No. 10-844

In the Supreme Court of the United States

CARACO PHARMACEUTICAL LABORATORIES, LTD. AND SUN PHARMACEUTICAL INDUSTRIES, LTD., PETITIONERS

v.

NOVO NORDISK A/S AND NOVO NORDISK, INC., RESPONDENTS

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

BRIEF FOR APOTEX, INC. AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

When the Food & Drug Administration (FDA) approves a drug for multiple uses, the Hatch-Waxman Act allows generic drug makers to avoid contested patent litigation by marketing generic versions of the drug solely for non-patented uses. The FDA lacks the authority and expertise needed to verify the patent information submitted by name-brand drug companies, however, so it defers to their descriptions of the scope of their patents. Such companies can therefore block the approval of generic drugs by submitting overbroad patent descriptions to the FDA, effectively extending their patents to cover non-infringing uses. To combat this problem, the Act allows a "counterclaim seeking an order requiring the [patent] holder to correct or delete the patent information submitted by the holder * * * on the ground that the patent does not claim * * * an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I). In a 2-1 decision that conflicts with this Court's precedents and recent D.C. Circuit authority, the Federal Circuit held that the counterclaim provision effectively authorizes only "delet[ing]" improperly listed patents, but not "correct[ing]" information that misrepresents the scope of the approved uses claimed by a patent. That ruling expressly invalidates longstanding FDA regulations defining "patent information," which the FDA deems "essential" to administering the Act, without seeking the agency's views. The question presented is:

Whether this counterclaim provision applies where (1) there is "an approved method of using the drug" that "the patent does not claim," and (2) the brand submits "patent information" to the FDA that misstates the patent's scope, requiring "correct[ion]."

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES AND REGULATIONS

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*

Amicus curiae Apotex, Inc. is a global generic drug company that frequently files Abbreviated New Drug Applications (ANDAs) seeking U.S. FDA approval to market its drugs and frequently uses "Section viii" statements to carve out information from FDA labels. Annually, in the U.S., Apotex is engaged in dozens of patent lawsuits under the Hatch Waxman Act "HWA", 21 U.S.C. 355(j) et seq. Apotex files this brief because, without correction, the underlying panel decision will gut the Act's "section viii" approval process, which Congress designed as an *alternative* to Hatch-Waxman litigation.[1]

INTRODUCTION

Apotex fully supports the Petitioners. The Federal Circuit panel majority's reading of the Hatch-Waxman Act's counterclaim provision is contrary to the Act's text, structure, legislative history, and purpose. The panel decision is fundamentally flawed and will result in expensive, time-consuming, and complex patent litigation that can all be avoided by

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[1] Apotex received consent of the parties to file this amicus brief. Thus, no motion for leave to file is required. The parties' letters of consent to the filing of this brief have been filed with the Clerk. Pursuant to this Court's Rule 37.6, *amicus curiae* states that no counsel for a party wrote this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to this brief's preparation or submission.

reinserting the plain statutory language that the panel judicially redacted. Judge Dyk's dissent in the panel decision and Judges Gajarsa's and Dyk's dissent from the denial of the petition for panel rehearing or rehearing en banc both noted that gamesmanship is in play, not actual controversy over the facts. See, 601 F.3d 1359, 1368 (panel decision); 615 F.3d 1374, 1377 (petition for rehearing en banc denied).

As Judge Dyk noted, in "adopting Novo's disingenuous argument blam[ing] the FDA," the majority overlooks "the manipulative nature of Novo's actions." 601 F.3d at 1380. This manipulation—causing the FDA to reject approval of a drug that Novo concedes would have been marketed for only non-infringing uses—is unconscionable. And now that the path for gaming the Act is clear, it will be followed by brand after brand, depriving sick patients of needed cost-effective drugs. The majority's reasoning effectively: wrote out language in the statute; deprives the FDA of authority to require patent descriptions; and renders obsolete a long-established regulatory system that has benefitted generic drug applicants innumerable times.

STATEMENT

The HWA provides the framework for filing generic drug applications ("ANDA's") and for quickly litigating potential patent disputes in expeditious manners. HWA follows a typical pattern: the ANDA is filed, the so-called Paragraph IV Notice Letter detailing the basis of non-infringement or invalidity is sent to the brand, which then has 45-days to sue for patent infringement. A timely filed suit invokes an automatic statutory 30-month stay that bars the FDA from approving the generic company's ANDA. The 30-

month stay provides time for the district court to vet out the patent issues before the generic company launches, but provides for an end-date of that injunction. But-for the 30-month stay (and for another reason not relevant here), the FDA normally approves the ANDA and permits a launch.

To avoid patent infringement and to avoid unnecessary delays to generic drug approval via the automatic 30-month stay, Congress enacted the so-called "Section viii" provision to allow generic companies to "carve out" parts of a label; the carve-out provision allows a generic company to seek FDA approval for something less than what the brand company has FDA approval to do. The panel decision effectively gutted it because it places the onus on the FDA to take action that the FDA has repeatedly said it will not take because it lacks the necessary expertise and resources (and courts have consistently upheld that determination). Furthermore it now requires generic companies to litigate expensive and all-consuming cases for which a previous statutory right existed to avoid having to do.

SUMMARY OF ARGUMENT

The panel decision mistakenly allocated the blame for gamesmanship on the FDA. When the brand company plays the game, it's apparently the FDA's fault. The FDA and Courts below admit that FDA cannot referee in the first place.

The panel decision also gutted statutory language by judicially redacting language out of the statute. By doing so, the panel wrongly reviewed full-bore patent litigation as an allowable, efficient, and effective tool to vet out patent issues. Left uncor-

rected, the court has created even further gamesmanship tools.

ARGUMENT

When a branded drug company has a patent on one of several FDA approved uses of a drug, this does not prevent generic competition on the other unpatented, approved uses. In those circumstances, the Act permits generics to file a "Section viii" statement indicating that it is not seeking approval to market the drug for any of the approved uses covered by the branded company's method-of-use patents. *See* 21 U.S.C. 355(j)(2)(A)(viii).[2] The Section viii process is important because it speeds the approval and marketing of a lower cost generic drug if there is no enforceable patent in issue.

For example, assume a brand company has an FDA approved psychiatric drug X to treat: (i) depression; (ii) social agoraphobia; (iii) fear of heights; and (iv) controlling anger. The original drug approval and patent covered the depression indication. Later patents and approvals were for the other indications. Now, assume the original patent on drug X and its

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[2] See, Shashank Upadhye, Generic Pharmaceutical Patent and FDA Law, Section 10:6, 10:7 (Thomson West, 2010 Ed.)(Westlaw database: GENPHARMA) ("Generic Pharmaceutical") for a detailed example of how Section viii statements are used. The author of this Brief is a recognized expert in the generic – brand patent field. FTC v. Bisaro, 2010 WL 4910266, at *2 (D.D.C., 2010)("From February 2 through March 3, 2009, FTC staff had approximately four conversations with Apotex's Vice President, who is a published expert in the field of generic drug patent and FDA law.").

depression indication are about to expire. It is perfectly permissible and the plain statutory language authorizes the generic company to file its ANDA seeking only approval for the depression indication, which will be unpatented soon. The generic company files Section viii statements to "carve out" (redact) indications (ii) through (iv) and to explicitly not seek approval for those other still-patented indications. Congress intended this via Section viii.[3] Indeed, because the generic drug applicant carves out still-patented indications, it specifically avers that it does not want FDA approval for those omitted indications.

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[3] *Purepac Pharmaceutical Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) ("A section viii statement indicates that a patent poses no bar to approval of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed by the patent."); see also, *Apotex, Inc. v. Food & Drug Admin.*, 393 F.3d 210, 213-214 (C.A.D.C.,2004)("Before turning to the factual background of the present dispute, we note that the four types of certifications enumerated in 21 U.S.C. § 355(j)(2)(A)(vii) are not the only mechanisms by which an ANDA applicant can address a potentially relevant patent. A generic company can instead submit a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii statement"). A section viii statement asserts that a patent does not prevent FDA from approving the company's ANDA because the ANDA applicant seeks to market the drug for a use other than that covered by the patent. See 21 U.S.C. § 355(j)(2)(A)(viii). As we have previously explained, applicants use paragraph IV certifications to challenge the validity of applicable patents, whereas they submit section viii statements to assert that patents do not apply. ANDA applicants who submit section viii statements are not eligible for generic marketing exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).")(internal citations omitted).

Because FDA rules require brand companies to create and file the so-called Use Code descriptions, a proper Use Code would state that, "Drug X for the use and treatment of depression, social agoraphobia, fear of heights, and controlling anger/rage." But if the brand company creates a Use Code description that states, "Drug X for the treatment of mental health", then under the panel's decision, the generic company has no recourse except to file the so-called Paragraph IV certification and engage in costly litigation and use up scarce judicial resources to prove that the patent is not infringed because the generic company now proves what its label reflects: it does not want approval for patented indications and does not infringe. Here, the brand uses code prohibits the generic drug company from carving out the other indication because they are not present. In later Para IV litigation the generic drug company would need to disprove that is not marketing the drug for the still patented indications.

Recourse to FDA is not available because the FDA and the Courts stated *ad nauseum* that FDA's role in Orange Book maintenance is simply ministerial. It does not and will not police Orange Book listings. It lacks the requisite expertise, resources, and statutory authority. The brand company could further game the system to include a Use Code for Drug X stating, "the use of Drug X for the treatment of any ailment or health issue," which would encompass every malady heretofore known. FDA subjectively knows that the Use Code is ridiculous but is objectively powerless to do anything. Now, according to the panel majority below, the affected generic company is powerless to do anything to force the brand company to change the code back to something more appropriate.

I. THE PANEL ERRED BY CONCLUDING THAT "REGULAR" PARAGRAPH IV LITIGATION IS AN EFFECTIVE TOOL TO VET OUT THE PATENT ISSUES

The panel majority below correctly recognized that the result of its decision is that patent litigation that ought not to be brought in the first place will now be housed within the so-called Paragraph IV litigation scheme. 601 F.3d at 1365. That litigation allows the generic company to prove that its generic drug use "will not cause infringement of the patented use." 601 F.3d at 1365. The panel then wrongfully allocated the burden of non-infringement to the generic company whereas this Court has squarely placed the burden of infringement proof on the patentee. *Price v. Kelley*, 154 U.S. 669 (1881).

The Caraco case is not even one where the patentee presented a *prima facie* case of infringement and shifted the burden to Caraco to rebut the infringement.[4] Here, Caraco specifically excluded the patented indications from its label. The panel, however, without one iota of infringement proof, shifted the burden to Caraco (as with any future generic manufacturer) to disprove infringement:

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[4] Method-of-use patents are usually enforced through 35 U.S.C. §271(b) – Indirect Infringement, especially for inducement to infringe. This Court is currently reviewing the Federal Circuit's standard of inducement to infringe (the requisite state of mind of the inducer) in Global Tech Appliances v. SEB, SA, Supreme Court Docket No. 10-006 (set for argument 23 Feb. 2011). See also, Generic Pharmaceutical Sections for a discussion on indirect infringement.

> This court recognizes that a broad use code covering all uses of a pharmaceutical could require generic manufacturers to prove specifically that their use will not overlap with and infringe the patented use. This proof, under Hatch-Waxman procedures, will take the form of a Paragraph IV lawsuit. In that context, the generic may provide proof that their use will not cause infringement of the patented use. This court perceives that the Hatch-Waxman Act will thus ensure that a generic drug for non-patented purposes will not be used for patented purposes via a simple section viii certification. Instead, the generic manufacturer will need to alleviate the risk of infringement or induced infringement in a proceeding that fully tests for infringement and its implications, including potential health and safety risks.
> 601 F.3d at 1365.

Accordingly, the generic company is left to prove that it will *not* infringe. This is contrary to law.

More generally, patent litigation under the so-called Paragraph IV scheme is not an effective tool to vet out this omitted indication patent issues. First, as with any patent litigation, the litigation is expensive, time consuming, and taxes scarce judicial resources. See, *Blonder-Tongue Labs v. Univ. of Illinois Found.,* 402 U.S. 313, 334 (1971)("the expense of defending a patent suit is often staggering to the small businessman."); *Schering-Plough Corp. v. F.T.C.,* 402 F.3d 1056, 1075 (C.A.11, 2005)("Patent litigation breeds a litany of direct and indirect costs, ranging from attorney and expert fees to the expenses associated with discovery compliance. Other costs accrue for a variety of reasons, be it the result of uncompromising

legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie."); *Marctec, LLC v. Johnson & Johnson,* 2010 WL 680490, at *6 (S.D.Ill., 2010)("According to a 2007 American Intellectual Property Law Association ("AIPLA") survey, the average total cost of patent infringement litigation where more than $25 million is at risk (considering 419 respondents throughout the United States) was $5.5 million.").

Generic companies have vastly different marketing programs than brand companies. Brand companies have no effect on the generic company's putative infringement. Brand companies "detail" the brand drug to doctors, traditionally by visiting doctor offices, offering tchotchkes like pens, mugs, toys, to sporting event tickets, etc. Indeed, the brand drug company detailing program is big business. *IMS Health Inc. v. Ayotte,* 550 F.3d 42, 56 (C.A.1, 2008)("The fact that the pharmaceutical industry spends over $4,000,000,000 annually on detailing bears loud witness to its efficacy.") Generic companies do not detail generic drugs. Rather, a majority of States have mandatory substitution laws, wherein a prescription for a branded drug must be filled, at the pharmacist level, with a generic version if it exists. Furthermore, generic drug companies compete usually only on price because all generic drug companies that have the underlying product necessarily means that the medicine is the same 21USC§ 355(j). Accordingly, no generic company puts out ads in magazines, buy television advertising spots, have direct-to-consumer advertising, have detailing to doctors, or give out "freebies", etc. All this effort is expected to show what the generic company does not do and agrees it won't do to market the product for the patented use.

Furthermore, a winning generic company after Para IV litigation cannot even be made whole because of the lost market opportunity whilst the patent litigation was pending (for generally at least 30-months) and that it cannot usually recover meaningful attorney fees or costs under the "American Rule." See, *Buckhannon Bd. and Care Home, Inc. v. West Virginia Dept. of Health & Human Resources*, 532 U.S. 598, 602 (2001)("In the United States, parties are ordinarily required to bear their own attorney's fees-the prevailing party is not entitled to collect from the loser. Under this "American Rule," we follow a general practice of not awarding fees to a prevailing party absent explicit statutory authority."). In short, simply by filing an abusive lawsuit, the brand company enjoys a 30-month stay of generic competition, thereby needlessly depriving the public of a valid generic drug.[5]

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[5] See, Generic Pharmaceutical, Section 11:2; See also, aai-Pharma Inc. v. Thompson, 296 F.3d 227, 236 (C.A.4, 2002) ("The question is important because, as we explained earlier, listing of a patent in the Orange Book triggers the availability of the thirty-month stay. If there is no enforcement mechanism to ensure that an NDA holder complies with its statutory obligations, an NDA holder can abuse the Orange Book listing process in such a way that (1) the NDA holder enjoys the protection of the thirty-month stay when it is not entitled to do so, or (2) a third party patentee (a person or entity other than the pioneer drug company that holds a patent claiming a pioneer drug) fails to receive the protection of the stay even though it is entitled to receive that protection. The first (and more serious) problem arises when an NDA holder wrongly lists a patent in the Orange Book that does not actually claim its approved drug under the standard set forth in § 355(c)(2). Once the patent is listed, the NDA

II. Left Uncorrected, the divided ruling below incorrectly placed blame on the FDA that is now hampered in its ability to administer the Act

Judge Clevenger, in his concurrence, erred in blaming the FDA for gumming up the works. Novo instigated the situation, not the FDA.

Novo's exchanges with FDA. Before changing its use code, Novo asked the FDA to adopt the position that, "[a]s there will only be a single indication for PRANDIN, there is no additional indication or use that can be carved out by a section viii statement." But the FDA said no. Even though the FDA requested "a simplified indication" in the "'INDICATIONS AND USAGE section of the labels," it explained, the "DOSAGE AND ADMINISTRATION section" would "carv[e] out the metformin information," which it noted "will not render the product less safe or effective." Pet. 44a-49a & nn.17-20. In other words, the simplified indication would affect one por-

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holder can delay an ANDA applicant's entry into the marketplace for up to thirty months (and extend its monopoly power) simply by filing a patent infringement suit. The NDA holder receives this benefit regardless of whether the patent meets the statutory criteria for Orange Book listing. Thus, the absence of any mechanism for ensuring the accuracy of Orange Book listings means that "the patentee/NDA holder [can receive] almost automatic injunctive relief for even marginal infringement claims." Terry G. Mahn, Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process, 54 Food Drug Cosm. L.J. 245, 250 (1999). The harm to generic drug manufacturers, and ultimately to the consuming public, is obvious.

tion of the repaglinide label; the carve-out would affect another.

It is, therefore, wrong to say, as did the majority, that the FDA "gummed up the works," "created" Caraco's problem, or "tipped the careful balance in the favor of pioneering manufacturers." 601 F.3d at 1368. The FDA did no such thing. Instead, FDA *accepted* Caraco's carve-out, and *approved* its Section viii statement. As the agency put it, "FDA has concluded when information regarding the combination use of repaglinide with metformin is carved out, generic repaglinide will remain safe and effective for the remaining, nonprotected conditions of use." It doesn't get any clearer than that. Judges Clevenger and Rader ignored this straightforward FDA decision and declared that FDA did the opposite. 601 F.3d 1367-68.

Novo's admissions at oral argument. Judge Clevenger was also mistaken in asserting that the FDA "instructed Novo to '[s]ubmit the description of the approved indication *or* method of use that you propose FDA include as the 'Use Code' in the Orange Book," 601 F.3d at 136 (emphasis added)—as if the FDA somehow "instructed" Novo to switch from its accurate use code to the misleading one. Here again, the FDA did no such thing—which is why "Novo *admitted* that FDA did not direct or request that Novo changes its use code, nor was this required under FDA regulations." 601 F.3d at 1380 (emphasis added).

Indeed, the rest of the form (to propose the use code) shows that, contrary to Judge Clevenger's suggestion, Novo *violated* the form by changing its use code. On the prior page, the form explains that the "information" to be provided is "*[f]or each approved method of use claimed by the patent.*" Pet. 212a (em-

phasis added); *see also* 21 C.F.R. § 314.53(c)(2)(ii)(P)(2) (requiring Novo to identify "the specific section of the approved labeling for the drug product *that corresponds to the method of use claimed by the patent submitted*.") (emphasis added). When Novo changed its use code, it violated this instruction because Novo's new code covers uses *not* claimed by the patent. 601 F.3d at 1380. The majority erred in blaming FDA for "gumm[ing] up the works." 601 F.3d at 1368.

III. Left Uncorrected, the Majority Opinion Facilitates Gaming of the Act to Delay Generic Drug Approvals.

Though the majority erred in blaming FDA, it correctly perceived that the result here tips the Hatch-Waxman balance in favor of brands—in situations where the generic concededly does not infringe. This is indeed an "extraordinary result", which, as Judges Clevenger and Dyk recognized, cannot adequately be addressed by Paragraph IV litigation. To the contrary, the decision will open the floodgates to brand abuse of method patents and even threaten FDA's authority to implement the statute.

Brand abuse. Congress enacted the counterclaim provision precisely "to prevent manipulative practices by patent holders with respect to Orange Book listings," which "were designed to *delay* the onset of competition from generic drug manufacturers." 601 F.3d at 1368 (emphasis added). But now, under the majority's ruling, any time a brand holds a compound patent with multiple approved uses, it can block all generic competition so long as it has a patent covering a *single* approved use. The only ques-

tion left by the majority's decision is, who will suffer next?

As noted by Judge Dyk, "[t]he manipulative nature of Novo's actions is confirmed not only by the lack of justification for the change, but also by the timing of the change (two years after the labeling change was initiated by the FDA and immediately after the FDA approved Caraco's section viii carve-out), and by its own admission that preventing approval of Caraco's ANDA was part of the motivation for changing the use code." 601 F.3d at 1381. To this, we must add Novo's admission that "FDA did not direct or request that Novo change its use code, nor was this required under FDA regulations." 601 F.3d at 1380.[6]

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[6] Many drugs are also combined with other drugs to form combination drugs, eg., cough + sinus combination product. A patent expiring on the "cough" medicine ought to allow generic companies to make and sell a generic cough medicine. But if the brand company has a combination patent (to the cough + sinus combination) and submits a Use Code that states, "use of cough medicine to treat cold and flu symptoms" then in effect, the expiring cough medicine patent cannot be practiced because the generic company would be forced to include the full Use Code description, which could colorably include the use in combination with sinus medicine, and hence possibly infringing the combination patent. Thus, one cannot ever practice the so-called monotherapy using cough medicine alone even though the relevant patent is now expired. This court has reaffirmed that subject matter claimed in an expired patent is dedicated to the public, and remains free for the public to use. *Bonito Boats v. Thundercraft Boats*, 489 U.S. 141,152 (1989). The Founders and this Court understood that the presumption is that all technology is fair-game for the public to freely exploit subject to patent protection existing. *Bonito Boats*, 489 U.S. at 146-147. Accordingly, this

It is no answer to say that FDA should not take use code descriptors at face value. 601 F.3d at 1368. *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004) ("FDA . . . does not evaluate patent information"; it simply "publishes information it receives"). "[I]ssues of patent claim and infringement are matters of patent law, and FDA does not have the authority . . . to assess whether a submitted patent claims an approved drug and whether a claim of patent infringement could reasonably be made against an unauthorized use of the patented drug." Testimony of Lester M. Crawford, Dep. Comm'r of Food & Drugs, House Committee on Energy & Commerce, Oct. 9, 2002. After all, the Hatch-Waxman Act requires the FDA to "*publish*" patent information—not to evaluate it. 21 U.S.C. § 355(c)(2) (emphasis added). FDA simply does not possess the expertise to evaluate patents.[7] Nor does FDA have the resources to do so.

FDA is now deprived of authority to require use codes. The majority opinion also extinguishes FDA's authority to require use codes. "According to the majority, method of use information is not 'patent information.' The majority construes the term as limited to the patent number and expiration date: '[T]he Act defined the term 'patent information' as 'the patent number and expiration date.'" 601 F.3d at

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Court should construe close-calls in favor of free-exploitation.

[7] *Watson Pharmaceuticals, Inc. v. Henney*, 194 F.Supp.2d 442, 445-446 (D.Md. 2001) ("In this case, it is paramount to keep in mind that the FDA, in deciding to make an Orange Book listing, is not acting as a patent tribunal. It has no expertise-much less any statutory franchise-to determine matters of substantive patent law.").

1370-71. FDA's settled reading of the term (and Congressional adoption too) require patent descriptions. But it also means the FDA has no authority to require use codes in the first place, which leaves FDA without its well-established tool to implement Section viii. Congress could not have intended this result.

Finally the panel decision emphasized certain parts of the statute, but judicially eviscerated other parts of the same statute. The panel emphasized the portions relating to "patent" and "expiration":

> If *the patent information described in subsection (b)* of this section could not be filed with the submission of an application under subsection (b) of this section ..., the holder of an approved application shall file with the Secretary *the patent number* and *the expiration date* of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. [601 F.3d at 1361]

But the panel ignored the rest, rendering the following language superfluous:

> If *the patent information described in subsection (b)* of this section could not be filed with the submission of an application under subsection (b) of this section ..., the holder of an approved application shall file with the Secretary *the patent number* and *the expiration date* of any patent ~~which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could~~

~~reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.~~

IV. Proper Use of Section viii Has Resulted in Successful Generic Drug Launches Saving Billions for Patients

When the compound patent expired protecting King Pharma's blockbuster drug, Altace® (generic – ramipril), indicated for cardiac treatment, generic companies successfully launched because generic companies used Section viii statements to carve out those other patented uses. Altace® had 2006 brand sales of over $650 million. Pravachol's® (generic – pravastatin) sole remaining patent in the Orange Book relates to a method of use patent. Pravachol® was a blockbuster cardiac statin that went generic in 2006 and recorded 2004 sales of over $2.6 billion. With generic drugs, patients benefit because insurance co-pays are dramatically reduced. For example, a particular insurance plan may charge the patient a $25 co-pay for branded drugs whereas only charge $5 co-pay for generic drugs. In this regard, a switch to generic drugs saves the patient $20 – this savings could be used to purchase another 4 generic drugs thereby increasing overall patient health.

This issue is now percolating in the Crestor® (generic – rosuvastatin) litigation, wherein the brand company alleges that the Section viii is inappropriate and cheats the brand company of its day in court. See, *Astrazeneca Pharmaceuticals LP v. Apotex Corp.*, 2010 WL 5376310, at *13 -14 (D. Del., 2010)("Plaintiffs next argue that Section 271(e)(2) will be rendered meaningless if generic manufacturers can evade suit under Section 271(e)(2) by simply

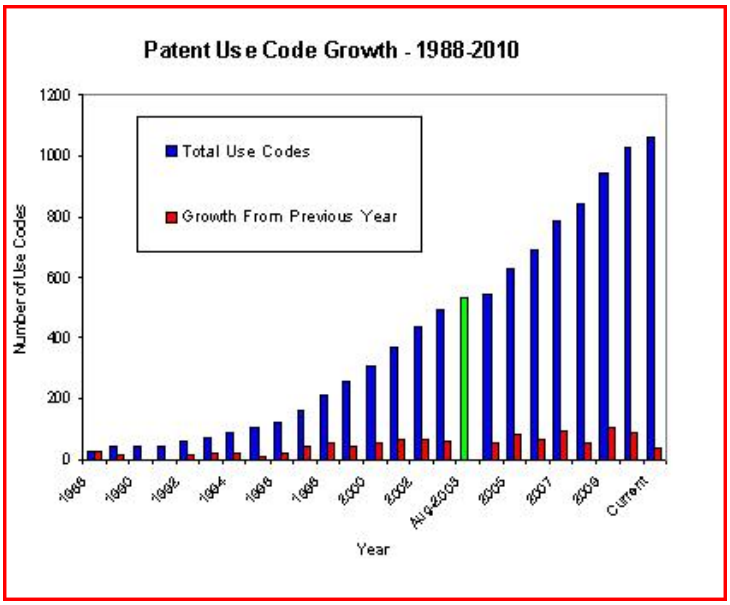
filing a conclusory section viii statement that they are not seeking approval for any patented indications. According to Plaintiffs, "[s]uch an approach would improperly and unfairly allow generic companies to define and dictate the circumstances under which the filing of an ANDA would constitute infringement under § 271(e)(2)." (Pl. Opp. Br. at 19). This argument is also misguided, and the Federal Circuit rejected it in Warner-Lambert. See Warner-Lambert, 316 F.3d at 1360. The formality of submitting a section viii statement does not immunize a generic manufacturer from suit under Section 271(e)(2).").

A recent investment banking research report even laid out the pathway for the brand company to play the use code game to protect Crestor®:

> File section viii seeking a restricted label to avoid infringing both the '152 and '618 Orange Book patents. AZN (AstraZeneca) will likely respond with (i) filing a Citizens Petition (ii) Argue that its PUC (patent use code) code prevents a carve out approval. Risk assessment – we anticipate a 90% probability that the FDA is unable to carve out an indication for the ANDA.

Source: Morgan Stanley Research Europe, 01 Sept. 2010, Pharmaceuticals Report, entitled, "Potential Selective Upside for Industry post Prandin Ruling," at page 6.

The Morgan Stanley report also shows the rapid growth of use codes.



CONCLUSION

This Court's intervention is urgently needed to prevent that "extraordinary result" of gamesmanship of the use code system and evisceration of the Section viii program. The petition for a writ of certiorari should be granted.

Respectfully submitted,

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