AIPLA QUARTERLY JOURNAL

Volume 47, Number 1 Page 99 Winter 2019

THE ANALYTICAL FRAMEWORK FOR THE SPECIFIC INTENT TO INDUCE INFRINGEMENT IN HATCH-WAXMAN DISPUTES

*Gregory Bischoping**

 Law Clerk to the Honorable Leonard P. Stark of the United States District Court for the District of Delaware. All views expressed herein are held by Mr. Bischoping in his individual capacity. Thanks are due to the editors of the Volume 47 AIPLA Quarterly Journal for their diligent and perceptive work on this Article, especially Kelly Elder, Lexy Khella, and Palak Sharma.

I. INTRODUCTION

"Whoever actively induces infringement of a patent shall be liable as an infringer."[1] Inducement is a long-established form of infringement under Federal Circuit law, requiring three steps be met: (1) infringing acts occurred; (2) the defendant knew or should have known their acts would induce these acts of infringement; and (3) defendant had "actual intent to cause the acts which constitute the infringement."[2] This Article will focus on the third step of this analysis, the "actual intent" prong of induced infringement, focusing on its application to generic drug companies allegedly inducing infringement in Hatch-Waxman suits.[3]

This Article will begin in Part II by summarizing the Federal Circuit's indecision on the appropriate standard of intent for induced infringement in a general patent context. The Federal Circuit initially split between two lines of cases, *Hewlett-Packard v. Bausch & Lomb*—requiring a comparatively low standard, "actual intent to cause the acts that constitute infringement"[4]—and *Manville Sales v. Paramount*—requiring knowledge of the legal consequences of their acts of

---

1 35 U.S.C.A. § 271(b) (2012).

2 Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1304–05 (Fed. Cir. 2002) (citing Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990), Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990)); *see also* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed. Cir. 2003).

3 Formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417, the Hatch-Waxman Act was passed "to expedite and streamline both generic drug approvals and patent litigation involving generic drugs." Lisa B. Pensabene & Dennis Gregory, *Hatch-Waxman Act: Overview*, PRACTICAL L. CO. 1, https://www.fitzpatrickcella.com/wp-content/uploads/Hatch-Waxman-Act-Overview-lpensabene_dgregory.pdf [https://perma.cc/N85H-EE3X]. Although the Act has been amended numerous times, its basic structure consists of (1) "An expedited FDA approval process for generic drug applications"; (2) "Certain market and patent exclusivity periods for both branded and generic drug companies"; (3) "Patent term extension to adjust for delays caused by the FDA approval process"; and (4) "A unique patent litigation process triggered by a generic drug company's submission of an application for FDA approval." *Id.*

4 *Hewlett-Packard*, 909 F. 2d at 1469.

inducement.[5] In the mid-2000s, the Federal Circuit reconciled certain obvious differences in this induced infringement jurisprudence,[6] but there remained significant questions regarding the requisite level of specific intent.[7] After surveying intent to induce infringement in the general patent infringement context, this Article will turn to how specific intent plays out in the Hatch-Waxman cases. Part III will describe how certain features of Hatch-Waxman litigation make intent to induce infringement a distinctly challenging concept, including the artificial nature of the infringement, the judge's role as the factfinder, and that the evidentiary standard is often based on the generic drug company's proposed labeling. The Article will then look to how the Federal Circuit and district courts vary in the type of evidence they will consider, and in the legal weight they give to circumstantial evidence. Lastly, in Part IV this Article will argue that it is appropriate and proper for courts to look beyond the drug's labeling to determine intent, still grounding their analyses in the actions of the defendant, but also inferring intent from external sources of information.

II. FEDERAL CIRCUIT INDECISION ON SPECIFIC INTENT

The Federal Circuit has, since the 1990s, debated the necessary level of intent to support induced infringement. While certain aspects of this debate have been resolved, there remains a fundamental tension between the circumstantial as opposed to direct approach to proving intent to induce.[8] However, because the induced infringement prong is a question of fact, the Federal Circuit has rarely overturned jury determinations, absent clearly mistaken instructions, instead

---

5 *Manville*, 917 F.2d at 553. For a helpful description of the Federal Circuit's induced intent divide, *see* Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. DAVIS L. REV. 225, 238 (2005) (describing the state of Federal Circuit law and the ongoing division between *Hewlett-Packard* and *Manville Sales*).

6 *See* DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304 (Fed. Cir. 2006) (*en banc*) (choosing *Manville*'s more demanding standard as the appropriate line of precedent).

7 *See, e.g.*, Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1928 (2015) (addressing one such remaining question by finding that a good faith belief in patent invalidity is not a defense to induced infringement).

8 *See, e.g.*, Power Integrations, Inc. v. Fairchild Semiconductor Intl., Inc., 843 F.3d 1315, 1330–31 (Fed. Cir. 2016) (overturning jury instruction that "left the jury with the incorrect understanding that a party may be liable for induced infringement even where it does not successfully communicate with and induce a third-party direct infringer").

implicitly (and at times, explicitly) stretching and contracting the analytical framework.[9]

Over a three-month span in 1990, the Federal Circuit set the stage for decades of debate on the level of specific intent required for induced infringement. In July of 1990, the *Hewlett-Packard* court ruled that the defendant need not know of the existence of the infringed patent, but must only induce the acts necessary to infringe that patent to possess the appropriate intent.[10] Then, in October, the *Manville* court ruled that the defendant must be aware of the existence of the patent in order to have the requisite level of intent.[11] The Federal Circuit attempted to reconcile these differing judgments and their underlying policies for the next 16 years, at first believing the two could be rationalized[12] and later noting the conflict but deferring to the district court's instruction and fact finding.[13]

After years of percolating, the Federal Circuit took up this contradiction in *DSU Medical Corporation v. JMS Company*. In *DSU*, the Federal Circuit was asked

---

9 *See, e.g.*, Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 699 (Fed. Cir. 2008); Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1329 (Fed. Cir. 2009). *But see Power Integrations*, 843 F.3d at 1330–31.

10 Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990).

11 Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990).

12 *See* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed. Cir. 2003) (describing a combined standard where *Hewlett-Packard* and *Manville* build off each other rather than contradicting each other); *see also* Water Techs. Corp. v. Calco Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988) ("While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice.").

13 *See* Insituform Techs., Inc. v. CAT Contracting, Inc., 385 F.3d 1360, 1378 (Fed. Cir. 2004) (noting that "there is a lack of clarity concerning whether the required intent must be merely to induce the specific acts or additionally to cause an infringement," and reviewing the district court for clear error); Fuji Photo Film Co. v. Jazz Photo Corp., 394 F.3d 1368, 1378 (Fed. Cir. 2005) (finding that repeat attempts to license sufficiently evidenced an intent to induce under the nebulous standard); MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed. Cir. 2005) (finding a material dispute of fact as to intent, but noting that an indemnity provision in a purchase order did not establish that intent); MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1333 (Fed. Cir. 2005) (noting the lack of clarity, but overturning the infringement judgment because not all elements were induced).

to review jury instructions stating "that to induce infringement, the inducer need only intend to cause the acts of the third party that constitute direct infringement."[14] The Court affirmed these instructions, siding decidedly with *Manville*, and requiring "evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities."[15] This decision, while explicitly choosing a side in this narrow contest—requiring that the defendant knew or should have known of the patent[16]—did very little to clarify the overall analysis. *DSU* created a framework for analysis that remains littered with contradiction: The decision holds that a defendant must "knowingly aide[] and abet[] another's direct infringement," notes that knowledge of downstream direct infringement is insufficient by itself to prove intent, but confirms that circumstantial evidence of actual intent "may suffice."[17] What emerged was a framework where the defendant must have an actual intent to infringe a known patent, but the judge/jury is given contradictory directives regarding what evidence it may rely on to establish this intent.

The Federal Circuit, in the 12 years since *DSU*, has waxed and waned on the requisite proof of intent, often bending to the judgment of the lower court and providing precedent for both narrow and broad interpretations. In *Broadcom Corp. v. Qualcomm Inc.*, the court affirmed a finding of induced infringement, based in part on the defendant's failure to obtain legal counsel on infringement.[18] The court sustained the jury instruction to "consider all the circumstances" and affirmed the ultimate finding of inducement entirely based on the circumstantial evidence of the defendant's failures to investigate other patents, design-around other patents, take remedial steps against inducement, or seek legal advice.[19]

Moving in the opposite direction, a year later, in *Vita-Mix Corp. v. Basic Holding, Inc.*, the court affirmed a judgment of no inducement and provided a specific evidentiary tool for defendants, acknowledging that "where a product has substantial non-infringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may

---

[14] DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (*en banc*).

[15] *Id.* at 1306 (citing *Manville*, 917 F.2d at 553).

[16] *Id.* at 1304.

[17] *Id.* at 1305–06.

[18] 543 F.3d 683, 699 (Fed. Cir. 2008) (holding failure to obtain opinion-of-counsel evidence to be relevant to induced infringement analysis).

[19] *Id.* at 700 (internal quotation marks omitted).

be infringing the patent."[20] The Federal Circuit next waned flexible, allowing fully circumstantial proof of intent. In *Lucent Technologies, Inc. v. Gateway, Inc.*, the court affirmed a jury verdict of inducement despite noting that the evidence was weak.[21] In this case, the only evidence of intent came from the plaintiff's expert who testified that because the defendant's computer program induced infringement, the defendant intended the program to do so.[22]

The Federal Circuit further loosened the *DSU* framework in *SEB S.A. v. Montgomery Ward & Co.*, when it found that "a claim for inducement is viable even where the patentee has not produced direct evidence that the accused infringer actually knew of the patent-in-suit."[23] This allowed the plaintiff to proceed on a theory of willful blindness by the defendant to the risk that the plaintiff had a patent.[24] Later cases continued to defer to jury decisions, even at the expense of the judge's grant of judgment as a matter of law.[25]

In sum, the Federal Circuit has established a legal vocabulary through which induced infringement intent is addressed. The defendant must either have

---

20 Vita-Mix Corp. v. Basic Holding Inc., 581 F.3d 1317, 1329 (Fed. Cir. 2009) (citing Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003) (rejecting argument that default vertical position of stir stick leads to infringing use)).

21 580 F.3d 1301, 1323 (Fed. Cir. 2009) (finding inducement due to slightly stronger circumstantial evidence).

22 *Id.* (concluding expert witness testimony not strong evidence but sufficient for a reasonable jury to find requisite intent).

23 594 F.3d 1360, 1377 (Fed. Cir. 2010).

24 *See id.* (finding adequate evidence for conclusion that defendant deliberately disregarded a known risk that plaintiff had a protective patent). *But see* Commil USA, L.L.C. v. Cisco Sys., 720 F.3d 1361, 1366 (Fed. Cir. 2013), *vacated in part*, 135 S. Ct. 1920 (2015), *and adhered to in part*, 813 F.3d 994 (Fed. Cir. 2015) (confirming the viability of willful blindness as a theory of intentional inducement, but denouncing negligence or recklessness as viable theories).

25 *See* Smith & Nephew, Inc. v. Arthrex, Inc., 502 F. App'x 945, 950 (Fed. Cir. 2013) (overturning the districts court's Rule 50 grant of judgment as a matter of law and reinstating the jury verdict of induced infringement). Rule 50 of the Federal Rules of Civil Rules of Civil Procedure allows a judge to grant judgment as a matter of law on some or all issues, either before or after the case is submitted to the jury, if "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50.

known or should have known that a patent existed and should have more than mere knowledge of possible downstream infringement.[26] The defendant must possess "specific intent" to induce infringement.[27] But this intent to induce infringement can be shown circumstantially.[28] Proof thereof is a question of fact.[29]

III. INTENT AS APPLIED IN HATCH-WAXMAN CASES

The Federal Circuit has ruled that "[t]he principles that can be distilled from [induced infringement] cases are applicable in the Hatch–Waxman Act context."[30] Given the distinct features of Hatch-Waxman cases, this has led to difficulty and variability in structuring a test for the intent prong of induced infringement, both at the Federal Circuit and among district courts.

A. DISTINCT FEATURES OF HATCH-WAXMAN CASES

While the Federal Circuit has suggested an undifferentiated analytical framework to intent in the Hatch-Waxman context, there are important substantive and procedural distinctions that merit discussion. First and foremost, there is almost always no actual infringement in a Hatch-Waxman suit, because the suit is premised on the generic drug company's ANDA filing—an artificial act of infringement.[31] The first prong of induced infringement—actual downstream acts of infringement—cannot (and indeed need not) be met. Although, theoretically, this actual infringement prong is distinct from the intent prong, the fact finder likely would be influenced—rationally so—by the prevalence of actual

---

[26] *See* Vita-Mix Corp. v. Basic Holding Inc., 581 F.3d 1317, 1328 (Fed. Cir. 2009) (discussing requirements to prove inducement of copyright infringement).

[27] *Id.*

[28] *Id.*

[29] *See* John C. Paul, D. Brian Kacedon & Robert C. MacKichan III, *Induced Infringement Requires Active Encouragement that Results in Direct Infringement*, FINNEGAN LES INSIGHTS (Jan. 10, 2017), https://www.finnegan.com/en/insights/induced-infringement-requires-active-encouragement-that-results.html [https://perma.cc/UD9C-YHY7].

[30] Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp., 785 F.3d 625, 631 (Fed. Cir. 2015).

[31] *See* Bristol-Myers Squibb Co. v. Mylan Pharm. Inc., No. 17–379–LPS, 2017 WL 3980155, at *7 (D. Del. Sept. 11, 2017) ("[A] 'highly artificial act of infringement' precipitates litigation between the branded drug company and the generic drug company for the express purpose of resolving patent disputes before a generic drug product is launched.").

infringement in its consideration on intent to induce. In fact, the Federal Circuit created an evidentiary tool by which to bridge these prongs, when it ruled that evidence of "substantial non-infringing uses" supports a finding of no inducement.[32] While this tool can still be used by branded drug companies, they must rely on theoretical infringing/noninfringing uses, rather than citing actual usage statistics. The speculative nature of infringement makes the evidentiary burden practically higher in Hatch-Waxman cases.

Second, the factual nature of the intent analysis tests the Federal Circuit's typical evidentiary deference, given that Hatch-Waxman suits are not entitled to a jury trial.[33] The author found no decision in regular patent infringement suits where the Federal Circuit overturned a jury decision as an unreasonable interpretation of evidence of intent to induce infringement. However, in bench trials the evidentiary weighing and legal analysis are inextricably intertwined, meaning that affirmation of the factfinder often means affirmation of legal conclusions.[34] Thus the Federal Circuit's deferential review has led to affirmation of both fact finding mixed with legal rulings. This deference has led to lawmaking at the District Court level, creating variations and contradictions in the analytical frameworks applied to intent, both across and within districts.[35]

Lastly, Hatch-Waxman induced infringement cases are distinctive because they are predominantly based on one form of evidence, the generic drug company's proposed labeling.[36] While one might assume this would lead to

---

[32] Vita-Mix Corp. v. Basic Holding Inc., 581 F.3d 1317, 1329 (Fed. Cir. 2009) (quoting Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003)).

[33] *See generally* Brian D. Coggio & Sandra A. Bresnick, *The Right to a Jury Trial in Actions Under the Hatch-Waxman Act*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 765, 767, 771 (1997).

[34] *See* Alza Corp. v. Mylan Labs, Inc., 464 F.3d 1286, 1289 (Fed. Cir. 2006) ("Infringement is a question of fact that, after a bench trial, we review for clear error.").

[35] *See infra* Section C (highlighting cases that demonstrate the contradictory analytical framework applied by district courts resulting in non-uniformity).

[36] *See* Joseph W. Arico, Andrea L.C. Reid & Carl A. Morales, *Skinny Labels and the Line Between Mere Information and Inducement to Infringe in ANDA Litigation*, BLOOMBERG L. (May 7, 2018, 10:33 AM), https://news.bloomberglaw.com/health-law-and-business/skinny-labels-and-the-line-between-mere-information-and-inducement-to-infringe-in-anda-litigation [https://perma.cc/V53U-DAV3] (obtaining FDA approval for

uniformity in the analysis, it has not done so; some courts are willing to look beyond the label and others are unwilling to do so.[37] This characteristic of Hatch-Waxman litigation is especially distinguishing because the label is impermanent; it can be and often is changed after the ANDA is filed.[38] While courts are willing to adjudicate claims based on changes to the label, either during or after the conclusion of the initial litigation,[39] such an action creates a unique strain on judicial resources, especially given the pressure to complete the case before the close of the 30-month stay.[40] The branded company, if asserting that a changed label induces infringement, must establish that the labeling "differences are tangibly real and are more than merely colorable."[41] This labeling impermanence underlies the very basis of the parties' arguments, straining a district court's ability to analyze intent to induce infringement and giving the generic flexibility and power in forming its non-inducement argument.[42]

---

generic drugs and labeling for alternative uses not covered by the patent enables generic manufacturers to avoid direct infringement).

37 *Id.*

38 *See* L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co., No. LA CV13–08567 JAK (JCGx), 2014 WL 11241786, at *2 (C.D. Cal. May 12, 2014) (confirming labels are impermanent as defendant received FDA approval to revise its Cialis prescription label post ANDA filing); *see also* Eli Lilly & Co. v. Dr. Reddy's Labs., Ltd., No. 1:16-cv-00308-TWP-MPB, 2017 WL 6387316, at *3 (S.D. Ind. Dec. 14, 2017) (changing the generic drug's label per FDA instruction did not preclude the Court from moving forward with the proceedings as the change did not alter the substance or legal theories of the parties' previously submitted briefings).

39 *See Eli Lilly*, 2017 WL 6387316, at *3; *L.A. Biomedical Research*, 2014 WL 11241786, at *2.

40 *See, e.g.*, Meredith H. Boerschlein & Shana K. Cyr, *Intricacies of the 30-Month Stay in Pharmaceutical Patent Cases*, AM. PHARMACEUTICAL REV. (Mar. 25, 2018), https://www.americanpharmaceuticalreview.com/Featured-Articles/348913-Intricacies-of-the-30-Month-Stay-in-Pharmaceutical-Patent-Cases [https://perma.cc/42HA-JKB5] ("A suit by the patent owner within 45 days of receiving the notice triggers a 30-month stay of regulatory approval, during which the U.S. Food and Drug Administration (FDA) cannot approve the generic drug.").

41 Allergan Sales, LLC. v. Sandoz, Inc., 211 F. Supp. 3d 907, 918 (E.D. Tex. 2016), *aff'd in part, rev'd in part*, 717 Fed. App'x. 991 (Fed. Cir. 2017).

42 *See* Sanofi v. Glenmark Pharm. USA, 204 F. Supp. 3d 665, 685 (D. Del. 2016), *aff'd sub. nom.*, *Sanofi*, 875 F.3d 636 (noting that the defendant's reliance on an

B. CONTRADICTION AT THE FEDERAL CIRCUIT

It wasn't until 2010 that the Federal Circuit directly addressed the labeling-based analysis framework for Hatch-Waxman intent to induce.[43] In *AstraZeneca LP v. Apotex, Inc.*, the Federal Circuit reviewed the district court's finding that the generic's labeling implicitly instructed infringement of the patent by teaching a titration that included patented dosages.[44] This instruction on the label was also used as evidence of affirmative intent, when coupled with the lack of evidence of attempts to draft a non-infringing label.[45] Apotex argued that because there were substantial non-infringing uses of the patent, the inference of intent to induce without any affirmative evidence was improper.[46] The Federal Circuit sided with AstraZenica and the district court, because reliance on circumstantial evidence is proper and the proposed labeling implicitly instructed infringement.[47] The court explained, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of Apotex's affirmative intent to induce infringement."[48] Because the Federal Circuit was "not left with a definite and firm conviction that a mistake has been made," it deferred to the court below.[49]

In *Takeda Pharmaceutical U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, the Federal Circuit began by fully explaining, for the first time, the standard of intent to induce in Hatch-Waxman cases.[50] This, Takeda said, should lead to an inference

---

older version of its labeling "is an unconvincing, litigation-inspired explanation of its advertising activities"); *c.f.* Classen Immunotherapies, Inc. v. Elan Pharm., Inc., 786 F.3d 892, 898 (Fed. Cir. 2015) (finding that changes to the label were protected under the safe harbor).

43 AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042 (Fed. Cir. 2010). *Warner-Lambert*, a 2003 seminal decision in the Federal Circuit's inducement jurisprudence, was in fact a Hatch-Waxman case, but did not employ the standard label-centric framework. Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed. Cir. 2003).

44 633 F.3d at 1057.

45 *Id.* at 1058.

46 *Id.* at 1059.

47 *Id.* at 1060.

48 *Id.*

49 *Id.* at 1061.

50 *See* Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp., 785 F.3d 625, 630 (Fed. Cir. 2015).

of intent to infringe.[51] Judge Dyk, writing for the 2-1 panel, explained that even if evidence would sustain a theory of inevitable infringement, the presence of alternatives for treating gout flares undermines such a theory.[52] He concluded that "[s]peculation or even proof that some, or even many, doctors would prescribe [the generic] for [infringing conditions] is hardly evidence of inevitability."[53] Judge Dyk affirmed the district court's decision of no probability of success on the question of induced infringement.[54]

In 2017, Judge Newman, who dissented in *Takeda*, wrote for the majority in *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, and cited both *DSU* and *Takeda* for the standard of induced infringement.[55] However, in a clear step back from *Takeda*, Judge Newman stated that intent could be inferred from instructions on a label that do not directly teach an infringing method.[56] Relying heavily on *AstraZenica* instead of *Takeda*, Judge Newman wrote that "the decision to continue seeking FDA approval of those instructions may be sufficient evidence of specific intent to induce infringement."[57] Judge Newman claimed to fit this decision within the boundaries of *Takeda* by explaining that the instructions here were clearer and the connection between the instructions and the patented use less tenuous.[58] However, this is a difference in degree rather than kind, and Judge Dyk, in *Takeda*, had suggested that looking beyond the wording of the label was wholly impermissible.[59] Judge Newman concluded that because the label "would inevitably lead some physicians to infringe establishes the requisite intent for inducement," the requisite intent existed.[60] She affirmed the district court.[61]

In the most recent case in this back-and-forth saga, Judge Taranto affirmed the district judge's decision in *Sanofi v. Watson Labs. Inc*, finding requisite intent for

---

51 *Id.*

52 *Id.* at 632–33.

53 *Id.* at 633.

54 *Id.* at 633.

55 Eli Lilly & Co. v. Teva Parenteral Medicines, 845 F.3d 1357, 1368 (Fed. Cir. 2017).

56 *Id.*

57 *Id.*

58 *See id.* at 1369.

59 *See Takeda Pharm.*, 785 F.3d at 634.

60 *Eli Lilly*, 845 F.3d at 1369.

61 *Id.*

inducement infringement.[62] *Sanofi* was based on testimony that the "label encourages—and would be known . . . to encourage—administration of the drug to those patients, thereby causing infringement."[63] The plaintiff's expert testified that a person of ordinary skill would read the label of the generic drug in connection with the FDA-approved use of the drug, thus encouraging a physician to prescribe an infringing use of the drug.[64] The defendant's expert did not seem to directly rebut this testimony but contended that substantial noninfringing uses prevented an inference of intent from this circumstantial and external evidence.[65] Citing the Supreme Court's decision in *MGM Studios, Inc. v. Grokster, Ltd.*[66] and seemingly ignoring *Takeda*, Judge Taranto wrote that a person can be liable for inducing infringement "even if the product has substantial noninfringing uses."[67] While this evidentiary tool—substantial noninfringement—is still available post-*Sanofi*, its significance is unclear.[68] The Federal Circuit's decision to affirm induced infringement rested on the fact that the labeling, unlike in *Takeda*, internally referenced studies that clarify indications of use in infringing ways.[69]

Despite these attempts in *Sanofi* and *Eli Lilly & Co.* to distinguish *Takeda*, there are clear inconsistencies in the type of evidence that the Federal Circuit will permit in determining intent to induce infringement. Can a study that is not referenced by the label, that would be known to a person of skill in the art, and that would lead a physician to prescribe a generic drug in infringing ways, be evidence of intent? Can evidence of inevitable infringing use in the absence of other evidence be sufficient to prove intent? What is the significance of substantial noninfringing uses? While there is little consistency or clarity in the Federal Circuit's precedent, the court's willingness to grant a large degree of deference to the district judge is evident.

---

62 *See* Sanofi v. Watson Labs. Inc., 875 F.3d 636, 646 (Fed. Cir. 2017).

63 *Id.* at 645.

64 *Id.*

65 *See id.* at 646.

66 545 U.S. 913 (2005).

67 *Sanofi*, 875 F.3d at 646.

68 *See e.g.*, Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117, 1133 (Fed. Cir. 2018) ("Accordingly, even if the proposed ANDA product has 'substantial noninfringing uses,' West-Ward may still be held liable for induced infringement.").

69 *See id.*

C. DISTRICT COURT DIVIDE

Different districts have used this varying precedent to reach varying and contradictory answers to the above questions. Some judges have allowed external evidence of likelihood of infringement to prove intent to induce, while others have more stringently followed *Takeda* and limited the analysis to the wording and explicit teaching of the label.[70] Even within districts, there are few definite patterns in the analytical frameworks applied, and the Federal Circuit's consistent deference has permitted these contradictory decisions to persist and grow.[71]

1. District of Delaware

The District of Delaware, a favorite forum for Hatch-Waxman disputes,[72] has often favored the *Sanofi/Eli Lilly & Co.* line of Federal circuit precedent, relying on a more permissive evidentiary standard to establish intent. The label was identical to that of a different drug that met the claims limitations.[73] This district has looked beyond the express wording of the label, and at times beyond the label itself. For instance, the court in *GlaxoSmithKline LLC v. Glenmark Generics Inc., USA*, wrote that "there is no requirement that Defendants need to have mimicked the precise wording" of the patent.[74] The Court found that implicit readings of the label, as well as the teachings of referenced studies, plausibly suggested intent to induce infringement.[75] The label taught treatment of a "*chronic* heart failure," and according to the court this indicated a lengthy period of treatment, thus inducing infringement of the claimed six-month treatment period.[76] Lastly, the label also promoted data from clinical studies, in which every treatment studied was for

---

70 *See infra* Sections C.1–2.

71 *See id.*

72 *See* BRIAN C. HOWARD, LEX MACHINA HATCH-WAXMAN/ANDA LITIGATION REPORT 2017 3–4 (2017) (noting that 1,114 54% of the 2,646 total Hatch-Waxman cases filed, between 2009 and 2017, were filed in the District of Delaware).

73 *See id.* at *8.

74 Nos. 14–877–LPS, 14–878–LPS, 2015 WL 3793757, at *8 (D. Del. Apr. 22, 2015), *report and recommendation adopted sub nom.* Glaxosmithkline LLC v. Teva Pharm. USA, Inc., Nos. 14–878–LPS–CJB, 14–877–LPS–CJB, 2015 WL 4730913 (D. Del. Aug. 10, 2015).

75 *Id.*

76 *Id.* at *7.

greater than six months.[77] It was not clear which of these pieces of evidence the judge weighed most heavily.[78]

In *Sanofi v. Glenmark Pharm. Inc., USA*, the precursor to the previously described Federal Circuit *Sanofi* case, district court Judge Andrews seemed to hold that knowledge of likely infringement, with circumstantial evidence of intent, might carry sufficient weight for inducement.[79] His finding that the defendants "knew that their proposed labels would actually cause physicians to prescribe [the generic]" in infringing ways was based on evidence that an identical label had already led to infringing uses.[80] Judge Andrews also relied on expert testimony that a person of ordinary skill would read a study noted on the label and also know of past studies (not noted in the label) that teach infringing uses of the drug.[81] Because the label did not directly disclaim the infringing uses, it would effectively teach a physician to infringe.[82] Judge Andrews concluded that the label provided "clear encouragement" of infringement, because "the law does not require that a label expressly limit a drug only to a specific use in order to induce infringement of a method of treatment claim."[83] This decision presents a highwater mark for the flexible approach to specific intent, with the district court relying on an ambiguously over-inclusive label, a cited study, non-cited studies, and probable knowledge of downstream infringement. As discussed above, the Federal Circuit affirmed the district court, but the Federal Circuit's analysis relied on more traditionally accepted evidence, suggesting that Judge Andrews' methodology stretched the bounds of Federal Circuit tolerance.[84]

Delaware is not uniform in its application of Judge Andrews expansive reasoning. Judge Robinson, in *Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC*, favorably cited *Takeda* for the proposition that "'knowledge of off-label

---

77 *Id.*

78 *See id.* at *7–8 (suggesting that the finding of a plausible intent to induce infringement is due to the Court's evaluation of the evidence in its entirety and in context as opposed to the Court exclusively focusing on any one particular piece of evidence).

79 204 F. Supp. 3d 665, 677 (D. Del. 2016).

80 *Id.*

81 *Id.* at 678.

82 *Id.* at 677–78.

83 *Id.* at 680.

84 *See* Sanofi v. Watson Labs. Inc., 875 F.3d 636, 646 (Fed. Cir. 2017).

infringing uses' will not establish inducement."[85] In *Forest Laboratories*, the defendants affirmatively removed an infringing teaching (treatment of schizophrenia) from the label but retained a description that would be understood by one skilled in the art to instruct that same usage.[86] Furthermore, circumstantial evidence supported an intent to induce, because the defendant had not reduced its projected sales following its labeling change, despite the fact that the drug would now supposedly just target bipolar disorder instead of bipolar disorder and schizophrenia.[87] Judge Robinson concluded that the facts at hand were "unusual, but not more compelling than the facts reviewed by the Federal Circuit in *Takeda*."[88] This case is currently on appeal to the Federal Circuit.[89]

In a unique decision, based on an even more unique set of facts, Chief Judge Stark recently granted judgment as a matter of law in *GlaxoSmithKline v. Teva Pharmaceutical Industries* ("*GSK*"), overturning a jury verdict of induced infringement.[90] The ruling, while not directly addressing the *Takeda*/*Sanofi* tension, noted that the *Takeda*/*Sanofi* precedent was only tangentially applicable because in *GSK* the generic drug was launched seven years prior to suit, making it not "the ordinary Hatch-Waxman framework."[91] Judge Stark found that no reasonable factfinder could have concluded the defendant possessed the specific intent to induce infringement because the only evidence of intent presented was Teva's

---

85 Forest Labs., L.L.C. v. Sigmapharm Labs., L.L.C., 257 F. Supp. 3d 664, 684 (D. Del. 2017) (quoting *Takeda Pharm.*, 785 F.3d at 633).

86 *Id.* at 683 (finding the defendant removed the word "schizophrenia" from their proposed label but did not remove the description of asenapine as an "atypical antipsychotic").

87 *Id.* at 685.

88 *Id.* at 684.

89 Susan Decker, *Allergan Wins Ruling Against Sigmapharm Over Generic Saphris*, BLOOMBERG L. (Nov. 16, 2018), https://news.bloomberglaw.com/ip-law/allergan-wins-ruling-against-sigmapharm-over-generic-saphris [https://perma.cc/4WGZ-R84X] (describing the decision of the lower court).

90 GlaxoSmithKline LLC v. Teva Pharm. USA, Inc., 313 F. Supp. 3d 582, 599 (D. Del. 2018).

91 *Id.* at 596–97 n.14, 598 n.16 (distinguishing *Sanofi* and finding that because the drug was actually launched, the court must look for actual inducement, rather than speculative intent and noting that Teva cited *Takeda* as protecting against the "eviscerat[ion] [of] the section viii carve-out," though not weighing in on the argument).

failure to actively disclaim infringing uses of the generic drug.[92] To the contrary, Teva presented direct evidence that infringement occurred for reasons unrelated to its actions and that doctors did not change their prescribing patterns for the branded drug following the introduction of the generic.[93] Judge Stark's decision rested in large part on the fact that "[t]here was no direct evidence that [defendant]'s label caused even a single doctor to prescribe" the generic in an infringing manner, despite the drug being available for seven years.[94] While the decision suggests a preference for direct over circumstantial evidence, this interpretation of the case is heavily circumscribed by years of sales of the generic drug and the lack of any, even circumstantial, evidence of induced infringement.[95] Further, Judge Stark evinced a willingness to consider circumstantial evidence, including factors external to the label, but, in this case, those factors weighed against inducement.[96] While highly distinctive, this case may provide the Federal Circuit with a rare opportunity to review the legal requirements of intent.[97]

Delaware, while generally receptive to a flexible evidentiary standard, still exhibits the tension between *Takeda* and *Sanofi/Eli Lilly & Co.*,[98] especially between its *Forest Laboratories* and *Sanofi* decisions.[99] Thus far, the Federal Circuit has

---

92 *Id.* at 593 (describing how GSK's evidence of inducement revolved around Teva's advertisement of its generic drug as "AB" rated but noting that Teva had no duty to specify for which uses its drug was AB rated).

93 *Id.* at 594.

94 *Id.* at 595.

95 *See id.*

96 *GlaxoSmithKline*, 313 F. Supp. 3d at 593 (considering "the totality of this evidence" including non-label evidence).

97 The standard of review will follow the Third Circuit. *See generally* Ping-Hsun Chen, *Should We Have Federal Circuit Law for Reviewing JMOL Motions Arising from Patent Law Cases?*, 1 NTUT J. INTELL. PROP. L. & MGMT. 1 (2012).

98 *Compare* Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp., 785 F.3d 625, 631–32 (Fed. Cir. 2015), *with* Sanofi v. Glenmark Pharm. USA, 204 F. Supp. 3d 665, 677, 680 (D. Del. 2016), *and* L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co., No. LA CV13–08567 JAK (JCGx), 2014 WL 11241786, at *9 (C.D. Cal. May 12, 2014).

99 *See* Forest Labs., L.L.C. v. Sigmapharm Labs., L.L.C., 257 F. Supp. 3d 664, 680 (D. Del. 2017); *Sanofi*, 204 F. Supp. 3d at 680.

affirmed nearly every decision on appeal, but this deference may have to change as the contradictions in the law become more prominent.[100]

2. *District of New Jersey and Other Districts*

As one would expect, district court decisions vary in their acceptance of non-explicit labeling evidence to show intent to induce infringement,[101] furthering the need for clarity from the Federal Circuit. Although predating the competing Federal Circuit's recent contradicting decisions,[102] the District Court for the Central District of California, in *ICN Pharmaceutical, Inc. v. Geneva Pharmaceutical Technology Corp.*, held that "knowledge that, despite their labeling instructions, physicians may on their own administer a treatment dosage of [the generic] within the claimed range . . . is not sufficient to constitute the specific intent required for induced infringement."[103] Here, while the defendants had knowledge that their drug would likely be prescribed in infringing dosages, there could be no inducement because their label explicitly taught other dosages.[104] Conversely, the District Court for the Southern District of New York wrote that "[t]he spectrum of acts potentially demonstrating the requisite intent for inducing infringement is broad."[105] The court found that likely actual infringement was sufficient to sustain allegations of intent to induce infringement against a motion for summary judgment.[106]

The District of New Jersey[107] has, contrary to the District of Delaware, typically favored a rigid framework for demonstrating specific intent to induce infringement, requiring more directness of evidence. For example, in *United Therapeutics Corp. v. Sandoz, Inc.*, the District Court concluded that warnings in the

---

100 *See, e.g.*, *Forest Labs.*, 257 F. 3d at 680, 693; *Sanofi*, 204 F. Supp. 3d at 680, 704–05.

101 *See Forest Labs.*, 257 F.3d at 680; *Sanofi*, 204 F. Supp. 3d at 680.

102 *See, e.g.*, *Forest Labs.*, 257 F. 3d at 680; *Sanofi*, 204 F. Supp. 3d at 680.

103 ICN Pharm., Inc. v. Geneva Pharm. Tech. Corp., 272 F. Supp. 2d 1028, 1049 (C.D. Cal. 2003).

104 *See id.*

105 *In re* Omeprazole Patent Litig., 258 F. Supp. 2d 221, 234–35 (S.D.N.Y. 2001).

106 *See id.*

107 The District of New Jersey is the other primary forum for Hatch-Waxman disputes; 39% of all Hatch-Waxman filings were filed in this forum between 2009 and 2017. *See* HOWARD, *supra* note 72, at 3.

proposed label were not instructions to infringe.[108] While plaintiffs had established the possibility of downstream infringement, it was "not enough that 'a user following the instructions may end up' practicing the patented method."[109] This built off an earlier case, where the court dismissed an inducement claim because there was no direction or instruction to actively infringe.[110] Similarly, in *Otsuka Pharmaceuticals v. Torrent Pharmaceuticals* the District of New Jersey again found no intent for a warning that purportedly implied an infringing method.[111] This was because the generic drug company affirmatively removed the direct mention of the infringing use.[112] The *Otsuka* court noted that even express permission to practice an infringing method may not constitute the requisite intent.[113] It rejected the possibility of looking to sources outside the label to find intent, or even looking outside the specific context of the reference within the label.[114] This line of New Jersey cases, while predating *Takeda*, advance a similarly restrictive approach to analyzing intent to infringe.

IV. SUGGESTED APPROACH

Within the Federal Circuit there are increasingly deep divisions over the evidentiary framework to prove intent to induce infringement, demonstrated by the contrast between the District of New Jersey and the District of Delaware. The Federal Circuit's own contradictory decisions, while superficially reconcilable as factual deference, are in legal tension with each other and have resulted in varying

---

[108] Nos. 12–CV–01617, 13–CV–316, 2014 WL 4259153, at *21 (D.N.J. Aug. 29, 2014).

[109] *Id.* (quoting AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010)).

[110] *See* Novartis Pharm., Corp. v. Wockhardt USA LLC, No. 12-CV-3967, slip op. at *16 (D.N.J. Oct. 23, 2013).

[111] *See* Otsuka Pharm. Co., Ltd., v. Torrent Pharm. Ltd. Inc., 99 F. Supp. 3d 461, 490 (D.N.J. 2015).

[112] *Id.*

[113] *Id.* (citing Shire LLC v. Amneal Pharm., LLC, No. 11–3781 (SRC), 2014 WL 2861430, at *3–6 (D.N.J. June 23, 2014)).

[114] *See id.* at 492–93 ("[T]he Court cannot find that the information admittedly contained only in the warning provisions of Defendants' labels demonstrates the active instruction necessary for purposes of inducement.").

standards across and within districts.[115] The District of Delaware has more often leaned flexible, at times willing to rely on circumstantial and even off-label evidence of intent, including knowledge of likely infringement.[116] On the other hand, the District of New Jersey has proven consistently stricter, requiring affirmative steps indicating intent to induce.[117] Given this division within and below, the Federal Circuit has a duty, for the sake of predictability and uniformity, to acknowledge and correct the contradiction between its decisions in *Takeda* and *Sanofi/Eli Lilly & Co*.

This Article advocates for an expansive and flexible approach to intent, at the very least reiterating the superiority of *Sanofi/Eli Lilly & Co.* over *Takeda*, but preferably going even further toward a flexible and open-ended framework of analysis. This approach is best seen in the reasoning of Judge Andrews in *Sanofi v. Glenmark Pharmaceutical Inc., USA*—allowing all circumstantial evidence, at the judgment of the reasonable fact finder, to be sufficient to find intent to induce—circumscribing *Takeda* as an island in the law.[118] This approach would still heavily weigh affirmative, express, and direct evidence, but would allow a finding of intent based on circumstantial indicia, including off-label studies known to a person of skill in the art and knowledge of infringement.

A flexible approach is especially desirable because of the distinctive characteristics of Hatch-Waxman disputes. First, because actual infringement has not yet occurred,[119] a significant evidentiary tool – substantial noninfringing uses – is not available. Second, bench trials warrant open analytical frameworks, because the factfinding process is inherently intertwined with lawmaking.[120] By instituting analytical and evidentiary restrictions, and contradictory ones at that,

---

115 *Compare Takeda Pharm.*, 785 F.3d 625, *with* Sanofi v. Watson Labs. Inc., 875 F.3d 636 (Fed. Cir. 2017).

116 *See, e.g.*, Sanofi v. Glenmark Pharm. USA, 204 F. Supp. 3d 665 (D. Del. 2016).

117 *See, e.g.*, Otsuka Pharm. Co., Ltd., v. Torrent Pharm. Ltd. Inc., 99 F. Supp. 3d 461 (D.N.J. 2015).

118 *See* Forest Labs., L.L.C. v. Sigmapharm Labs., L.L.C., 257 F. Supp. 3d 664, 684–85 (D. Del. 2017) (quoting *Takeda Pharm.*, 785 F.3d at 632); *see also* GlaxoSmithKline LLC v. Teva Pharm. USA, Inc., No. 14-877-LPS-CJB, 2015 WL 4730913, at *7 (D. Del. Aug. 10, 2015).

119 *See* 35 U.S.C. § 271(e)(2) (2012).

120 *See* Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1289 (Fed. Cir. 2006) ("Infringement is a question of fact that, after a bench trial, we review for clear error.").

the Federal Circuit invites legal discord at the trial level.[121] And while judges will inevitably prefer varying types of evidence, with an open and flexible process, they will ground their reasoning in reconcilable evidentiary balancing and factfinding, rather than contradictory legal frameworks. Further, clarification from the Federal Circuit will teach practitioners which evidence is worth investing time and resources in presenting, and a flexible framework will lead to each side presenting their best case rather than a limited array of legally acceptable evidence. Third, intent in Hatch-Waxman suits centers on the proposed generic drug label, with stricter courts refusing to look beyond the label.[122] This rigidly grounded approach suffers from the impermanence of the label.

As the guardian of uniformity in the patent system, the Federal Circuit has an obligation to clarify the contradictions in its precedent regarding intent to induce infringement, especially in Hatch-Waxman disputes. In doing so, the court should adopt a flexible framework for evaluating intent.

[121] *See supra* Part III.B.

[122] *See supra* Part III.