No. 12-416

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION
Petitioner,
v.
ACTAVIS, INC., ET AL.
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Eleventh Circuit

BRIEF OF ENAVAIL, LLC AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICUS CURIAE*[1]

Amicus curiae Enavail, LLC ("Enavail") is an innovative, Austin-based company that develops new pharmaceutical formulation technologies. Enavail's founders initially developed the patented technology underlying Enavail's business at the University of Texas at Austin, which has licensed that patented technology to Enavail. Enavail's proprietary technology relates generally to new formulations for drugs that provide superior potency as well as enhanced bioavailability and dissolution. In other words, Enavail, like the developer of AndroGel®, develops the formulation technologies that help make the active pharmaceutical ingredients in drugs work better to treat patients.

Petitioner Federal Trade Commission ("FTC") and its *amici curiae* have attacked the pioneering formulation technologies that Enavail and other innovator companies develop, thereby threatening significant harm to Enavail and other innovators. Pejoratively referring to the patents covering these technologies as "secondary patents," and ignoring the statutory presumption of validity afforded these patents, the FTC and its *amicus curiae* seek a broad presumptive rule that effectively would permit the

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that (1) no counsel for a party in this case authored this brief, in whole or in part, and (2) no person or entity, other than Enavail or its counsel, made a monetary contribution to the preparation or submission of this brief. Copies of consents from the parties to file this brief have been provided to the Clerk of the Court.

FTC to substitute its judgment for that of the U.S. Patent and Trademark Office ("PTO") and scrutinize these patents under antitrust law using a "'quick look' rule of reason analysis." Adopting this extreme and unwarranted rule would devalue pharmaceutical formulation patents and the innovative technology they protect, and consequently Enavail's patented assets, in which Enavail has significantly invested, would diminish in value. Moreover, Enavail is representative of an entire industry whose patented assets would be devalued by the FTC's proposed rule. As a result, Enavail's interests in this case are substantial.

SUMMARY OF ARGUMENT

This case involves the intersection of antitrust law, patent law and prescription drug law. The Hatch-Waxman Act balances the inherent tensions among these laws, and Congress has generally left this balance intact. The FTC and its *amici curiae* acknowledge this balance but argue that the Court should intercede and permit the FTC to engage in broad antitrust scrutiny of pharmaceutical patents that the PTO duly issues, notwithstanding the strong statutory presumption of validity afforded these patents. In so doing, the FTC and its *amici curiae* mischaracterize the nature of these patents and trivialize the important role these patents serve in protecting and rewarding the significant research and development investments in innovative pharmaceutical technologies. Specifically, the FTC and its *amici curiae* disparage pharmaceutical formulation technology such as the technology underlying the drug at issue in this case, AndroGel®,

as allegedly "secondary" technology protected by "undeserved" patents.

In stark contrast to the unreasonable position of the FTC and its *amici curiae*, numerous examples of successful innovative pharmaceutical products, such as AndroGel®, exist for which the formulation technology has proven critical to the product's clinical and commercial success. As evidenced by consumer demand for these products, particularly in the face of competition from generic products containing the same active ingredient, an innovative formulation is often the ***primary*** technology associated with a successful pharmaceutical treatment. Accordingly, the derision by the FTC and its *amici curiae* of formulation technology as "secondary" and "undeserved" of patent protection is plainly unwarranted, and the Court should reject any proposal by the FTC and its *amici curiae* that would undermine the statutory presumption of validity accorded a lawfully issued patent.

Ignoring the fundamental strength of lawfully issued pharmaceutical formulation patents, the FTC and its *amici curiae* argue that the Court should overturn the Eleventh Circuit's decision and adopt a "'quick look' rule of reason" test for settlements of pharmaceutical patent infringement cases under the Hatch-Waxman Act. Under this proposed test, any settlement of Hatch-Waxman litigation involving a payment from an innovator company to a generic company would be presumptively illegal, thereby subjecting the patent at issue to enhanced antitrust scrutiny, even if the innovator company does not attempt to enforce the patent beyond the scope of its

lawfully obtained claims. This shift to a presumption of illegality would constrain the innovator's patent rights and thus diminish the value of lawfully issued pharmaceutical patents. By diminishing the value of pharmaceutical patents, particularly by engendering an air of suspicion around any patents directed to what the FTC and its *amici curiae* call "secondary" technology, the FTC's proposed "quick look" rule would thwart innovation of pharmaceutical formulation technologies, thereby depriving consumers of new and beneficial therapies.

Indeed, under the FTC's proposed rule, branded pharmaceutical companies would invest less in developing innovative formulations, because the patents that protect these innovations would be subject to enhanced antitrust scrutiny and therefore unquestionably would be weakened. Generic pharmaceutical companies, which rely on the research and development efforts of brand companies when seeking to market generic versions of brand products, in turn would suffer under the FTC's proposed rule. Moreover, weakened pharmaceutical patent protection, and the corresponding reduction in research and development investment in pharmaceutical formulation technology, inevitably would impact innovative formulation technology companies like Enavail as well as the academic research institutions where much pharmaceutical formulation technology originates, such as, for example, the University of Texas at Austin, where Enavail's core technology was first developed.

The FTC's proposed "quick look" rule is not only contrary to the statutory presumption of patent

validity that the Court recently reaffirmed in *Microsoft v. i4i* but also ignores the role of Congress in creating the Hatch-Waxman balance. In each of its past four sessions and its current session, Congress has considered proposed bills seeking to implement a nearly *per se* rule for Hatch-Waxman litigation settlements that is very similar to the FTC's proposed "quick look" rule. Yet Congress has not passed any such bill into law. Even though Congress has passed sweeping changes to both the Patent Act and the Federal Food, Drug and Cosmetic Act ("FDCA") during the same time period, Congress has declined to pass legislation that would accomplish what the FTC seeks through this case. Undeterred, the FTC now asks the Court to grant it additional power to scrutinize the PTO's grant of pharmaceutical patents, notwithstanding the statutory presumption of validity to which these patents are entitled. Such a decision should be left to Congress, and the Court accordingly should affirm the Eleventh Circuit's decision to reject the FTC's requested rule.

ARGUMENT

I. THE CRITICISM OF INNOVATIVE PHARMACEUTICAL FORMULATION TECHNOLOGIES BY THE FTC AND ITS *AMICI CURIAE* IS UNFOUNDED

The FTC and its *amici curiae* start from the premise that pharmaceutical companies such as Respondents have achieved their phenomenal growth over the past decades by obtaining "undeserved" patents related to "secondary" aspects

of the innovative drugs they sell. *See, e.g.*, Pet. Br. at 7; Br. of The Public Patent Foundation as *Amicus Curiae* in Support of Pet. at 8-9; *see also* Br. of Apotex, Inc. as *Amicus Curiae* in Support of Pet. at 8-9. Nothing could be further from the truth. Contrary to the arguments of the FTC and its *amici curiae*, the pharmaceutical industry has experienced unparalleled growth because health care professionals and their patients demand the innovative formulations that the pharmaceutical industry develops. Far from being "undeserved," the patents protecting these innovative formulations reward research and development and ensure future technological advances.

A. The Growth and Success of the Pharmaceutical Industry Owe to the Development of Innovative Formulations

Indeed, the growth and success of the pharmaceutical industry, which the FTC and its *amici curiae* criticize, owe to the development of innovative formulations that benefit consumers. For example, the well-known heartburn medication Prilosec®, which was the best-selling pharmaceutical product in the United States in the late 1990s, is an innovative formulation of the active ingredient omeprazole. *See*, *e.g.*, B.A. Berkowitz and G. Sachs, *Life cycle of a block buster drug: discovery and development of omeprazole (Prilosec)*, 2 Molecular Interventions 6 (2002). Omeprazole itself was invented in 1979, but the key to its success was the development of a pioneering formulation including an enteric coating to protect the active ingredient.

In 2008, the Court of Appeals for the Federal Circuit affirmed judgments of infringement, validity and enforceability of the patents covering this formulation. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, at 1373, 1375 (Fed. Cir. 2008) ("Impax argues that it was known in 1979—the year Astra filed its first patent application for omeprazole—that omeprazole could provide a safe and effective treatment. Impax's argument misses the point. . . . The challenge they faced was developing a formulation to deliver omeprazole to the small intestine, a challenge that was made difficult by omeprazole's sensitivity to acidic environments, such as the stomach."). Because of this innovative formulation, Prilosec® greatly exceeded expectations in a crowded field of acid reflux treatments known as proton pump inhibitors. *See* Berkowitz.

Prilosec®, like Androgel®, is a dramatic success story in the high-risk/high-reward pharmaceutical industry, where there are a thousand failures for every drug that successfully enters the clinical study stage. *See*, *e.g.*, Rosa M. Abrantes, Christopher P. Adams, and Albert Metz, *Pharmaceutical Phases: A Duration Analysis* 5 (FTC Bureau of Economics, Working Paper No. 274, October 2004) ("[A]ccording to the FDA, 1 in 1,000 drugs pass the preclinical stage and are proposed for testing in humans (FDA, 2002), however almost half the R&D expenditures occur in the preclinical stage of development."), *available at* http://www.ftc.gov/be/workpapers/wp274.pdf. Moreover, recent studies indicate that once a 1-in-1000 drug enters the clinic, the success rate is only about 25%, with an average clinical development period of over eight years and a total

cost from preclinical research to approval averaging $802 million. *See id.* at 4, 8; *see also* Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* 19 (October 2006), *available at* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf. More recent studies found the clinical success rate to be less than 20% and the cost to develop a single approved drug to be up to $1.8 billion. Joseph A. DiMasi, *Pharmaceutical R&D Performance by Firm Size: Approval Success Rates and Economic Returns*, Am. J. Therapeutics, (published online Jan. 23, 2013), *available at* http://journals.lww.com/americantherapeutics/Abstract/publishahead/Pharmaceutical_R_D_Performance_by_Firm_Size__.99463.aspx; Joseph A. DiMasi and Henry G. Grabowski, *R&D Costs and Returns to New Drug Development: A Review of the Evidence*, *in The Oxford Handbook of the Economics of the Biopharmaceutical Industry* 21, 23 (Patricia M. Danzon and Sean Nicholson ed., 2012).

Like other successful innovative formulations, AndroGel® is a successful product because health care professionals and patients value the treatment AndroGel® provides. The FTC and its *amici curiae* criticize AndroGel®, however, arguing that its active ingredient, testosterone, has been known for over a century and methods for synthesizing testosterone were developed decades ago.[2] This criticism begs the

[2] The first testosterone synthesis was published in 1935. John M. Hoberman and Charles E. Yesalis, *The History of Synthetic Testosterone*, 272 Sci. Am. 76 (1995).

question why AndroGel® has attained such success that consumers purchased over $1 billion worth of AndroGel® in 2011 alone, particularly given that numerous generic testosterone products containing the same active ingredient are commercially available. *See* Top 100 Drugs for 2011 by Sales, http://www.drugs.com/stats/top100/2011/sales; *see, e.g.*, Drugs@FDA: FDA Approved Drug Products, Testosterone Cypionate, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=TESTOSTERONE%20CYPIONATE. Quite simply, the unique formulation of AndroGel®, which the FTC downplays as merely containing "certain other ingredients," Pet. Br. at 9, makes it safer and more effective than other treatment options. Christina Wang et al., *Long-Term Testosterone Gel (AndroGel) Treatment Maintains Beneficial Effects on Sexual Function and Mood, Lean and Fat Mass, and Bone Mineral Density in Hypogonadal Men*, 89 J. Clin. Endocrin. & Metabol. 2085 (May 2004) (noting that AndroGel® has fewer side effects, particularly affecting bone density, than other testosterone treatments). Moreover, that the innovative AndroGel® formulation was not developed until the 1990s, despite that synthetic testosterone products had been available for decades, strongly suggests that AndroGel® has satisfied a longstanding need for a safer, more effective treatment where others had failed. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 405 (2007) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1083 (Fed. Cir. 2012) (holding that claims directed to an innovative

formulation of a known drug were nonobvious in light of the fact that the "objective indicia of failure of others and longfelt need are particularly telling").

Notwithstanding the success of pioneering formulations such as AndroGel®, the FTC and its supporting *amici curiae* deride such innovative formulations as "secondary" technology and suggest that the only meritorious pharmaceutical technology is the active ingredient itself. *See, e.g.*, Pet. Br. at 4, 7; Br. of The Public Patent Foundation as *Amicus Curiae* in Support of Pet. at 8-9; Br. of 118 Law, Economics and Business Professors and Am. Antitrust Inst. as *Amicus Curiae* in Support of Pet. at 4. This suggestion ignores the successful and beneficial nature of pharmaceutical formulation technology. As discussed above, for example, the success of AndroGel® owes to its unique formulation, as evidenced by AndroGel®'s phenomenal success in the marketplace competing against numerous generic testosterone products having the same active ingredient, as well as AndroGel®'s satisfaction of a long-felt need for a safer, better treatment of hypogonadism than other therapeutic options.

B. Courts Repeatedly Have Rejected the Suggestion of the FTC and its *Amici Curiae* that Formulation Patents are "Secondary" or "Undeserved"

Moreover, courts repeatedly have rejected the suggestion that patents directed to new formulations of existing active pharmaceutical ingredients are "secondary" or "undeserved." Indeed, recent cases

before the Court of Appeals for the Federal Circuit illustrate the ***primary*** importance of formulation technology and the strength of patents covering this technology. *See*, *e.g.*, *Pozen Inc. v. Par Pharmaceutical Inc.*, 696 F.3d 1151 (Fed. Cir. 2012) (affirming non-obviousness of patent claims covering formulations of Treximet®, a combination therapy for treating migraines); *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1082-84 (reversing district court's finding of obviousness for patent claims covering formulations of the well-known drug cyclobenzaprine hydrochloride); *Unigene Laboratories Inc. v. Apotex Inc.*, 655 F.3d 1352 (Fed. Cir. 2011) (affirming district court's finding of non-obviousness for patent claims covering formulations of calcitonin with enhanced bioavailability); *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011) (reversing Patent Office Board of Patent Appeals and Interferences holding of obviousness of patent claims covering controlled release formulations of oxymorphone); *In re Omeprazole*, 536 F.3d at 1380-81.

The Federal Circuit's opinion in *In re Cyclobenzaprine Hydrochloride* is particularly illustrative. In reversing the district court's finding of obviousness of the claimed pharmaceutical formulation as not supported by clear and convincing evidence, the Federal Circuit stated, "If we were to affirm the district court's obviousness ruling on the basis of this record, we effectively would announce . . . a categorical rule that it is always obvious to try to target bioequivalence when formulating an extended-release formulation." *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1083-84.

Contrary to the posture of the FTC and its supporting *amici curiae*, the Federal Circuit's *Cyclobenzaprine* opinion makes clear that formulation technology should not be relegated to "secondary" status. *Id.* If such technology were merely "secondary," which it is not, it would not take decades of research and hundreds of millions of dollars to develop innovative formulations, and consumers would not choose them over available less expensive generic options having the same active ingredient.

C. The FTC's Proposed Rule Would Undermine the Statutory Presumption of Validity for Formulation Patents

In spite of the wealth of recent case law supporting the strength of pharmaceutical formulation patents, the FTC and its *amici curiae* ask this Court to give the FTC broad authority to review the decisions of the PTO and scrutinize these patents under antitrust law. Such enhanced antitrust scrutiny, which would create a presumption of illegality with respect to settlements of Hatch-Waxman litigations involving payments from patent owners to generic challengers, would undermine the statutory presumption of patent validity. Indeed, as the Court recently reaffirmed, duly issued patent claims are entitled to a statutory presumption of validity, and clear and convincing evidence is required to overcome this presumption. *Microsoft Corp. v. i4i Limited Partnership*, 131 S.Ct. 2238 (2011). In *Microsoft v. i4i*, Microsoft and its

amici curiae attacked this statutory presumption, propounding arguments regarding allegedly "undeserved" patents similar to the arguments that the FTC and its *amici curiae* advance in this case. *Id.* at 2251-52. The *Microsoft* Court rejected those arguments, and the Court likewise should reject them here. *Id.*

Contrary to the arguments of the FTC and its *amici curiae*, the Eleventh Circuit's "scope of the patent" test is consistent with the statutory presumption of validity to which every lawfully issued patent is entitled. *F.T.C. v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1308 (11th Cir. 2012). Upholding the "scope of the patent" test in turn would prevent the FTC from substituting its judgment for that of the PTO and consequently weakening pharmaceutical formulation patent claims, such as those covering AndroGel®. Enavail respectfully requests that the Court reject the unwarranted attack by the FTC and its *amici curiae* against the important technological advances such as those at issue in this case.

II. ADOPTION OF THE FTC'S "'QUICK LOOK' RULE OF REASON" WILL THWART PHARMACEUTICAL FORMULATION INNOVATION

The FTC and its *amici curiae* argue that, because pharmaceutical innovators obtain and enforce formulation patents such as those covering AndroGel®, the Court should adopt a "quick look" standard under which payments from innovator companies to generic companies in connection with

patent litigation settlements would be presumptively illegal. As discussed above, this argument is premised upon the derogation of formulation patents as "secondary" or "undeserved," which is an entirely unsound premise. Moreover, hampering the ability of patent owners to settle expensive, risky patent litigation will harm pharmaceutical innovation by diminishing the value of formulation patents that protect innovation. As discussed below, this harm will thwart a broad range of research and development activities, including those of pharmaceutical companies, innovative formulation development companies such as Enavail, and academic research institutions.

A. The Pharmaceutical Industry's Research and Development of Innovative Formulation Technology Will Diminish If Patent Protection Is Weakened

The pharmaceutical industry relies on patent protection to obtain positive returns on investments of hundreds of millions or even billions of dollars in research and development expenditures. *See* Henry G. Grabowski and Jeffrey L. Moe, *Impact of Economic, Regulatory and Patent Policies on Innovation in Cancer Chemoprevention* 13 (Duke Univ. Econ. Working Paper Series, Nov. 2007) ("several studies have found that the pharmaceutical industry places the highest importance on strong patent protection to support research and development activities"), *available at* http://econ.duke.edu/research/working-paper-series#2000-2004; Meir Perez Pugatch, David Torstensson,

& Rachel Chu, *Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights* 5, Pugatch Consilium (June 2012), at 5 (report commissioned by the Biotechnology Industry Organization summarizing a meta-analysis of research on the effects of patents on biopharmaceutical innovation and finding "IPRs [intellectual property rights], especially patents, are actively facilitating and contributing to upstream and downstream biotechnology activities"), *available at* http://www.bio.org/articles/taking-stock-how-global-biotechnology-benefits-intellectual-property-rights. Absent strong patent protection, innovator pharmaceutical companies simply will not invest in critical formulation technology such as the technology underlying AndroGel®. *See* Grabowski & Moe, at 26 ("Early patent challenges with uncertain outcomes also have a chilling effect on the development of new indications and formulations."). Without question, the value of pharmaceutical formulation patent claims, and hence the incentive for the pharmaceutical industry to continue its research and development efforts, would diminish substantially if the statutory presumption of validity afforded to these patents is undermined by the "quick look" rule proposed by the FTC and its *amici curiae*. *See id.*

As discussed above, such weakening of formulation patent claims invariably would disincentivize brand pharmaceutical companies from investing in the research and development of innovative pharmaceutical formulations, thereby harming consumers by depriving them of new therapeutic options. *See id.* Moreover,

disincentivizing brand pharmaceutical companies from developing and marketing new pharmaceutical formulations would deprive consumers of additional potential generic options, as generic companies rely on the research and development efforts of brand companies when seeking to market generic versions of brand drugs. *See, e.g.*, 21 U.S.C. 355(j)(2)(A) (setting forth requirements for applicants seeking to market generic versions of approved brand drugs). Accordingly, and ironically, the very consumer interests that the FTC and its *amici curiae* purport to espouse would in fact suffer from the "quick look" rule, as the pharmaceutical industry's development of new and innovative formulations would be disincentivized.

B. Companies Such as Enavail and the Innovative Formulation Technology They Develop Will Be Jeopardized by the "Quick Look" Rule

Innovative formulation technology companies such as Enavail likewise would be jeopardized under the "'quick look' rule of reason" that the FTC and its *amici curiae* seek. Particularly for start-up formulation technology companies like Enavail, which typically do not have the organizational infrastructure and capital necessary to carry out clinical trials or market innovative new therapies themselves, and which typically do not own many fixed assets or hold substantial brand equity, the patents protecting their innovative formulations are even more important than they are for a branded pharmaceutical company. Often, in fact, these patents are the primary valuable assets of

formulation technology companies. *See*, *e.g.*, Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 Berkeley Tech. L.J. 1255, 1305 (2009) ("A reason why patents are so important in the biotechnology industry in particular is that, when one makes a biotech investment, fundamentally one is making an IP investment. Consequentially, the early-stage venture investors dig very deeply into the validity of that IP."). Accordingly, adopting the "quick look" rule, which would diminish the value of pharmaceutical formulation patents, would significantly harm these innovative companies.

Moreover, because formulation development companies typically license their innovative technology to pharmaceutical companies for use in marketed drugs, the deleterious effect of the "quick look" test on the pharmaceutical industry would invariably harm formulation development companies as well. *See*, *e.g.*, *Elan Drug Technologies Wins Award*, Drug Discovery & Development, Feb. 24, 2011, http://www.dddmag.com/news/2011/02/elan-drug-technologies-wins-award (noting that Elan Drug Technologies' innovative formulations technologies "have been incorporated in over 35 products which have been commercialised in over 100 countries worldwide" through partnerships with branded pharmaceutical companies); Chris V. Nicholson, *Alkermes to Merge With Irish Drug Business*, N.Y. Times, May 9, 2011, http://dealbook.nytimes.com/ 2011/05/09/alkermes-to-merge-with-irish-drug-business (reporting the purchase of Elan Drug Technologies, a company

focused on drug delivery technologies, for $960 million). Opportunities for formulation development companies to market their innovative technologies to pharmaceutical companies would evaporate. Without these opportunities, pharmaceutical innovation would decline and consumers would be deprived of additional therapeutic options, such as, for example, innovative formulations that improve the bioavailability, potency, and toxicology profile of drug treatments. *See* Grabowski & Moe, at 25-26 ("It is worth noting that many important drug products such as the first AIDS therapy, AZT (Zidovudine), relied on formulation or method of use patents because their product patents had already expired.").

For instance, Enavail has developed formulation technologies that improve the potency and bioavailability of drugs such as cyclosporin A and danazol. *See* Enavail Technology, *available at* http://www.enavail.com/technology.html. Both branded and generic manufacturers market these drugs, but the original formulations have problems with their potency and bioavailability. *Id.* Enavail's innovative, patented formulation technology overcomes the shortcomings of the original formulations. *Id.* As discussed above, however, adoption of the "quick look" rule would inevitably harm the value of Enavail's patents and disincentivize companies such as Enavail from developing innovative formulations for consumers.

C. Treating Formulation Patents as "Secondary" Will Significantly Reduce Academic Research

Academic research also will suffer if the "'quick look' rule of reason" that the FTC and its *amici curiae* propose is adopted. Indeed, much academic research in fields such as pharmaceutics, pharmacology and medicinal chemistry is funded by the pharmaceutical industry, and many marketed pharmaceutical products are developed in university laboratories and licensed to pharmaceutical companies. For example, a scientist at Northwestern University developed and patented the blockbuster anti-seizure drug Lyrica®. As a result, Northwestern University was able to sell its royalty rights in Lyrica® for $700 million to be reinvested in the university. *See* Matthew Keenan, *Royalty Pharma Buys Lyrica Rights From Northwestern*, Bloomberg, Dec. 18, 2007, http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aNAeicA8ZdB8.

Academic institutions invest significantly in patenting pharmaceutical formulation technologies and are often co-plaintiffs in Hatch-Waxman litigations. *See*, *e.g.*, *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368 (Fed. Cir. 2012) (licensor Princeton University named co-plaintiff); *Pfizer Inc. v. Teva Pharmaceuticals U.S.A., Inc.*, 882 F. Supp. 2d 643 (D. Del. 2012) (licensor Northwestern University named co-plaintiff). Moreover, the patented technology underlying the business of innovative technology companies like Enavail often is developed at universities and subsequently licensed. *See* Pugatch et al., at 36-37.

Devaluing pharmaceutical formulation patents by adopting the FTC's proposed "quick look" rule invariably would dissuade pharmaceutical companies and formulation development companies from licensing patented formulation technology from universities. Accordingly, just as the FTC's proposed "quick look" rule would significantly harm pharmaceutical companies and formulation development companies, so would it harm academic research into innovative formulation technologies.

III. CONGRESS COULD HAVE ADDRESSED HATCH-WAXMAN LITIGATION SETTLEMENTS WHEN IT RECENTLY ENACTED SWEEPING CHANGES TO THE PATENT ACT AND THE FDCA, BUT CONGRESS DID NOT DO SO

Nearly every year since 2006 Congress considered but did not pass legislation proposing a rule for Hatch-Waxman litigation settlements nearly identical to the rule that the FTC and its *amici curiae* have proposed. *See* H.R. 3995, 112th Cong. (2012); S. 27, 112th Cong. (2011); S. 3677, 111th Cong. § 746 (2010); S. 369, 111th Cong. (2009); H.R. 3962, 111th Cong. § 2573 (2009); H.R. 1706, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1902, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2006). In each of those years, Senator Herbert Kohl (D-WI) and others attempted to convince Congress to pass the Preserve Access to Affordable Generics Act ("PAAGA"). The PAAGA would have made it illegal for a branded pharmaceutical company to settle a patent

infringement claim in Hatch-Waxman litigation by transferring anything of value to a generic company, unless the FTC authorized the transfer to further competition and benefit consumers. In each of those years, the proposed legislation failed to pass.

Congress did not sit idle, however, during that time period. Rather, Congress passed the most sweeping changes to both the Patent Act and the FDCA in decades. Enacted in September 2011, the America Invents Act, Pub. L. No. 112-29, 125 Stat 284 (2011), is the most significant change to U.S. patent law in over half a century. *See* Press Release, The White House, *President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs* (Sept. 16, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim ("the *America Invents Act* represents the most significant reform of the Patent Act since 1952"). Few areas of the Patent Act were left untouched by the America Invents Act, from the first-to-invent system that has been a hallmark of U.S. patent law since its inception to the new post-grant trial system and nearly everything in between. *Id.* (summarizing changes to Patent Act).

In 2009, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, § 7002, 124 Stat 119, 804-21 (2010), creating a pathway analogous to the Hatch-Waxman framework to allow generic manufacturers to enter the biologics market. Like the America Invents Act,

the BPCIA implements sweeping changes to the FDCA to provide a regulatory pathway for "biosimilars," which are to biologics what generics are to pharmaceuticals. The BPCIA provides a complex framework for patent litigation between a holder of a Biologics License Application, the biologics equivalent of a New Drug Application, and a manufacturer of a proposed biosimilar. Nowhere in the specific instructions for its complicated patent litigation scheme, however, does the BPCIA address payments from innovators to biosimilar challengers in connection with patent litigation settlements, despite the co-pendency of the PAAGA during the time Congress debated the BPCIA.

Despite this fervor of changes to the Patent Act and the FDCA, and despite the FTC's urging, Congress did not address the PAAGA and instead left in place the "scope of the patent" test as the *status quo*.[3] Just over three weeks ago, Senator Amy Klobuchar (D-MN) once again introduced the PAAGA for Congress to consider. S. 214, 113th Cong. (introduced Feb. 4, 2013). As this Court stated in *Microsoft*, any "recalibration" of the applicable

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[3] Congress also enacted numerous changes to the Hatch-Waxman statutory scheme when it passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). *See* Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066 (2003) (codified at 21 U.S.C. § 355). In passing the MMA, however, Congress did not adopt the FTC's proposed presumption of illegality with respect to Hatch-Waxman litigation settlements involving payments from innovators to generic challengers. *See id.*

standard should remain in Congress's hands. *Microsoft*, 131 S. Ct. at 2252.

CONCLUSION

For at least the foregoing reasons, the Court should affirm the judgment of the Court of Appeals for the Eleventh Circuit and hold that the "scope of the patent" test is the proper level of antitrust scrutiny for Hatch-Waxman litigation settlements.

Respectfully submitted,

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