No. 18-1976, -2023

In the 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

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE, NO. 1:14-CV-00878-LPS-CJB
CHIEF JUDGE LEONARD P. STARK, PRESIDING

BRIEF OF *AMICUS CURIAE* ASSOCIATION FOR ACCESSIBLE MEDICINES IN SUPPORT OF DEFENDANT-CROSS-APPELLANT IN SUPPORT OF AFFIRMANCE [CORRECTED]

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CERTIFICATE OF INTEREST

Pursuant to Rules 27(a)(7) and 47.4(a), we certify the following:

1. The full name of every party or *amicus* we represent is:

Association for Accessible Medicines

2. The name of the real party in interest (if the party in the caption is not the real party in interest) we represent is:

N/A

3. All parent corporations and any publicly held companies that own 10% or more of the stock of any party we represent are:

Association for Accessible Medicines has no parent corporation, and no publicly traded company owns 10% or more of its stock.

4. The names of all law firms and the partners or associates that appeared for the parties we now represent in the trial court or expected to appear in this court are:

From Winston & Strawn LLP: Andrew C. Nichols; George C. Lombardi; Kurt A. Mathas.

From Association for Accessible Medicines: Jeffrey K. Francer.

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:

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

Dated: November 2, 2018

/s/ Andrew C. Nichols
Andrew C. Nichols

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STATEMENT OF RELATED CASES

We are aware of no related cases pending in this Court. One case involving the same patent is stayed, pending the outcome of this appeal, in the District of Delaware: *GlaxoSmithKline LLC, et al. v. Glenmark Pharmaceuticals Inc., USA, et al.*, No. 14-cv-877-LPS-CJB (D. Del.).

INTRODUCTION & INTEREST OF *AMICUS CURIAE*[1]

In the Hatch-Waxman Amendments, Congress provided "that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012). Generics may take this course by omitting—or "carving out" under a provision called section viii—patented uses from their FDA-approved labels. This useful statutory tool provides consumers access to affordable generic equivalents of branded drugs, while protecting brand patents. If adopted, the position of GSK and its *amici* would destroy section viii and upend the law of induced infringement, harming consumers. The Court should affirm.

In this case, GSK waited seven years while generic versions of its heart medicine were marketed under a carved-out label for non-infringing uses. Then GSK sued Teva for "actively inducing" infringement of GSK's patent by: (1) characterizing Teva's generic product as equivalent to GSK's; and (2) failing to tell healthcare providers not to

[1] All parties consented to the filing of this brief. No party's counsel authored the brief in whole or in part, and no one other than the *amicus* paid to prepare or submit the brief.

use the generic for the patented use. If accepted, GSK's theory would wreck the section viii process, because generics *must be* equivalent (or "AB rated") to their branded counterparts. It would also upend the law of inducement itself, which requires that infringers "actively induce" infringement. 35 U.S.C. § 271(b). Yet GSK demands that generics *actively forbid* infringing uses, which "turns the legal test on its head." *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 632 n.4 (Fed. Cir. 2015)). If that were not enough, GSK and its *amici* urge the Court to ignore Teva's conduct and consult the subjective view of one physician; and, if that still does not produce a reversal, to drop any requirement that GSK show causation. If Hatch-Waxman and inducement law are to be rewritten, that is a job for Congress.

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing the interests of the generic and biosimilar medicines industry. AAM represents manufacturers and distributors of finished generic and biosimilar pharmaceuticals, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services. Its members provide Americans with generic and biosimilar medicines that are as safe and effective as

their brand-name counterparts, but are substantially more affordable. In 2017, generics accounted for roughly 90% of all U.S. prescriptions but only 23% of spending. In 2017, generic medicines saved patients, taxpayers, and health-care payers over $265 billion.

AAM seeks to provide courts with the perspective of the generic and biosimilar pharmaceutical industry on important legal issues impacting its members, and to highlight the potential industry-wide consequences of significant pending cases. This is such a case. AAM's members are frequently involved in pharmaceutical patent litigation in which they rely on section viii carve-outs and the stringent statutory requirements of induced infringement—both of which ensure consumers' access to low-cost medicines. AAM's members have a significant interest in preserving the law's protections for accused infringers who do not actively infringe.

BACKGROUND

A. The nature of section viii carve-outs

This case turns on section viii of the Hatch-Waxman Amendments, a key tool in a statutory regime "designed to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405.

In *Caraco*—the Supreme Court's recent unanimous decision construing section viii—the Court explained section viii's crucial role.

"When a brand manufacturer wishes to market a novel drug, it must submit a new drug application (NDA) to the FDA," providing "a statement of the drug's components, scientific data showing that the drug is safe and effective, and proposed labeling describing the uses for which the drug may be marketed." *Id.* at 404. The statute "allow[s] a generic competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA. Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." 566 U.S. at 404–05.

Section viii fits in as follows. "Because the FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug." 566 U.S. at 405. Brands provide patent information to FDA via something called a use code. *Id.* "[T]he FDA does not attempt to verify the accuracy of the use codes"; "[i]t simply publishes the codes" in a volume called the Orange Book. *Id.* at 405–06.

"When no patents are listed in the Orange Book or all listed patents have expired (or will expire prior to the ANDA's approval), the generic manufacturer simply certifies to that effect." 566 U.S. at 406 (citing 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(III)). If use codes reveal a relevant patent, however, the generic manufacturer has two options.

The first option is a "section viii statement, which asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents." 566 U.S. at 406. "If the ANDA applicant follows this route, it will propose labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use." *Id.* (citation omitted). "The FDA may approve such a modified label … as an exception to the usual rule that a generic drug must bear the same label as the brand-name product." *Id.* Once its carved-out label is approved, the generic may "place its drug on the market … but only for a subset of approved uses—*i.e.*, those not covered by the brand's patents." *Id.* (internal citations omitted).

"The generic manufacturer's second option is to file a so-called paragraph IV certification, which states that a listed patent 'is invalid or will not be infringed by the manufacture, use, or sale of the [generic]

drug.'" 566 U.S. at 407 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). The Paragraph IV approach makes sense if the generic "wants to market the drug for all uses, rather than carving out those still allegedly under patent" or if the generic's carved-out label "cannot avoid the brand's use code." 566 U.S. at 407.

Unlike the streamlined section viii process, which allows a generic to go straight to market if FDA approves the carved-out label, "[f]iling a paragraph IV certification means provoking litigation. The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue." 566 U.S. at 407. Meanwhile, "the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed." *Id.* As a result "the paragraph IV process is likely to keep the generic drug off the market for a lengthy period." *Id.* at 407–08.

B. Carve-outs help patients access low-cost drugs

While a generic is bottled up in the Paragraph IV process, patients pay monopoly prices. Indeed, the principal difference between generic and brand-name drugs is cost.

"For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." U.S. Food & Drug Admin., *Generic Competition and Drug Prices* (Nov. 28, 2017) (*available at*: https://bit.ly/2Aezddo). Thus, it is not surprising that generics account for 90% of prescriptions in the United States, but only 23% of total drug costs. Association for Accessible Medicines, *Generic Drug Access & Savings in the U.S.* 10 (2018). In total, generics saved the American health care system $265 billion in 2017, and almost $2 trillion over the last decade. *Id*. at 4, 11. Every year, generics save the Medicaid system $40.6 billion and save the Medicare system $82.7 billion. *Id*. at 4.

None of these savings accrue while a Paragraph IV 30-month stay is in place. And after the stay ends, a generic that enters the market before the litigation is fully resolved does so at risk of being held liable for substantial damages if the brand prevails. 35 U.S.C. § 271(e)(4)(C). And when it comes to generic drugs, even modest delays have high costs. One study, for example, concluded that delays ranging from 21 to 33 months in generic substitutes cost the Medicaid program alone

more than $1.5 billion. Aaron S. Kesselheim *et al.*, *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 Health Affairs 1637, 1643 (2006).

In multiple ways, then, Paragraph IV litigation inhibits generic competition. It keeps the generic off the market for 30 months and, thereafter, leaves the generic open to lost-profit damages. What is more, the 30-month stay does not depend on the strength of the brand's infringement claims or on the merits of its asserted patents. It is automatic. Even invalid patents thus may block generics for years.

By contrast, section viii allows a generic to avoid infringement and litigation by selling lower-cost drugs for unpatented uses, immediately helping patients. That is the value of the carve-out.

Without the carve-out, a brand "would be able to maintain its exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its [current approval]." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003). The method patent would thus act "as a sword" to prevent sales of "an off-patent drug for an approved use *not* covered by the patent. Generic manufacturers would effectively be barred altogether from entering

the market. That would certainly not advance the purpose of making available more low cost generic drugs, and was not what Congress intended." *Id.* (internal quotation and citation omitted) (emphasis added). This temptation, moreover, will be most acute with the most profitable drugs, which impose the greatest costs on patients.

C. The carve-out here is enforced below

The drug at issue here is called carvedilol, which GSK has marketed under the brand name Coreg® since 1997. Teva launched its generic version of carvedilol in 2007, along with seven other generic companies, after the patent covering the carvedilol compound expired. Relying on section viii, FDA approved labels carving out one of Coreg's three indications—treating congestive heart failure. This is the only indication GSK certified was covered by its patents, and thus the only indication for which it listed a use code in the Orange Book.

The generics were labeled for the remaining two, unpatented indications, hypertension and left ventricular dysfunction following a

myocardial infarction ("post-MI LVD").[2] GSK did not assert the patent-in-suit against Teva or any other generic when these competing products entered the market with their carved-out labels. GSK did not sue until 2014, seven years after Teva launched and a year before the patent expired. GSK demanded more than half a billion dollars in lost profits. GSK filed a similar damages action against Glenmark, which the parties have agreed to stay pending the outcome of this appeal.

GSK initially prevailed, receiving a jury award of $235 million for induced infringement. The district court set aside that verdict and granted Teva's motion for judgment as a matter of law, holding that no reasonable jury could have found that Teva induced infringement.

As it does here, GSK argued that Teva induced infringement by marketing its product as "AB-rated" to Coreg® and by failing to discourage providers from practicing GSK's patented use. As evidence, GSK pointed to the testimony of one doctor, who (according to GSK) subjectively understood Teva to have promoted its product for all uses.

[2] Years after launching under a carved-out label, Teva reinserted the carved-out indications at the instruction of FDA. This brief concentrates on Teva's carved-out label, as that is GSK's focus on appeal.

The district court rejected all these arguments, ultimately holding that "substantial evidence does not support the jury's finding on causation, and therefore does not support its verdict that Teva is liable for induced infringement." Appx24. This appeal followed.

ARGUMENT

I. Reversal would ruin Hatch-Waxman's carve-out process, harming patients and generic manufacturers.

In this appeal, GSK and its *amici* take dead aim at one of the pillars of the Hatch-Waxman Amendments: section viii carve-outs, which the Supreme Court and this Court have long held allow generics to avoid infringing patented uses by omitting those uses from their labels. According to GSK and its *amici*, any time a generic states that its product is equivalent (or "AB rated") to its branded counterpart, the generic induces infringement of all patented methods. GSK Br. 13 ("Teva's product catalogs stated its generic was "AB"-rated and juxtaposed it next to 'Coreg®[.]'"); *id.* at 14 (same); *id.* at 16–17 (same); *id.* at 20 (same); *id.* at 29 (same); *id.* at 30 (same); *id.* at 40 (same). If true, why would a generic ever use section viii, then? GSK and its *amici* never say. The answer is that they would not; the provision would be useless. The Court should reject this attack on section viii out of hand.

A. As the Supreme Court held in *Caraco*, section viii allows generics to avoid patented uses; a brand may not "throw[] a wrench" into that process.

Under section viii, a generic may request to market a drug for an unpatented use by filing with FDA "a statement that the method of use patent does not claim [the] use" the generic plans to market. 21 U.S.C. § 355(j)(2)(A)(viii). "A section viii statement is typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug. If the ANDA applicant follows this route, it will propose labeling for the generic drug that 'carves out' from the brand's approved label the still-patented methods of use." *Caraco*, 566 U.S. at 406 (citation omitted). "FDA acceptance of the carve-out label allows the generic company to place its drug on the market (assuming the ANDA meets other requirements), but only for a subset of approved uses—*i.e.,* those not covered by the brand's patents." *Id.*

Thus, Hatch-Waxman authorizes generics to do what Teva did here—namely, "market[] … a generic drug for particular unpatented uses; and section viii provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can

quickly come to market." 566 U.S. at 415. By handing generics and FDA this statutory scalpel, Congress "contemplate[d] that one patented use will not foreclose marketing a generic drug for other unpatented ones." *Id.*

But brands struck back—by submitting to FDA "overbroad" descriptions of their patents, called "use codes." *Caraco*, 566 U.S. at 424. That is what happened in *Caraco*. The brand held a patent on one use, but inflated its use code to cover *three* uses. *Id.* at 409–10. FDA accepted the code at face value and refused to let the generic carve out two non-infringing uses. *Id.* at 411. That thwarted the statutory plan. "An overbroad use code … throws a wrench into the FDA's ability to approve generic drugs as [section viii] contemplates." *Id.* at 419.

Fortunately, to prevent such mischief, Congress had enacted a counterclaim "to challenge the brand's assertion of rights over whichever discrete use (or uses) the generic company wishes to pursue." 566 U.S. at 415; *id.* at 403 (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I)). The counterclaim allows generics to remove the wrench from the section viii carve-out system. "A company may bring a counterclaim to show that

a method of use is unpatented because establishing that fact allows the FDA to authorize a generic drug via section viii." 566 U.S. at 415.

As *Caraco* shows, if GSK intended to accuse Teva of infringing multiple indications—as GSK does today—it should have filed use codes covering all those indications. The section viii process depends on brands providing complete and accurate information to FDA about the scope of their patents. That allows FDA to confirm that generics have carved out from their labels patented methods. If GSK believed its use codes did not reflect its patents, it could have approached FDA to broaden the codes—just as the brand did in *Caraco*. Of course, as in *Caraco*, that would have opened GSK to a counterclaim showing that the asserted methods were not patented.

So GSK chose a different tack. It waited seven years while Teva went to market, and then sued Teva for hundreds of millions of dollars in purported lost profits for induced infringement. According to GSK's *amicus*, Teva induced infringement in two ways: *first*, it "advertised its product as an AB-rated generic copy of GSK's product"; and *second*, it did so "without instructing that its product should not be used for the patented use." BIO Br. 5. The first of these theories would destroy

section viii. *Infra* at 15–23. The second would destroy the law of active inducement. *Infra* at 24–30. Both theories should be rejected.

B. If calling a generic "AB rated" to a brand induces infringement, that would throw the ultimate wrench into the section viii process.

GSK's AB-rating-equals-infringement theory would nullify section viii every bit as effectively as allowing brands to file overbroad use codes. Here is why.

1. "AB rating" is merely an FDA code for brand equivalence, which Teva rightly cited here.

To receive FDA approval, a generic must be equivalent to its brand counterpart. "Once the FDA has approved a brand manufacturer's drug, another company may seek permission to market a generic version." *Caraco*, 566 U.S. at 404. As noted, to obtain FDA approval, the generic company "file[s] an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA. Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.* at 404–05 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). "[T]his process is designed to speed the introduction of low-cost generic drugs to market." *Id.* at 405.

Enter the "AB rating"—which is one way FDA signals that a generic is therapeutically equivalent to a brand. As the Orange Book explains, FDA uses a two-letter coding system "to allow users to determine quickly whether the Agency has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter)." U.S. Food & Drug Admin., *Approved Drug Products With Therapeutic Evaluations* (Orange Book) (38th ed. 2018) (preface) (available at: https://bit.ly/2Au5o85).

In other words, the code is relative. The first letter of the code speaks to equivalence (which is all that is relevant here); the second letter says *why* FDA concluded the drug was, or was not, equivalent (not relevant here). Equivalent drugs bear an "A" rating (*e.g.*, AA, AB). Non-equivalent drugs carry a "B" rating (*e.g.*, BC, BD).

As FDA puts it, "A" products are those FDA *does* "consider[] to be therapeutically equivalent to other pharmaceutically equivalent products, *i.e.*, drug products for which":

> (1) there are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP, or AT, depending on the dosage form; or

> (2) actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. *These are designated AB.*

Id. (emphasis added). It was this last designation—AB—that Teva's product earned, signaling that it was therapeutically equivalent for approved, on-label indications to GSK's Coreg®. The FDA's press release put the point in layman's terms: "FDA Approves First Generic Versions of Coreg." Appx7116.

GSK disputes none of this. To the contrary, "[a]s both parties showed at trial, being AB rated signifies that a generic drug is therapeutically equivalent to a branded drug." Appx17. "The undisputed evidence demonstrates that a generic drug cannot be listed as 'AB rated' generally, as 'AB rated' is a relative term; it necessarily requires a comparison between the generic drug and some branded reference drug." Appx17.

In fact, GSK's expert acknowledged that "the meaning of … AB rating is if the generic drug is used *in accordance with its label*, you would expect it to have the same clinical effect in a person as if that person had taken the brand drug." Appx17 (emphasis in original) (citation omitted). She added: "AB rating means ... if a patient took the

generic carvedilol *for one of the uses in its label*, you would expect it to have the same clinical effect as if the patient is taking Coreg." *Id.* (citation omitted). Thus, GSK's own evidence shows that an AB rating is not only relative, but extends only to the limits of the generic label. And here, that label carved out GSK's patented indication. Using the term "AB rating" therefore, does not remotely induce infringement because the term itself speaks only of unpatented uses.

Nor *could* Teva have qualified its AB rating to make its carve-out even clearer. To obtain FDA approval, a generic applicant must "show that the labeling proposed for the [generic] drug is the same as the labeling approved for the [brand]." 21 U.S.C. § 355(j)(2)(A)(v). To enforce this "sameness" requirement, FDA demands that an ANDA contain a side-by-side comparison of the proposed labeling with the approved labeling for the brand. 21 C.F.R. § 314.94(a)(8)(iv). Even proposing a simple carve-out can trigger rejection. Before approving a carved-out label, FDA must find that the "differences do not render the proposed drug product less safe or effective than the [brand] for all remaining, nonprotected conditions of use." 21 C.F.R. § 314.127(a)(7). FDA provided Teva a carved-out label to use as a template. Appx6908–

6952, Appx11024–11026. Other than the carve-out, the FDA template label matched Coreg's®.

By flagging its product as AB-rated to Coreg®, Teva did no more or less than is required, and done, by FDA.

2. If tying AB rating to a brand induces infringement, then all generics induce infringement even with carved-out labels.

It follows that if citing an AB or another comparable FDA rating induces infringement, then *all* generics induce infringement; and indeed *FDA itself* induces infringement. And that is as true for carved-out indications as any other indications—because the underlying drug is still rated by FDA as equivalent to the brand. *Supra* 15–19.

This is why GSK's position would take a wrecking ball to section viii. If tying a generic's AB rating to its brand counterpart always induces infringement, then carve-outs are useless. They fail to avoid inducement, which is their sole purpose. All generics facing unexpired patents will either have to: (a) wait until those patents expire; or (b) engage in costly, time-consuming Paragraph IV litigation—which will be limited to showing no direct infringement (inducement having been established by the AB rating) or invalidity. Meanwhile, brands will

enjoy an extension of their monopolies, and patients will be deprived of cheaper, non-infringing products. This is the opposite of what Congress intended, which was "to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405.

Here again, GSK does not dispute this. It is what GSK believes is necessary to stop generics from using carve-outs to "piggyback" on brand efforts. GSK Br. 45 ("Teva's marketing piggybacked on GSK's"); *id*. at 48 (generics should not "piggyback[] on … prior marketing"). As a threshold matter, under Hatch-Waxman piggybacking is generally not a bug; it is a feature. The statute "allow[s] a generic competitor to file an abbreviated new drug application (ANDA) *piggy-backing on the brand's NDA*. Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco*, 566 U.S. at 404–05 (emphasis added).

The same is true of generics marketing their non-infringing uses while a brand markets its infringing use. Inevitably, generics will benefit from being AB-rated; after all, that is what allows the generic prod-

uct to be substituted for the brand product. But that is where the piggybacking stops—thanks to the section viii carve-out. GSK is thus mistaken to say that "nothing in the statute … lets a defendant off the hook when it induces infringement by capitalizing on the innovator's own efforts to build the market for the patented treatment." GSK Br. 45. A generic marketing with a carved-out label was never "on the hook" in the first place. The carve-out ensures that a generic promotes only non-infringing uses. If a carve-out does *not* ensure non-infringement, then section viii is worthless, for that is its only purpose. And all that will be left to the generic is Paragraph IV litigation.

3. Paragraph IV litigation is no substitute for the efficient section viii process.

Paragraph IV litigation is no substitute for the streamlined section viii process. Filing a Paragraph IV certification is a technical act of patent infringement; it "means provoking litigation." *Caraco*, 566 U.S. at 407. Such a lawsuit imposes significant burdens a generic never faces in filing a section viii carve-out statement.

For one thing, in defending a Paragraph IV infringement suit, the generic must prove that the brand's patent is invalid or will not be infringed by manufacturing, using, or selling the generic. Of course, if publicly tying AB-rating to the brand is inducement, then the infringement inquiry is half over; all that is left is for the generic to show that no direct infringement will occur or that the brand's method patent is invalid. Or, again, the generic may simply give up and wait until the very last relevant method patent held by the brand expires. Neither option is fair to consumers or to the generic drug-maker, which seeks to market only an unpatented method.

Even if a generic prevails, moreover, consumers will have suffered a long delay because Paragraph IV litigation triggers an automatic 30-month stay in marketing. *See* 21 U.S.C. § 355(j)(5)(B)(iii). That punishes patients, who must wait to receive lower-cost, often life-saving drugs. The wait not only threatens lives, it is costly. As one commentator estimates, a mere one-year delay in generic competition "represents, under conservative assumptions, a transfer from consumers to producers of about $14 billion." C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve*

Drug Competition, 109 Colum. L. Rev. 629, 650 (2009). On top of this, patients will also pay indirectly for the costs inherent in all federal cases—especially complex patent litigation. *Cf. Teva Pharm., USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) (filing paragraph IV certification introduces the "hazard of sparking costly litigation").

The section viii process, by contrast, avoids litigation altogether. Indeed, the whole point of a section viii statement is to permit a generic manufacturer to sell a drug immediately when it is approved for only an unpatented use. *See, e.g.*, *Purepac Pharm. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002) (immediate approval offered by section viii makes it "an attractive route for generic manufacturers"), *aff'd*, 354 F.3d 877 (D.C. Cir. 2004). Just as the Supreme Court forcefully—and unanimously—defended the section viii process in *Caraco* from the abuse of overbroad use codes, this Court should defend it here from an overbroad conception of induced infringement.

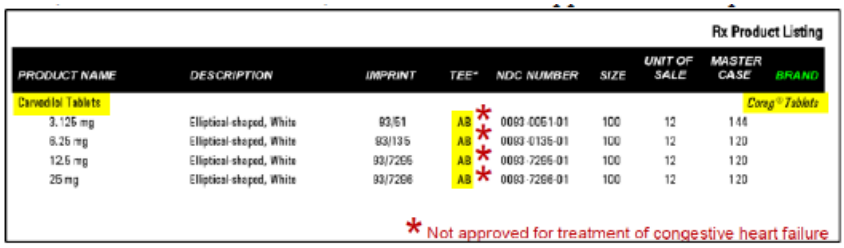
The Court should affirm.

II. Reversal would upend the law of induced infringement, again hurting both patients and generic drug-makers.

Underneath GSK's attack on section viii is an attack on the law of induced infringement itself. After all, the problem with GSK's AB-rating-equals-inducement theory is not merely that it would destroy section viii (though it would), *but that it does not induce infringement*. "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Under this standard, the accused infringer must have "encourage[d], recommend[ed], or promote[d] infringement." *Takeda Pharms. U.S.A.*, 785 F.3d at 631 (citation omitted). But merely tying FDA's "AB rating" to a branded drug does not encourage, recommend, or promote any particular method of using that drug—much less, as the law also requires, *cause* direct infringement. *Infra* at 28–30. To create liability, therefore, GSK and its *amici* press the Court to rewrite the law of induced infringement in three ways.

First, they fault Teva for failing "to discourage doctors from using its product for the infringing use" and for "electing not to put any disclaimers in its marketing materials." GSK Br. 35; BIO Br. 5 (same).

This was one of GSK's primary arguments to the jury—that Teva induced infringement because it failed to discourage infringement. GSK showed the jury a picture of Teva's product catalogue and complained that Teva did not add—in bright red font, which GSK superimposed—"*Not approved for treatment of congestive heart failure":



Rx Product Listing

PRODUCT NAME	DESCRIPTION	IMPRINT	TE*	NDC NUMBER	SIZE	UNIT OF SALE	MASTER CASE	BRAND
Carvedilol Tablets								Coreg® Tablets
3.125 mg	Elliptical-shaped, White	93/51	AB *	0093-0051-01	100	12	144	
6.25 mg	Elliptical-shaped, White	93/135	AB *	0093-0135-01	100	12	120	
12.5 mg	Elliptical-shaped, White	93/7266	AB *	0093-7266-01	100	12	120	
25 mg	Elliptical-shaped, White	93/7266	AB *	0093-7266-01	100	12	120	

* Not approved for treatment of congestive heart failure

Appx12473. That is not the law.

Again, inducement requires "affirmative steps" by the alleged inducer—such as encouraging, recommending, or promoting infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011); *Takeda Pharms. U.S.A.*, 785 F.3d at 630. To demand that Teva actively discourage infringement thus "turns the legal test on its head." 785 F.3d at 632. GSK needs to show that Teva "took affirmative steps to induce, not affirmative steps to make sure others avoid infringement." *Id.* at 632 n.4.

The warnings GSK demands are not required by any law—and, as noted, would be rejected by FDA under its brand-generic "sameness"

requirement. *Supra* 18–19. Nor is this surprising. Hatch-Waxman does not govern the practice of medicine or pharmacy. Thus, even under Hatch-Waxman's carve-out regime, doctors may prescribe drugs for uses omitted from drug labels ("off-label" uses); and pharmacies may follow state automatic-substitution laws no matter what the label says. Generic manufacturers police none of this. But that is what GSK insists generics must do to avoid inducing infringement of carved-out indications. If that is to be the law, the word must come from Congress.

Second, GSK endorses a subjective test for whether a generic induced infringement—looking away from Teva's conduct to the private impression of one doctor who purportedly said "that Teva's marketing materials led him to believe its product was a 'complete replacement' for Coreg® and thus caused him to administer it for the infringing use." GSK Br. 34. What matters, says GSK, is what the doctor thought Teva's marketing meant, not what Teva actually said and intended. GSK quotes this exchange:

> Doctor: [H]ere in 2007, Teva is telling doctors … that they have approval and actual shipment of generic Coreg tablets, that the FDA granted final approval of Teva's generic version of GSK's cardiovascular drug, Coreg.

> Attorney: Now, what did that tell you, Dr. McCullough, and your colleagues, as a physician about what Teva's generic carvedilol, what indications it could be used for?
>
> Doctor: It could be used for all the indications.
>
> Attorney: *Would that include heart failure in your mind*?
>
> Doctor: *Sure*.

GSK Br. 12–13 (citations omitted; emphasis added). But the active-encouragement inquiry considers the "specific intent and action to induce" of the generic manufacturer (*Takeda*, 785 F.3d at 631; *Warner–Lambert Co.*, 316 F.3d at 1364); it does not attempt to peer into the "mind" of a lone doctor.

This Court underscored that point in *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012). There, the brand urged the Court to accept the views of "an obstetrician-gynecologist with experience in the clinical use of contraceptives" who insisted that, in his view, certain indications for the generic drug at issue were "clearly stated and on-label." *Id.* at 1325. This Court discounted the doctor's views and read the label itself, holding that his "opinion is contrary to the contents of the FDA-approved label." *Id.* The Court continued: "[N]otwithstanding [the doctor's] understanding to the contrary, any

prescription of [the generic] to produce either [effect at issue] has not been approved by the FDA and is therefore 'off label.'" *Id*.

The Court's approach in *Bayer* is common sense. If the law were otherwise, all a brand would need to do to establish infringement would be to find one physician who misread a label (or the significance of an "AB rating") and relied on that misreading to infringe, and inducement would be established. But providers make mistakes, and knowing that they will do so does not amount to inducing them to infringe. "The mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement. … [I]t is well-established that mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Takeda*, 785 F.3d at 631 (citation omitted).

Third, GSK's *amicus* urges the Court in inducement cases to avoid a "discrete 'causation' analysis." BIO Br. 27. According to the *amicus*, mere "moral support" by the generic is enough. *Id*. at 10. And "[i]f the encouragement or assistance is a substantial factor in causing the resulting tort, the one giving it is himself a tortfeasor." *Id*. at 11.

As a threshold matter, GSK itself does not directly dispute that it must show causation. That is not surprising, as GSK did not challenge the jury instructions here, which say just that. *See, e.g.*, Appx21 n.13 (noting that GSK counsel "conced[ed]" that "the law is and ... the [C]ourt's rulings have shown there [are] causation requirements")).

Nor could GSK have disputed this element of its burden. This Court has rejected jury instructions that—as the following excerpt shows—expressly disclaim causation:

> *[I]nfringement need not have been actually caused by the party's actions*. All that is required is that the party took steps to encourage or assist that infringement, regardless of whether that encouragement succeeded, or was even received.

Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1330 (Fed. Cir. 2016) (quoting jury instructions). As this Court held, such instructions cannot survive under a statute requiring that an infringer "actively induce" infringement. 35 U.S.C. § 271(b). After all, "the term 'induce' as it is used in § 271(b) means '[t]o lean on; to influence; to prevail on; to move by persuasion.'" *Power Integrations, Inc.*, 843 F.3d at 1331 (quoting *Global–Tech Appliances, Inc.*, 563 U.S.

at 760 (alteration in original)). That was exactly right. "Influence," "prevail on," "move"—these are terms of causation.

To *omit* causation from the inducement inquiry, then, is to omit inducement itself. As *Power Integrations* put it, "[t]he jury instruction incorrectly stated that liability exists even where no inducement actually occurred. This is contrary to the law." 843 F.3d at 1331. For this reason, to jettison a "discrete 'causation' analysis" (BIO Br. 27) would likewise be contrary to law and, indeed, "expressly misstate[] the law on actual inducement." *Power Integrations*, 843 F.3d at 1332. Thus, the district court here was right. Teva induced no infringement because it caused no infringement. Appx24.

CONCLUSION

By attacking both section viii and the law of induced infringement, GSK and its *amici* seek a revolution in the Hatch-Waxman regime. That is not only a job for Congress, it is also ill advised. For the reasons this Court and the Supreme Court have given in case after case, from *Warner-Lambert* to *Caraco*, it would hamstring generic drug makers and harm patients. The judgment should be affirmed.

Respectfully submitted.

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CERTIFICATE OF COMPLIANCE

The foregoing brief is submitted in accordance with the type-volume limitations of Rule 32(a)(7)(B)(i) of the Federal Circuit Rules of Appellate Procedure. This brief contains 5,867 words.

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CERTIFICATE OF SERVICE

I certify that on November 14, 2018, I electronically filed the foregoing brief using the Court's CM/ECF filing system. All counsel of record were electronically served by and through the Court's CM/ECF filing system per Fed. R. App. P. 25 and Fed. Cir. R. 25(a) and 25(b).

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