Nos. 18-1976, 18-2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

GLAXOSMITHKLINE LLC and SMITHKLINE BEECHAM (CORK) LIMITED,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Cross-Appellant.

Appeal from the U.S. District Court for the District of Delaware,
No. 1:14-cv-00878-LPS-CJB (Stark, C.J.)

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF REHEARING EN BANC

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October 21, 2021

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Association for Accessible Medicines certifies the following information and any attached sheets are accurate and complete to the best of my knowledge.

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Association for Accessible Medicines.

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

See above: same as entities.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Not applicable.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Not applicable.

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

GlaxoSmithKline LLC et al. v. Glenmark Pharmaceuticals Inc., USA, No. 1:14-cv-877 (D. Del.).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not applicable.

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AAM	Association of American Medicines
ANDA	Abbreviated New Drug Application (generic drug application)
FDA	Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
GSK	Plaintiffs-Appellants GlaxoSmithKline LLC and SmithKline Beecham (Cork) Limited
Hatch-Waxman	Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (formally, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585)
Post-MI LVD	Post-myocardial infarction left ventricular dysfunction
Section viii	21 U.S.C. § 355(j)(2)(A)(viii)
Teva	Defendant-Cross-Appellant Teva Pharmaceuticals USA, Inc.

INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve patient lives by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet account for only 18% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

Amicus and its members have a significant interest in the issues raised by Teva's petition for rehearing en banc: namely, whether generic pharmaceutical manufacturers can be held liable for inducing infringement when their FDA-approved labeling excludes patented indications of the

[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than *amicus*, its members, and its counsel contributed money to fund the preparation and submission of this brief, and all parties consent to the filing of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

drug consistent with the Federal Food, Drug, and Cosmetic Act (FDCA). By allowing massive damages whenever pharmacists lawfully fill prescriptions with generics for patented off-label uses—even when generics purposely omit (*i.e.*, "carve out") those uses from FDA-approved labeling and do not encourage off-label use—the panel's decision nullifies the so-called "skinny-label" regime Congress adopted in the FDCA.

INTRODUCTION

AAM and its members urgently request that the full Court review this case. After a first rehearing petition, the panel sought to correct its decision in light of concerns expressed by AAM and others that the Court had undermined Congress's decision to allow generic manufacturers to omit patented uses from their labels to allow generics to come to market. Maj. 10, 28 n.7. The sequel, however, is worse than the original. Far from correcting the original decision's harms to the "skinny label" regime, the new decision "exacerbates" them. Dissent 38.

Put simply, inducement requires proof of *intentional* infringement, yet the panel decision holds Teva liable for inducement based on label language that the law *required* Teva to include. Complying with the law is not intentional infringement. Worse yet, Teva had to include that language

precisely because the brand manufacturer—and FDA, which relies upon the brand's assertions regarding patent scope—did not identify the information as covered by the patented use. The result is that a brand manufactuer can lie in wait for years while a generic manufacturer employs an FDA-required label dictated by the brand's disclosures. The brand manufacturer can then sue for hundreds of millions of dollars in infringement damages on the ground that passages of the label—snippets that the brand manufacturer did *not* identify as being covered by the patent, that FDA determined *cannot* be carved out, and that the law thus *required* the generic to include—supposedly induce infringement. That is not the law of inducement nor is it the law of Hatch-Waxman, and it would be difficult for any generic manufacturer to risk using a skinny label if the panel decision is allowed to stand.

As media reports have recounted,[2] branded manufacturers have already started to use the panel decisions to seek prohibitive damages

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[2] *See, e.g.*, Khadijah M. Silver, *Teva's Generic Label Not Skinny Enough To Protect from $234M Damages to GSK*, MedCityNews (Aug. 6, 2021), https://medcitynews.com/2021/08/tevas-generic-label-not-skinny-enough-to-protect-from-234m-damages-to-gsk/; Sara W. Koblitz, *Ding Dong Is the Skinny Label (Effectively) Dead?*, FDA Law Blog (Sept. 7, 2021),

awards against generic manufacturers who have done nothing more than what the law permits—and indeed *intends*—and that FDA has determined is permissible. Those brand manufacturers contend that the panel's revised opinion is just as much of a bar to skinny labels as the prior opinion. Absent review by the full Court, the losers will be American patients, who will be deprived of low-cost, high-quality generic and biosimilar alternatives that are non-infringing.

To secure the patent regime that Congress chose and ensure that the American public has access to generic and biosimilar medicines as Congress intended, this Court must act now to correct the panel's ruling. The petition for en banc rehearing should be granted. At a minimum, given the decision's catastrophic impact on FDA's generic drug program, the Court should not deny rehearing without first inviting the federal government's views. *E.g.*, *Guarantee Co. of N. Am., USA, Inc. v. Ikhana, LLC*, 959 F.3d 1354, 1354 (Fed. Cir. 2020).

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https://www.thefdalawblog.com/2021/09/ding-dong-is-the-skinny-label-effectively-dead/.

ARGUMENT

I. The Skinny-Label Provision Lets Manufacturers Omit Patented Uses to Speed the Availability of Low-Cost Generic and Biosimilar Drugs to Patients and Thereby Save the Public Billions of Dollars.

As part of the Hatch-Waxman Amendments, Congress made the policy decision to let generics "seek approval for less than all of th[e] indications" for which a brand-name drug was approved. *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (quotation marks omitted). This way, brands could not use new method-of-treatment patents to block competitors from selling generics for old, unpatented methods of use. *See Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 414-15 (2012). Congress thus allowed generic applicants to inform the FDA that they seek approval only for unpatented indications. 21 U.S.C. § 355(j)(2)(A)(viii).

Since 1984, patients (and the taxpayers who fund public health programs like Medicare) have saved billions of dollars by using generic versions of expensive drugs for unpatented uses. Skinny labels have proven particularly important for generic competitors of blockbuster drugs where patent owners frequently seek to extend their monopolies by obtaining seriatim method-of-use patents.

For example, Crestor, a branded drug used to treat high cholesterol cost patients and payors $6.2 billion annually before the entry of generics.[3] AstraZeneca's patent on the compound expired in 2016, but AstraZeneca had two method-of-use patents that did not expire until 2018 and 2021.[4] Because the generics were able to omit those patented uses and obtain FDA approval of a skinny label, they were able to enter the market in 2016 rather than waiting until 2021.[5] Patients benefitted immediately from the introduction of generics—the average wholesale cost for the generics was 70% lower than for the branded drug.

II. The Panel Revised Decision Remains at Odds with the Skinny-Label Provision and Cannot be Reconciled with This Court's Inducement Precedents.

Much like its initial decision, the panel's revised decision fundamentally undermines Hatch-Waxman. Far from providing reassurance that a generic manufacturer cannot be held liable for following Congress's skinny-label requirements, the new decision alarmingly

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[3] Eric Palmer, *Nexium, AstraZeneca*, FiercePharma (Oct. 28, 2013), https://www.fiercepharma.com/special-report/nexium-astrazeneca.

[4] FDA, *Petition Denial Response – Final* 19 n.59, No. FDA-2016-P-1485 (July 20, 2016).

[5] *Id.* at 1.

illustrates how a generic may face massive infringement damages for conduct that has never remotely met the standards for inducement under controlling case law.

The crux of the panel's reasoning was that scattered snippets of language on the label—language *not* in the Indications and Usage section and language broadly describing clinical trial patients, that FDA required remain in labeling because it does not identify a protected use—could supposedly be stitched together to constitute inducement. Maj. 14-15. Teva has ably explained why those passages do not even describe an infringing use—let alone encourage one—under this Court's precedents. *See* Petition for En Banc Rehearing at 11-14 (Oct. 7, 2021), ECF No. 195. That conflicts with this Court's prior decisions and provides ample reason to grant review and correct the panel's misstatement of the law. But AAM particularly wishes to emphasize another pernicious aspect of the panel's opinion: Teva was held liable for inducement—which requires specific intent—for using language that it was *required* to include on its label precisely because GSK had *not* included that language as part of the use code it submitted to FDA.

Abbreviated new drug applications ("ANDA") are statutorily obligated to contain "information to show that the labeling proposed for the

new drug *is the same* as the labeling approved for the listed drug. . .." 21 U.S.C. § 355(j)(2)(A)(v) (emphasis added). Critically, when a generic manufacturer seeks to omit a protected use from a label that must otherwise be identical to the brand label, FDA relies on the use code *provided by the brand company* to assess whether a carve-out is permissible. FDA Final Rule, ANDAs and 505(b)(2) Applications, 81 Fed. Reg. 69,580, 69,599-600 (Oct. 6, 2016) ("FDA evaluates the. . . proposed labeling to determine whether the applicant is not seeking approval for the protected use *based on the use code submitted by the NDA holder. . .*") (emphasis added).[6] While FDA may "use its independent scientific judgment to determine which section(s) and/or subsection(s) of labeling contain language that must be carved out based on the use code provided" by the brand manufacturer," the generic manufacturer is bound to include the language on its skinny label that FDA requires.[7] 81 Fed. Reg. at 69,600.

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[6] Additionally, a brand manufacturer should "list the specific section(s) and subsection(s) of the approved product labeling that contain information describing the specific approved method of use claimed by the patent." Instructions for Filling Out Form FDA 3542 , Field 4.2a.

[7] FDA practice confirms this. *See, e.g.*, FDA Letter Decision, Dexmedetomidine Hydrochloride Injection at 8, No. FDA-2014-N-0087 (Aug. 18, 2014). ("[FDA] evaluate[s] what portions of labeling appropriately

In short, the generic manufacturer *must* use the label language FDA requires, and FDA relies on the use code provided by the brand manufacturer. As Judge Prost explained, what is at issue here is GSK's own statements about the scope of its patent: "Teva asked to carve out GSK's patented uses, and the FDA in return used GSK's representations to provide Teva with a carved-out label. The FDA itself took no non-infringement position; GSK did." Dissent 17.

The panel majority responded by claiming that a generic manufactuer is charged with doing its own investigation and "may not rely upon the Orange Book use codes provided by the brand for patent infringement purposes." Maj. 21. But, regardless of any investigation the generic manufacturer does, it *must still* include the label passages FDA requires.[8]

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correspond to the use code provided [by the brand manufacturer] and whether ANDAs may be approvable with labeling that carves out protected information that corresponds to the use code provided."

[8] Indeed, FDA specifically considered and rejected a proposal aimed at addressing the accuracy or relevance of a branded manufacturer's patent use code by giving deference to a generic manufacturer's interpretation of the scope of a patent. 81 Fed. Reg. at 69,581.

This is the procedure Teva followed and relied upon, and for which Teva now faces liability for supposedly intentional inducement.[9]

The panel majority's reasoning does not merely tolerate gamesmanship by branded manufacturers, it richly rewards it. If GSK believed other indications—such as the post-MI LVD indication—were claimed by their method-of-use patents, GSK could have—and was *required* to—designate those claimed indications for the Orange Book. FDA would then have directed Teva to modify its label accordingly. Instead, GSK waited for years before raising an inducement claim. *See* Dissent 13. No generic manufacturer could risk bringing a skinny-label generic to market if that is the law.

III. The Panel Decision Will Deprive Patients of Low-Cost Generic Medicines.

The decision in this case is deeply unjust, but its ramfications extend far beyond this particular dispute. The panel's attack on Hatch-Waxman will harm the millions of American patients who benefit from cost-effective

[9] It is also no answer to say that the decision merely leaves it to the jury to determine whether inducement exists. A rule that exposes a generic manufacturer to a jury verdict and massive damages liability for doing what the law allows—and FDA directs—creates a regime too risky for a generic manufacturer to use.

generic drugs. The decision continues to provide a roadmap for bringing inducement claims that will chill generic availability—even for manufacturers such as Teva that were "about as faithful as it gets" in adhering to Congress's skinny label framework. Dissent 36. If allowed to stand, the panel's revised decision "would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer," by allowing single method-of-use patents accounting for a small fraction of all uses of a drug to stifle the launch of generics. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003). For patients, this means one thing: higher prices.

Industry observers recognize the that the panel's revised decision—like its predecessor—has unsettled the safe harbor previously afforded by the skinny label regime, noting that "[b]randed drug manufacturers and reference product sponsors in skinny label cases may use the GSK opinion as a road map to argue for induced infringement, even when the generic drug manufacturer has expressly carved out the infringing use from the generic's

FDA-approved label."[10] The panel's revised decision makes clear that "the FDA's Skinny-Label Carveout approval process does not create a genuine safe-harbor for the generic launch."[11] Practitioners have observed that the panel's revised decision indicates that "[a]ny amount of evidence can be pieced together to say there is inducement."[12]

Indeed, the panel decision has already transformed brand companies' legal strategies, a telling example of which is a suit involving Amarin, manufacturer of Vascepa® (icosapent). In September 2020, this Court held that Amarin's patents for treating high trigycerides were invalid, paving the way for generic manufacturer Hikma's launch of an FDA-approved generic icosapent. *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, 819 F. App'x 932 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 2794 (2021). On November 30,

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[10] Daniel Knauss, Cameron Vanderwall, & Michelle Rhyu, *Fed. Circ. Teva Ruling May Shake Up Skinny Label Strategies*, Law360 (Sept. 1, 2021), https://www.law360.com/articles/1417824/fed-circ-teva-ruling-may-shake-up-skinny-label-strategies.

[11] Dennis Crouch, *GSK v. Teva: Skinny Label Approval is Not a Patent Safe Harbor*, PatentlyO (Aug. 5, 2021), https://patentlyo.com/patent/2021/08/skinny-approval-patent.html.

[12] Dani Kass, *GSK Redo Doesn't Cure Generics' 'Skinny Label' Uncertainty*, Law360 (Aug. 9, 2021), https://www.law360.com/articles/1410679/gsk-redo-doesn-t-cure-generics-skinny-label-uncertainty (quoting Imron Aly of Schiff Hardin LLP).

Amarin, represented by the same counsel as GSK, filed an inducement suit against Hikma relying on the panel's first holding in this case, even though Hikma had explicitly carved out the patented indication. Compl. ¶¶ 120-143, *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*, No. 1:20-cv-01630 (D. Del. Nov. 30, 2020) ("*Amarin*"), ECF No. 1; First. Am. Compl. ¶¶ 163-186, *Amarin* (Jan. 25, 2021) ECF No. 17, https://bit.ly/3aUOIrJ.

The magistrate recommended denying Hikma's motion to dismiss. The magistrate, citing the panel's prior opinion, found that Amarin had plausibly pled a claim of inducement on the basis of Hikma's omission—at FDA's direction—of language limiting or discouraging use for a patented indication, and pointed to multiple sections of Hikma's label having minimal overlap with the asserted claim limitations to conclude that the label and public statements "could instruct and/or encourage" use for the patented indication. Report and Recommendation at 12-14, *Amarin* (Aug. 3, 2021), ECF No. 64.

Hikma objected to the report, and Amarin opposed, arguing that the panel's new rehearing opinion did "not at all" affect the infringement analysis. Hearing Transcript at 38:19-25, *Amarin* (Oct. 20, 2021), ECF No. 85.; *see also* Plaintiff's Response to Hikma's Objections to Report and

Recommendation at 6-7, *Amarin* (Aug. 31, 2021), ECF No. 78. The case powerfully illustrates that if such allegations are sufficient, carve-outs will become meaningless, and patients and taxpayers will be deprived of more affordable medicines.

CONCLUSION

Amicus respectfully requests that the Court grant Teva's petition for en banc rehearing.

Respectfully submitted,

Dated: October 21, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2021, I caused the foregoing brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which caused a copy of the foregoing to be delivered by electronic means to counsel of record.

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This Brief complies with the type-volume limitation of Fed. R. App. P. 29(b)(4) because this Brief contains 2,592 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b).

2. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this Brief has been prepared in a proportionately spaced typeface using Microsoft Office Word 2016 in Century Expanded LT Std, Font Size 14.

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