

IN THE
Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., *et al.*,
Petitioners,

v.

AMARIN PHARMA, INC., *et al.*,
Respondents.

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

**BRIEF OF THE ACADEMIC MEDICAL
CENTERS AS *AMICI CURIAE*
IN SUPPORT OF RESPONDENTS**

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**IDENTIFICATION AND
INTEREST OF THE
ACADEMIC MEDICAL
CENTERS¹**

Pursuant to Supreme Court Rule 37, the Academic Medical Centers respectfully submit this brief *amici curiae* in support of Respondent. The Academic Medical Centers include The Dana-Farber Cancer Institute, Memorial Sloan-Kettering Cancer Center, Memorial Hospital for Cancer and Allied Diseases, Sloan-Kettering Institute for Cancer Research, and The Johns Hopkins University on behalf of the Johns Hopkins University School of Medicine.

The Dana–Farber Cancer Institute blends leading science and exceptional care into transformative medicine. Founded in Boston in 1947, Dana-Farber is a teaching affiliate of Harvard Medical School and federally designated a Comprehensive Cancer Center that develops and disseminates innovative patient therapies and scientific discoveries throughout the world.

Memorial Sloan-Kettering Cancer Center, Memorial Hospital for Cancer and Allied Diseases, and Sloan-Kettering Institute for Cancer Research (collectively, “MSK”) are not-for-profit corporations united by a singular mission: ending cancer for life. Founded in New York City in 1884, MSK is committed

¹ This brief conforms to the Court’s Rule 37, in that no counsel for a party authored this brief in whole or in part, and no person or entity other than *Amici Curiae* funded its preparation or submission.

to delivering exceptional patient care, conducting leading-edge research, and providing superb educational programs. A National Cancer Institute-designated Comprehensive Cancer Center, MSK has been recognized as one of the top two cancer hospitals in the country by U.S. News & World Report for more than 30 years.

The Johns Hopkins University School of Medicine, established in 1893 in Baltimore, is a globally renowned institution and premier biomedical research center, recognized for pioneering modern medical education, consistently ranking among the top medical schools in the United States, and operating in close affiliation with the top-ranked Johns Hopkins Hospital founded in 1889. Considered to be the founding institution of modern American medicine, The Johns Hopkins University School of Medicine was the birthplace of numerous famed medical traditions, including rounds, residents, and house staff.

These Academic Medical Centers represent world-leading research institutions in the fight against cancer and other life-threatening diseases. We represent both the clinical interests of our patients as well as the basic research that leads to tomorrow's cures. As such, we are sensitive to the need for unpatented generic drugs to be readily available and affordable to patients. We also have unique and profound insight into discoveries of new uses of old drugs made in our laboratories and clinics that fail to reach patients broadly due to the failure to protect the exclusivity of the patented uses. We understand that robust protection of the patented uses is necessary to

enable the investment necessary for these uses to secure FDA approval and reach patients and see a current system that too often fails patients waiting for cures.

Amici submit this brief in hope that the Court rectifies the delicate balance that Congress intended to protect – and therefore to provide a viable path to clinical and commercial development – patented new uses of old drugs while enabling unfettered access to unpatented indications. Doing so in the unique marketplace of prescription generic products will enable the promising discoveries in our laboratories to save the lives of patients.

SUMMARY OF THE ARGUMENT

The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act sought to strike a delicate balance of supporting critical research and innovation to discover and develop drugs, including new uses of drugs, while providing generic companies a clear path to compete for unpatented treatments. Due to judicial interpretation, measures by federal regulators and states, and the influence of pharmacy benefit managers, this balance has been lost over time, so much so that there is no longer a viable path for investment in new uses of old drugs. That is a travesty to patients waiting for tomorrow's cures.

Reversing the Federal Circuit and dismissing the complaint at this early stage of the proceedings would undermine any remaining semblance of balance in the statutory scheme. It would recast 21 U.S.C. 355(j)(2)(A)(viii) (the statutory section that allows a generic manufacturer to “carve out” patented

indications), not as an integral component of the compromise between innovator and generic interests, but as a free pass from even an allegation of infringement. In allowing “skinny labels,” Congress did not intend to hand broad power to the FDA to decide questions of patent infringement, nor did Congress intend to insulate a generic manufacturer from infringing acts relating to the patented indication.

The delicate balance of the Hatch Waxman Act should be restored. There need to be clear paths to support the investment necessary to develop innovative, patented new treatment options for patients and for generic companies to enter the market for unpatented indications. The first step to restore this balance is for this Court to affirm the Federal Circuit that sufficient facts have been pled for the case to continue.

ARGUMENT

I. The Hatch-Waxman Amendments Struck a Delicate Balance of Supporting Critical Research to Discover and Develop Drugs, Including New Uses of Old Drugs, While Providing Generic Companies a Path to Compete for Unpatented Uses.

As this Court has recognized in its precedents such as *Actavis*, *Caraco* and *Eli Lilly*,² the Hatch-Waxman Act struck a delicate balance between

² *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013); *Caraco Pharma. Labs., Ltd. V. Novo Nordisk A/S*, 566 U.S. 399 (2012); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

providing financial incentives sufficient to allow companies to expend the time and money needed to research and develop new drugs and treatments, while at the same time, providing a pathway for generic companies to provide nonpatented medicines at a low cost. “Old drugs”, *i.e.* drugs for which there is no remaining patent protection, constitute an important class under the Hatch-Waxman legal framework. Such old drugs may be used to treat a new disease or a new sub-population of patients, or they may be used in a different way for an existing indication. Congress clearly intended that such old drugs be researched for new methods and indications, specifically allowing for patents and data package exclusivity to be granted for new methods of using these old drugs to treat patients.

Congress sought to foster these new methods of using old drugs for good reason—they are a potential goldmine of new treatment options for patients.³

³ Sreeji Pushpakom et al., *Drug Repurposing: Progress, Challenges and Recommendations*, 18 **Nat. Rev. Drug Discov.** 41 (2019) (“First, and perhaps most importantly, the risk of failure is lower; because the repurposed drug has already been found to be sufficiently safe in preclinical models and humans if early-stage trials have been completed, it is less likely to fail at least from a safety point of view in subsequent efficacy trials. Second, the time frame for drug development can be reduced, because most of the preclinical testing, safety assessment and, in some cases, formulation development will already have been completed. Third, less investment is needed, although this will vary greatly depending on the stage and process of development of the repurposing candidate. The regulatory and phase III costs may remain more or less the same for a repurposed drug as for a new drug in the same indication, but there could still be substantial savings in preclinical and phase I and II costs. Together, these advantages have the potential to

Researchers now suspect that our current arsenal of drugs could provide effective medical treatments for most of the major diseases, including cancer and Alzheimer’s disease, and effective treatments for most or all 8000 rare diseases, which together afflict 15 to 20 percent of the global population.⁴

A classic example of this is the molecule amantadine, which was developed in the 1960s for anti-influenza, but in the 1970s became a significant treatment for Parkinson’s disease.⁵ The amantadine story highlights exactly why *amici* submit this brief. This medicine was repurposed from its initial use and later became an important treatment for Parkinson’s disease. However, the potential to develop known compounds for new uses today is severely limited because drug companies will not invest in the clinical trials needed to bring this new, second use to the

result in a less risky and more rapid return on investment in the development of repurposed drugs, with lower average associated costs once failures have been accounted for (indeed, the costs of bringing a repurposed drug to market have been estimated to be US\$300 million on average, compared with an estimated ~\$2–3 billion for a new chemical entity). Finally, repurposed drugs may reveal new targets and pathways that can be further exploited.”) (footnotes removed).

⁴ *E.g.*, Benjamin N. Roin, *Solving the Problem of New Uses* at 46 (Oct. 1, 2013) (unpublished manuscript), <https://ssrn.com/abstract=2337821> (“Many researchers now suspect that our current arsenal of drugs could provide effective medical treatments for most of the major remaining diseases, including cancer and Alzheimer’s disease. There is also hope that repurposing old drugs for new indications will allow researchers to identify effective treatments for most or all of the 8000 rare diseases, which together afflict 15 to 20 percent of the global population.”).

⁵ Wojciech Danysz et al., *Parkinson’s Disease Therapy: What Lies Ahead?*, 128 **J. Neural Transmission** 127 (2021).

marketplace because they worry that section viii carve-outs—if taken too far—will prevent them from recouping their investment. Thus, there needs to be a proper balance to section viii that will allow companies who invest in research of new uses of old compounds to protect their interests and be rewarded financially for their research and development. Otherwise, these promising treatments simply fail to reach patients.⁶

Often, these old compounds are available to researchers and thus can be studied at reasonable costs, especially at academic research centers like the present *amici*. Congress and patients—like the multiple sclerosis and Parkinson’s patients who take these old drugs—want and need these old molecules to be studied, researched and developed for new indications.

At the same time, Congress also wants generic versions of old drugs on the market—which is why it allowed for the section viii carve-out. Thus, if a drug is off-patent for one indication, but there is a new method of use for a second, later treatment (as is the case here), the congressional intent in passing section viii was to allow the generic to sell the drug for the unpatented method and “not foreclose marketing a

⁶ See, also, K. Budde et al., *FTY720 (Fingolimod) in Renal Transplantation*, 20 **Clin. Transplantation** 15 (2006). (providing the further example of the therapeutic fingolimod, which was initially researched and failed clinical trials for patients receiving a kidney transplant, but later was studied, approved and became a game-changing treatment for multiple sclerosis).

generic drug for other unpatented ones.” *Caraco*, 566 U.S. at 415.

Yet, the section viii carve-out can be taken too far. Permission to sell the generic drug for the unpatented use is not *carte blanche* for the generic drug marketer to sell for all uses where one or more of those further uses is patented. The reason for that is obvious—if the generic company essentially receives a free pass to produce and sell the drug without consequence for all uses, that would effectively obviate the later patent. That would destroy all incentives to research new uses of an old drug. There would be no way for a party to recoup their investment and drug companies would simply stop researching new uses of old drugs as the end of patent exclusivity approaches. Under these circumstances, the discovery of new uses by academic researchers will fail to spur the investment necessary for commercial development. The position advocated by Hikma and the supporting *amici* would be the nail in the coffin for new uses.

Amici submit this fear is not ethereal. Rather, it is one that *amici* deal with every day. *Amici*, which often conduct research of new uses of old drugs due to their known properties and availability of the drug, cannot get industry to license and partner with them to develop these new uses because industry cannot get a return on their investment. For example, the therapeutic metformin, which was approved for treatment of diabetes in 1995 and for which generics entered the market in 2002, has been viewed for many years as a promising compound for cancer treatment, but (as of 2025) no one is willing to fund a clinical trial

because the market participants understand that the section viii carve-out provisions will prevent them from being able to recoup their investment. Eric Budish et al., *Missing Markets for Innovation: Evidence from New Uses of Existing Drugs* (Nat'l Bureau of Econ. Rsch., Working Paper No. 34222, 2025) at 2-3; *See, also*, Roin, *supra* n. 4, at 42 (noting that a known cancer-treating molecule bexarotene has been shown to be “remarkably effective against Alzheimer’s in several important preclinical models”, yet because the patent life on this molecule is limited, “finding industry sponsors for these trials will be difficult, if not impossible.”); Budish at 4 (finding that market dynamics for new uses, i.e. first 10 years see 7% of drugs re-approved for a new indication, then declines dramatically after that and is roughly zero at loss of patent exclusivity).

This result does not help patients and needs to be rectified. One step to doing this is to ensure that section viii carve-outs do not “swallow the whole” and destroy the incentives to fund research on old, known drugs.

II. The Drug Market is a Complex Payer, Rather Than Consumer or Physician, Driven Market, Which Impacts the Type of Evidence That Shows Induced Infringement

The substitution of generic drugs in place of brand name drugs is a unique market driven strongly by the structure of the healthcare industry. The unique market structure and incentives also impact the types of activities that might constitute active inducement of infringement.

A. How Prescriptions Are Filled When Generic Drugs Are Available

A healthcare provider examines a patient, selects the drug best suited for treatment, and writes a prescription for a drug. The prescription identifies the drug, either by brand name or non-proprietary name and dosage. The prescription is provided to the pharmacy, nowadays often electronically. Unless the prescriber indicates “dispense as written,” state generic-substitution rules generally permit the pharmacy to dispense FDA therapeutically equivalent generic drug in place of the brand name drug.⁷ How the prescription is filled, however, is most often dictated by the pharmacy benefit managers (PBM).⁸ The three largest PBMs control more than 80% of prescriptions in the United States.⁹ The PBM effectively determines whether the prescription is filled with the generic drug, and which generic drug if generic drugs from multiple manufactures are available. Notably, PBM and pharmacies profit more from dispensing generic drugs versus brand-name

⁷ In some states, generic substitution rules are mandated. *See*, Yan Song & Douglas Barthold, *The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs*, 27 **Health Econ.** 1717 (2018).

⁸ The Role of Pharmacy Benefits Managers in Prescription Drug Markets Part III: Transparency and Accountability: Hearing Before the H. Comm. on Oversight & Accountability, 118th Cong., Serial No. 118-123 (2024) (“House Report”).

⁹ *Id.* at 53. (“The PBM market has become highly consolidated with the three largest PBMs controlling roughly 80 percent of prescriptions. The top six PBMs account for 97 percent and in Medicare Part D, four PBMs managed benefits for a combined 90 percent of beneficiaries.”)

drugs.¹⁰ Therefore, the choice about which generic drug is available through the PBM or pharmacy is not made by the patient or the doctor and it is not influenced by consumer marketing. The choice of which generic drug is dispensed is determined by the economics negotiated between the generic drug manufacturer and PBM and/or pharmacy.¹¹

The consequence of this economic system is that generic drug manufacturers are pushing through an open door to have the prescription filled by a generic drug. The FDA enables generic drug substitution by assigning a therapeutic equivalence rating. State law encourages or mandates filling the prescription with the generic drug for on-label indications, and the PBM and pharmacies are more profitable dispensing the generic drug. The generic drug company needs to do nothing to effectuate the sale—other than privately contract with PBM and/or pharmacy to be included on the drug formulary.¹²

The complaint alleges that Hikma deleted from its final labeling that the generic drug was not approved for the use that remains under patent

¹⁰ Song, *supra* n.7 (“Indeed, gross profit dollars are approximately 50 percent higher for generic drugs than for brand name drugs ... pharmacists have a strong incentive to substitute generic for brand name drugs”)

¹¹ The three largest PBMs are vertically integrated. That is, the pharmacy is owned or managed by the PBM. House Report, *supra* n. 8, at 31.

¹² Garth Boehm et al., *Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984*, 3 **Acta Pharmaceutica Sinica B** 297, 308 (2013) (“Generic profitability to the pharmacy ensures that new generic products are ‘pulled’ into the distribution chain and that generic substitution rate is rapid.”).

protection.¹³ Therefore, while the change in labeling may appear facially immaterial to the issue of active inducement of the patented indication, this change is consequential to generic substitution as there is no express limitation on the label that indicates that it is unapproved for the patented indication that could limit the substitution of the generic drug for the patented use.

B. In the Generic Drug Market Subtle Acts Can Induce Infringement, and More Overt Acts, if Any, Are Embedded in Private Contracts Between the Generic Drug Company and PBM/Insurance Companies

The real-world dynamics of the generic drug market are clear—there is no consumer advertising or promotion of the drug to physicians or patients. There is no role of the consumer or physician in the selection of which generic drug will be dispensed by the pharmacy for administration to the patient.¹⁴ The typical acts of inducement for a consumer product, such as advertising or instructions to consumers, are not relevant in this market. All that is needed is an agreement with the PBM and/or pharmacy with

¹³ *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1373 (Fed. Cir. 2024) (“Although Hikma’s original proposed label included the CV Limitation of Use, Hikma later amended the label to remove that limitation around the same time it submitted its section viii statement carving out the uses covered by the asserted patents.”)

¹⁴ Absent a “dispense as written” for the brand designation.

financial terms that place the generic drug in a preferred placement on the formulary.

The negotiation of the generic-PBM/pharmacy agreement(s) would only be available through discovery. Whether or not representations were made relating to patented use in this case are not part of the record. But, what has been alleged—label changes to delete reference to the drug not being approved for the patented indication, various unqualified statements of being generic version, reference to whole market (patented and unpatented sales data), the “small lettering” on the website vaguely describing that the generic version was not approved for all approved uses—in the context of this market should be enough to plausibly state a claim.¹⁵

Finding otherwise and accepting Hikma’s position that the complaint be dismissed before discovery based on the labeling effectively gives a free pass to the generic drug industry to exploit the patented indication. This eliminates any remaining semblance of the balance Congress sought between supporting innovative new treatments by the brand manufacturers and ensuring the accessibility of generic drugs on unpatented treatments when the Hatch Waxman Amendments were promulgated.

¹⁵ *Amarin*, 104 F.4th at 1373-75. *Amici* take no position whether on a more fulsome record the evidence is sufficient to establish Hikma actively induced infringement.

III. Active Inducement is Context Dependent, and in the Complex, Payer Driven Pharmaceutical Market, Minimal Acts are Sufficient to Induce Infringement

This Court's and the Federal Circuit's decisions make clear that evidence of all of the accused inducer's actions, as well as its intent, are important to the inducement analysis. While the courts below were correct to consider evidence beyond the label in determining whether inducement had been sufficiently pleaded, none considered the unique circumstances of the market into which the products were being delivered. Set in the proper economic context, it is even more important that the Federal Circuit decision not be reversed.

A. Intent is a Critical Aspect of the Legal Requirements for Active Inducement

“Whoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). “The addition of the adverb “actively” suggests that the inducement must involve the taking of affirmative steps to bring about the desired result.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760 (2011)

“The patentee must also show that the alleged infringer possessed the requisite intent to induce infringement, which we have held requires that the alleged infringer knew or should have known his actions would induce actual infringements.” *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017) (internal quotation marks

omitted). “Circumstantial evidence can support a finding of specific intent to induce infringement.” *Vanda Pharm. Inc. v. W.-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018); *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016).

B. The Evidence of Intent for Proving Active Inducement is Context Dependent and Relies Upon the Relevant Market

The case law shows that the circumstantial evidence used to support a finding of specific intent in support of active inducement varies with the context of the alleged infringement.

In *Barry v. Medtronic*, the patent claims recited a method that involved rotating vertebrae to ameliorate an aberrant spinal column deviation during surgery. *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1317-18 (Fed. Cir. 2019). There, evidence supporting a finding of liability for induced infringement included a survey of spine surgeons, training materials for surgeons, instructions for using surgical tools, and the education of surgeons by salespeople. *Id.* at 1336. This evidence was tied to the context—the market for medical devices and their sales and marketing in the U.S.

In the consumer product market, this Court found evidence showing the copying of a cool-touch fryer along with the arranging of U.S. product distribution and a willful avoidance of an understanding of the patents covering the copied product to be appropriate to the active inducement

analysis. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 758-59 (2011).

Like this case, *GlaxoSmithKline v. Teva* involved a “skinny label.” *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320, 1327-28 (2021). Because, as in the present case, the accused product was on the market, the evidence for active inducement went beyond the label and included marketing efforts, catalogs, press releases, and testimony from the defendant’s witnesses. *Id.* at 1335-37, 1338-40. In addition, the plaintiff presented evidence that the label did not successfully carve out the patented use. *Id.* at 1338.

Importantly, the Federal Circuit recognized with respect to the labeling that, “the FDA is not the arbiter of patent infringement issues.” *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1061 (Fed. Cir. 2010). In fact, the FDA has made clear that use codes in the Orange Book “are not meant to substitute for the [ANDA] applicant’s review of the patent and the approved labeling.” Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) (codified at 21 C.F.R. pt. 314). The FDA further concluded that it has no expertise in patent law and that a court is the appropriate forum for determining the scope of patent rights. *Id.* That is, simply because the FDA allows the use of skinny labels, that does not mean that the FDA weighs in on whether use according to skinny labels infringes a use patent.

In each case, the evidence depends upon context—in particular, the manner in which sales are made and to whom the product is being sold.

C. In *Grokster*, this Court Highlighted the Importance of Understanding the Relevant Market and Defendant’s Profit Motives to the Active Inducement Analysis

In analyzing the inducement of copyright infringement, this Court looked to the inducement of patent infringement as a model. *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936-37 (2005). Looking to patent law, the Court summarized the relevant evidence for inducing patent infringement this way:

Evidence of “active steps ... taken to encourage direct infringement,” *Oak Industries, Inc. v. Zenith Electronics Corp.*, 697 F.Supp. 988, 992 (N.D.Ill. 1988), such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.

Id. at 936. The Court went on to compare evidence of intent for inducing patent infringement to evidence of intent applied to tort liability. *Id.* (citing, W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and Keeton on Law of Torts* 37 (5th ed. 1984), “There is a definite tendency to impose greater responsibility upon a defendant whose conduct was intended to do harm, or was morally wrong.”).

In *Grokster*, the Court found “particularly notable” three aspects of the evidence of defendants’ intent, all of which are relevant here. *Id.* at 939-40. First, the defendants were “aiming to satisfy a known source of demand for copyright infringement, the market comprising former Napster users.” *Id.* Similarly in this case, defendant is distributing its generic drug to PBMs that are already supplying the brand name drug to physicians for the patented use. Second, the “evidence of unlawful objective is given added significance by [plaintiff’s] showing that neither [defendant] attempted to develop filtering tools or other mechanism to diminish the infringing activity” *Id.* In the present case, defendant removed from its label the instruction not to apply its generic drug to the patented use. Third, the Court looked to the market and the manner in which defendants generated revenue—by selling advertising revenue, which increased with increasing infringing use of defendants’ product. *Id.* In this case, defendant’s revenue increases with increasing replacement of plaintiff’s brand name drug with defendant’s generic version, including when that replacement is for patented uses.

This Court distinguished the *Sony* case, in which liability for induced infringement was not found, from the *Grokster* case, in which liability for induced infringement was found, in this way:

Sony dealt with a claim of liability based solely on distributing a product with alternative lawful and unlawful uses, with knowledge that some users would follow the unlawful course.

* * *

Here, evidence of the distributors' words and deeds going beyond distribution as such shows a purpose to cause and profit from third-party acts of copyright infringement.

Id. at 941. The Court then explained the critical import of the evidence of intent:

If liability for inducing infringement is ultimately found, it will not be on the basis of presuming or imputing fault, but from inferring a patently illegal objective from statements and actions showing what that objective was.

Id.

In this case, evidence of the defendant's statements and actions with respect to the PBMs and whether they planned to profit from infringing use of their generic drug will be informed through discovery.

D. Law and Policy in the Case Counsel Affirming and Remanding to Allow the Development of a Fulsome Factual Record, Tied Specifically to the Market, to Determine Whether Active Inducement Occurred as Alleged

Without discovery, a patentee cannot know whether the negotiations between the accused inducer and the PBM(s) evidence an intent to induce infringement of a patented use by making a generic substitution for that use. Without discovery, a patentee cannot know whether the accused inducer expected revenue from infringing uses. In *Grokster*,

applying patent law inducement principles, the Court found a “purpose to cause and profit from third party acts of copyright infringement.” Such a finding can only be based on discovery. At the pleading stage, we know that the defendant issued press releases touting their pharmaceutical as a generic replacement for all purposes. We also know that the defendant removed from the label a contraindication for the patented use and that the defendant provided in press releases reference to full U.S. sales (i.e., patented and unpatented indications) of Vascepa®. One could draw the conclusion that defendant planned to profit from all uses of the generic equivalent, including the patented one. Of course, these circumstances could also be completely innocent, but only discovery could provide the evidence needed for one side or the other.

The parties correctly frame the issues as including whether any steps taken by the defendant amount to “active” inducement. But again, the framing is short on details about the relevant market and what kind of guidance should be considered “active” in the context of generic substitution by PBMs.

Amici submit that patent protection for new uses of existing pharmaceuticals and the critical incentives that such patent protection provides for treating patients counsel affirmance and remand to allow discovery to further develop the facts supporting or denying active inducement. Patients are counting on us to get this balance right.

CONCLUSION

For the foregoing reasons, the Court should affirm and remand.

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Respectfully submitted,

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