Testimony of

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On behalf of Barr Laboratories, Inc.
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"PERSPECTIVE ON PATENTS: HARMONIZATION AND OTHER MATTERS"

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMMITTEE ON THE JUDICIARY,U.S. SENATE, CONGRESS OF THE UNITED STATES
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Chairman Hatch, Ranking Member Leahy, and members of the Subcommittee, my name is Christine Siwik and I am a partner at Rakoczy Molino Mazzochi Siwik LLP. I am pleased to testify today about these important patent-related issues on behalf of Barr Laboratories, Inc.

Barr is a generic pharmaceutical company that develops, manufactures, and markets prescription pharmaceuticals. The Company's product portfolio includes more than 100 generic pharmaceutical products in core therapeutic categories, including female healthcare,oncology, cardiovascular, anti-infective, and psychotherapeutic pharmaceuticals. Barr is a founding member of America's generic industry, and a founding member of the Generic Pharmaceutical Association, the generic industry's trade association.

As a generic drug company, Barr utilizes the abbreviated new drug application procedures detailed in the ground-breaking Hatch-Waxman legislation of 1984 in order to bring generic products to market. In some cases, Barr invokes the procedure that Congress established for challenging suspect and overbroad drug patents - patents that provide monopoly price protection for drugs that should be subject to immediate generic competition. Through its efforts, Barr has brought numerous lower-priced generic versions of life-saving drugs to market years earlier than would otherwise have been possible. Barr, for example, saved the American public literally billions of dollars by bringing a generic Prozac® product to market at least two years before the brand company's invalid patent would have expired. Barr did so after spending millions to develop its generic product, and after spending years litigating the invalidity of the brand company's patent, which, as part of that legal team, I can tell you was no easy feat given the brand's resources. And earlier this month Barr also launched a less-expensive generic version of the drug DDAVP® after the district court found the brand company's patent to be unenforceable due to misconduct before the Patent and Trademark Office (PTO).

As a company that must deal with patents in order to compete, Barr is particularly interested in Congress' look at possible Patent Act reform legislation. Any change to the Patent

Act could have a profound impact on Barr's business, and could undermine the ability of consumers and taxpayers to continue to have access to the quality and affordable generic medicines upon which they have come to rely.

EXECUTIVE SUMMARY

Today, I would like to address the following points on Barr's behalf:

First, any attempt to improve patent quality should start with the PTO. At present, several aspects of PTO policy and procedure foster the issuance of patents without regard to their quality. For example, the current system for compensating patent examiners, which rewards those who issue a large number of patents and punishes examiners who do not meet their production goals, is counter-productive. Instead, examiners should be encouraged to focus on the quality, and not the quantity, of patents issued. Until such basic issues at the PTO



level are addressed, Congress should move cautiously when it comes to possible Patent Act reform legislation. This is a sentiment voiced by many who work daily with the patent laws, including, we understand, some federal judges.

Second, harmonizing U.S. and international patent law might well be a laudable goal in theory, but it could prove extremely problematic in practice. Care must be taken to ensure that any change that Congress makes strikes the right balance between encouraging innovation, on the one hand, and limiting competition, which necessarily flows from the patent grant, on the other. Harmonization should not be used as an excuse to undermine successful federal statutes, including the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, which has saved taxpayers and consumers billions of dollars and has become an essential component of our health care system.

Third, if Congress does pursue Patent Act reform, such legislation should strengthen, and not weaken, the standards for determining patentability. Simply put, making it easier to obtain and maintain a patent will not improve patent quality. Today, some brand companies have erected seemingly insurmountable patent barriers around their products. For instance, one product on which Barr currently is working has over 200 patents, which translates into nearly four decades of patent protection for that drug. Instead of addressing abuses of the patent system, provisions in H.R. 2795 relax the patentability requirements, making it even easier for brand companies to obtain and successfully enforce dubious and overbroad drug patents.

Congress should be clear about the consequences of enacting such proposals: the public will pay more, likely much more, for prescription drugs. For example, more patents means longer patent monopolies, and that could add billions to the cost of the prescription drug benefit set to begin in 2006 under the Medicare Modernization Act (MMA). According to one source, the Medicare prescription drug benefit is expected to account for roughly forty percent of all prescriptions dispensed in the United States as of January 1, 2006. The House Appropriations/Labor, HHS & Education Subcommittee has budgeted the prescription drug benefit at $53.6 billion for just the first nine months. According to a CMS analysis prepared for the Bush Administration's fiscal year 2006 budget, CMS projects payments to Medicare drug plans to total $1.2 trillion over the 10-year budget window beginning in October 2005. While CMS expects the net costs to the federal government to be smaller, it still estimates the 10-year total for federal spending on the drug benefit to be $724 billion.

Fourth, any patent reform legislation should include provisions designed to eliminate some of the unjustifiable advantages that the case law currently bestows on patentees.

Over the years, the courts have created several presumptions and imposed certain burdens on alleged patent infringers that cannot be justified under the Patent Act. These inequities should be remedied.

Finally, if Congress does enact patent reform, close attention should be paid when implementing any such legislation. Specifically, the effective dates of any changes should not upset the settled expectations of regulated industry, or on-going litigation. Effective date



provisions such as those found in H.R. 2795 could have immediate, negative consequences for generic drug companies and the public.

DISCUSSION

I. Efforts To Improve Patent Quality Should Start At The PTO, With Major Changes To The Patent Act Being Broached Cautiously.

Any effort to improve patent quality should start at the PTO. As the U.S. Court of Appeals for the Federal Circuit recently reiterated, the entire patent system relies primarily on the PTO to screen out invalid patents:

> [W]e are mindful that if an invalid patent is issued, competitors may be deterred from challenging it by the substantial cost of litigation. Even if a successful challenge is brought, competition may be suppressed during the pendency of the litigation. The risk of antitrust liability or litigation sanctions may deter some from seeking to secure or enforce invalid patents, but our patent system depends primarily on the Patent and Trademark Office's ("PTO's") care in screening out invalid patents during prosecution.

Prima Tek II, L.L.C. v. Polypap, S.A.R.L., - F.3d -, No. 04-1411, 2005 WL 1459332 (Fed. Cir. June 22, 2005) (emphasis added).

While patent examiners no doubt strive to issue patents only on those applications satisfying the statutory criteria for patentability, some aspects of PTO policy and procedure foster the issuance of patents irrespective of quality. The system for compensating patent examiners, for example, rewards those who issue a large number of patents and punishes those who do not meet established production goals.

As Barr understands it, patent examiners are salaried employees paid pursuant to a special patent examiner GS pay scale. An examiner can, however, receive several types of monetary performance bonuses if he or she exceeds the established production goal and/or meets certain timeliness requirements. Generally speaking, the PTO calculates the production goal that an examiner must meet by considering a variety of factors, such as the difficulty of technology and length of the applications that the examiner reviews. The production goal typically is expressed in terms of the number of "counts" that the examiner must accumulate. An examiner receives two counts for each application. The examiner receives one count for sending out the first office action on an application. The examiner receives a second count for that patent application by disposing of it in one of the following ways: by allowing the patent, by abandonment of the application by the applicant, or by completing an Examiner's Answer in the appeal process. The examiner receives no counts for rejecting an application in a final office action, in second or subsequent non-final office actions, or in similar scenarios.

The PTO meticulously analyzes each examiner's count total every two weeks, with supervisors following up with any examiner that fails to meet his or her required count quota during that two-week period. The pressure on examiners to meet their count quota is substantial and constant. An examiner who exceeds his or her production goal for the fiscal year

is eligible for a monetary reward in the form of a performance bonus. It is Barr's understanding that those performance bonuses can reach 9% of base salary, with additional bonuses possible when an examiner meets a timeliness goal for two consecutive quarters. Equally as important, however, an examiner that fails to meet his or her production goal can be penalized. Failure to meet the assigned count quota for an entire quarter could, based upon the information we have received, result in an examiner being placed on probation, which can lead to the examiner losing his or her job. As a result, it is critically important for examiners to meet their count quotas. The PTO compensation system thus encourages examiners to allow patents in order to receive increased performance bonuses and to avoid penalization, irrespective of the quality of those patents. Changing the system in a way that eliminates any incentive to issue questionable patents, Barr believes, would go far toward increasing the quality of patents. Others, including the Executive Director of the Public Patent Foundation, also have raised the need for reforms within the PTO in order to improve patent quality.

Finally, until the issues within the PTO are adequately addressed, Congress should approach any sweeping changes to the Patent Act carefully, and with a full understanding of how those changes would impact industries such as the generic drug industry. Barr, in fact, is not the first to raise concerns about moving too quickly in this area. For instance, speaking at the National Academy of Sciences and the American Intellectual Property Law Association, a panel of federal judges recently suggested that Congress should proceed slowly, adding that more review is needed before moving forward with the types of changes contained in H.R. 2795. According to published reports, Judge Pauline Newman of the U.S. Court of Appeals for the Federal Circuit expressed the opinion that Congress and industry need to carefully examine the impact of the bill on a broad national and global scale before moving forward with H.R. 2795. The reason for such caution is simple: Patent rights play an important role in many, many industries and drastic changes to the Patent Act, such as those proposed in H.R. 2795, could have far-reaching, negative consequences for those industries and the public. Such legislation likely would hurt the generic pharmaceutical industry - an industry already struggling to cope with brand tactics like authorized generics, which create a significant disincentive to invest in the lower-priced products needed to help ease the skyrocketing costs of health care in America.

II. Relaxing The Requirements For Patentability, Even If Done In The Name Of Harmonization, Will Not Improve Patent Quality, But Will Increase The Cost Of Prescription Drugs.

In 1984, Congress enacted the Hatch-Waxman Amendments, in part, to increase the public's access to lower-priced generic alternatives. In the words of the U.S. Court of Appeals for the D.C. Circuit, Congress' goal was to "get generic drugs into the hands of patients at reasonable prices - fast." In re Barr Labs., 930 F.2d 72, 76 (D.C. Cir. 1991). In designing this important legislation, Congress recognized that if generic drug companies waited for all of the patents protecting brand-name drugs to expire before marketing a lower-priced drug alternative, the public could be forced to pay monopoly drug prices for decades.

Today, unlike in 1984, brand companies routinely obtain patent after patent on a single drug product. A majority of these patents contribute little, if anything, by way of

technological advancement. Instead, these generic-blocking patents serve as part of a litigation strategy designed to make it as difficult, costly, and time-consuming as possible for generic companies to enter the market. For example, on a product that Barr currently is pursuing, the

innovator drug company has obtained over 200 patents relating in some way to this single drug product. The first patent, covering the actual drug compound, issued in 1983. At present, the term of the latest-expiring patent related to this drug ends 38 years later, in 2021. Let's put that in perspective - after reviewing a patent portfolio on the drug in Prozac®, the Federal Circuit declared it "a progeny of divisional applications, continuation applications, and patents that rivals the Hapsburg legacy." Eli Lilly and Co. v. Barr Labs., Inc., 222 F.3d 973 (Fed. Cir. 2000). That portfolio involved just six patents. One can only imagine how the Federal Circuit would describe a portfolio consisting of over 200 patents, and this innovator company might not yet be finished obtaining patents on this drug. One thing does seem clear, though, the sheer number of patents surrounding this product likely explains why no company, other than Barr, currently is seeking to market a generic version of this product - a product that generated over $700 million in sales for the 12-month period ending May 2005, according to IMS Health - before expiration of the Orange Book patents.

Given today's realities, challenging suspect drug patents plays an even more important and necessary role in helping to contain healthcare costs. As a result, any changes to the Patent Act must strengthen the requirements for patentability. At the very least, such changes should not relax the patentability standards. Indeed, making it easier for brand companies to get patents, and harder for generic companies to avoid them, threatens to undo much of the tremendous good that Congress accomplished with Hatch-Waxman, and the subsequent MMA provisions. To be clear: Loosening the patentability standards, even if done in the name of harmonization, would create longer patent monopolies on brand-name drugs. This, in turn, keeps the price of brand-name products higher for longer periods of time, and delayed marketing of generic drugs will cost the public billions of dollars.

Moreover, relaxing the patentability requirements, by eliminating and weakening existing defenses to patent infringement claims, obviously would not improve patent quality. Indeed, loosening the patentability standards would have the exact opposite effect - making it easier for companies to obtain dubious patents and more difficult for companies to have such patents set aside.

Many of the proposals in H.R. 2795 exemplify the type of provisions that should be avoided. The bill relaxes patentability standards by, inter alia, eliminating current requirements for obtaining and maintaining a patent, and weakening other patentability requirements. In these important respects, H.R. 2795 works against enhanced patent quality.

A. H.R. 2795 Makes It Easier To Obtain And Maintain Suspect And Overbroad Patents.

H.R. 2795 would make it easier to obtain and maintain suspect and overbroad patents by eliminating: (1) the requirement that patentees act with good faith when prosecuting patents before the PTO; (2) the best mode requirement of 35 U.S.C. § 112; and (3) several of the novelty requirements found in current 35 U.S.C. § 102. Such changes, if enacted, would have



negative, real-life consequences for those that must defend against unwarranted patent infringement claims in order to compete.

Unenforceability. Section 5(a) of H.R. 2795 would represent a drastic and negative shift in the law. Under proposed § 136(d), one or more claims of the patent-in-suit must be declared invalid before a claim of unenforceability could be made. By making an invalidity finding a prerequisite to an unenforceability claim, the bill removes inequitable conduct as an independent defense to infringement. As a result, patentees arguably could outright lie to the

PTO without having the patent declared unenforceable, so long as the patent otherwise is valid. Plainly, rewarding such misconduct before the PTO would not improve the quality of patents. Allowing patentees to fraudulently obtain patents from the PTO and enforce those patents, so long as they otherwise are valid, would have dramatic consequences for consumers. For example, in just the last eighteen months, patents in seven pharmaceutical-related cases were struck down solely on unenforceability grounds due to patentee misconduct before the PTO, including:

? Purdue Pharma, L.P. v. Endo Pharms. Inc., Nos. 00-8029, 01-2109, and 01-8177, 2004 WL 26523 (S.D.N.Y. Jan 5, 2004), aff'd, - F.3d - , 2005 WL 1330933 (Fed. Cir. June 7, 2005), which involved an attempt to market a generic version of OxyContin®. Purdue told the PTO that it had "surprisingly discovered" that oxycodone required a reduced dosage form as compared to other comparable drugs. 2004 WL 26523, at *21. Purdue failed to tell the PTO, however, that it had absolutely "no scientific proof" to back up its claim. Id. Purdue had conducted no testing that would support this result at the time it made this representation that was "of extreme clinical importance" and on which it heavily relied to distinguish its invention from the prior art and to ultimately obtain its patents. Id. at *23. The court struck down the patents on unenforceability grounds based upon the patentee's misconduct. Yet, Purdue Pharma's lawsuit kept Endo off the market for nearly three years - years during which Purdue Pharma generated billions of dollars in sales with its unenforceable patent.

? Aventis Pharma S.A. v. Amphastar Pharms., Inc., No. 03887 RT, slip op. (C.D. Cal. June 15, 2005), which involved an attempt to market a generic version of Lovenox®. The PTO examiner rejected the proposed claims as obvious over the prior art. See id. at 9-13. In response, the patentee repeatedly represented that its data showed that the half-life of its drug was improved over the prior art. See id. The patentee failed to disclose to the patent examiner, however, that its data compared different dosages of the drugs, and that a comparison of the drugs at the same dosages did not result in significantly different half-lives. See id. at 13-14. In its opinion, the court rejected Aventis' argument that the representations were immaterial because the patent examiner allegedly did not rely on these representations in allowing the claims, explaining that, according to the law, information is material if it is in the realm of the examiner's consideration. See id. at 17-18. The court struck down the patent on unenforceability grounds based upon the patentee's misconduct.



? Ferring B.V. v. Barr Labs, No. 7:02-CV-9851, 2005 WL 437981 (S.D.N.Y. Feb. 7, 2005), which involved an attempt to market a generic version of DDAVP®. During patent prosecution, the PTO asked the patent applicant to provide objective, "non-inventor testimony" supporting the inventor's understanding of a term in the patent application. See id. at *9. Instead, Ferring provided affidavits from a former employee of the company, and two Ferring consultants who had received research money from Ferring. See id. at *3-*5. Ferring never disclosed to the PTO the three affiants' affiliations to Ferring, despite "the very clear understanding of Ferring that the PTO was interested in receiving non-inventor testimony, which, again, had to have indicated that an objective perspective was

sought." See id. at *9. The court struck down the patent on unenforceability grounds based upon the patentee's misconduct.

? Pharmacia Corp. v. Par Pharm., No. 01-6011 (D.N.J. July 6, 2004), which involved an attempt to market a generic version of Xalatan®. During prosecution of a patent-in-suit, the patent applicant submitted a false declaration. The declarant made claims about the efficacy of a drug that were exactly the opposite of the claims that he had made in an article that he had authored. See id. at 25-27. The court struck down the patent on unenforceability grounds based upon the patentee's misconduct.

These pro-consumer decisions, and others like them, would not be possible if H.R. 2795 is enacted as currently written because alleged infringers could no longer raise unenforceability as an independent defense. Such a result would be devastating for consumers, who would be forced to pay unnecessarily high prices for drugs protected by ill-gotten patents.

The bill also could be construed as eliminating yet another independent defense to patent infringement claims - patent misuse. If a court finds that a patentee has misused a patent, the court will declare the patent unenforceable. Thus, the defense of patent misuse focuses on the patentee's behavior after obtaining the patent, while inequitable conduct focuses on the patentee's behavior before the PTO. But some might argue that H.R. 2795 could be construed as requiring all claims of unenforceability to be pursued pursuant to the terms of proposed § 136. If so construed, the bill possibly could do away with the patent misuse defense because proposed § 136 arguably contains no mechanism for asserting or otherwise pursuing a patent misuse claim (as opposed to an inequitable conduct claim).

Moreover, the scheme that the bill would impose for addressing inequitable conduct claims virtually guarantees that patents would rarely, if ever, be found to be unenforceable. Consider just these few examples:

? The bill would establish a nearly impossible-to-meet standard for proving a violation of the duty of candor. Specifically, H.R. 2795 arguably eliminates the Federal Circuit's sliding-scale standard for determining whether a patentee has committed inequitable conduct. Under current law, the more material the withheld information, the less intent to deceive that the challenger need show. Proposed § 136(b) requires all misconduct to



have been done "knowingly." But the courts repeatedly have recognized that direct evidence of a knowing intent to deceive rarely exists.

? Under current law, a breach of the duty of candor by anyone deemed to have substantially participated in prosecuting the patent will render that patent unenforceable. But proposed § 136(d)(1) and (d)(3) would require the patent owner itself to have violated the duty of candor before a patent could be held unenforceable. This means that a patent attorney for a brand company arguably could withhold material prior art with an intent to deceive without such misconduct leading to an unenforceability finding. But deceit before the PTO, regardless of its origin, equally infects the patent and should render it unenforceable.

? Under proposed § 136(d)(2), once a patent claim has been declared invalid, the defendant must seek leave of court to amend the pleadings to include an inequitable conduct charge. If the court grants the motion, the court remits the charge to the PTO to determine whether inequitable conduct occurred. But the alleged infringer must plead its claim with particularity, which could be problematic because courts sometimes are reluctant to allow

discovery on defenses that have not been pled. Because the accused infringer cannot plead inequitable conduct until after a finding of invalidity, the bill could prevent parties from getting the discovery that they might need to establish this defense with enough specificity to have it referred to the PTO.

? The bill would require the PTO to establish a "special office" to investigate these types of claims. (Proposed § 136(e)). Such an office sounds similar the PTO's so-called "fraud squad," which investigated allegations of misconduct in the 1980s. The PTO disbanded the fraud squad, leaving the courts to address inequitable conduct claims, because the situation proved unmanageable at the PTO level. For example, Harry Manbeck, the PTO Commissioner from 1990 to 1992, explained: "[T]he PTO found itself having considerable difficulty evaluating alleged violations of the duty of disclosure requirement." H.F. Manbeck, The Evolution and Issue of New Rule 56, 20 AIPLA Q.J. 136, 139 (1992).

? The bill appears to contemplate an ex parte process where only the patentee can participate. Such a process makes unenforceability findings even less likely, as the ex parte nature of the patent process likely allowed the original fraud to go undiscovered, and would put the federal government in the inexplicable position of rewarding, rather than punishing, those who engage in misconduct and fraud. Further, the party submitting the challenge to the PTO has no recourse if, at any point in the process, the PTO elects not to proceed with the investigation, or concludes that no inequitable conduct was committed. In contrast, the patentee can appeal any adverse decision up multiple levels of review.

Finally, the penalty provisions are weak, ensuring that they will not deter misconduct when it comes to pharmaceutical patents. Under proposed § 136(e)(6), at most, a patentee would face a $5,000,000 fine per act of misconduct. This fine pales in comparison to the revenues that an improperly obtained patent could generate for the brand company. Indeed,



many drugs generate sales in excess of $1,000,000 per day. Purdue Pharma's OxyContin® product, for example, generated sales exceeding $5,000,000 per day during the 12-month period ending May 2005, according to IMS Health data. Equally distressing is the fact that if the court found fewer than all of the patent's claims to be invalid, it appears as though H.R. 2795 would allow the patentee to continue asserting those valid claims against alleged infringers, even if the PTO finds misconduct to have occurred, so long as the patentee timely pays any fine that the PTO imposes.

Given the dire consequences that could result from such provisions, Congress should carefully consider whether harmonization and harmonization alone provides sufficient justification for enacting this type of legislation. In Barr's view, the answer is a resounding "no." The U.S. patent laws should not countenance, let alone encourage and reward, misconduct before the PTO.

Best Mode. Section 4(d)(1)(B) of H.R. 2795 would relax the patentability requirements by eliminating entirely the so-called "best mode" requirement. Currently, under 35 U.S.C. § 112, the patentee must disclose the best way, or mode, of carrying out the claimed invention. Failure to do so renders a patent invalid, and courts do, in fact, strike down patents in light of best mode violations. But H.R. 2795 allows companies to obtain valid patents even if they decide for strategic and/or commercial reasons to keep the best mode of carrying out the claimed invention a secret. Such a measure would not improve patent quality.

Some have suggested that removing this requirement can be justified on harmonization grounds. But this is a situation where Congress needs to weigh carefully whether harmonization per se provides a sufficient excuse for jettisoning this fundamental patent law principle.

The best mode requirement of § 112 is part of the foundation upon which the Patent Act rests. Patents, by their very nature, involve the public disclosure of a novel invention. See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 477-78 (1974). Indeed, that is the "bargain" that the patent law strikes - the patentee receives a period of exclusivity in exchange for complete disclosure of the invention to the public. See id. at 489; Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51 (1989). In other words, the public suffers monopoly prices for a limited period of time in exchange for complete disclosure of the claimed invention and the right to use that invention once the patent expires. The best mode requirement ensures that patentees live up to their end of the deal. See Teleflex Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1330 (Fed. Cir. 2002). Thus, without the best mode requirement, the public is deprived of the benefit of the bargain that the patent laws are supposed to strike. Patentees get exclusivity, but the public does not get all of the information needed to practice that invention once the patent expires. This represents a significant loss for the public.

Furthermore, the elimination of the best mode requirement could have a particularly profound impact on efforts to develop generic biologics. In short, companies developing such products rely, often times heavily, upon the disclosures in brand patents to assist them in their development efforts. This disclosure is, after all, for the benefit of others to use as part of the bargain that the patentee makes for receiving the right to exclude accompanying the



patent grant. If brand companies no longer need to disclose their best mode in such patents, generic companies will lose a valuable source of information, even though the brand companies will continue to enjoy the full monopoly benefits provided by their patents. The public necessarily suffers in this case, especially given the fact that biologics represent a major part of health care expenditures in the United States each year.

In 2003, as Barr understands it, just six biologic pharmaceutical products generated sales of more than $9.5 billion. Three of the top biotech pharmaceuticals can cost as much as $24,000, $10,000 and $20,000 per patient, per year.1 Another product, a biologic drug approved for an enzyme deficiency, costs over $170,000 per patient per year.2 Generic competition would ensure increased access and lower prices. Measures that make it more difficult for generics to enter the market ensure less access and unnecessarily high prices. Thus, fundamental fairness, the core principles of the Patent Act, and plain common sense all cry out for the best mode requirement to remain in § 112.

Eliminated Novelty Requirements Of § 102. Section 3(d) of H.R. 2795 also would relax the current patentability requirements by eliminating the novelty requirements found in 35 U.S.C. §§ 102(c), (d), (f), and, arguably, (g). These provisions purportedly would be eliminated as a result of the bill's adoption of a "first-inventor-to-file" patent system - a change being considered as part of a harmonization effort.

Even if Congress decides to harmonize U.S. patent law by adopting a firstinventor-to-file system, caution should be taken to avoid doing unnecessary violence to existing patentability requirements and infringement defenses. Legislation that eliminates current § 102(g)'s prior invention requirement/defense, for example, could be particularly troublesome for generic drug companies if corrective measures are not taken.

Some generic companies have started to obtain and enforce patents against fellow generic competitors. Companies without their own drug product also have started to get patents on lucrative drug products in the hope of using such patents to obtain quick cash settlements from generic companies attempting to enter the market. A company tried this approach when it obtained patents relating to the drug fluoxetine (Prozac®) years after Barr filed the first ANDA seeking to launch a generic fluoxetine product. That company asserted one of its patents against Barr the day that Barr obtained FDA approval to market its product.

The prior invention defense in current § 102(g) can provide defendants in such suits with a vital invalidity defense. Indeed, the more common such suits become, the more important the defense could become. Thus, if Congress does adopt a first-inventor-to-file system, careful attention should be paid to implementing the system in a way that does not deprive alleged infringers of existing defenses to infringement claims. In the case of § 102(g), 35 U.S.C. § 273 should be strengthened to ensure that generic companies continue to have an infringement defense to these later-issued patents.

1 See DESERET NEWS, December 15, 2002 (Neupogen®, $15,000 to $24,000); ST. PETERSBURG TIMES, July 22, 2003 (Procrit®, $7,000 to $10,000; Humatrope®, $12,000 to $20,000).

2 THE NEWS & OBSERVER, May 13, 2003 (Cerezyme®).



B. H.R. 2795 Could Severely Relax Other Patentability Requirements.

H.R. 2795 could relax, possibly severely, other patentability requirements. Of most importance is the bill's redrafting of 35 U.S.C. § 102, but Barr also is concerned about the changes that would be made to § 103. As previously explained, while adopting a first-inventorto-file system necessarily would do away with some of the novelty requirements of § 102, Congress need not rewrite § 102 in toto. Indeed, several witnesses testifying before the House Judiciary Subcommittee on Court, the Internet and Intellectual Property also noted that the changes made to § 102 go well beyond those necessary to implement to first-inventor-to-file system. They cautioned against making changes that would unnecessarily diminish the scope of prior art, and would disrupt long-established legal concepts and definitions. Barr, too, urges Congress to ensure that any patent reform measures do not needlessly destroy the existing statutory scheme, and the extensive case law that has developed out of that scheme.

Changes to 35 U.S.C. § 102. In essence, the patent universe can be thought of as containing two types of subject matter: new and old. Only new subject matter can be patented. Old subject matter, often referred to as "prior art," cannot be patented. Prior art can thus be thought of as limiting or restricting what is "new" and thus patentable. H.R. 2795 re-defines prior art in a way that narrows that body of information, and anything that narrows the universe of prior art necessarily expands the universe of patentable subject matter. Accordingly, Section 3(b)(1) of the bill makes it easier for brand companies to obtain patents (even on non-inventive or old subject matter), while simultaneously making it more difficult for generic companies to successfully challenge such patents. For example, the bill arguably relaxes the current patentability requirements as relates to:

? a public use;
? a sale or offer for sale;
? foreign patents;
? foreign patent applications;
? foreign publications;

? so-called "negative" prior art (that which reaches the opposite conclusion while still teaching the invention); and
? patents or patent applications owned by or subject to an obligation of assignment to the patentee.

The anti-consumer consequences of H.R. 2795 result from several different aspects of the proposed revisions to § 102:

First, the definition of "publicly known" in proposed § 102(b) is problematic in several key respects. Proposed § 102(a)(1) talks, in part, about the invention lacking novelty if the claimed subject matter was "otherwise publicly known." Under § 102(b)(3)(A), something is "publicly known" "only when it becomes reasonably and effectively accessible, either through its use, sale, or disclosure by other means" or if "it is embodied in or otherwise inherent in subject matter that has become reasonably and effectively accessible," and for purposes of proposed § 102(b)(3)(A):



(i) subject matter is reasonably accessible if persons of ordinary skill in the art to which the subject matter pertains are able to gain access to the subject matter without resort to undue efforts; and
(ii) subject matter is effectively accessible if persons of ordinary skill in the art to which the subject matter pertains are able to comprehend the content of the subject matter without resort to undue efforts.

(Proposed § 102(b)(3)(B)). Thus, on its face, the definition of "publicly known" arguably narrows the information that otherwise would have qualified as prior art under current law. At a minimum, proposed § 102(b)(3) arguably narrows the universe of prior art presently available, thus making it easier to obtain and enforce a patent, in the following respects:

The definition of "publicly known" requires all prior art to be "reasonably and effectively accessible" such that a person of skill in the art can gain access and comprehend it "without resort to undue efforts." This represents a significant change in the law for several types of activities that currently serve to restrict what can be patented. The courts generally have not, for example, required sales, offers for sale, or the like to be "publicly known," as defined in H.R. 2795, in order to be invalidating.

? Under current § 102(b), a sale or an offer for sale can be done entirely in secret and still invalidate a patent claim. See, e.g., Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353, 1357 (Fed. Cir. 2001).
? Under current § 102(b), "public," in context of a public use, "does not necessarily mean open and visible in the ordinary sense; it includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor." New Railhead Mfg. Co. v. Vermeer Mfg. Co., 298 F.3d 1290, 1297 (Fed. Cir. 2002). Thus, "[i]t is not necessary for a product to actually be accessible to the public to fall under Section 102(b)." System Mgmt. Arts v. Avesta Tech., Inc., 87 F. Supp. 2d 258, 269 (S.D.N.Y. 2000). Indeed, the Federal Circuit has expressly rejected a patentee's assertion that, to be invalidating, a public use must be "publicly known or accessible." Baxter Int'l, Inc. v. COBE Labs., Inc., 88 F.3d 1054, 1058 (Fed. Cir. 1996). Thus, the patentee's clinical trials could constitute an invalidating "public use" under § 102. SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306 (Fed. Cir. 2004), vacated on rehearing by, 403 F.3d 1331 (Fed. Cir. 2005); see also Eolas Tech. Corp. v. Microsoft Corp., 399 F.3d 1325 (Fed. Cir. 2005) (stating that use by a third party under

no obligation to maintain the secrecy of the invention can be an invalidating public use); but see Janssen Pharm. N.V. v. Eon Labs Mfg. Inc., No. 04-1539, 2005 WL 1384230 (Fed. Cir. June 13, 2005) (finding specific clinical trials did not constitute a "public use" in light of the circumstances surrounding those trials).

? Under current § 102(a), a "public" use by others merely means a "not secret" use that can take place in the usual course of producing materials for commercial use. Levi Strauss & Co. v. Golden Trade, No. 92-1667, 1995 WL 710822, at *18 (S.D.N.Y. Dec. 1, 1995). Consequently, the use of a patented product or process in a single shop can constitute



prior art under current § 102(a). See Giora George Angres, Ltd. v. Tinney Beauty & Figure, Inc., 116 F.3d 1497 (Fed. Cir. 1997).

Additionally, the "publicly known" definition could be construed as limiting reliance on foreign patents, foreign patent applications, and/or foreign publications as prior art. For instance, if a publication or patent application exists only in a foreign language, a court could find that locating and translating such material constitutes "undue efforts," such that the publication or patent application would not constitute "prior art." This could be significant in the generic drug context, as generic companies in particular routinely rely on foreign art when arguing the invalidity of drug patents. In just the last year, courts in several pharmaceutical patent cases have found brand patents invalid in light of foreign art. And, not surprisingly, foreign art also comes into play in other subject matter areas, where courts also have struck down patents as invalid in light of foreign art.

Second, setting aside the definition of "publicly known," other aspects of proposed § 102(a)(1) will curtail the universe of information that can constitute prior art. For example, under proposed § 102(a)(1)(B), patents and printed publications by anyone who obtained "the subject matter disclosed directly or indirectly from the inventor or a joint inventor" no longer would qualify as prior art. The bill does not define what is meant by "directly or indirectly." If given a broad construction by the courts, the universe of information that can constitute "prior art" could be significantly narrowed.

Third, proposed § 102(a)(2) could have significant consequences by limiting what can be used as prior art. Under proposed § 102(b)(1), subject matter that would otherwise qualify as prior art under proposed § 102(a)(2) cannot be considered prior art if the subject matter and claimed invention are "owned by the same person or subject to an obligation of assignment to the same person." This restriction on what constitutes prior art would be particularly useful to a large, brand drug company attempting to protect generic-blocking patents from invalidity claims. For example, the Federal Circuit recently relied upon a prior art patent that the patentee had previously licensed in order to strike down a pharmaceutical patent. See SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331 (Fed. Cir. 2005). District courts, too, recently have done so in both pharmaceutical and non-pharmaceutical cases.

Changes to 35 U.S.C. § 103. Section 3(c) of H.R. 2795 contains proposed § 102(b)(2). Under that proposal, subject matter that would otherwise qualify as prior art under proposed § 102(a)(2) cannot be considered prior art for purposes of § 103 if the claimed invention "was made by or on behalf of parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention." This change could eliminate key literature and other material as prior art.

C. By Eliminating The Requirement That Patentees And Applicants Act In Good Faith, H.R. 2795 Will Not Improve Patent Quality.

Presently, patentees can take certain actions or invoke certain procedures only if they do so with a lack of "deceptive intent." In other words, the Patent Act presently requires patentees and patent applicants to act in good faith before taking various actions or invoking

certain procedures. However, Section 5(c) of H.R. 2795 removes the lack of deceptive intent requirement from all such provisions, including in current § 116, § 256, § 184, § 185, § 251, § 253, and § 288. Precisely how patent quality will be improved by eliminating the good faith requirement from these provisions is unclear.

## III. If Congress Pursues Patent Reform, Any Such Legislation Should Include Provisions Designed To Eliminate Unjustifiable Advantages That The Case Law Currently Bestows On Patentees.

Presently, the case law in some key respects is unfairly stacked in favor of patentees. If Congress decides to pursue patent reform legislation, these inequities should be remedied. Examples of unwarranted inequities include the following:

Patentees currently enjoy a statutorily-unsupported presumption with respect to certain prior art. In essence, the case law currently presumes that the PTO reviewed and expressly considered any information that the patentee submitted during prosecution. See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984) (observing that patent examiner is presumed to have properly done his or her job and interpreted references presented during prosecution). This presumption exists even if there is no evidence that the patent examiner ever fully evaluated the information. In subsequent litigation, this presumption can translate into a heightened burden of proof for the alleged infringer, which, as discussed below, already must satisfy the clear and convincing evidence standard to begin with. See Metabolite Labs, Inc. v. Lab. Corp. of Am., 370 F.3d 1354, 1368 (Fed. Cir. 2004); Al-Site Corp. v. VSI Int'l, 174 F.3d 1308, 1323 (Fed. Cir. 1999). Nothing in the Patent Act warrants imposing any heightened burden merely because the patentee provided a copy of an article to the PTO. To remedy these inequities, Congress should consider amending the Patent Act to provide that information and references referred to during examination shall be deemed to have been considered by the PTO if, and only if, the patent examiner makes an explicit indication of the information's or a reference's scope and relevance to examination. A mere listing of information or references by the patent examiner should not be sufficient to establish that the PTO actually considered specific information or references.

Additionally, an alleged infringer currently must establish invalidity by clear and convincing evidence. But nothing in the statute itself requires this heightened showing. The mere fact that the patent is presumed valid does not, by itself, justify imposing this considerable burden. At most, the clear and convincing evidence standard should apply only when an alleged infringer attempts to establish invalidity using information or references that were expressly considered by the PTO during patent prosecution. The burden of proving invalidity of a patent based, in whole or in part, on any information or references not considered by the PTO should be by a preponderance of the evidence.

Further, patentees enjoy unwarranted presumptions when it comes to injunctive relief. For example, a plaintiff in any type of civil action must, generally speaking, establish four elements in order to obtain preliminary injunctive relief: a likelihood of success on the merits, irreparable harm, that the balance of hardships favors injunctive relief, and that the public would benefit from the granting of such relief. Under the current case law, however, a patentee seeking

an injunction against an alleged patent infringer often enjoys a presumption that it will suffer irreparable harm if an injunction does not issue. See, e.g., Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1367-68 (Fed. Cir. 2001) (upholding the grant of a preliminary injunction preventing drug company from launching its competing product).

Barr believes that if Congress moves forward with patent reform legislation, the public interest is best served by revising 35 U.S.C. § 283 to include the following concepts:

? a preliminary or permanent injunction should not be issued unless the court finds that the patentee is likely to suffer irreparable harm that cannot be remedied by the payment of money damages; and

? the court will not presume the existence of irreparable harm, but instead will consider and weigh evidence that establishes or negates any equitable factor relevant to a determination of the existence of irreparable harm, including the extent to which the patentee makes use of the invention.

The April 2005 Committee Print of H.R. 2795 contained most of these concepts. Unfortunately, that language does not appear in the bill.

IV. If Congress Enacts Patent Reform Legislation, Caution Should Be Exercised When Implementing Such Changes.

If Congress enacts patent reform legislation, it should ensure that those changes are implemented in a way that does not upset settled expectations. For example, the effective date provisions of H.R. 2795 could, and likely would, have immediate negative consequences for industry. Among other things, Section 11(g) of the bill provides:

(g) DETERMINING VALIDITY OF CLAIMS.--For the purpose of determining the validity of a claim in any patent or the patentability of any claim in a nonprovisional application for patent that is made before the effective date of the amendments made by section 3, other than in an action brought in a court before the date of the enactment of this Act--

(1) the provisions of sections 102(c) and 102(d) of title 35, United States Code, shall be deemed to be repealed;

(2) the provisions of sections 102(f) of title 35, United States Code, shall be deemed to be repealed and replaced by the provisions of section 101 of title 35, United States Code, as amended by section 4(a) of this Act, relating to the inventor's right to seek and obtain a patent, except that a claim in a patent that is otherwise valid shall not be invalidated by reason of this paragraph; and

(3) the term "in public use or on sale" as used in section 102(b) of title 35, United States Code, shall be deemed to exclude the use, sale, or offer for sale of any subject matter that had not become reasonably and effectively



accessible to persons of ordinary skill in the art to which the subject matter pertains, as defined in the amendments made by section 3 of this Act.

Enacting such a provision could be immediately harmful for at least the following reasons. First, it upsets the settled expectations of generic drug companies, and perhaps competitors in other industries. The process for preparing a generic drug application takes years. For drugs currently under development, generic companies have reviewed the relevant patent landscape and made decisions about what drugs to pursue based upon the law as it currently stands. Section 11(g), if enacted, could significantly change that law to the detriment of those companies. For example, Section 11(g)(3) would eliminate the current law involving the public

use and on-sale bar defenses of § 102(b), and replace it with "reasonably and effectively accessible" standard found in Section 3 of H.R. 2795. For the previously-discussed reasons, such a change could negatively impact generic drug companies.

Second, the provision conceivably could create situations where different patents in the same law suit are governed by different law. For example, Generic Company X currently is engaged in litigation involving several patents, but Brand Company Y has other patent applications pending in the PTO. H.R. 2795 is enacted, as written, today. The PTO grants two new patents to Brand Company Y next week. Brand Company Y adds those patents to its existing litigation against Generic Company X. The current law governs the patents issued before enactment of H.R. 2795, but Section 11(g)(3) arguably can be construed as applying to the patents issued after its enactment. If so, Generic Company X now has two sets of patents, each governed by different legal standards, in the same litigation. Such a situation plainly should be avoided, as it severely prejudices the generic company.

CONCLUSION

Thank you, Mr. Chairman, Ranking Member Leahy, and Members of the Subcommittee, for giving Barr the opportunity to explain its views and concerns about this important topic. Barr looks forward to continuing to assist Congress in this area.