No. 22-37

IN THE
Supreme Court of the United States

TEVA PHARMACEUTICALS USA, INC.,

Petitioner,

v.

GLAXOSMITHKLINE LLC,
SMITHKLINE BEECHAM (CORK) LIMITED,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTERESTS 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 the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 20% 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 certiorari: namely, whether generic pharmaceutical manufacturers can be held liable for ***intentional*** infringement for conduct that is expressly permitted—and, in fact, strongly encouraged—under the Hatch-Waxman Act. By putting generic drug manufacturers at risk of

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[1] Pursuant to this Court's Rule 37.6, counsel for *amicus curiae* certifies that this brief was not authored in whole or in part by counsel for any party and that no person or entity other than *amicus curiae*, its members, or its counsel has made a monetary contribution intended to fund the preparation or submission of this brief. All parties received notice of and consented to the filing of this brief. Counsel for respondent received notice of and consented to the filing of this brief eight days before filing.

extraordinary liability when they follow Hatch-Waxman to the letter, the panel's decision nullifies the so-called "skinny-label" regime Congress adopted.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court's review is urgently needed to address one of the most consequential, detrimental, and misguided drug patent rulings in decades. Nearly 40 years ago, Congress recognized that American patients should not be deprived of access to high-quality, low-cost generic drugs simply because some *uses* of those drugs were covered (oftentimes serially) by follow-on method-of-treatment patents long after the original compound patent on the molecule expired. These method-of-use patents could be for changes as minor as how many times a day the patient takes the drug, or whether the medication is delivered orally or intra-nasally. Congress's solution was elegant and effective. Generic manufacturers could come to market with a "skinny label," *i.e.*, a label that excluded the uses that remained under patent. With skinny labels, American patients would no longer have to pay branded drug prices for uses that were not patented. And the skinny-label regime has indisputably worked. Generics launch skinny-labeled versions of no-longer-patented drugs with some patented uses nearly 50% of the time. And since its enactment as part of the Hatch-Waxman Act in 1984, skinny labels have saved the American public—both patients and taxpayers—billions of dollars in unnecessary costs.

The Federal Circuit's divided decision below nullifies Congress's skinny-label regime. As set out by Congress, the skinny-label regime depends on the branded drug manufacturer identifying the uses it patented. And here, Teva carved out each and every one of those uses from its label based on GSK's representations. Yet the panel majority below held that petitioner could still be held liable for intentionally inducing infringement, to the tune of millions of dollars in damages, based on the carved-out label. As the dissent explained, that decision makes a mockery of Congress's statutory protections. Not only did Petitioner Teva exclude the uses that Respondent GSK had previously claimed were protected, but Teva was *required* by law to include the remaining label language that the Federal Circuit held evinced inducement. Put another way: 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 and detailed drug information it submitted to the FDA. No generic manufacturer would dare risk coming to market with a skinny label if it could face enormous liability for using a label the law required it to use.

The opinion below went through multiple iterations over multiple dissents. By the end, the author of the majority opinion contended that even if the panel majority result was unfair (which it surely was), Teva could still seek to prevail on equitable estoppel grounds on remand. But the very fact that the majority was looking to equity to right the wrongs of the decision shows just how misguided its interpretation is.

Congress created a *statutory* right to come to market with a skinny label. It is no answer to truncate a statutory right and then look to equity to fix the problem. The very suggestion is essentially a concession that the majority's statutory interpretation went badly awry. And as a practical matter, no generic manufacturer could take the risk of being hit with an enormous jury verdict for a skinny label in the hope of getting equitable relief. And no generic manufacturer *should* have to take that risk, because Congress legislated otherwise. Given the Federal Circuit's nationwide jurisdiction, only this Court can restore what Congress has mandated.

By imposing liability on a generic company that "did everything right," Pet. App. 118a, the decision below richly rewards gamesmanship on the part of branded manufacturers. Just as this Court rejected attempts to "exploit[] this statutory scheme to prevent or delay the marketing of generic drugs" once before, it should do so again in this case. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012). Ultimately, the true losers in this decision are American patients. Those patients will be deprived of affordable generic alternatives for uses that, by definition, are not patented. And American taxpayers will suffer as insurance companies are forced to pay for more expensive versions of drugs once generics refuse to enter the market.

All of this could be avoided by honoring Congress's scheme as written. This Court should grant certiorari to correct this important mistake of law.

ARGUMENT

I. The Hatch-Waxman Act Reflects Careful Congressional Design.

As part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (more commonly known as the Hatch-Waxman Act), Congress carefully balanced patent-holders' interests with the interests of the American public in swift and affordable access to life-saving medication. Congress sought to tackle two problems: First, Americans were "paying too much for drugs whose patents ha[d] expired"; and second, American drug manufacturers were losing their "prominence in pharmaceutical innovation" to manufacturers abroad. *Drug Price Competition and Patent Term Restoration Act of 1984: Hearings on S. 2748 Before the S. Comm. on Labor & Hum. Res.*, 98th Cong. 1 (1984) (statement of Sen. Hatch). In an effort to combat these two problems, Congress "str[uck] a balance among the varying interests of research drug firms, generic firms, and consumers." *Id.* The resulting scheme fostered innovation in drug manufacturing—by adequately protecting patent rights—and ensuring that American consumers could access affordable medications—by paving the way for generics' quick and efficient entry into the market. As a result, both medical innovation and affordable medications have flourished.

Key to that balance was ensuring that generics could come to market on unpatented uses. Congress decided 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 generic drugs for old, unpatented methods of use. *See Caraco*, 566 U.S. at 414-15. Congress thus allowed generic applicants to inform the FDA that they were seeking approval only for unpatented indications. 21 U.S.C. § 355(j)(2)(A)(viii).

Congress outlined a thorough procedure to govern the process of seeking and obtaining approval for unpatented indications—the "skinny-label" process. A generic manufacturer filing an Abbreviated New Drug Application (ANDA) generally *must* submit information that will allow the FDA to determine that the new drug is equivalent to the existing drug, including that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug." *Id.* § 355(j)(2)(A)(v). But when generics submit ANDAs for drugs seeking approval for only the unpatented uses, the generics are permitted to file a statement with the FDA that they are not seeking approval for all uses. *Id.* § 355(j)(2)(A)(viii).

At that point, the FDA turns to the information it received from the brand-name manufacturer, who is required under penalty of perjury to specifically identify "each patent . . . that … claims a method of using [the] drug." *Id.* § 355(b)(1)(A)(viii)(I)-(II). Brand manufacturers do this by submitting a sworn declaration to the FDA, which they sign under penalty of perjury, identifying every single "method of use and related patent claim," along with the "specific section(s) and

subsection(s)" of the label "that describes the method of use." 21 C.F.R. § 314.53(c)(2)(i)(O), (ii)(P). So when a generic manufacturer comes to the FDA with an ANDA and explains precisely which uses it does and does not seek approval for, the FDA in turn relies on the information the brand-name manufacturers have provided. "The FDA does not attempt to determine if that information is accurate. Rather, the FDA assumes that it is so and decides whether to approve a generic drug on that basis." *Caraco*, 566 U.S. at 403. If the FDA, looking to the information provided by the branded manufacturer, determines that an ANDA applicant can "'carve out' the method of use," the FDA will approve the drug with that carved-out (or "skinny") label. Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,682 (June 18, 2003).

These provisions are critical to the functioning of Hatch-Waxman as a whole. Other provisions of the statute provide robust protection for patent-holders, including provisions permitting brand-name manufacturers to initiate pre-launch litigation and obtain a 30-month stay of FDA approval, which bars the generic from getting *any* approval for *any* use, simply because the brand has filed suit on any one patent, no matter how narrow, 21 U.S.C. § 355(j)(5)(B)(iii). The stay provision, which prevents generics from entering the market while the branded manufacturer's patent claims remain pending, "keep[s] the generic drug off the market for a lengthy period." *Caraco*, 566 U.S. at 408-09. Without a regime like the skinny-label provision, then, generics would be required to wait 30 months, while fighting out the infringement and patent-validity

questions even after the patent on the underlying compound—and at least some uses—has expired.

For that reason, Congress gave generics (and American patients) a necessary counterweight. The skinny-label provision ensured that, although patent protections would remain robust for the life of the patent, there was a clear and administrable path for generics to offer cheaper drugs for unpatented uses.

The Hatch-Waxman Act was quickly successful in increasing the availability of generics and bringing down drug prices for U.S. patients. By 1996, just a few years after the law was enacted, generics accounted for roughly 42.5% of all prescriptions dispensed—a huge victory for patients, as they were roughly three times less expensive than their branded counterparts.[2] Today, generics make up roughly 90% of all prescriptions dispensed,[3] while the median price of generics is a fraction of the price of branded drugs.[4] And across the United States, the robust market for generics has led to enormous financial and health benefits.[5]

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[2] Kaiser Family Found., *Prescription Drug Trends* 27, 36 (Nov. 2001), https://bit.ly/3A5mWpN.

[3] FDA, *Office of Generic Drugs 2021 Annual Report* (Feb. 14, 2022), https://bit.ly/3da4X8K.

[4] FDA, *Generic Competition and Drug Prices* (Dec. 13, 2019), https://bit.ly/3A2Im78.

[5] AAM, *The U.S. Generic & Biosimilar Medicines Savings Report* 7 (Oct. 2021), https://https://bit.ly/3oPqCFZ (estimating $388 billion in savings in 2020 alone); Niteesh K. Choudhry et al., *Improving Adherence to Therapy and Clinical Outcomes While Containing*

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. Generic versions of no-longer-patented drugs with patented uses launch with a skinny label nearly 50% of the time,[6] saving patients and the federal government billions. For example, Crestor, a branded drug used to treat high cholesterol, cost patients and payors $6.2 billion annually before the entry of generics.[7] 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.[8] 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.[9] Patients benefitted immediately from the introduction of generics—the savings were in excess of $8.4 billion in 2019 alone for

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Costs: Opportunities From the Greater use of Generic Medications, Annals of Internal Med. (Jan. 5, 2016), https://bit.ly/3A3IuD9; Becky A. Briesacher, et al., *Medication Adherence and the Use of Generic Drug Therapies*, 15 Am. J. Managed Care 450 (2009).

[6] Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With "Skinny Labels" in the United States*, 181 JAMA Intern. Med. 995, 997 (2021), https://bit.ly/3SWSjdM.

[7] Eric Palmer, *Nexium, AstraZeneca*, FiercePharma (Oct. 28, 2013), https://bit.ly/3QtH4Hu.

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

[9] *Id.* at 1.

just that one drug.[10] In these and other cases, the use of skinny labels saved patients money and improved their access to life saving medications.

II. The Decision Below Frustrates Congress's Policy Decision To Allow Skinny Labels.

The decision below subjects generics to the risk of massive infringement liability for conduct that is expressly authorized by Hatch-Waxman and does not remotely meet the standards for inducement.

The Federal Circuit's decision was incorrect as a matter of black-letter infringement law, as Teva ably explains. *Amicus* writes to emphasize another pernicious aspect of the panel's opinion. The decision found Teva liable for *intentionally* encouraging others to infringe, based entirely on 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 the FDA. The Federal Circuit's decision thus directly conflicts with Congress's plan for skinny labeling. The decision will lead to liability for companies that follow the statutory scheme to the letter, invites gamesmanship on the part of branded manufacturers, will lead generics to hesitate before entering the market, and will result in billions of added dollars for consumers and taxpayers.

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[10] AAM, *2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 21 (Sept. 2020), https://bit.ly/3Qq0ZYw.

A. Generics Can Now Be Held Liable For Complying With Congress's Skinny-Labeling Scheme.

In drafting its label, Teva did everything right. Teva filed an ANDA; it identified the uses for which it wanted to market the drug; and it followed the FDA's instructions regarding what uses to carve out.

Every step Teva took was not just permitted, but indeed *required* by the scheme outlined above. ANDAs 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). The baseline, therefore, is that the generic label is statutorily required to be identical. *See id.* And when a generic manufacturer seeks to omit a protected use from a label that must otherwise be identical to the brand label, the FDA relies on the use code provided by the brand company. Abbreviated New Drug Applications 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)). This is a key reason why the FDA requires brand manufacturers to list, under penalty of perjury, "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. While the 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 the FDA requires.[11] 81 Fed. Reg. at 69,600; *see also* 21 C.F.R. § 314.127(a)(7) (the FDA "will refuse" to approve an ANDA if the information fails to show "that the labeling proposed for the drug *is the same* as the labeling approved for the listed drug referred to in the ANDA except for changes required … because aspects of the listed drug's labeling are protected by patent" (emphasis added)).

In short, the generic manufacturer *must* use the label language the FDA requires. It may not change the label language to avoid inducement liability. Moreover, when it comes to choosing the specific language to be included or excised, the FDA relies on the use code provided by the brand manufacturer. As Judge Prost explained: "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." Pet. App. 64a. Under these circumstances, it makes no sense to hold

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

that Teva intentionally induced infringement of GSK's patent.

The Federal Circuit responded by claiming that a generic manufacturer 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." Pet. App. 24a. But this misses the point: Whether or not the manufacturer conducts its own research into the appropriate labels for the various use codes, the generic *must include* the label passages the FDA requires. *See* 81 Fed. Reg. at 69,600 (describing how the FDA "determine[s] which section(s) and/or subsections of labeling contain language that *must* be carved out" (emphasis added)); 21 C.F.R. § 314.127(a)(7) (the FDA "will refuse" an ANDA if the information fails to show "that the labeling proposed for the drug is the same").

Moreover, the Federal Circuit's suggestion that parties other than the brand-name manufacturer conduct their own investigation contradicts both Congress's and the FDA's reasoned decisions. Congress included no such requirement in the statute, and in fact the FDA specifically considered and rejected such a requirement. In 2016, the FDA solicited public comment on a rule that would have allowed generics to dispute use codes and would have tasked the FDA with "review[ing] a proposed labeling carve-out(s) for the" new application "with deference to the . . . applicant's interpretation of the scope of the patent." 81 Fed. Reg. at 69,604. But after reviewing those comments, the FDA declined to adopt this rule. *Id.* The FDA thus chose a policy of

taking brand manufacturers at their word—and under penalty of perjury. *See also Caraco*, 566 U.S. at 419 (noting that the FDA relies on use codes because it "views itself as lacking expertise"). Because the FDA relies on brand-name manufacturers when instructing generics on what language to carve out, and because generics are required by law to comply with the FDA's instructions, it is no answer to say that generics ought to have conducted their own independent analysis of the method-of-use label language.

Having followed and relied upon Hatch-Waxman's provisions and the FDA's instructions, Teva now faces significant liability for supposedly intentional inducement.[12] As this Court has already recognized, interpretations that "throw[] a wrench into the FDA's ability to approve generic drugs as the statute contemplates" are unlikely to be the correct ones. *Caraco*, 566 U.S. at 419.

B. The Decision Will Invite Gamesmanship And Chill Production Of Generic Drugs.

The reasoning below 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

[12] 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 the FDA directs—creates a regime too risky for a generic manufacturer to use.

required to—designate those claimed indications. The FDA would then have directed Teva to modify its label accordingly. Instead, GSK waited for years before raising an inducement claim—until just before its final patent expired. *See* Pet. App. 59a. By carrying out this bait and switch, GSK was able to obtain a nine-figure jury award from Teva.

The decision below, if left uncorrected, will encourage other brand-name manufacturers to deliberately mimic GSK's tactics. Brand-name manufacturers already have every incentive to pursue scores of patents on the same drug.[13] Thanks to skinny labeling, however, a string of new use patents does not actually prevent generics from coming to market as the older use patents expire. But the cost to generics—and patients—of these patent estates will increase enormously if each added use patent adds a de facto new period of exclusivity during which generics cannot bring their drugs to the market, even if the vast majority of uses are no longer patented.

The decision below provides 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. Pet. App. 85a. 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

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[13] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 Can. Med. Ass'n J. E385 (2013).

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).

Industry observers recognize that the Federal Circuit's decisions have 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."[14] 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."[15] 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."[16] This potential whipsaw of liability will be enough to convince many generic and biosimilar manufacturers to avoid the risk altogether.

In *Caraco*, this Court rejected a different attempt by

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[14] Daniel Knauss, Cameron Vanderwall, & Michelle Rhyu, *Fed. Circ. Teva Ruling May Shake Up Skinny Label Strategies*, Law360 (Sept. 1, 2021), https://bit.ly/3BLDeFG.

[15] Dennis Crouch, *GSK v. Teva: Skinny Label Approval is Not a Patent Safe Harbor*, PatentlyO (Aug. 5, 2021), https://bit.ly/3P5Y8m0.

[16] Dani Kass, *GSK Redo Doesn't Cure Generics' 'Skinny Label' Uncertainty*, Law360 (Aug. 9, 2021), https://bit.ly/3byK9Yg (quoting Imron Aly of Schiff Hardin LLP).

brand-name manufacturers to "exploit[] this statutory scheme to prevent or delay the marketing of generic drugs." 566 U.S. at 408. There, too, the concern was that "a brand whose original patent on a drug was set to expire [would] list[] a new patent ostensibly extending its rights over the drug." *Id.* To resolve the problem of branded drug manufacturers submitting overbroad and inaccurate patent information to the FDA, the *Caraco* Court affirmed that Congress had indeed provided a counterclaim for generics. *See id.* Likewise, to respond to the problem of branded drug manufacturers suing generics for using the very labels they asked the generics to use, the Court should hold that following the FDA's skinny-label instructions is not inducement.

C. The Decision Will Harm American Patients And Taxpayers.

The panel's attack on Hatch-Waxman will harm the millions of American patients who benefit from cost-effective generic drugs.

If generic manufacturers face the risk of infringement liability when they follow the FDA-prescribed process, they will be deterred from entering the market until all use patents expire. This would delay the introduction of low-cost generic medications for years or decades—even for unpatented uses. These increased costs will burden patients and increase the strain on taxpayers as both public and private insurance strain to bear this burden.[17] Patients unable to afford

[17] *See* Cong. Budget Office, *A Comparison of Brand-Name Drug*

these more expensive versions may be less likely to adhere to their regimen, leading to worse health outcomes.

All told, the decision threatens to bring us back to precisely the quandary that inspired the Hatch-Waxman Act in the first place. This is not the outcome Congress intended, and it is not the correct outcome under the statute Congress drafted.

III. Equitable Estoppel Is Not A Solution.

In a last-ditch effort to downplay the immediate and harmful effects its decision will have on the pharmaceutical industry, the Federal Circuit suggested that equitable doctrines might shield generics from the crushing liability its decision condoned. But the possibility of an equitable estoppel defense does not justify the misguided decision below, and it should not deter this Court from stepping in to halt the disruption the Federal Circuit's decision will cause.

Equitable estoppel is a poor substitute for the legal protection that ought to be afforded to generics under the Hatch-Waxman Act and traditional inducement law. Because Teva was legally entitled to judgment as a matter of law, this case should be over—not moving to another stage of litigation. Equitable estoppel cannot

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Prices Among Selected Federal Programs 3 (2021), https://bit.ly/3by59hP (noting that 75% of Medicare Part D drug spending was on brand-name drugs).

remedy the defect of the decision below for three reasons.

First, and most fundamentally, the Federal Circuit cannot justify an error of law by telling litigants to resort to equity. Below, the court asserted that "equitable estoppel [was] the natural vehicle to address" any arguments regarding Teva's compliance with the Hatch-Waxman Act. Pet. App. 192a. But the court should have never reached equitable estoppel, much less treat it as the "natural vehicle" for Teva to assert its defense based on Hatch-Waxman. Equitable estoppel is a "flexible" doctrine "invoked to avoid injustice in particular cases." *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 59 (1984). But implicit in the application of doctrines like equitable estoppel is that, absent equity's intervention, the unfairly treated party would lose under the law. *See generally id.* at 59-61. The fact that Teva complied with the FDA's requirements for drug labeling means that it is wrong, as a matter of law, to find that its label induced infringement. Equitable estoppel cannot be a "natural vehicle to address" Teva's concerns when it rests on the incorrect premise that Teva could be found to infringe by adopting GSK's own language on its label.

Second, as a functional matter, equitable estoppel is a poor substitute for legal protection. Both the procedural posture and the substantive elements of equitable estoppel render it an inadequate alternative to a rule establishing that there can be no liability for a label like Teva's.

Generic manufacturers seeking to rely on equitable estoppel will first need to endure a second trial *after* the trial on the merits has concluded. This alone, even if the generic is eventually successful, will prolong these proceedings and further delay the entry of generic drugs into the market. Moreover, at this second stage of the proceedings, the generic manufacturers will bear the burden of proof (as opposed to at the liability phase, where the brand-name manufacturers bear the burden). Moreover, equitable estoppel depends on the subjective *mens rea* of both the patentee and the accused infringer. To prevail on an equitable defense, the accused infringer would be required to show the patentee's subjective intent to induce reliance. *See, e.g.*, *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. 663, 684-85 (2014). Litigating these issues thus requires a complex and messy inquiry into corporate officials' mental states with respect to the label—an inquiry that should not be necessary under the scheme enacted by Congress. Worse still, the district court's ultimate balancing of equitable considerations would be reviewable only for abuse of discretion. *Monsanto Co. v. Geerston Seed Farms*, 561 U.S. 139, 175 (2010).

Third, even assuming that some manufacturers might prevail in showing equitable estoppel, those sporadic victories will not blunt the chilling effect this decision will have on generics as a whole. The Hatch-Waxman Act recognized that in order to incentivize generics to come to market, clarity and structure—including the precise steps to follow to avoid infringement liability—were needed. Equitable estoppel provides no such clarity. Few generic

manufacturers will be willing to risk a protracted and expensive trial, resulting in potentially billion-dollar verdicts, in the hopes of convincing a court of the unfairness of the result at the eleventh hour. Instead, the far safer course will be for generics to wait the patents out or live with the 30-month stay, depriving American consumers and taxpayers of the very benefits Hatch-Waxman sought to provide.

For these reasons, equity is no substitute for an accurate legal test. Only a more sensible approach to inducement liability—one that will allow generics that have complied with the letter of the law to obtain *legal* relief—will adequately protect generic manufacturers, consumers, and taxpayers.

The effects of the decision below are already being felt in the pharmaceutical industry. This Court should intervene now to fend off the harmful downstream consequences to generics, as well as American patients and taxpayers.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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