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Innovation versus Access: The Great Debate between Pharmaceutical Patent Holders and Generic Manufacturers

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I. INTRODUCTION

Pharmaceutical patent holders (brand name drug) and generic drug manufactures (generic drug) continually debate the optimal balance between innovation and access. Policymakers must confront brand name companies that argue, "research and development is a 'costly and risky activity,'" as well as social groups that contend, "the right of every individual [is] to enjoy the benefits of scientific progress and its applications."[1] In response to these challenges, the United States government is taking legislative steps to lower the cost of pharmaceuticals by promoting generic drugs while still permitting brand name drug manufactures to maintain exclusivity of their patents.[2] With that in mind,

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[1] Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188, 2191 (2002) (quoting Joseph A. Dimasi, Henry G. Grabowski & John Vernon, *R&D Costs, Innovative Output and Firm Size in the Pharmaceutical Industry*, 2 INT'L J. ECON. BUS. 201-19 (1995)); Sheja Ehtesham and Niranjan Mansingh, *Conflicting Interests in Drug Pricing: Innovation vs Social Needs*, 94 CURRENT SCI. 168, 168 (2008) *available at* http://www.ias.ac.in/currsci/jan252008/168.pdf (referencing International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI), ¶ 15, U.N. Doc 14531 (Dec. 16, 1966) *available at* http://www.unhchr.ch/html/menu3/b/a_cescr.htm).

[2] Press Release, The White House, President Takes Action to Lower Prescription Drug Prices By Improving Access to Generic Drugs (Oct. 21, 2002), http://www.whitehouse.gov/news/releases/2002/10/print/20021021-4.html [hereinafter *President*]; *cf.* ROBIN J. STRONGIN, NAT'L. HEALTH POL'Y FORUM., HATCH-WAXMAN, GENERICS, AND PATENTS: BALANCING PRESCRIPTION DRUG INNOVATION, COMPETITION AND AFFORDABILITY 15 (2002) *available at*

policymakers need to balance intellectual property rights with public health that is "consistent with [the] broadly defined social objectives."[3]

II. THE APPROVAL PROCESS FOR DRUG PATENTS BY THE FDA AND USPTO

A brand name patent holder is granted the maximum patent term of twenty years.[4] However, the Federal Drug and Administration (FDA) must approve a drug before the drug can be marketed and sold to consumers.[5] The patent term begins to run from the time that the United States Patent and Trademark Office (USPTO) grants the patent, and not from the time of FDA approval.[6] Therefore, while a drug is pending FDA approval, the term of the patent is encroached upon, thus reducing the effective patent term to below twenty years.[7] Between the years of 1966 and 1979, a patent holder was granted a maximum patent term of seventeen years, and the average market exclusivity of a brand name drug patent declined from 13.6 years to 9.5 years.[8] This decline primarily resulted from the increase in the time that brand name drug companies awaited FDA regulatory approval.[9] Thus, brand name drug companies sought legislation that would allow term extensions on pharmaceutical patents to compensate for market time lost while the pharmaceutical awaited approval.[10]

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http://www.nhpf.org/pdfs_bp/BP_HatchWaxman_6-02.pdf (explaining how exclusivity is maintained).

[3] *See* Ehtesham, *supra* note 1, at 169 (explaining the conflicting interests between providing incentives for innovation and availability of drugs based on social welfare); Internal Centre for Trade and Sustainable Development, *Fostering R&D and Promoting Access to Medicines*, http://ictsd.net/i/events/dialogues/11554/ (last visited Oct. 9, 2008) (explaining how the World Trade Organization has tried to promote innovation and creativity while increasing the public's access to medicines).

[4] Consumer Project on Technology, The Hatch-Waxman Act and New Legislation to Close Its Loopholes, http://www.cptech.org/ip/health/generic/hw.html (last visited Oct. 9, 2008).

[5] U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Frequently Asked Questions on the Patent Term Restoration Program, http://www.fda.gov/CDER/about/smallbiz/patent_term.htm (last visited Oct. 24, 2008) [hereinafter *CDER*].

[6] *Id.*

[7] *Id.*

[8] Frederick Tong, *Widening the Bottleneck of Pharmaceutical Patent Exclusivity*, 24 WHITTIER L. REV. 775, 778 (2003); *see also* CDER *supra* note 5.

[9] Tong, *supra* note 8, at 778.

[10] *Id.*

Further, the FDA treated generic drug manufacturers seeking regulatory approval as new drug applicants.[11] Generic drug manufactures, often relatively small in size, had problems meeting the additional demands and documentation required for a new drug application because they had access to fewer resources than big brand name drug companies.[12] As a result, there was a large disparity in the number of drugs being produced between brand name drug companies and generic manufacturers.[13]

III. THE HATCH-WAXMAN ACT: A SOLUTION BETWEEN INNOVATION AND ACCESS

Legislation could be used to strike a balance between the marketing exclusivity afforded to brand name drug patent holders and the need of generic drug manufacturers to have access to those patented drugs for timely FDA approval. Senator Orrin Hatch and Representative Henry Waxman introduced legislation to solve the problems of patent term extension and generic drugs approval. [14] The purpose of the legislation was (1) "to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval" and (2) "to make available more low cost generic drugs by establishing a generic approval procedure." [15]

Congress codified the Hatch-Waxman Act under 35 U.S.C. § 156 and § 271(e).[16] The first provision under the Hatch-Waxman Act, section 156, provides the patent holder with a term extension for the time lost during the premarket approval process.[17] Under section 156:

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[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] Tong, *supra* note 8, at 777.
[15] Alison Ladd, *Integra v. Merck: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & POL'Y 311, 316 (2005) (quoting H.R. Rep. No. 98-857(I), at 14-15 (1985)).
[16] Hatch-Waxman Act, 35 U.S.C. §156 (2006); Hatch-Waxman Act, 35 U.S.C. §271 (2006). *See generally Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed. Cir. 2008) (providing an example where the patent infringement involved related to an aerosol spray commonly used in various drug delivery devices, such as nasal spray pumps and inhalers).
[17] *Proveris*, 536 F.3d at 1260-61.

> The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended . . . from the original expiration date of the patent . . . [if] the product has been subject to a regulatory review period before its commercial marketing or use . . .[18]

Additionally, Congress capped the term extension on a patent at a maximum of five years.[19]

Brand name drug companies claim that if market exclusivity on drug patents issued is not "adhered to, then investment in research and development will dwindle" and that "[n]ew drugs will cease to be created," causing everyone to suffer consequences.[20] Further, selling drugs at a price far above the cost of manufacturing is "the only way to recoup the enormous costs of years of research and development, and continue to fund research."[21] Brand name drug companies spend years developing and researching drugs that include "extremely expensive clinical trials" and the abandonment of many drugs that never produce positive results.[22] Extensions on drug patents will allow brand name drug manufacturers to recover the costs of new drug research and development.[23] Therefore, by providing brand name drug companies with extensions on drug patents, pharmaceutical companies will be able to recoup the portion of time lost while the patent was going through the FDA approval process.[24]

The second provision under the Hatch-Waxman Act, section 271(e), eliminates the infringement cause of action against generic drug manufacturers during the FDA approval process by "providing a safe harbor that immunize[s] competitors from infringement."[25] Prior to the passage of section 271(e), a generic drug manufacturer could be found to infringe upon a brand name drug

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[18] Hatch-Waxman Act, 35 U.S.C. §156(a) (2006).
[19] Consumer Project on Technology, *supra* note 4.
[20] *Innovation vs. Access: Two Epidemics Transform the Pharmaceutical Patent Law Debate into an International Controversy*, 19 J. YOUNG INVESTIGATORS 1, 1 (2008) *available at* http://www.jyi.org/features/ft.php?id=467 [hereinafter *Innovation*].
[21] *Id.*
[22] Ehtesham, *supra* note 1, at 168.
[23] Ladd, *supra* note 15, at 348.
[24] *Id.* at 318.
[25] *Proveris*, 536 F.3d at 1261.

patent because "a generic manufacturer could not begin the testing necessary for FDA approval of the generic drug product prior to the expiration of the innovative drug's patent."[26] Further, brand name drug companies prevent generic drug manufactures from bringing generic drugs to market by using "extra market exclusivity" extensions to "keep generics off the market by protecting their drugs." [27] Under section 271(e),

> [i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.[28]

As a result, section 271 allows "competitors to begin the regulatory approval process while the patent [is] still in force, followed by market entry immediately upon patent expiration."[29] Thus, the combination of sections 156 and 271(e) allows for the promotion of generic drugs and permits continued incentives for research and development.[30]

The Hatch-Waxman Act restricted the regulation of term extensions to brand name drug patents. However, the safe harbor provision in section 271(e) did not clearly define the breadth of the term "drugs" and the specific type of drug patents that are covered by the provision.[31] In *Proveris Scientific Corp. v. Innovasystems, Inc.*, the Federal Circuit held that Congress created the safe harbor provision under section 271(e) to provide "generic drug developers with the means to compete commercially immediately upon the expiration of a drug's patent."[32]

While section 156 "adversely affected patentees," section 271(e) "adversely affected those seeking FDA approval in order to enter the market to

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[26] Ladd, *supra* note 15, at 319.
[27] Consumer Project on Technology, *supra* note 4.
[28] Hatch-Waxman Act, 35 U.S.C. §271 (2006).
[29] *Proveris*, 536 F.3d at 1261.
[30] Consumer Project on Technology, *supra* note 4.
[31] Ladd, *supra* note 15, at 316.
[32] *Proveris*, 536 F.3d at 1264.

complete with patentees."[33] The court concluded that to be eligible for the safe harbor provision under section 271(e), the drug patent had to be defined under section 156(f) resulting in a "nearly perfect product correlation" between the two sections.[34] Therefore, the decision by the court narrowly determines the protection for generic drug companies under the safe harbor provision for section 271(e).

As a result, the safe harbor provision will help "promote drug discovery and development, with an objective to make affordable novel drugs to major infectious diseases."[35] In addition, the UK-based pharmaceutical group GlaxoSmithKline claims that lowering prices on pharmaceuticals will help "free[] up governments' scarce health resources."[36] Therefore, the increase in accessibility to generic drugs could result in savings of three-billion dollars per year in drug savings for Americans.[37]

IV. CONCLUSION

Throughout the decades, Congress has tried to find an optimal balance between innovation by brand name drug companies and access to brand name drug patents by generic drug manufactures. In an attempt to achieve this balance, Congress passed the Hatch-Waxman Act, codified under section 156 and section 271(e). The Act provides benefits to pharmaceutical companies by extending the market exclusivity of patents for the time the patent was under review by the FDA and precludes generic drug manufactures from being held liable of certain types of infringement of brand name drug patents towards the end of a patent's life. Although legislation has been passed, problems remain. As Congress moves

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[33] *Id.* at 1265.
[34] *Id.*
[35] Ehtesham, *supra* note 1, at 168.
[36] Andrew Jack, *GSK Varies Prices to Raise Sales*, Financial Times, (2008) http://www.ft.com/cms/s/0/4dc2b3bc-f380-11dc-b6bc-0000779fd2ac.htm (last visited Nov. 5, 2008).
[37] President, *supra* note 2.

forward, it needs to balance the interests of both innovation and access to develop legislation that will benefit everyone.