No. 24-889

IN THE

Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC.
AND HIKMA PHARMACEUTICALS PLC,

Petitioners,

v.

AMARIN PHARMA, INC., AMARIN
PHARMACEUTICALS IRELAND LTD., AND
MOCHIDA PHARMACEUTICAL CO., LTD.,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF 30 SCHOLARS OF LAW, ECONOMICS, AND MEDICINE AS *AMICI CURIAE* IN SUPPORT OF THE PETITION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

Statutes and Regulations

OTHER SOURCES

INTEREST OF *AMICI CURIAE*

Amici curiae[1] are scholars of law, economics, and medicine, listed in the Appendix. Their interest is in the proper development of patent law in ways that best promote the interests of innovation access and the public interest.

SUMMARY OF ARGUMENT

Any well-stocked grocery store sells Kellogg's brand Rice Krispies beside a house-brand puffed rice cereal. No surprise: Patents on puffed rice cereals expired a century ago, enabling classic competition. Kellogg's may patent new uses for its cereal—binding with melted marshmallows to form bar-shaped treats, for example. But these new-use patents ought not force the house brand off the shelves. Future patents on novel cereal uses cannot foreclose competition over the market for *cereal eating*.

Yet the Federal Circuit here held that a generic may be liable under new-use patents, and might even be forced off the shelves, based on the routine additional act of truthfully characterizing the generic as a generic equivalent. This conflicts with basic principles of law, is contrary to patent policy, and injures competition, consumer protection, and efficient government. Certiorari is warranted to reverse this decision and restore the proper balance between patent law and competitive markets.

[1]Pursuant to Supreme Court Rule 37.2(a), all parties received timely notice of intention to file this brief. Pursuant to Rule 37.6, 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.

I. To reach this remarkable result, the Federal Circuit relied on the doctrine of patent inducement, which imposes liability on one who actively encourages others to infringe. The patent here covers a new use of an otherwise off-patent drug compound to treat certain cardiovascular risks. The allegedly inducing acts were press releases characterizing a generic version of that drug as a "generic version," in combination with factual statements about the overall sales of the brand-name product—akin to the advertising trope "just like the leading brand."

A mere descriptive statement about a product's equivalence, however, "actively encourages" nothing. To turn generalized equivalence statements into specific acts of encouragement, the Federal Circuit heaped inference upon inference: that (1) describing a drug as a "generic version" implies that the drug is equivalent for all known uses; and (2) relevant consumers would voluntarily research and perform the specific, patented use as a result. It was this tenuously connected theory of inferential reasoning that sufficed, in the Federal Circuit's view, to force the generic drug manufacturer through full-blown litigation over patent inducement.

II. This vague conception of patent inducement is contrary to law and policy. Patent inducement is not a sui generis form of liability, but rather derives from the common law of inchoate crimes and secondary tort liability. The Federal Circuit's freewheeling inferential theory is directly at odds with the common law tradition. Patent law is not exceptional, and certiorari is warranted to bring it back into line with general legal principles.

And leaving Federal Circuit's theory of equivalence-statement liability unchecked would conflict with the basic purposes of the patent system. New uses of a product

can be discovered at any time, even decades or centuries after the original product. So a savvy manufacturer could repeatedly obtain new-use patents every twenty-year patent term, thereby precluding competitors from communicating product equivalence *forever*. That result would contravene the most fundamental tenet that patent rights are granted only for limited times.

III. This unfounded expansion of patent inducement liability is not just jurisprudentially unreasonable, but also economically and societally dangerous. Statements of equivalence are not limited to the pharmaceutical industry, but abound in industries as diverse as information technology, manufacturing, construction, and groceries. The reach of this decision is potentially tremendous.

Across that broad economic spectrum of industries, multiple harms could arise out of uncertainty about patent inducement. Free markets depend on open entry of substitutable, equivalent products, meaning that the decision will be a powerful tool to stifle competition. Administrative processes also depend on statements of equivalence to determine regulatory approval, so the decision will result in government waste and inefficiency. And potential legal liability for statements of equivalence denies consumers access to important information, potentially creating consumer confusion. These harms are the unnecessary result of an erroneous expansion of patent inducement law, so this Court's correction of that error would be broadly beneficial.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION CREATES A CLOUD OF LIABILITY OVER PRODUCT EQUIVALENCE STATEMENTS

Under the Federal Circuit's decision, public statements about a product's equivalence to another might sustain a plausible claim of patent inducement liability, with virtually no guidance as to which statements qualify. Here, Hikma is a generic manufacturer of the drug icosapent ethyl, a compound derived from cod liver oil that has been known to have cardiovascular and cholesterol-reducing benefits since at least the 1980s.[2] The compound is unpatentable now, so Amarin's patents are instead directed to using icosapent ethyl to treat specific cardiovascular risks. (Pet. App. 4a–5a.) Hikma's generic product is only approved for a different use, and Hikma never mentioned the patented indication on any of its marketing or labeling materials. (*Id.* at 5a–7a.) Amarin relied on three facts to support its inducement claim: Hikma's drug safety label (which the Federal Circuit conceded was insufficient, at 17a), Hikma's recitation of facts about Amarin's aggregate sales, and most importantly, Hikma's press releases calling its product a "generic version" of Amarin's. (*Id.* at 6a–7a.)

Typically, these facts would fail to state a claim of inducement. Longstanding precedents require "active steps taken to encourage direct infringement" before in-

[2] *See, e.g.*, T.A.B. Sanders et al., *Effect on Blood Lipids and Haemostasis of a Supplement of Cod-Liver Oil, Rich in Eicosapentaenoic and Docosahexaenoic Acids, in Healthy Young Men*, 61 CLINICAL SCI. 317 (1981).

ducement will be found.[3] Neither Hikma's assertion of equivalence nor its recitation of factual sales data made any mention of the specific patented indication. Without specific instructions on what a direct infringer should do, it is difficult to see how these general, passive facts actively induce anything.

To reach its counterintuitive result, the Federal Circuit made two inferential leaps. First, it allowed (at 19a) the possibility that a physician reading the press releases, reciting generic equivalence and Amarin's aggregate sales data, could interpret them "as an instruction or encouragement to prescribe that drug for *any* of the approved uses of icosapent ethyl." But even this inference was not enough, because a doctor reading these statements would still not know of the infringing indication as a possible use at all—nothing in the statement of equivalence or sales data identified that indication. Thus, the decision required a second inference, that a doctor would independently research Amarin's product to find the particular patent-infringing use, and then would actually undertake that use.

Which statements of equivalence or marketing materials can trigger these inferential leaps leading to potential inducement liability, the Federal Circuit does not say. Its decision (at 21a) draws a distinction between the phrases "generic version" and "AB-rated," even though AB-rated is a regulatory term indicating product equiva-

[3] *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (ellipses omitted) (quoting *Oak Indus., Inc. v. Zenith Elecs. Corp.*, 697 F. Supp. 988, 992 (N.D. Ill. 1988)); *DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc).

lence.[4] The generalized sales data that the Federal Circuit deems incriminating for inducement is not far off of ordinary comparative advertising—"just like the leading brand." The undefined, potentially unbounded scope of the Federal Circuit's inducement-by-inference theory thus puts at risk a wide range of commonplace marketing statements.

II. Liability Based on Product Equivalence Statements Is Contrary to Law and Policy

A cloud of liability over public communications about product equivalence is the erroneous consequence of an inducement doctrine contrary to basic principles of law. Certiorari is warranted to correct this error.

A. The Federal Circuit's Decision Renders Patent Doctrine Inconsistent with Its Common Law Basis

Inducement of patent infringement is not a sui generis cause of action, but rather derives from a long tradition of common law, in particular tort and criminal liability.[5] Historically, courts recognized the action for "contributory infringement" of a patent by derivation from aiding

[4] *See* Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations xiii—xiv (45th ed. 2025).

[5] *See, e.g., Nat'l Presto Indus., Inc. v. W. Bend Co.*, 76 F.3d 1185, 1194 (Fed. Cir. 1996) (citing *Sims v. W. Steel Co.*, 551 F.2d 811, 817 (10th Cir. 1977)); Charles E. Miller, *Some Views on the Law of Patent Infringement By Inducement*, 53 J. Pat. Off. Soc'y 86, 89–94 (1971); Charles W. Adams, *A Brief History of Indirect Liability for Patent Infringement*, 22 Santa Clara Comput. & High Tech. L.J. 369, 371–84 (2006).

and abetting liability.[6] Case law consistently adopted a requirement of "culpable conduct" for inducement liability, borrowing another common-law phrase.[7] When in 1952 Congress recodified the Patent Act, it divided the common law doctrine into two parts: 35 U.S.C. § 271(c) for sale of a component with no substantial noninfringing uses, and § 271(b) for other acts of active inducement of infringement.[8] Nevertheless, Congress recognized the continued connection between both forms of indirect patent liability and their common law origins, characterizing the new § 271(b) as providing liability for "one who actively induces infringement as by aiding and abetting."[9]

Since that codification, decisions of this Court and others have continued to place patent inducement within that common law tradition. *Global-Tech Appliances, Inc. v. SEB SA* applied the criminal-law willful blindness doctrine to inducement, seeing "no reason why the doctrine should not apply" to patent law when it applied "to a wide range of criminal statutes."[10] *Commil USA, LLC v. Cisco Systems, Inc.* relied on principles of tortious interference and trespass to determine the scope of patent in-

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[6] *See, e.g., Wallace v. Holmes*, 29 F. Cas. 74 (C.C.D. Conn. 1871); *Tubular Rivet & Stud Co. v. O'Brien*, 93 F. 200, 202–03 (C.C.D. Mass. 1989).

[7] *E.g., DSU Med.*, 471 F.3d at 1306 (citing *Grokster*, 545 U.S. at 937); *cf. Borden v. United States*, 141 S. Ct. 1817, 1823 (2021) (defining "culpability" under criminal law).

[8] *See generally Glob.-Tech Appliances, Inc. v. SEB SA*, 563 U.S. 754, 761–63 (2011) (reciting history of statute).

[9] REVISION OF TITLE 35, UNITED STATES CODE, H.R. REP. NO. 82-1923, at 28 (1952); *see Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) ("[N]o substantive change . . . was intended by the enactment of § 271.").

[10] 563 U.S. at 766–67.

ducement.[11] And *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, a copyright case that would adopt patent law's inducement doctrine, characterized that doctrine as one with "common law" origins in "purposeful, culpable expression and conduct."[12]

Expansion of patent inducement potentially to cover mere statements of equivalence defies these common law principles of culpable aiding and abetting. Aiding and abetting under tort law holds liable only one who "gives *substantial* assistance or encouragement" to a tortfeasor; it is not enough merely to make passive, general statements not directly encouraging the direct tortfeasor.[13] Indeed, this Court only recently explained the "need to cabin aiding-and-abetting liability to cases of truly culpable conduct," or else "ordinary merchants could become liable for any misuse of their goods and services."[14] Similarly, criminal conspiracy liability based on sales of legal goods used in crimes has long been limited to situations where the seller had an active role beyond mere sale of those goods.[15]

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[11] *See* 575 U.S. 632, 646 (2015).

[12] 545 U.S. at 936–37.

[13] RESTATEMENT (SECOND) OF TORTS § 876(b) (AM. L. INST. 1978); *see, e.g.*, *Sindell v. Abbott Lab'ys*, 26 Cal. 3d 588, 605 (Cal. 1980) (drug manufacturers' "parallel or imitative conduct" in marketing cannot give rise to indirect tort liability; alternative "would render virtually any manufacturer liable for the defective products of an entire industry"); *Juhl v. Airington*, 936 S.W.2d 640, 645 (Tex. 1996) (rejecting aiding-and-abetting tort liability where defendants' passive actions, which "could have acted as moral support" to the direct tortfeasor, did not "give any verbal encouragement").

[14] *See Twitter, Inc. v. Taamneh*, 143 S. Ct. 1206, 1221 (2023) (citing RESTATEMENT (SECOND) OF TORTS § 876, cmt. d (AM. L. INST. 1978)).

[15] *See* Dylan Niederland, *The Software Inducement Paradox*, AM. U. L. REV. (forthcoming Feb. 22, 2025) (manuscript at 16), *available*

The Federal Circuit's overbroad theory of patent inducement liability is thus exceptional when compared to basic, longstanding principles of culpability under the common law. In that sense, this case is much like numerous recent others, in which this Court has disapproved of a patent-specific Federal Circuit rule contrary to the law as a whole.[16] The present decision is as much an outlier as the others, and requires realignment.

B. Patent Liability Could Now Theoretically Run Forever, Contrary to the Limited Patent Term

The grand bargain of the U.S. patent system, enshrined in the Constitution, permits patents to last only for "limited times." Yet patent inducement liability based on equivalence statements could control competitors' behavior forever, dismantling the patent bargain and the

online. Perhaps the closest case in opposition is *Grokster*, in which inducement of copyright infringement was premised on a filesharing service's advertisements that it was "offering the same file-sharing ability as" another infringing service. *See* 545 U.S. at 938. While this could be seen as a statement of equivalence, this Court was clear that far more was involved: "other unequivocal indications of unlawful purpose" made inducement "unmistakable." *Id.* at 938–840. Most importantly, the target of equivalence in *Grokster* was understood to be overwhelmingly a tool for infringement. *See id.* at 924. Here, by contrast, both the brand-name drug and the generic advertised as equivalent have the same substantial noninfringing uses, namely treatment of unpatented indications. Locations of authorities available online are shown in the Table of Authorities.

[16] *See, e.g., Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93 (2016); *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 572 U.S. 559 (2014); *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006). *See generally* Tejas N. Narechania, *Certiorari, Universality, and a Patent Puzzle*, 116 Mich. L. Rev. 1345, 1349 (2018) (noting this Court's "general trend for disciplining 'patent exceptionalism'").

underlying innovation incentives that the patent system is supposed to serve.

There is no time limit on obtaining new-use patents, on a drug or any other product.[17] An invention is patentable consistent with the requirements of the Patent Act, most significantly that it be new and nonobvious.[18] It is long settled that "earlier disclosure of a genus does not necessarily prevent patenting a species member of the genus" unless the genus and species are sufficiently related so as to render the latter obvious.[19] Thus, the prior use of a drug for a broad indication will generally not invalidate a later patent on using the drug on a more specific indication.[20] A simple way of finding potentially patentable new uses, then, is to subdivide an existing use into ever smaller subcategories, obtaining new-use patents seriatim for each of them.

This subgroup-division strategy is the source of the patents in this case.[21] As noted earlier, the icosapent ethyl drug at issue here is a fish oil derivative known since at least the 1980s.[22] Amarin's first wave of patents was

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[17]*See* S. Sean Tu & Aaron S. Kesselheim, *Preserving Timely Generic Drug Competition with Legislation on "Skinny Labeling,"* 115 CLINICAL PHARMACOLOGY & THERAPEUTICS 22 (2024).

[18]*See* 35 U.S.C. § 102; § 103.

[19]*See, e.g., Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1270 (Fed. Cir. 2003) (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001)); *Abbvie Inc. v. Mathilda & Terence Kennedy Inst.*, 764 F.3d 1366, 1379 (Fed. Cir. 2014).

[20]*See Prometheus Lab'ys v. Roxane Lab'ys*, 805 F.3d 1092, 1098 (Fed. Cir. 2015).

[21]*See generally* S. Sean Tu & Charles Duan, *Pharmaceutical Patent Two-Step: The Adverse Advent of Amarin v. Hikma Type Litigation*, 12 N.Y.U. J. INTELL. PROP. & ENT. L. 1, 14 (2022).

[22]*See supra* p. 4.

directed not to the drug chemical itself, but rather to a method of using icosapent ethyl to the small class of patients with especially high triglyceride levels.[23] Amarin subsequently filed a second wave of patent applications, seeking to cover a different patient population with moderately high triglyceride levels but also with "good cholesterol" (HDL-C) levels below a usual threshold, and further limited to patients who have "not previously had a cardiovascular event."[24] Later-expiring patents apply to patients within different ranges of triglyceride levels.[25] Once these patents expire, Amarin could further discern yet more patient subpopulations that respond well to icosapent ethyl, and thereby continue its chain of new-use patents.[26]

Under the Federal Circuit's theory of inducement, any of these future new-use patents—even those decades from the original drug patent expiration and covering a minuscule subpopulation—could open the door to an inducement case against a generic competitor advertising its product as an equivalent. The bar on the generic's ability to truthfully advertise about its own product would not end after the twenty-year patent term, but could potentially last forever. And indeed, a rising number of new-

[23] *See Amarin Pharma v. Hikma Pharms. USA*, 449 F. Supp. 3d 967, 987 (D. Nev. 2020).

[24] U.S. Patent No. 9,700,537 cl. 1 (issued July 11, 2017) (patients with triglycerides of at least 150mg/dl).

[25] *See, e.g.*, U.S. Patent No. 8,399,446 cl. 1 (issued Mar. 19, 2013) (500 to 1500mg/dl); U.S. Patent No. 12,171,738 cl. 1 (issued Dec. 24, 2024) (200 to 500mg/dl).

[26] Importantly, Amarin could likely do so without the expense of new clinical trials, instead just mining its existing trial data with statistical analysis to find appropriate patient groups. The cost of "discovering" these new uses would be minimal.

use pharmaceutical patents suggests that firms are aware of and beginning to take advantage of this strategy.[27]

Beyond flouting the limited-times restriction on patents, the Federal Circuit's rule misaligns the incentives for innovation that patents are supposed to provide. The exclusive rights of a patent are designed to be a market-based reward, where the more valuable an invention is, the greater market share the patent captures.[28] Yet the Federal Circuit's inducement rule, particularly in light of the potential injunctive relief available, potentially makes even the narrowest new-use patent equally effective for interfering with equivalent product purveyors such as generic firms.[29] The incentives for patent holders will be to aggregate tremendous estates of new-use patents of minor value, contributing minimally to the larger project of innovation, but plenty enough to foreclose competitive and fair markets.

III. Impediments to Product Equivalence Statements Would Cause Multiple Societal Harms

Uncertainty over the permissibility of equivalence statements, resulting from an erroneous expansion of patent inducement liability, invites multiple harms to competition, good government, and consumer welfare. Those harms are perhaps most acute in the pharmaceutical industry due to the importance of generic drugs. But

[27] *See* S. Sean Tu & Ameet Sarpatwari, *A "Method of Use" to Prevent Generic and Biosimilar Entry*, 388 New Eng. J. Med. 483, 485 & fig. (2023).

[28] *See, e.g.*, Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 Yale L.J. 544, 553 (2019).

[29] *See* Charles Duan, *Mandatory Infringement*, 75 Fla. L. Rev. 219, 256–57 (2023).

they also extend to many other markets. The ramifications of this error in patent law thus potentially ripple far throughout the economy.

A. Numerous Industries Beyond Pharmaceuticals Depend on Equivalence Statements

Opening the door to patent inducement liability based on mere statements of product equivalence affects not just pharmaceutical products like those in the present case, but a wide variety of products and industries. This is because statements of product equivalence, in one form or another, are found in many places.

Consider, for example, computer and information technology. Compatibility, and statements advertising compatibility, abound here.[30] Laptops and mobile phones tout compatibility with the latest 5G cellular standards. Email systems advertise their compatibility with the technical standards for email transport. The Supreme Court's electronic filing system requires uploaded documents to be compatible with the PDF/A file format, that format defined in a technical standard.[31]

Yet computer compatibility claims are arguably a sort of equivalence statement, insofar as a system asserting

[30] *See Google LLC v. Oracle Am., Inc.*, 141 S. Ct. 1183, 1203–04 (2021); *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1208–09 (Fed. Cir. 2014).

[31] *See* Sup. Ct. of the U.S., Electronic Filing System User Guide B–1 (Nov. 2017), *available online*; Int'l Org. for Standardization, ISO 19005-1, Electronic Document File Format for Long-Term Preservation—Part 1: Use of PDF 1.4 (PDF/A-4) (2005). *See generally* Charles Duan, *Internet of Infringing Things: The Effect of Computer Interface Copyrights on Technology Standards*, 45 Rutgers Comput. & Tech. L.J. 1, 5–7 (2019).

compatibility with a certain technology essentially describes itself as equivalent to other similarly compatible systems—an Apple iPhone is "equivalent" to a Samsung phone in that both are compatible with 5G networks. The Federal Circuit's inducement-by-inference theory could thus plausibly be adapted to computer devices: (1) a statement of compatibility could be interpreted as an instruction to use a device for any compatible purpose; and (2) consumers would research, discover, and perform patented uses based on the device's compatibility.[32] Nothing in the Federal Circuit's decision clearly rejects this possibility, and given the ubiquity of compatibility statements in the information technology industry, the mere possibility that this theory of liability could succeed invites tremendous uncertainty and risk.

Beyond computer technology, equivalent consumer products are abundant and a staple of competition. Multiple manufacturers produce equivalent puffed-rice cereals, car tires, screws, lightbulbs, batteries, and more.[33] These products, sometimes called house brands or private labels, often advertise as equivalents to other products either expressly on their labels or implicitly through packaging appearance and design.[34]

Sometimes, product equivalence is driven by compatibility needs—car tires must be equivalent in order to fit onto a particular make and model of car. In other cases, though, equivalence is the natural consequence of

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[32] *Cf. supra* p. 5. *See generally* Niederland, *supra* note 15, at 11–12.

[33] *See McNeil Nutritionals, LLC v. Heartland Sweeteners, LLC*, 511 F.3d 350, 353–54 (3d Cir. 2007); Eric Goldman, *Brand Spillovers*, 22 HARV. J.L. & TECH. 381, 390 & n.40 (2009).

[34] *See* Andrew W. Coleman, *National Brands, Private Labels and Unfair Competition*, 87 TRADEMARK REP. 79, 81 & n.6 (1997).

a competitive market. House-brand products are regularly priced lower than their name-brand equivalents, giving consumers choices and driving prices down overall.[35] But for in order for consumers to make those informed choices, competing products identify themselves as equivalent. As one court observed about the ubiquity of house brands, "any shopper" in a typical retail store "has likely been exposed to generic or discount house brands before . . . observing the many 'compare and save' signs."[36]

Patents on methods of using consumer products—the kinds of patents that could be the subject of inducement litigation under the Federal Circuit's theory of inference—are common outside the pharmaceutical sector.[37] General Mills does in fact have patents on using breakfast cereals to make snack bars.[38] The existence of such patents means that questions about the legal consequences of statements of equivalence, arising from the Federal Circuit decision's ambiguity, affect a potentially wide range of consumer products and goods.

B. Equivalence Statements Are Necessary for Efficient Free-Market Competition

In these many industries, product equivalence is the prerequisite to market efficiency. An ideally efficient

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[35] *See* Coleman, *supra* note 34, at 82–83.

[36] *Warner Lambert Co. v. McCrory's Corp.*, 718 F. Supp. 389, 399–400 (D.N.J. 1989).

[37] *See, e.g.*, Courtenay C. Brinckerhoff, *Yes, You Can Patent Food Products!*, Foley & Lardner LLP (Aug. 22, 2024), *available online*. Business method patents, as well, are patents on methods of using computers or other systems. *See, e.g., Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

[38] *See, e.g.*, U.S. Patent No. 7,431,955 (issued Oct. 7, 2008).

market, in which the discipline of competition avoids monopolistic profit and deadweight loss, depends on the ability of firms to enter the market freely with perfect substitutes. Where only imperfect substitutes are available, the equilibrium price to consumers will be higher than a fully competitive market, because product differentiation enables suppliers to raise prices without losing all sales.[39] And barriers to entry, which raise the cost of new firms hoping to introduce products, also allow incumbents to charge higher prices with diminished concern for inviting competitive new entrants.[40]

Products can, of course, be equivalent without advertising themselves as such. Nevertheless, a bar on statements of product equivalence introduces economic inefficiency. An inability to market a product as equivalent to another adds an information cost to the product.[41] If the house-brand puffed rice cereal cannot promote itself as just as good as the leading brand, then buyers will have to expend resources to find out, or guess and hope for the best. And the house-brand cereal's label would have to be filled with detailed descriptions of the crunchiness and taste of the cereal—information that could be much more compactly expressed with a statement of equivalence. So a bar on equivalence statements creates barriers to entry that gives incumbents an inappropriate edge over competitors.

For competition among pharmaceuticals, statements of equivalence take on even greater importance for two reasons. First, those statements have legal effect.

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[39] *See, e.g.*, W. Kip Viscusi et al., Economics of Regulation and Antitrust 87 (4th ed. 2005).

[40] *See* Viscusi et al., *supra* note 39, at 165.

[41] *Cf.* Coleman, *supra* note 34, at 85.

State drug substitution laws enable pharmacies to dispense generic equivalents of brand-name drugs where available—but only if those generic equivalents are asserted to be equivalent.[42] Absent such a statement of equivalence, a generic would only be dispensed if the prescription explicitly called for the generic. Statements of equivalence of generic drugs are thus not just helpful for competition, but legally necessary.

Second, competitive pharmaceutical markets are of such importance that Congress has explicitly sought to foster such competition. A primary objective of the Hatch–Waxman Act, enacted in 1984, was to stimulate entry of generic drugs after expiration of original compound patents, reaping tremendous cost savings to patients resulting from such competition.[43] That statute recognized the potential for new-use patents to inhibit this valuable generic competition, and created a specific "skinny labeling" pathway giving the U.S. Food and Drug Administration ("FDA") the ability to approve generic, off-patent drugs despite later-obtained patents on specific uses and indications.[44] The skinny labeling pathway has saved Medicare Part D $15 billion and accelerated generic drug entry by an average of 2.5 years between

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[42] *See, e.g.*, Jesse C. Vivian, *Generic-Substitution Laws*, 33 US PHARMACIST 30 (2008), *available online*.

[43] Pub. L. No. 98-417, 98 STAT. 1585 (1984); *see Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 42 (2009).

[44] *See* Federal Food, Drug, and Cosmetics Act (FFDCA) § 505(j)(2)(A)(viii), 21 U.S.C. § 355; Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA INTERNAL MED. 995, 997 (2021).

2015 and 2019,[45] with similar benefits for biologic therapeutics.[46] A robustly competitive generic drug market produces these tremendous cost savings, and that market depends on the continued marketing of generics truthfully as generic equivalents.

C. Equivalence Statements Reduce Regulatory Compliance Costs and Avoid Administrative Waste

While equivalence statements are important enough in unregulated markets, they take on even further importance where products are regulated. Here, statements of equivalence promote efficiency and fairness in the regulatory process, and preclusion of statements risks government waste and unfairness.

Multiple fields of regulation turn on statements of product equivalence. Most prominently, as in this case, generic drugs must assert several levels of equivalence to another drug in order to win approval before the FDA. The generic drug itself must be "bioequivalent," and labeling attached to the generic must be "the same" as that for its brand-name counterpart.[47] Regulations for pesticides, medical devices, and marine vessels similarly require statements of equivalence in order to take advantage of expedited regulatory approval pathways.[48]

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[45] *See* Alexander C. Egilman et al., *Estimated Medicare Part D Savings from Generic Drugs with a Skinny Label*, 177 Annals Internal Med. 833 (2024).

[46] *See* Alexander C. Egilman et al., *Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings*, 183 JAMA Internal Med. 82 (2023).

[47] *See* FFDCA § 505(j)(2)(A)(iii)–(iv).

[48] *See, e.g.*, Federal Food, Drug, and Cosmetics Act § 513(f)(1)(A)(ii), 21 U.S.C. § 360c (exempting, from stringent class III regulation,

Television broadcasts are required to be compatible with government-approved technical standards, which is a form of equivalence as explained above.[49]

Impediments to equivalence statements are harmful to these regulated fields in at least two ways. First, where a regulation requires a statement of equivalence, a bar on that statement puts regulated entities into an impossible double bind.[50] In *SmithKline Beecham Corp. v. Apotex Corp.*, for example, the manufacturer of brand-name nicotine patches sued a generic competitor seeking to enter the market.[51] Patents on the patches had expired, but the brand firm instead alleged copyright infringement in the text of the generic's warning labels—despite the fact that, by regulatory command, the generic's labels were required to use identical text.[52]

Absent the Second Circuit's determination that the regulation's authorizing statute overrode the Copyright Act, generic firms would have been unable to comply with both copyright law and the regulatory equivalence requirement.[53] That would have created a de facto monopoly over nicotine patches, even after those patches were off patents and open to competition.[54] And the lure

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medical devices that are "substantially equivalent" to certain preexisting devices); Federal Insecticide, Fungicide, and Rodenticide Act § 3(c)(3)(B)(i)(I), 7 U.S.C. § 136a (providing for expedited review of pesticides "identical or substantially similar in composition and labeling to a currently-registered pesticide"); 46 C.F.R. § 175.540(b) (permitting approval of certain high-speed craft based on equivalence to international safety standards).

[49] *See* 47 C.F.R. 73.682/d1.

[50] *See generally* Duan, *supra* note 29.

[51] *See* 403 F.3d 1331, 22–23 (Fed. Cir. 2005).

[52] *See* 403 F.3d at 23–24 (discussing § 505(j)(2)(A)(v)).

[53] *See* 403 F.3d at 27–28.

[54] *See* 403 F.3d at 28; Duan, *supra* note 29, at 237–38.

of post-patent monopolies would almost certainly invite manipulation of regulations involving regulatory equivalence requirements, leveraging them to stifle rivals.[55]

Second, even where product equivalence only expedites regulatory processes rather than being mandatory, those statements avoid wasteful, duplicative costs for both the government and regulated entities. Proof that a product is equivalent to an already approved one may allow administrators to avoid a full regime of compliance testing, which often is costly.[56] For example, approval of a new drug requires multiple phases of clinical trials, which run a median of $19 million.[57] Bioequivalence studies, by contrast, require simple blood test measurements, which cost about $250,000, or 1.3% of full clinical trials.[58] Government regulators, too, must review submitted testing data, which presumably is simpler and faster when the only data is evidence of equivalence.

Equivalence statements allow regulators to do their jobs more efficiently and effectively. Taxpayers save

[55] *See* Duan, *supra* note 29, at 255–58.

[56] *See* Francesco Trebbi & Miao Ben Zhang, *The Cost of Regulatory Compliance in the United States* 12 n.25 (Nat'l Bureau of Econ. Rsch., Working Paper 30691, Nov. 2022), *available online* (estimating "aggregate nominal regulatory compliance costs" in the United States in 2014 to be $103 billion). The authors of the study caution that they measure "the costs of regulation without addressing the benefits of regulation." *Id.* at 4.

[57] *See* Thomas J Moore et al., *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015–2016*, 178 JAMA Internal Med. 1451, 1454 (Sept. 24, 2018), *available online*.

[58] *See* Jack A. Cook & Howard N. Bockbrader, *An Industrial Implementation of the Biopharmaceutics Classification System*, Dissolution Techs., May 2002, at 6, *available online*; Aylin Sertkaya et al., E. Rsch. Grp., Inc., Cost of Generic Drug Development and Approval 12–13 tbl.4 (Dec. 31, 2021), *available online*.

when government avoids duplicative activity, and consumers enjoy lower prices when regulatory compliance is simplified. Prohibitions on equivalence statements would create unnecessary government waste, and are likely also invite improper manipulation of the regulatory process.

D. Equivalence Statements Protect Consumers from Confusion

Ultimately, the benefits of equivalence statements and the harms of barring them fall upon consumers who buy equivalents, like generic drugs or store brand cereals. Consumers pay for oligopoly pricing resulting from reduced competition, and they bear the costs of regulatory inefficiency in the form of higher taxes.

And beyond these harms, equivalence statements protect against potentially significant consumer confusion. A claim that one product is equivalent to another is a simple, compact way of conveying a great deal of information about the product, as noted above. But where a product expected to equivalent lacks any such claim, the potential implication is that the two products are not the same. Any lawyer is familiar with the canon of construction that "a material variation in terms suggests a variation in meaning."[59] If the Goodyear Tire company cannot promote its products as equivalent to original Ford F-150 tires, then truck owners would reasonably ques-

[59] Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 170 (2012); *Russello v. United States*, 464 U.S. 16, 23 (1983) ("[I]t is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)).

tion whether Goodyear tires would fit their trucks—even if those tires in reality are equivalent.

Equivalence statements are especially important for consumers of pharmaceuticals. Many consumers question whether generic equivalents are, in fact, equivalent to their brand-name counterparts.[60] These questions persist despite federal policy designed to boost public confidence in the equivalence of generic drugs, and a regulatory apparatus for proving such equivalence.[61] If generic manufacturers are forced to employ awkward, legalistic explanations of equivalence to avoid liability under the Federal Circuit's uncertain inducement standard, that would only stoke further unnecessary skepticism, increasing costs in an already strained American healthcare system.

Across a wide range of industries, statements of product equivalence promote efficient competition, streamline regulatory processes, avoid undue legal gamesmanship, and avoid consumer confusion. A legal cloud over statements of equivalence, such as that created by the Federal Circuit's ambiguous inducement doctrine, risks harming these interests of national importance.

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[60] *See, e.g.*, Suzanne S. Dunne & Colum P. Dunne, *What Do People Really Think of Generic Medicines?* 20, *in* 13 BMC MED. no. 173 (2015), *available online*; *cf.* Aaron S. Kesselheim et al., *Variations in Patients' Perceptions and Use of Generic Drugs*, 31 J. GEN. INTERNAL MED. 609, 611, 613 (2016), *available online*.

[61] *See* Ed Silverman, *FDA Scolds Drugmaker over Promotion That Touts "Misleading" Comparison with Generics*, STAT NEWS (Mar. 4, 2005), *available online*; Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch–Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 311–12 (2015).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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APPENDIX A
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