United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Judge Leonard P. Stark.

ON PETITION FOR REHEARING EN BANC

JUANITA ROSE BROOKS, Fish & Richardson, P.C., San Diego, CA, filed a response to the petition for plaintiffs-appellants. Also represented by MICHAEL ARI AMON, CRAIG E. COUNTRYMAN, JONATHAN ELLIOT SINGER; ELIZABETH M. FLANAGAN, MICHAEL J. KANE, Minneapolis, MN; NITIKA GUPTA FIORELLA, DOUGLAS E. MCCANN, Wilmington, DE.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, filed a petition for rehearing en banc for defendant-cross-appellant. Also represented by JAIME SANTOS;

ELAINE BLAIS, ROBERT FREDERICKSON, III, CHRISTOPHER T. HOLDING, ALEXANDRA LU, LANA S. SHIFERMAN, DARYL L. WIESEN, Boston, MA.

MATTHEW S. HELLMAN, Jenner & Block LLP, Washington, DC, for amicus curiae Association for Accessible Medicines. Also represented by ASHWINI BHARATKUMAR; JEFFREY FRANCER, The Association for Accessible Medicines, Washington, DC.

ANDREW M. ALUL, Taft, Stettinius & Hollister, LLP, Chicago, IL, for amicus curiae Apotex Inc.

STEFFEN NATHANAEL JOHNSON, Wilson Sonsini Goodrich & Rosati, Washington, DC, for amicus curiae Mylan Pharmaceuticals Inc. Also represented by JOHN BERNARD KENNEY, GEORGE E. POWELL, III; WENDY L. DEVINE, TUNG ON KONG, San Francisco, CA; ADAM WILLIAM BURROWBRIDGE, McDermott Will & Emery, Washington, DC.

WILLIAM BARNETT SCHULTZ, Zuckerman Spaeder LLP, Washington, DC, for amicus curiae Henry A. Waxman. Also represented by MARGARET DOTZEL, CASSANDRA TROMBLEY-SHAPIRO JONAS.

CHARLES DUAN, Washington, DC, for amici curiae Michael Carrier, Michael Carroll, Bernard Chao, Samuel F. Ernst, Yaniv Heled, Amy Kapczynski, Mark A. Lemley, Lee Ann Wheelis Lockridge, Christopher Morten, Tyler T. Ochoa, Luigi Palombi, Ana Santos Rutschman, Joshua David Sarnoff, Jason Michael Schultz.

Before MOORE, *Chief Judge*, NEWMAN, DYK, PROST, O'MALLEY, REYNA, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.*

MOORE, *Chief Judge*, with whom NEWMAN, O'MALLEY, TARANTO, CHEN, and STOLL, *Circuit Judges*, join, concurs in the denial of the petition for rehearing en banc.

PROST, *Circuit Judge*, with whom DYK and REYNA, *Circuit Judges*, join, dissents from the denial of the petition for rehearing en banc.

DYK, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

REYNA, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

O R D E R

Teva Pharmaceuticals USA, Inc. filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited. The court also accepted amicus briefs filed by Apotex, Inc.; the Association for Accessible Medicines; Mylan Pharmaceuticals Inc.; Henry A. Waxman; and 14 Professors of Law. The petition was first referred to the panel that heard the appeal, which denied panel rehearing. Thereafter, the petition was referred to the circuit judges who are in regular active service. The court conducted a poll on request, and the poll failed.

Upon consideration thereof,

IT IS ORDERED THAT:

---

* Circuit Judge Lourie and Circuit Judge Cunningham did not participate.

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

FOR THE COURT

February 11, 2022
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Chief Judge Leonard P. Stark.

MOORE, *Chief Judge*, with whom NEWMAN, O'MALLEY, TARANTO, CHEN, and STOLL, *Circuit Judges*, join, concurring in the denial of the petition for rehearing en banc.

The dissents advance, as bases for en banc review, legal positions that Teva has not asserted or developed. Teva never objected to the admission of the partial label as evidence, and in this court, it never challenged the jury's finding on the separately instructed requirement that it knew that the uses it was encouraging would infringe. Besides challenging causation (not raised by the dissents), Teva challenged, as to the partial label period, the jury's verdict that Teva actively encouraged certain patent-covered uses,

including one (for post-MI LVD) it retained as an indication on its partial label. But Teva did not argue to the panel, and has not argued on rehearing, that GSK's representations to the FDA constituted a bar to admission of the partial label or to satisfaction of the inducement liability standard during the partial label period. But that is the legal position advanced in the dissents, whether under a theory that those communications preclude meeting the encouragement element or under a preemption theory. Prost Dis. 2–4; *accord* Dyk Dis. 2–3; Reyna Dis. 2.

What the parties presented to the panel was the question whether, considering all the facts, substantial evidence supports the jury's verdict that Teva actively encouraged infringement. To be sure, Teva cited and discussed the FDA's regulatory framework. *See* Prost Dis. 7. But it did so only as background and support for its cobbling together argument. Teva never argued that there was a conflict between the FDA regulatory framework and patent law (as the dissents now claim); nor did it argue that the partial label was not evidence relevant to or otherwise impermissible for deciding inducement (as the dissents now suggest). Teva cited GSK's representations to the FDA to try to refute GSK's contention that one of the indications Teva retained on its partial label (use for post-MI LVD) was an infringing use, not to present the broader legal positions the dissents advance.

The majority reinstated the jury's verdict as supported by substantial evidence. Specifically, it answered the encouragement question (the subject of the dissents) based on all the evidence presented below—including the labels, press releases, testimony, marketing materials, and the GSK representations.[1] The majority discussed how Teva's

---

[1] GSK "presented extensive expert testimony along with Teva's marketing efforts, catalogs, press releases, and

compliance with GSK's representations to the FDA was "contrary . . . evidence" to GSK's argument that Teva's partial label "instructed physicians to prescribe carvedilol for an infringing use." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1330–33 (Fed. Cir. 2021). As district courts have already recognized, the majority's decision is narrow and fact dependent. *See* Memorandum Opinion at 5, *Amarin Pharma, Inc. v. Hikma Pharma. USA Inc.*, No. 1:20-cv-1630 (D. Del. Jan. 4, 2022).

Teva's petition for rehearing is no broader. The petition focuses on a single argument (causation aside): that the majority "eviscerate[d] this Court's construction of § 271(b)'s active encouragement element." Pet. 2. It faults the majority for looking to "testimony that disparate portions of the label mention or meet individual claim limitations." Pet. 13. Rephrased, Teva presents the "cobbling together" argument from Judge Prost's panel dissent for full court review. *See GlaxoSmithKline*, 7 F.4th at 1349–53 (Prost, J., dissenting). Teva's focus—cobbling together—is clear:

> As to rehearing, Teva's petition set forth the statutory carve-out provision and presented its first question for review as: Where a product has substantial noninfringing uses and the defendant has deleted instructions to practice the patented method from its labeling, may the plaintiff prove

---

testimony from Teva's own witnesses, showing that Teva encouraged carvedilol sales for CHF despite its attempted carve-out." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021). Teva's press releases on its website expressly encouraged doctors to prescribe carvedilol *for the treatment of congestive heart failure*. *Id.* at 1335–37. And there was testimony that doctors read and rely upon press releases and that Teva told doctors to look to its website for prescribing information.

> active inducement *by claiming that several disparate sections of the labeling "met" or "satisfied" the individual elements of the patented method, or does proof of active inducement require proof that the defendant encouraged the patented method*?

Id. (quoting Pet. viii); *see also* Pet. 11–15. The dissents abandon this cobbling together argument in favor of seeking en banc adoption of different legal positions.[2]

Ultimately, it is a sense of fairness that drives the dissents to advance these positions. They believe Teva's partial label cannot be evidence of the intent required for active encouragement when Teva "play[ed] by the skinny-label rules." Prost Dis. 4; *accord* Prost Dis. 5; *see also* Dyk Dis. 2–3. And they cannot see how it would be fair for Teva to be "liab[le] for using a label required by the FDA." Dyk Dis. 1; *accord* Prost Dis. 4. On the other hand, they view Teva's conduct as blameless. Prost Dis. 4 ("Ultimately, if playing by the skinny-label rules doesn't give generics some security from label-based liability, generics simply won't play. And who could blame them?"); *accord* Dyk Dis. 2 ("Teva was obligated to use the label at issue.").

---

[2] And for good reason: the cobbling together argument is a nonstarter. We regularly allow claim elements to be found in different portions of a label. *See, e.g.*, *Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017). FDA regulations and guidance even instruct applicants to break out drug indications, dosages, and clinical studies into *separate* sections. *See, e.g.*, 21 C.F.R. § 201.57(c) (listing requirements for different subsections for indications, dosage, and clinical studies); *Prescription Drug Labeling Resources*, U.S. Food & Drug Admin. (last accessed January 30, 2021), https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources.

I too am concerned that GSK's representations to the FDA are at odds with its enforcement efforts in this case. It would be troubling to hold Teva liable for relying on GSK's representations to the FDA. But that concern does not readily fit the standards governing inducement, given the sufficient evidence of active encouragement and that Teva never disputed in this court the jury's finding that it knew that the uses it encouraged, through the partial label and otherwise, infringed. On the other hand, it fits squarely within the affirmative defense of equitable estoppel that Teva pleaded and that the district court must still decide on remand. Teva alleged, "GSK's failure to communicate to Teva or FDA that the Post-MI LVD was an alleged infringing use of the '000 patent led Teva to reasonably infer that GSK did not intend *to enforce* its patent against Teva for the use of carvedilol for Post-MI LVD." Answer ¶ 100, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, No. 1:14-cv-0087 (Feb. 9, 2016) (pleading equitable estoppel).

Equitable estoppel, a doctrine designed to avoid injustice, has three elements: misleading conduct, reliance, and prejudice. *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130 (Fed. Cir. 2013). The patentee's conduct must "lead[] the alleged infringer to reasonably infer *that the patentee does not intend to enforce its patent against the alleged infringer*" in circumstances presented in the patentee's later enforcement suit. *Id.* (emphasis added). And the alleged infringer must rely on that belief to its detriment, altering its conduct because the patentee removed any threat of litigation. *See id.* Estoppel focuses on the patentee's conduct in communicating a relied-on message of non-enforcement, rather than the accused infringer's intent to encourage others to engage in infringing conduct or even the accused infringer's own knowledge or beliefs about infringement.

The dissents' fairness concerns—which are limited to the partial label period—track this three-element framework precisely. First, the dissents claim GSK

misrepresented its patent rights, "provid[ing] a sworn declaration to the FDA that identified *only* the CHF use as still patent-covered." Prost Dis. 2. Second, they note how Teva "faithfully followed" that representation. Prost Dis. 3; *accord* Dyk Dis. 2. And third, the dissents blame GSK for suing Teva despite its representations to the FDA. Prost Dis. 2 ("GSK sued nonetheless. . . . Never mind that GSK hadn't said this language was patent-covered."); *accord* Dyk Dis. 2. This theory fits the textbook structure of an equitable estoppel argument. And as Teva pleaded the defense, consistent with case law, the theory is not dependent on the "hallmark of inducement"—Teva's culpable intent defined by the inducement elements of active encouragement of acts known to be infringing. *See* Prost Dis. 3. Teva's allegation does not demand proof of how the FDA process affected Teva's knowledge or intent required for the inducement elements. It focuses on GSK's conduct in communicating a message of non-enforcement and Teva's reliance on that message.

Judge Prost "ha[s] doubts that an equitable-estoppel theory applies here," Prost Dis. 9, but that hesitancy does not match Teva's allegation of equitable estoppel and its supporting case law. She claims "the panel majority already undercut [equitable estoppel]" by saying "a generic may not rely upon the Orange Book use codes provided by the brand *for patent infringement purposes*." Prost Dis. 9 (quoting *GlaxoSmithKline*, 7 F.4th at 1332). But this statement is directed at infringement, not estoppel. *See also, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1332 ("GSK's submissions to the FDA are not absolutely dispositive *of infringement*."). Equitable estoppel applies when the alleged infringer has a reasonable belief, based on the patentee's representations, that the patentee *will not sue*—which is precisely what Teva alleged in its answer here, consistent with what our case law deems sufficient, *e.g., Radio Sys. Corp.*, 709 F.3d at 1130. An infringer can both know its label infringes (as Teva did here) and reasonably believe

the patentee will not sue (as Teva alleges here). Estoppel here is about Teva's belief about whether GSK will enforce, not Teva's infringement or even its beliefs about what constitutes infringement. That, in a nutshell, makes equitable estoppel the natural vehicle to address the concerns the dissents express over GSK's representations to the FDA.

In fact, the dissents' arguments parallel our treatment of patentees' representations to standards setting organizations, a context in which we have relied on equitable estoppel to resolve nearly identical concerns. "A member of a[] standard setting organization may be equitably estopped" from "assert[ing] infringement claims against standard-compliant products" based on the patentee's conduct in the standard setting organization that, under the organization's rules, would reasonably be understood as a representation of nonenforcement against products following a particular standard. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1347–48 (Fed. Cir. 2011). Essentially, the dissents (and Teva) claim GSK engaged in the same type of nonenforcement-communicating conduct in the FDA.

Importantly, equitable estoppel could remedy the dissents' concerns completely. In most cases, "[e]quitable estoppel serves as an absolute bar to a patentee's infringement action." *John Bean Techs. Corp. v. Morris & Assocs., Inc.*, 887 F.3d 1322, 1327 (Fed. Cir. 2018). And it is well established that "[e]quitable remedies must be flexible." *Freeman v. Pitts*, 503 U.S. 467, 487 (1992). At a minimum, a finding of equitable estoppel by the district court would result in the exclusion of the label as evidence of inducement during the partial-label period. Excluding the partial label as evidence (a remedy never requested by Teva) would require a new trial. If the district court finds GSK's representations trigger estoppel, it has the discretion to craft a just remedy—which could even eliminate the

need for a new trial. But we should leave the equitable question to the district court in the first instance.[3]

We should not grant Teva's en banc petition to consider altering our settled inducement law standards based on fairness concerns that are central to the equitable estoppel defense not yet addressed. Let us allow the district court to address these fairness concerns by adjudicating that defense on remand. If the result is unsatisfying, we will surely have a chance to review it. I concur in the denial of rehearing en banc.

---

[3] And in future cases, if equitable estoppel applies in circumstances like those presented by the partial label period here, the issue could be decided early, entirely obviating the need for a trial on inducement for the period covered by the estoppel.

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Judge Leonard P. Stark.

PROST, *Circuit Judge*, with whom DYK and REYNA, *Circuit Judges*, join, dissenting from the denial of the petition for rehearing en banc.

The court's decision not to rehear this case en banc is disappointing. The issues in this case, at the intersection of patent law and pharmaceutical regulation, are unquestionably important—affecting millions of Americans. The panel majority's treatment of these issues has raised enough alarm to warrant the full court's attention. As the circuit court vested with exclusive jurisdiction to review such issues, it was our responsibility to do so here. I respectfully dissent from what I view as the court's abdication of that responsibility.

This case concerns the Hatch-Waxman Act's skinny-label provisions, enacted to "speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Typically, brand-drug patents forestall generics' market entry. But all patents eventually expire. And, once patents no longer cover a brand drug itself and an FDA-approved use of it, a cheaper, generic version of that drug may come to market with a "skinny" label—one that copies the brand's label but omits, or "carves out," any uses for which the brand still holds a patent (leaving behind just unpatented uses). Regulations require the brand to identify exactly what label language corresponds to its patented uses, thus eliminating any guesswork as to what needs omitting to avoid infringement. This is the pathway Congress paved for generics. It sorts out the patent issues up front and assures generics that they may launch a product for unpatented uses without violating a brand's patent rights.

Teva, the generic here, followed that pathway. The patent on carvedilol expired in 2007. Teva then sought to market a generic version of carvedilol, which had three FDA-approved uses: hypertension, left ventricular dysfunction following myocardial infarction ("post-MI LVD"), and congestive heart failure ("CHF"). GSK, the brand, had provided a sworn declaration to the FDA that identified *only* the CHF use as still patent-covered. So, Teva carved out the CHF language GSK identified and came to market with its FDA-blessed, brand-compliant skinny label.

GSK sued nonetheless. It alleged that, by leaving post-MI LVD language on the skinny label, Teva induced infringement—i.e., intentionally encouraged something it knew was infringing, *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760, 766 (2011). Never mind that GSK hadn't said this language was patent-covered. GSK's theory was that, even with the CHF language properly carved out, remnants of the skinny label pertaining to post-MI LVD could be pieced together to spell out the patented CHF

use, thus showing Teva's culpable intent—the hallmark of inducement, *see Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 934–37 (2005). A jury found for GSK, the district court granted JMOL of no inducement, and GSK appealed.

The panel majority reinstated the inducement verdict, though it needed a couple of tries to justify how. Its first opinion was difficult to defend and was quickly abandoned. Its revised opinion (designated "per curiam" this time) is, ironically, more problematic than the first. That's because it leans heavily on the skinny label itself—with the CHF language carved out—as evidence that Teva induced infringement of the patented CHF method. In particular, the panel majority embraces GSK's theory that Teva's culpable intent could be found in various remaining portions of the label that "met" or mentioned the elements of the patent claim. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1328–29 (Fed. Cir. 2021). As to the statutory and regulatory process that gave rise to the skinny label—including that GSK's sworn filings never said this language was patent-covered—the panel majority's treatment is quite unsatisfactory. It refuses to confront the obvious question: how could this label, which faithfully followed what the brand said about its own patents and which the FDA required Teva to use, *itself* be evidence that Teva *intentionally encouraged* something it *knew* would infringe?

Now, no skinny-label generic is safe. Using this statutory pathway—and following the brand's directions—becomes just another fact thrown into the mix when assessing a generic's intent. And, as amici observe, because most skinny labels contain language that (with clever expert testimony) could be pieced together to satisfy a patent claim, essentially all of these cases will now go to trial. *See, e.g.*, Apotex Amicus Br. 7 (lamenting that brands will always "be able to present expert testimony at trial showing that physicians will subjectively 'understand' the generic's label to 'show' or 'meet' elements of the claimed

methods" (cleaned up)); Mylan Amicus Br. 1 (noting that, under the panel majority's "'Where's Waldo?' approach to reading labels," "[g]enerics cannot know if their labels are 'true' carve-outs until the jury speaks—years into litigation, itself filed years after the product launched").

The system can't work like this. Congress enacted the skinny-label provisions as a way for generics to *avoid* inducement liability—and thus litigation itself. Under the statute, "a generic drug must bear the same label as the brand-name product," *Caraco*, 566 U.S. at 406 (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G)), except for certain acceptable differences allowed by FDA regulation, including the "omission of an indication or other aspect of labeling protected by patent," 21 C.F.R § 314.94(a)(8)(iv). The FDA "rel[ies] on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book" to determine "whether an ANDA applicant can 'carve out' the method of use." Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003).

When a generic plays by the skinny-label rules, the FDA-required label can't be evidence of intent. Even *if* remaining label language might be pieced together to "meet" the elements of a patent claim, the extent to which that's true is an unreliable gauge of a generic's "intent" in this highly regulated area; it can't meaningfully separate the liable from the lawful. That's especially so given that it's the *brand* who dictates what label language is omitted—and thus what language *remains*. Indeed, the panel majority's decision doesn't just eliminate a generic's ability to depend on the skinny-label system; it also gives brands a powerful tactic: neglect to identify language as patent-covered, then sue a generic for including that very language.

Ultimately, if playing by the skinny-label rules doesn't give generics some security from label-based liability, generics simply won't play. And who could blame them? The

risk is too great. Generics sell their products for considerably less than brands, so a jury's award of lost profits to the brand can dwarf whatever profits a generic could make. Here, for example, Teva's *revenues* (it made no profit) from selling carvedilol were $74 million, yet it owes GSK $234 million in lost-profit damages. It seems implausible that Congress, when enacting the skinny-label provisions against the backdrop of the inducement statute, intended to put generics in this position.

The Hatch-Waxman Act was a seminal patent act—containing hard-fought compromises as the product of extended negotiations and stakeholder involvement. Congress's effort deserved better from this court.

* * *

To conclude, I offer a few comments about the concurrence.

The panel majority and dissent agreed on one thing: the undisputed facts of Teva's skinny-label compliance are relevant to inducement. *Compare, e.g.*, *GlaxoSmithKline*, 7 F.4th at 1331 (panel majority recognizing that "GSK's failure to identify the post-MI LVD use" in its patent declarations "is relevant to intent to induce infringement"), *with id.* at 1342 (Prost, J., dissenting) (questioning why "the majority finds it reasonable to infer that Teva *intentionally encouraged* infringement . . . . even though Teva, by carving out everything that GSK said would infringe, was trying to *avoid* having its label encourage infringement"). The opinions' disagreement concerned the legal significance of these facts. The majority dismissed the skinny-label compliance as mere "contrary or equivocal evidence" over which the jury could have still found that the skinny label showed inducement. *Id.* at 1331. I maintained in dissent—as I do now—that these facts prevent the skinny label from showing inducement. *Compare, e.g.*, *id.* at 1351, 1357 ("That Teva first carved out exactly what GSK said would infringe should settle the question of what

intent could be reasonably inferred from the label itself on these facts."), *with supra* at 4 ("When a generic plays by the skinny-label rules, the FDA-required label can't be evidence of intent."). This was, and remains, the dispute. None of this is new.

What's new is the concurrence's justification for the panel majority's decision. Still lacking a persuasive response to the argument that Teva's skinny-label compliance prevents its label from showing inducement, the concurrence now urges that the argument was never really there—that we didn't discuss it at length. In particular, the concurrence now offers a hodgepodge of forfeiture-like rationales to suggest that the argument wasn't made specifically enough. Moore Concurring Op. 1–2. None of these rationales appeared in the panel majority's opinion (which is unsurprising, given that the panel majority addressed and rejected the argument on its merits). *GlaxoSmithKline*, 7 F.4th at 1331–33. That uncomfortable fact makes it rather awkward for the concurrence to now maintain, here at the last minute, that the argument wasn't properly before us after all.[1] If it were *really* the case that this argument (or some aspect thereof) wasn't properly before us, I imagine the panel majority would have said so.

---

[1] For example, the concurrence says that "Teva cited GSK's representations to the FDA to try to refute GSK's contention that one of the indications Teva retained on its partial label (use for post-MI LVD) was an infringing use, not to present the broader legal positions" this dissent advances. Moore Concurring Op. 2. Yet the panel majority didn't understand Teva's argument to be so narrow; it allowed that GSK's FDA representations were relevant *both* "to whether the post-MI LVD use infringe[d]" *and* "to intent to induce infringement." *GlaxoSmithKline*, 7 F.4th at 1331. The concurrence declines to acknowledge this portion of the opinion.

But of course, it's not the case. Teva made this straightforward argument to the panel. It argued that "[GSK's] attempt to cobble together scattered references to 'heart failure' is not proof of inducement *given Teva's actions in carving out this very indication*." Teva's Principal & Resp. Br. 50 (emphasis added). Teva then highlighted GSK's failure to identify the post-MI LVD use in its patent declarations, argued that "[t]he very purpose of use codes is to give generic manufacturers notice of what uses they would need to carve out to *avoid infringement*," and explained that it "carved out the listed CHF indication so it could launch, precisely as Congress intended." *Id.* at 50–52 (emphasis added) (citing GSK's patent declarations at J.A. 6880–87, 6894–907); *see also id.* at 9, 12–15 (outlining the statutory carve-out process, related regulations, GSK's patent declarations, and how the FDA instructed Teva to use the skinny label based on GSK's representations).

I therefore don't see how the concurrence can credibly maintain, for example, that "Teva never argued that there was a conflict between the FDA regulatory framework and patent law," or that the skinny label was "impermissible for deciding inducement." Moore Concurring Op. 2; *see id.* (maintaining that "Teva did not argue" that "GSK's representations to the FDA constituted a bar to . . . satisfaction of the inducement liability standard during the partial label period"). Nor is it credible to say that this dissent "advance[s] . . . legal positions that Teva has not asserted or developed." *Id.* at 1.[2]

As to rehearing, Teva's petition set forth the statutory carve-out provision (21 U.S.C. § 355(j)(2)(A)(viii)) and

---

[2] Although the concurrence at times says that this dissent has "not raised" or has even "abandon[ed]" a point included in the panel dissent, Moore Concurring Op. 1, 4, I maintain the points made in my panel dissent, *see GlaxoSmithKline*, 7 F.4th at 1342–61.

presented its first question for review as: "Where a product has substantial noninfringing uses *and the defendant has deleted instructions to practice the patented method from its labeling*, may the plaintiff prove active inducement . . . ?" Teva's Pet. for Reh'g vii–viii (emphasis added). It complained that the majority "held that Teva's *skinny label* induced infringement, too—even though Teva had omitted everything that *GSK told FDA* corresponded to its patented method-of-use." *Id.* at 2; *see id.* at 4–5 (describing the carve-out process and GSK's sworn declarations), 11 (noting that Teva "carv[ed] out the CHF indication as FDA instructed"), 18 (arguing that "the panel opinion makes clear that following FDA's instructions, based on the brand's explicit claims, is no safe harbor").[3] And amici uniformly made this point in supporting rehearing. Ass'n for Accessible Meds. Br. 7; Apotex Br. 8–9; Law Professors' Br. 3–5; Mylan Br. 5, 10–11; Waxman Br. 6–7.

Put simply: this argument was made to the panel, the panel addressed it on its merits, and the majority resolved it against Teva. *GlaxoSmithKline*, 7 F.4th at 1331–33.[4] If the concurrence now truly believes that this argument is somehow new, then the panel majority should revise its

---

[3] The concurrence insists that the "focus" of Teva's rehearing petition concerned what language remained on the skinny label. Moore Concurring Op. 3–4. But if Teva's argument relied solely on the post-carve-out label language—to the exclusion of the carve-out *itself*—there would have been little point in explaining the regulatory process, or why it removed the language it did.

[4] Although the concurrence now suggests that this case involves just an ordinary substantial-evidence question, Moore Concurring Op. 2, I note that such questions at this court typically do not produce two panel opinions, two dissents, two rehearing processes, and over a dozen amicus briefs throughout.

opinion (yet again) to say as much, thus leaving the argument open for a future skinny-label generic to make. But it won't do that. It keeps binding precedent that rejects this argument on its merits, while justifying that decision by acting as though the argument was never really there.

Regardless of how it's styled, the concurrence has to admit that there's a problem here. Moore Concurring Op. 5 ("It would be troubling to hold Teva liable for relying on GSK's representations to the FDA."). But instead of *inducement*, the concurrence maintains that the facts surrounding Teva's Hatch-Waxman compliance go only to the judge-made doctrine of equitable estoppel—a position that no party has endorsed. Nevertheless, I address that theory briefly.

I have doubts that an equitable-estoppel theory applies here. For one, the panel majority already undercut that theory. As the concurrence (accurately) observes, equitable estoppel requires Teva to have relied on GSK's conduct (i.e., GSK's patent declarations). Moore Concurring Op. 4–6. Yet the panel majority characterized Teva's expert as having "agreed that a generic *may not rely* upon the Orange Book use codes provided by the brand for patent infringement purposes," somehow implying that Teva may not rely on the skinny label itself. *GlaxoSmithKline*, 7 F.4th at 1332 (emphasis added); *id.* at 1331–32 (emphasizing a generic's purported independent duty to analyze a brand's patents).

More globally, however, equitable estoppel is a general defense—"no[t] subject to resolution by simple or hard and fast rules"—for which the accused infringer bears the burden, and whose application rests with the trial court's discretion. *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1041–43 (Fed. Cir. 1992) (en banc), *abrogated on other grounds by SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954 (2017). I'm not aware of any indication that Congress, when

enacting this specific statutory skinny-label system (implemented by copious detailed regulations), intended to stake the efficacy of that system on a generic's case-by-case equity showing.

Contrary to the concurrence's characterization, my concerns here do not go merely to fairness. My concerns go to what inducement law permits in view of the Hatch-Waxman Act. And, as I've said from the start, I do not believe that Teva's compliant skinny label supports an inducement finding.

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Judge Leonard P. Stark.

DYK, *Circuit Judge*, dissenting from the denial of the petition for rehearing en banc.

I join Judge Prost's dissent and write separately to further elaborate why there cannot be infringement liability for using a label required by the FDA during the partial label period at issue in this case.

Generic manufacturers are statutorily obligated to use "the same label as the brand-name product," *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(v), (j)(4)(G)), except for certain differences allowed by FDA regulation, including the "omission of an indication or other aspect of labeling protected by patent," 21 C.F.R. § 314.94(a)(8)(iv). The

"indication or other aspect of labeling protected by patent" is determined by the patentee's submissions to the FDA. The FDA relies on these patentee submissions to determine "whether an ANDA applicant can 'carve out' [a] method of use." Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003); *see also* 21 C.F.R. § 314.53(b)(1) (Any applicant who submits an NDA must "separately identify each pending or approved method of use and related patent claim(s)" for each patent "with respect to which a claim of patent infringement could reasonably be asserted . . . .").

Here, GSK's brand label contained three indications: congestive heart failure, left ventricular dysfunction following myocardial infarction, and hypertension. GSK twice submitted patent information to the FDA identifying congestive heart failure as the only method of use claimed by its patents. The FDA provided Teva with a redline for its skinny label, carving out the patented indication for congestive heart failure from GSK's branded label and keeping the remaining uses in the label. Teva amended the label for its ANDA using the text provided by the FDA. Thus, Teva was obligated to use the label at issue.

In similar circumstances where states have sought to impose tort liability on generic drug manufacturers for using the label required under federal law, the Supreme Court has made clear that federal law preempts tort liability on the part of the manufacturers. *See Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013) ("[S]tate-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law . . . ."); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 609 (2011) ("[F]ederal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt" state-law tort claims). The Supreme Court has recognized that "[i]nfringement, whether direct or contributory, is essentially a tort . . . ." *Carbice Corp. of Am. v. Am. Pats. Dev. Corp.*, 283 U.S. 27, 33 (1931). Here, as in *Mutual* and *PLIVA*, there is a direct

conflict between the FDA-required labelling and the supposed requirements of federal patent infringement law. Canons of statutory construction demonstrate that the more specific and later-enacted provisions of the Hatch-Waxman Act override the general infringement provisions of the Patent Act. *See, e.g.*, *United States v. Estate of Romani*, 523 U.S. 517, 532 (1998) ("later" and "more specific" statute governs); *Morton v. Mancari*, 417 U.S. 535, 550–51 (1974) ("Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment." (first citing *Bulova Watch Co. v. United States*, 365 U.S. 753, 758 (1961); and then citing *Rodgers v. United States*, 185 U.S. 83, 87–89 (1902))). It is hard to see how Congress could have intended that a mandated label could be used as evidence of infringement.

The concurrence recognizes that there is a potential fairness issue but suggests that the problem can be solved by an affirmative defense of equitable estoppel. Moore Concurring Op. 4–6. This theory is a poor fit for the facts of this case. The problem is not with GSK's submissions to the FDA,[1] but with GSK's reliance on the FDA-required skinny label as evidence of intent to induce infringement.

Finally, the concurrence suggests that Teva forfeited these arguments. Moore Concurring Op. 1. As Judge Prost notes in her dissent, Teva fairly raised these issues in its

---

[1] FDA regulations provide that "[i]f the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted . . . ." 21 C.F.R. § 314.53(b)(1). GSK accurately described the patent scope to the FDA. *See* GSK Opening Br. at 33; GSK Reply Br. at 31.

briefing and petition for rehearing. Prost Dis. 6–8. I respectfully dissent.

United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LIMITED,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Cross-Appellant

2018-1976, 2018-2023

Appeals from the United States District Court for the District of Delaware in No. 1:14-cv-00878-LPS-CJB, Chief Judge Leonard P. Stark.

REYNA, *Circuit Judge*, dissenting from denial of the petition for rehearing en banc.

I dissent from the court's decision to abstain from addressing en banc the important issues sparked by the majority opinion. This court's Internal Operating Procedure No. 13(2)(b) provides that en banc consideration is warranted for issues of exceptional importance. As evidenced by the briefs, the majority opinion, the dissent, and the number of amicus briefs filed to date, I believe this case involves an issue of exceptional importance. I am concerned that, if left untouched, the majority's opinion may reasonably be read to mean that companies like Teva may be held liable for induced infringement despite

demonstrated compliance with the statutory and regulatory requirements to carve out everything from a skinny label that the patent owner (GSK) itself designated as covered by its patent. I am doubly concerned that the majority opinion could be read to support such a finding of induced infringement where evidence as to intent is scant at best. Combined, these two factors portend instability in the general ANDA process and, specifically, the skinny label process, an area of patent law where we should affirmatively seek to maintain certainty and predictability as best as possible.