescribe the cheaper generic to patients as doctors are aware that a generic *must* operate equivalently to the brand.[226] The current verdict is punishing Teva for doctors' requisite knowledge about the gold standard of cardiovascular care, carvedilol, and its prescribing uses. It is unreasonable to conjecture that a doctor who prescribes carvedilol to a patient would only prescribe it for hypertension and post-MI LVD because that is what the label explicitly instructs. Practically, regardless of the exact language printed on the label, many doctors would likely assume that because carvedilol is the generic version of Coreg® that it can treat CHF because Coreg® treats CHF.[227]

GSK attempts to argue that if a patient is suffering from post-MI LVD, then the patient is also suffering from CHF.[228] The majority opinion relies on Dr. Zusman's testimony that a "a patient who has a left ventricular ejection fraction of less than or equal to 40% with symptomatic heart failure (as recited on Teva's partial label) would be diagnosed as suffering from congestive heart failure."[229] Consequently, if a doctor prescribes carvedilol for the post-MI LVD symptoms and in conjunction ends up treating a subset of patients who also happen to have CHF, there is induced infringement.

The district court recognized at JMOL that post-MI LVD and CHF are "distinct and require different clinical testing and different FDA approvals to treat."[230] Even GSK patented post-MI LVD and CHF as two *separate* indications and the two *separate* indications were approved by the FDA. Therefore, if a doctor prescribes carvedilol for post-MI LVD and inadvertently also treats CHF, that is a collateral consequence of doctors' requisite knowledge of cardiac drugs, not inducement.

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[225] *Id.* at 631–32.
[226] *See* GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1342–43 (Fed. Cir. 2021).
[227] *See id.* at 1360.
[228] *Id.* at 1330.
[229] *Id.* at 1328.
[230] *Id.* at 1329–30.

The CAFC should have concluded that Teva's label language did not induce the doctors to infringe because the label merely described carvedilol's uses, even in its press releases. As Judge Prost indicated, the CHF indication was removed from the label.[231] Therefore, any prescription of carvedilol for CHF or any patented use had to be inferred by doctors. That is not unreasonable to assume. The label did not explicitly encourage an infringing use because the label literally did not contain CHF.[232] The press releases were mute about using carvedilol to treat CHF. Teva should not be penalized for encouraging a use that it did not even print on the drug label or dispel in press releases.

Teva should not be punished for doctors' existing knowledge about the connection between generics and brands. Congress foresaw the consequences of the Act and accounted for potential off-label infringing uses in the balancing of brand and generic benefits.[233] This case is no different than the cases that have previously come to the court: there is inducement by the explicit label language or there is not; nothing is printed between the lines here.[234] Teva cannot be liable for encouragement when the label presents nothing to be encouraged.[235]

Historically, culpable intent has been inferred when one has "proof of actual intent to cause the acts which constitute the infringement."[236] The generic must have "knowingly aided and abetted another's direct infringement of the patent."[237] Nothing Teva did aided or abetted doctors' prescription of carvedilol for patented uses.[238] Teva effectively redlined all patented language so that there was absolutely nothing left on the label, standing alone, that could suffice to direct doctors to prescribe carvedilol for CHF. *Only* in combination with disparate and selective evidence, like decontextualized language from press releases, could intent be manufactured.[239] This kind of witch-hunt in search of condemning language by combing through disparate sources demonstrates the *unintentional* nature of Teva's behavior.

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[231] *Id.* at 1349 (Prost, J., dissenting).
[232] *Id.*
[233] *Id*. at 1342.
[234] *See id.*
[235] *Id.*
[236] *See* Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990).
[237] Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1306 (Fed. Cir. 1999).
[238] *See* GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1348 (Fed. Cir. 2021).
[239] *See id.* at 1358–59.

Even if a doctor was unaware of the equivalence between generic and brand drugs, she would be hard-pressed to devise a logical connection to prescribe carvedilol for CHF, because CHF is not indicated on the label. No reasonable doctor would jeopardize a patient by prescribing medications haphazardly and for reasons not indicated by the label. The *only* reason doctors prescribed carvedilol for CHF was because of requisite knowledge that generics are equivalent to brands.[240] Doctors assume, as contemplated by the Act, that because Coreg® treats CHF, and carvedilol is the Coreg® generic, that carvedilol also treats CHF.[241]

C. Discordant Evidence Does Not Suffice to Prove Intent

Judge Prost warned that hewing together discordant pieces of evidence to fabricate intent to satisfy inducement severely compromises the intent prong of inducement.[242] Dismantling the respected definition of intent opens the entire pharmaceutical industry, patent applicants, and patent owners to unprecedented liability. The now waning scaffolding of the definition of intent bears the weight of the industry's reliance on the pre-existing law and the fear of unknown legislation emanating from the bench.

AstraZeneca, a brand pharmaceutical, successfully alleged that Apotex induced infringement of its asthma medication.[243] Apotex's "DOSAGE AND ADMINISTRATION" information discloses that "[i]n all patients, it is desirable to downward-titrate to the lowest effective dose once asthma stability is achieved."[244] Apotex included a table with the recommended doses with downward-titration.[245] Apotex's dosing instruction, though it did not explicitly recommend the infringing dose, encouraged the infringing dose because following downward-titration would imminently lead to administering a protected dosage.[246] Thus, the dosage instructions induced infringement.[247]

The CAFC tries to condemn Teva under similar reasoning, but the inferences it attempts to draw are too attenuated upon which to rest

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[240] *Id*. at 1360.
[241] *See generally id*.
[242] *See id.* at 1343.
[243] *See* AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1045–47 (Fed. Cir. 2010).
[244] *Id*. at 1057.
[245] *See id.*
[246] *See id.* at 1060.
[247] *See id.*

liability. The cursory 2004 and 2007 press releases are separate from the label and were produced in "materially different regulatory circumstances" before Teva sought a section VIII carve out.[248] The majority weaponizes press releases from an entirely different scenario to serve as convicting evidence in this new situation.[249] The 2004 press release was released years in advance of the `000 patent's issue.[250] Unlike the dosage and administration instructions attached to Apotex's label that encouraged doses to be titrated down to infringing amounts, the 2004 press release is completely irrelevant to Teva's present label seeking a section VIII carveout for the `000 patent.[251] Teva should not be penalized for violating the `000 patent based on the 2004 press release because the `000 patent had not been issued in 2004.

The majority's attempt to align disparate facts to satisfy culpable intent falls short of proving inducement. Not only are the connections too attenuated, but they do not exist. Simply mending together disparate parts of a label to create a meaning that infringes is unprecedented and creates a fraught path forward for generic manufacturing.

The majority's reasoning opposes the Act's protocols that require carvedilol to be "equivalent" to Coreg®. Congress explicitly requires generics to be "equivalent" to brands.[252] Contrary to clear regulation, the court held that Teva's 2007 press release announcing final FDA approval for carvedilol was problematic because it stated that it was the "[g]eneric version of [GSK's] cardiovascular agent Coreg® (Carvedilol) tablets."[253] Like the 2004 press release, the 2007 press release predates the `000 patent.[254] As Judge Prost writes, "*all* ANDA generics are the 'generic version' or 'generic equivalent' of a brand drug," which is mandated by law.[255] Congress did not foresee its direct equivalence requirement being twisted to penalize Teva when the requirement was intended to protect Teva.[256] Thus, the CAFC's current ruling directly penalizes generics for following the law. The

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[248] *See* GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1354 (Fed. Cir. 2021).
[249] *Id*.
[250] *Id*.
[251] *See* AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1057 (Fed. Cir. 2010); GlaxoSmithKline, 7 F.4th at 1354.
[252] *See* 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.94(a)(7)(i) (2009).
[253] *See* GlaxoSmithKline, 7 F.4th at 1353.
[254] *Id.*
[255] *Id.*
[256] *Id*. at 1342.

Act states that generics must be equivalent,[257] but if generics are penalized for "equivalent" branding, then this directly contradicts written law.

Most concerningly, the majority failed to proffer guidance on what constitutes proper legal conduct in the future. The decision upends regulatory law which should be accompanied by prescriptive measures going forward. However, the majority fails to even recognize their redefined playing field. Teva abided by each procedural step contemplated by Congress, but it has been saddled with millions in damages.[258] If the majority announced what Teva should have done, this might have illuminated what Teva failed to do or did incorrectly. Instead, the absence of commentary adds more gloom to the murky regulatory climate that the CAFC has created in what was once an efficient and balanced system.

The CAFC's obfuscations should not impede Teva's ability to successfully market carvedilol and provide consumers physical and financial relief. Reinstating the initial verdict fails to clarify disoriented applications of the law. The decision decimates the intent prong of induced infringement as outlined by the Act and fails to redefine its unprecedented interpretation of "intent." Pharmaceuticals must play a guessing game to identify the proper ANDA procedures because the time-tested tenets outlined in the Act no longer exist according to the CAFC.

G. A New Look for the Law

Peering into the future reveals a drastically new trajectory for ensuing litigation that hinges upon the "intent" prong of induced infringement in 35 U.S.C. § 271(b). If the CAFC abides by its current ruling, and mere description or inference can satisfy "intent," then the likelihood of finding defendants liable for inducement increases astronomically. The true culpability associated with intentional infringement is diluted by errant findings of liability. Under this new standard, plaintiffs retain a low bar of proof to demonstrate that an infringer "intended" to infringe its patent.[259] Whether spotlighting pharmaceuticals or inventions spanning the patent field, plaintiffs have the freedom to equip themselves with evidence from disconnected

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[257] *See* 21 U.S.C. § 355(j)(2)(A)(iv).
[258] *See* GlaxoSmithKline LLC v. Teva Pharm. USA Inc., 7 F.4th 1320, 1342 (Fed. Cir. 2021).
[259] *See id*. at 1357.

sources to paint a picture of intent,[260] rather than looking to one source, such as a label or user manual, to demonstrate a defendant's affirmative intent to infringe.

Though unintended, the CAFC ushered in a new style of patent litigation regarding induced infringement. Despite making efforts *not* to infringe, defendants may be found liable for *intentionally* infringing patents.[261] The uncertainty of liability may cast a chilling effect on desirable activities, like pursuing section VIII skinny label carveouts. Consequently, generics will be deterred from developing skinny labels at the risk of being found liable under this stringent new standard. Brands will be empowered to indefinitely monopolize valuable drugs with extended patent periods at the expense of American consumers' well-being. Beyond the pharmaceutical industry, if intent can now be satisfied by mere description, there will be a rise in good-faith litigation rooted in uncertainty regarding where the new line for liability now lies.

The Act allowed potential pharmaceutical defendants to manufacture and market otherwise infringing drugs based on a narrow set of pre-defined section VIII carveouts.[262] However, removing section VIII skinny label protections dismantles the Act's balance between generics and brands, and will force generics to wait indefinitely for all secondary method-of-use patents to expire prior to marketing. If generics are forbidden from proceeding to market as contemplated by the Act, brands wield nearly unchecked authority to police their patents and control whole portions of the pharmaceutical industry.

IV. FOREBODING FORECAST

The CAFC's reinterpretation of the "intent" prong of induced infringement entangles straightforward legal precedent and forces American consumers to incur significant financial burdens to obtain life-changing medication. Without amelioration, the current holding inevitably compromises generics' path to market. The court's purported reasoning deconstructs the Act's foundational purpose: to manifest an intentional balance among brand innovation, generic affordability, and consumer well-being.[263] The decision revises the meaning of intent premised on Teva's skinny label, but without skinny

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[260] *See generally id.*
[261] *Id.*
[262] *Id*. at 1346.
[263] *Id*. at 1343.

labels functioning as designed by Congress, the balance of the Act is rendered meaningless. Brand companies will have nearly unbridled authority to gouge prices, but at the risk of loss of innovation. Generic companies will be precluded from manufacturing countless drugs until all secondary method of use patents expire, thus indefinitely extending a brand's patent period. The decision's repercussions will unravel the Act's overall balanced scheme resulting in confusion for brand and generic pharmaceutical companies alike, and the consequences of imbalance in the industry will be borne by American consumers and their bank accounts.

A. Brand and Generic Pharmaceutical Confusion

Despite Teva's obedience to the Act's ANDA process, the court determined that its actions amounted to encouraging infringement of GSK's Coreg®.[264] However, Teva's conduct abides by the Act's section VIII mandates for producing a skinny label.[265] Consequently, Teva, along with the rest of the generic pharmaceutical industry, is left to ponder what it possibly could have done to avoid such reprimand and hefty consequences.

In a sense, Teva was penalized for reprehensible behavior, encouraging infringement, yet the court refrained from articulating *how* Teva behaved badly and what it *should have* done to remain within the confines of the law.[266] One should not be punished for following the written law. If there was a nuance in the law that had not previously been explored, the CAFC chose not to explain it. Instead, the court deduced a new application of the law[267] from its respected understanding and claimed nothing had changed.

In response, the court tries to assuage critics that its decision is case-specific,[268] but all generics should be warned. One is hard-pressed to articulate an alternative path that Teva should have taken at the inception of its ANDA to curtail liability, hence the abundance of amicus briefs citing disbelief and confusion. If the majority could plausibly conjure a pathway that outlines what Teva should have done to properly comply, it refrained from including that in the opinion. Instead, the holding stands alone and sacrifices the affordability of generic drugs and American consumers' needs.

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[264] *Id*. at 1341–42.
[265] *Id*. at 1342.
[266] *Id*. at 1340–41.
[267] *See id*. at 1361.
[268] *See id.* at 1326.

Perhaps the court would have been pleased if Teva had waited until the CHF patent expired before marketing the drug, yet that directly conflicts with the Act's efforts via section VIII carveouts. Section VIII skinny labels were precisely designed to grant generics more room to develop and sell drugs while brands continued to innovate, even after the initial patent for the drug's compound was issued. Section VIII was designed exactly for this scenario—to allow carvedilol to be patented, to allow some methods of use to be patented, like post-MI LVD and hypertension, and later for more uses to be patented, like CHF. Meanwhile, generics were to be granted windows of opportunity to develop and market aspects of carvedilol without penalty of infringement. The CAFC's affirmation that Teva induced doctors to infringe the CHF secondary method of use patent because it described a use that might be subsumed by other uses is untenable. Merely because a patient might be suffering from post-MI LVD and simultaneously suffering from CHF does not mean that Teva *intended* for carvedilol to treat CHF in conjunction with post-MI LVD.

Perhaps the court desired for Teva to affirmatively renounce its generic's ability to treat CHF, but that would directly oppose common knowledge of how generics are required to operate as bioequivalents of the brand. Essentially, Teva is penalized as a generic manufacturer for producing generics. Consequently, all generics should be warned and alerted to potential threats of litigation for operating exactly as they *were* legally authorized to proceed. Teva's case is proof that even legal conduct does not render a generic safe from the threat of facing damages in the courtroom.

While this case superficially seems to purely affect generic pharmaceuticals, brand pharmaceuticals should also be wary of changes in the law. Though the current holding curtails generics' rights, brands must operate with an unprecedented level of caution to avoid even tiptoeing along lines of behavior that could result in litigation. The breadth of the current decision loudly demonstrates how apt the CAFC may be to overcome and overwrite legal precedent. The Act retained a crystalline structure of understanding that brands and generics abided by for decades, yet one starkly divided panel of judges shattered previous iterations of the law. If the law can be so easily manipulated, no one and no entity can rely on sturdy footing. When basic legal principles like intent are discarded, the entire Act becomes a playing field and winnerless guessing game as to what constitutes legal and illegal behavior.

B. The Ailing American Consumer

Days in court often result in adverse outcomes for one party or the other, and the effect of the blow is absorbed by those present in the courtroom. However, *GlaxoSmithKline v. Teva* will undoubtedly directly and significantly impact Americans across the country. While Teva felt the immediate brunt of its loss, the inexorable downstream effects will cause consumers egregious financial pains and compromised access to needed medications.

Since 1984, the Act has bestowed American consumers with the right to expect low-cost alternatives to brand medications in the form of generic pharmaceuticals.[269] However, in the wake of the CAFC's opinion, generics will not have the leeway to bring affordable drugs to market in a timely manner. In the meantime, brands will continue to innovate and manufacture cutting-edge drugs to change lives, but Americans will not be able to foot the bill for brands' high prices. One of the purposes of the Act is to expedite affordable access to new drugs, yet consumers are left with no choice but to incur financial distress or wait until a generic alternative is available. For many, the option to pay whatever it takes for a new drug is unimaginable. Thus, the current legal landscape post-decision leaves them with no choice but to wait and hope for a medical miracle. Waiting for legal knots to unravel prior to gaining access to needed remedies unleashes a litany of ethical dilemmas and consequences that will plague consumers and their families.

While Teva suffered $235 million in damages, the American people will continue to incur damages indefinitely while absorbing the increasing cost of brand drugs for medications they are entitled to access as generics by law. The legal system owes justice to Teva. The legal system owes clarity to generic pharmaceuticals. The legal system owes clarity to brand pharmaceuticals. The legal system owes an accurate interpretation of the Act to its drafters' intent. The legal system owes more to the American people.

The court should not have rewarded GSK's attempts to maintain control of Coreg® after the expiration of its patent term. Instead, the court should have upheld Congress's intent and restored Teva's authority to produce and market its non-infringing generic, carvedilol. The United States Supreme Court should intervene to right the record, protect American pharmaceuticals, and provide affordable and accessible medication to the American people.

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[269] *See id*. at 1343.

V. CONCLUSION

For decades, the Hatch-Waxman Act articulated the gold standard for pharmaceutical legal conduct by enforcing a thoughtful balance between brand innovation and generic affordability, both poised at promoting the well-being and needs of the American consumer. However, the CAFC's interpretation and application of the "intent" prong of induced infringement unjustly penalized Teva Pharmaceuticals and established a new understanding of "intent" as an element of induced infringement. According to the CAFC's reasoning in both of its opinions, "intent" can now be satisfied by mere description or inference of an infringing use.

Amidst criticism, the court reassured critics that the holding was case-specific and that the hallmark tenets of the Act remained untouched, but the reinterpretation of such a foundational principle of patent law inevitably poses a threat to brand and generic pharmaceuticals alike. The lack of clarity and solidity in the law ominously foreshadows a tumultuous future in the legal arena and opens the door to a redesigned 35 U.S.C. § 271(b) patent infringement framework. Though this holding pointedly affects the pharmaceutical industry and patent practice, regardless of the legal subject matter, all courts and potential litigants should be wary of drastic legal revisions and remain vigilant of future consequences that only time will unravel and reimplement.