Nos. 2018-1976, -2023

IN THE

# United States Court of Appeals for the Federal Circuit

GLAXOSMITHKLINE LLC, SMITHKLINE BEECHAM (CORK) LTD.,

*Plaintiffs-Appellants*,

v.

TEVA PHARMACEUTICALS USA, INC.,

*Defendant–Cross-Appellant.*

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE,
CHIEF JUDGE LEONARD P. STARK

## [CORRECTED] BRIEF OF 14 PROFESSORS OF LAW AS *AMICI CURIAE* IN SUPPORT OF THE PETITION FOR REHEARING EN BANC

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## CERTIFICATE OF INTEREST

Pursuant to Rules 29(a) and 47.4 of the Federal Circuit Rules of Practice, counsel certifies as follows:

(1) The full name of every party or amicus represented by me is **Michael A. Carrier, Michael W. 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 D. Sarnoff, and Jason M. Schultz**.

(2) The above-identified parties are the real parties in interest.

(3) The corporate disclosure statement of Rule 26.1 of the Federal Rules of Appellate Procedure is as follows: There is no parent corporation to or any corporation that owns 10% or more of stock in the above-identified parties.

(4) The names of all law firms and the partners and associates that have appeared for the party in the lower tribunal or are expected to appear for the party in this court, not including those who have entered or are expected to enter an appearance before this court, are: **None**.

(5) The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are: **None**.

(6) All information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees): **None**.

Dated: October 27, 2021

*/s/ Charles Duan*
Charles Duan
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## INTEREST OF *AMICI CURIAE*

*Amici curiae*[1] are 14 professors of law, economics, business, health, and medicine. A list of signatories is attached in Appendix A. Their sole interest in this case is to ensure that patent law develops in a way that serves the public interest and public health by promoting competition.

## SUMMARY OF ARGUMENT

Even as revised, the panel decision raises two exceptionally important questions about how inducement of patent infringement interacts with other laws and policies. The Court should grant en banc review to resolve these questions.

First, the panel's treatment of inducement opens up a direct conflict between patent law and the Hatch–Waxman Act amendments to the Federal Food, Drug, and Cosmetic Act. Those amendments, which enable abbreviated new drug applications (ANDAs), require a generic to use the same labeling as its equivalent brand-name product with only limited exceptions, as part of the carve-out procedure that deals specifically with inducement. By requiring ANDA applicants to

[1]Pursuant to Federal Rule of Appellate Procedure 29(a), all parties received appropriate notice of and consented to the filing of this brief. Pursuant to Rule 29(c)(5), no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

make scattered revisions throughout their labels lest they induce infringement despite FDA approval of the label otherwise, the panel decision conflicts with this aspect of Hatch–Waxman. Importantly, the decision does not merely create dual tracks of liability that ANDA applicants must navigate; it creates a tension *between the laws themselves* insofar as one threatens to frustrate the other. Such a tension must be resolved in the process of statutory construction, which the panel decision failed to do.

Second, the panel relies on product advertisements and government submissions that a product is "equivalent" to another to find inducement of a method-of-use patent. Such a result is problematic insofar as it denies basic comparative product information to consumers. That problem is especially concerning given that statements of product equivalence are found in a range of industries beyond generic drugs, such as biosimilars, mechanical repair parts, and information and communication technology. En banc review is necessary to reevaluate the panel's decision insofar as it potentially creates new and unexpected avenues of patent infringement in all of these fields.

## ARGUMENT

### I. En Banc Rehearing Should Be Granted to Resolve Newly-Created Conflicts Between the Patent Inducement Statute and the Hatch-Waxman Act

In construing patent inducement law in view of Teva's ANDA-proposed labeling, the panel decision failed to consider how the Hatch–Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), *codified at* Federal Food, Drug, and Cosmetic Act (FFDCA) § 505(j), 21 U.S.C. § 355, interacts with construction of the patent inducement statute, 35 U.S.C. § 271(b). En banc rehearing should be granted to resolve this important question and to avoid a serious conflict between the two statutes that has now arisen in view of the panel decision.

#### A. The Statutes Are in Conflict

A statutory conflict exists between the same-labeling requirements of Hatch–Waxman, *see* FFDCA § 505(j)(2)(A)(v), and the panel's expectation that generic ANDA applicants could make disjointed line-edits to their labels in order to avoid inducing infringement. ANDA approval requires that the generic's proposed label be "the same as the labeling approved for the listed drug," except where the FDA permits differences. *Id.*; *accord* 21 C.F.R. § 314.127(a)(7). In particular, differences in labeling to effect patent carve-outs are permissible, but only where the FDA concludes that "such differences do not render the proposed drug product

less safe or effective than the listed drug for all remaining, nonprotected conditions of use." 21 C.F.R. § 314.127(a)(7).

Where the label modification removes contiguous sentences, it is presumably straightforward to determine whether a label carve-out satisfies this exception to the same-labeling requirement. But the panel majority (at 15) found the statements of inducement in Teva's label not in a contiguous block, but in sentences embedded in three separate sections of the label, including the "Dosage and Administration" section. Avoidance of inducement by excising snippets of text across the label—including text on dosing and administration—would likely prompt the FDA to question whether the drug remains safe and effective with that whittled-down label. *See* Ctr. for Drug Evaluation & Research, FDA, *ANDA Submissions—Refuse-to-Receive Standards* 13 (2d rev. Dec. 2016), *available online* (describing alterations to dosing regimens as reason for FDA to reject an ANDA).[2] As a result, the panel's approach to inducement potentially forces ANDA applicants to jeopardize approval in order to avoid inducement of infringement.

This conflict is no mere technicality, but goes to the very heart of the purpose of Hatch–Waxman's carve-out provision under section 505(j)(2)(A)(viii). The "section viii carve-out" exists specifically to enable generic entrants to deal with method-of-use patents prior to ANDA approval. *Caraco Pharm. Labs., Ltd. v. Novo*

[2]Locations of authorities available online are shown in the Table of Authorities.

*Nordisk A/S*, 566 U.S. 399, 406 (2012). But method-of-use patents are largely irrelevant to generics: A generic manufacturer cannot infringe a method-of-use patent directly as it does not administer drugs, *see* 35 U.S.C. § 271(a), and it cannot contributorily infringe if the drug compound is solely patented for methods of use and is thus a staple article of commerce, *see id.* § 271(c). The purpose of the section viii carve-out, then, is to ensure that generic manufacturers can efficiently deal with inducement of infringement during the ANDA approval process, consistent with Hatch–Waxman being "designed to speed the introduction of low-cost generic drugs to market." *See Caraco*, 566 U.S. at 405 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)). The panel's expectation of scattered, intricate editing of generic labels to deal with inducement thus, as Judge Prost explained in dissent (at 3), "throw[s] a wrench into Congress's design for enabling quick public access to generic versions of unpatented drugs with unpatented uses."

### B. Case Law Requires Resolution of the Conflict

To resolve this conflict, the en banc Court must interpret the patent inducement statute not in a vacuum as the panel did, but in the context of Hatch–Waxman "in a way that preserves the purposes of both." *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999) (quoting *Vornado Air Sys. v. Duracraft Corp.*, 58 F.3d 1498, 1507 (10th Cir. 1995)).

*SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc.* is instructive. There, the Second Circuit considered whether a generic drug label, being identical in text to that of the reference product, was an infringement of copyright. *See* 211 F.3d 21, 23–24 (2d Cir. 2000). The generic manufacturer in fact had attempted to revise the label to avoid copyright concerns, but the FDA rejected the proposed alterations, requiring virtually identical label text in view of Hatch–Waxman's same-labeling requirement. *See id.* at 24. Determining that "[t]he purposes of the Hatch–Waxman Amendments would be severely undermined if copyright concerns were to shape the FDA's application of the 'same' labeling requirement," the Second Circuit declined to hold the generic label an infringement of copyright. *Id.* at 29. Given that Hatch–Waxman was later in time, more specific, and more likely to have its purposes frustrated, the court concluded that the Copyright Act was required to yield, such that copying of drug labels for ANDA approvals was noninfringing. *See id.* at 28 & n.3.

For analogous reasons, there is a serious question of how the panel's construction of § 271(b) interacts with Hatch–Waxman. Scattered editing throughout a label to avoid inducement, like editing of labels to avoid copyright infringement, does not simply create a risk of the FDA rejecting the label but also frustrates the purposes behind the same-labeling requirement itself, namely conserving FDA resources and enabling speedy introduction of generic drugs. *See SmithKline*,

211 F.3d at 28.[3] And as with the Copyright Act, the patent inducement statute is older in time and far broader in scope than Hatch–Waxman.

The present case also fits the logic of another conflict-of-statutes case, *Credit Suisse Securities (USA) LLC v. Billing*, 551 U.S. 264 (2007). That case laid out a four-factor test for implied repeal of an older statute in view of a newer regulatory delegation: (1) "regulatory authority . . . to supervise the activities in question"; (2) evidence that such authority is exercised; (3) a risk that two laws, if both applied, "would produce conflicting guidance, requirements, duties, privileges, or standards of conduct"; and (4) whether the conflict of laws affects "practices that lie squarely within an area" that the later law "seeks to regulate." *Id.* at 275–76.

There are, at a minimum, strong arguments to be made that Hatch–Waxman and § 271(b) meet these factors. The FDA supervises the marketing of generic drugs and the statements their manufacturers make in applying for ANDA approval, and in doing so "the FDA cannot authorize a generic drug that would infringe a patent." *Caraco*, 566 U.S. at 405. The agency vigorously exercises

[3] *Syngenta Crop Protection, LLC v. Willowood, LLC* is distinguishable because this Court found that the statute at issue there "does not require a me-too applicant to ensure that its product label is identical." 944 F.3d 1344, 1357 (Fed. Cir. 2019). Importantly, the *Syngenta* court agreed that Hatch–Waxman differed from that statute in that the former "requires" same-labeling, such that "generic applicants faced a double-bind." *Syngenta*, 944 F.3d at 1357 & n.4 (quoting *SmithKline*, 211 F.3d at 25).

this authority, having adopted regulations on section viii certifications to "permit ANDA . . . applicants, *and us*, to assess" whether a certification overcomes a method-of-use patent. *See* Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements, 68 Fed. Reg. 36676, 36682 (FDA June 18, 2003) (emphasis added). Requiring generic applicants to line-edit labels despite the same-labeling requirement creates conflicting standards for generic manufacturers. And approval of conflict-producing generic labels falls squarely within the FDA's regulatory purview. *See* 21 C.F.R. § 314.127(a)(7); *see also Pom Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 116 (2014) (noting relevance of FDA preapproval to construction of overlapping statutes, citing drug labeling under section 505 as an example).

To be sure, application of the *Credit Suisse* and *SmithKline* doctrines to the present case will require more nuanced analysis than this short brief can provide,[4] but that heightens the need for enhanced review of this case. The panel decision

[4]For example, the FDA's various disclaimers that "it lacks both the expertise and the authority to review patent claims," *Caraco*, 566 U.S. at 406–07 (punctuation and alterations omitted), present a complex question under the first two factors of *Credit Suisse*. It may seem that the FDA's inexpertise points away from the agency's ability to supervise inducement in labeling. *See* 551 U.S. at 275. Yet the agency's adopted procedure of requiring patent-holding drug companies to identify and disclose any FDA-approved methods of use that their patents cover—so-called "use codes"—is arguably a way to supervise inducement without the agency needing to evaluate patents itself. *See* 68 Fed. Reg. at 36683.

failed to address these important questions of conflicts between laws, and en banc rehearing should be granted to resolve them.

## II. The Panel Decision's Reliance on Statements of Equivalence to Find Inducement Is Problematic for Consumers in Multiple Industries

In addition to relying on statements in Teva's ANDA-submitted labeling, the panel decision (at 27–29) points to Teva's marketing statements that its generic product was "an AB rated therapeutic equivalent" as evidence of Teva's inducement of infringement and intent to do so. But there are serious difficulties with relying on a mere claim of equivalence to another product to find intent to induce infringement of a patent not on the product, but on a method of using that product. Claims of equivalence are a component of truthful comparative advertising, which "is a source of important information to consumers and assists them in making rational purchase decisions." *E.g., Triangle Publ'ns, Inc. v. Knight-Ridder Newspapers*, 626 F.2d 1171, 1176 n.13 (5th Cir. 1980) (quoting 16 C.F.R. § 14.15(c)). Consumers would likely question whether a generic, omitting claims of equivalence, was in fact safe and effective for use; patent law ought not to prevent consumers from receiving that sort of accurate information.

Should the panel's holding be extended beyond the generic drug context, § 271(b)'s concerning ability to dissuade truthful comparative advertising could extend well beyond generic drugs. Biosimilar manufacturers invest heavily in

product advertising to convince skeptical consumers that biosimilars are acceptable substitutes for brand-name biologics, and accurate comparative advertising is critical for consumers. *See* Joint Statement from FDA & FTC, *Collaboration to Advance Competition in the Biologic Marketplace* 3–4 (Feb. 3, 2020), *available online*. Repair parts necessarily are marketed as equivalents to the originals, and it would be surprising—and economically devastating—if a repair parts manufacturer could be liable for inducing infringement merely by advertising such compatibility.

And information and communication technology products are often promoted as compliant with technical standards—essentially a claim of equivalence, in certain respects, to other standards-compliant systems. *See Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1208–09 (Fed. Cir. 2014). That potentially means that an advertisement that a laptop or smartphone is "Wi-Fi compliant" could constitute inducement of infringement of a patent not on Wi-Fi technology itself, but on any patent that *uses* Wi-Fi for some purpose, on the theory that advertising compliance is tantamount to encouraging all uses including infringing ones. Such a result, to which the panel decision opens the door, would create chaos in the technology industry.

As with the conflict between Hatch–Waxman and § 271(b), the panel decision does not address these tensions with truthful advertising of product equivalence. En banc review is required.

## CONCLUSION

For the foregoing reasons, the petition for en banc rehearing should be granted.

Respectfully submitted,

Dated: October 27, 2021

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## APPENDIX A
### List of Academic Signatories

The brief presents the views of the individual signers. Institutions are listed for identification purposes only.

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## CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation of the Federal Rules of Appellate Procedure and the Circuit Rules. The document contains **2,315** words, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f).

This document complies with the typeface and type style requirements of the Federal Rules. The document has been prepared in a proportionally spaced typeface using the *xelatex* typesetting system, in the font Libertinus Serif Regular.

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