

**[Ed. Note: Due to the rapidly changing nature of this area of law, some of the content in this paper may be outdated, and should not be relied upon for legal research or citation.]**

The Effect of the Hatch-Waxman Act on Providing Affordable Pharmaceuticals: Boon or Bane?

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## I. INTRODUCTION

Pharmaceutical patents are big business. The \$300 billion pharmaceutical industry sold \$154 billion in prescription drugs in the United States in 2001, nearly doubling the \$78.9 billion sold in 1997.<sup>1</sup> Analysts estimate that as much as \$150 billion in revenues could be lost in the next five years as patents expire on a number of profitable brand-name drugs.<sup>2</sup> In this high-stakes business, development costs are staggering: typically \$400 to \$500 million for an average pharmaceutical.<sup>3</sup> The time span from discovery to market entry is ten to twelve years.<sup>4</sup> Of the pharmaceuticals patented, only about one percent actually make it to clinical trials, and of those, only four percent make it to market. Therefore, only about 1 in 2500 patented pharmaceuticals actually reach the marketplace.<sup>5</sup> According to 1996 data, the approximate U.S. sales figures for the antidepressant Prozac were \$4,750,000 *per day*.<sup>6</sup> It is small wonder that the manufacturers of patent pharmaceuticals are highly motivated to extend patent protection as much as possible.

There exists a sort of uneasy balancing between the interests of the pharmaceutical industry and

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<sup>1</sup> Terry Carter, *Drug Wars*, ABA Journal, December 2002, at 44.

<sup>2</sup> *Id.*

<sup>3</sup> Bill Christiansen II, *Presentation: The Experimental Use Exception and the Pharmaceutical Industry*, CASRIP Publication Series: Reconciling Int'l Intellectual Property, University of Washington School of Law 2001 <<http://www.law.washington.edu/casrip/Symposium/number7/1-Christiansen.pdf>>.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

the public at large. The basic purpose of the patent system in the United States is to encourage invention by granting exclusivity in the marketplace for a limited period of time.<sup>7</sup> There are competing public interests involved in this system. The public has an ongoing interest in the discovery and development of new pharmaceuticals, to promote its quality of life. At the same time the public also has an interest in keeping the prices of pharmaceuticals low enough that they may be within reach of as many people as possible while ensuring that new drugs are effective and safe. This paper will examine what impact the extension of patent terms, and some surrounding issues, have on the pharmaceutical market.

## II. DISCUSSION

### A. The Background of Modern Patent Law Protection for Pharmaceuticals

The heart of this matter revolves around a patent law provision legislated nearly two decades ago as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (“Hatch-Waxman”).<sup>8</sup> The patent term provisions of Hatch-Waxman allow a patent owner to recover time lost from the patent term due to pending regulatory approval by the U.S. Food and Drug Administration (“FDA”).<sup>9</sup> In order to qualify for

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<sup>7</sup> U.S. Const. Art. I, 8, cl. 8 “The Congress shall have Power ... To promote the Progress of Science ... by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries.”

<sup>8</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified as 35 U.S.C. §§ 155-156 (1984).

<sup>9</sup> 35 U.S.C. § 156(c) (1999).

a patent term extension (“restoration”), the product must be the subject of a regulatory review period before its commercial marketing or use.<sup>10</sup> The amount of restoration time is calculated by the U.S. Patent and Trademark Office (“USPTO”), and is generally based only on the testing and approval phases of review. In the United States, a utility patent is valid for a term of twenty years from date of filing.<sup>11</sup> The length of the patent term restoration equals half of the time spent in clinical testing after the patent is granted, plus all of the time that the FDA spends reviewing the new drug application.<sup>12</sup> The amount of restoration time is reduced by any period of time that the applicant fails to act with due diligence.<sup>13</sup> The maximum restoration time granted is five years and the total patent term may not extend beyond fourteen years after FDA approval.<sup>14</sup> Only one patent for each newly approved chemical substance is eligible for an extension under Hatch-Waxman.<sup>15</sup> If a drug is covered by more than one patent, the manufacturer must choose which patent will receive the extension.

Prior to Hatch-Waxman, the FDA required generic manufacturers to perform their own testing without the ability to rely on any data submitted by the patent-holding “innovator.” Since it was

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<sup>10</sup> *Id.*

<sup>11</sup> 35 U.S.C. § 154(a)(2) (1996).

<sup>12</sup> 35 U.S.C. § 156(c) (1999).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* For example, if a patent issues three years after filing, and FDA approval lasts another seven years, the patent owner could not receive the entire seven years. Since the remaining patent term would be ten years without the extension, the patent owner is only eligible for a maximum of four years of patent term restoration, thus providing a maximum post-FDA term of fourteen years.

<sup>15</sup> *Id.*

considered an act of infringement to manufacture or use a patented product during that product's patent term, the generic manufacturer could not commence testing until the innovator's patent term had expired. Thus the regulatory approval and subsequent market entry of a generic equivalent would not occur until years after the innovator's patent had expired, giving the innovator a de facto "patent term extension." Indeed, in the landmark case of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,<sup>16</sup> the court affirmed that a generic manufacturer is infringing by using the active ingredient of a patent drug in its pre-market FDA testing before the innovator's patent has expired.<sup>17</sup> Hatch-Waxman was enacted in 1984 to attempt to resolve these conflicts between the Patent Act<sup>18</sup> and the Food, Drug and Cosmetics Act.<sup>19</sup> In what is known as the "experimental use exception," Hatch-Waxman overruled *Roche*, allowing generic manufacturers to conduct testing of a product still protected by the innovator's patent.<sup>20</sup> In fact, the manufacturers of patent drugs are required to share relevant research data with generic manufacturers so that the latter can perform testing.<sup>21</sup> No other industry is required to share core research on a patented product with potential competitors.<sup>22</sup> This legislation enabled generic manufacturers to bring their copies of drugs to market in less than three months after the

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<sup>16</sup> 733 F.2d 858, 221 U.S.P.Q. (BNA) 937 (1984).

<sup>17</sup> *Id.*

<sup>18</sup> 35 U.S.C. §§1-376 (2001).

<sup>19</sup> 21 U.S.C. §§301-95 (1997).

<sup>20</sup> 35 U.S.C. § 271(e)(1) (2001).

<sup>21</sup> NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT, A PRIMER: GENERIC DRUGS, PATENTS AND THE PHARMACEUTICAL MARKETPLACE 4 (2002) <<http://www.nihcm.org>>.

<sup>22</sup> *Id.*

expiration of the innovator's patent, compared with the more than three year delay in the pre-Hatch-Waxman era.<sup>23</sup> The goal of Hatch-Waxman was to strike a balance between encouraging competition from generic drugs and maintaining the incentive for innovators to invest in the development of new drugs.<sup>24</sup> Many people would agree, as does this author, that the Hatch-Waxman provisions for patent term extension and the ability of generic companies to begin development prior to a patent's expiration, have contributed mightily to the increased market presence of lower-cost pharmaceuticals, and thus a great benefit to consumers.

#### B. The Rise of Generic Pharmaceuticals

Many factors have led to the market expansion of generic pharmaceuticals, including the effects of the Hatch-Waxman patent term extensions,<sup>25</sup> discussed *supra*. Other contributing factors included the repeal in many states of ant substitution laws that prohibited pharmacists from dispensing generic drugs,<sup>26</sup> and the trend of many health insurance companies to contract out the management of prescription drug benefits to so-called pharmaceutical benefit management companies ("PBMs").<sup>27</sup> The influx of generic drugs in the marketplace has exerted a downward

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<sup>23</sup> THE CONGRESS OF THE UNITED STATES CONGRESSIONAL BUDGET OFFICE, A CBO STUDY: HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ix (1998) <<http://www.cbo.gov/ftpdoc.cfm?index=655&type=1>>.

<sup>24</sup> *Id.*

<sup>25</sup> 35 U.S.C. § 156(c) (2001).

<sup>26</sup> CBO STUDY, *supra* note 23, at 1.

<sup>27</sup> *Id.*

pressure on the prices of brand-name pharmaceuticals, due in great part to the negotiating powers of PBMs and health maintenance organizations (“HMOs”) in selecting drug vendors.<sup>28</sup> It is estimated that this competition from generics has resulted in the average returns from marketing a new drug being lowered approximately 12 percent, or some \$27 million in 1990 dollars.<sup>29</sup> In 1984, generic drugs accounted for 18.6 percent of the pharmaceutical market. By 2000, that share had increased to 47 percent.<sup>30</sup>

Another factor opening the door to generic drug development was the streamlined approval process provided for in Hatch-Waxman. Under this process, generic manufacturers are required only to demonstrate “bioequivalence” to the existing innovator drug. Bioequivalence means that the active ingredient of the generic is absorbed at the same rate and to the same extent as that of the innovator drug. Bioequivalence testing is far less costly than testing required to prove safety and efficacy, thus relieving generic manufacturers of a major compliance burden.<sup>31</sup>

### C. So What’s all this Controversy Surrounding Patent Pharmaceuticals, Anyway?

The rising costs of prescription medications has stirred up a great deal of controversy in recent

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<sup>28</sup> *Id.*

<sup>29</sup> CBO STUDY, *supra* note 23, at ix.

<sup>30</sup> PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PRIMER (2001) <<http://www.phrma.org/publications/publications/10.08.2001.528.cfm>>.

<sup>31</sup> CBO STUDY, *supra* note 23, at xii.

years, garnering much attention from the media and the public at large. Manufacturer price increases for prescription pharmaceuticals in recent years have been higher than in the mid-1990s.<sup>32</sup> The overall average prescription price was \$45.79 in 2000, more than double the 1990 average price of \$22.06.<sup>33</sup> The average retail price of a prescription for a brand name drug was more than three times that of a generic drug in 2000 (\$65.29 compared to \$19.33).<sup>34</sup> This price ratio between average brand and generic prescription prices has increased over time, from just under 2.9 times in 1996 to 3.4 times in 2000.<sup>35</sup> Groups ranging from consumer organizations,<sup>36</sup> to elder advocacy groups,<sup>37</sup> to generic pharmaceutical industry trade groups,<sup>38</sup> have joined the fray. Federal legislation is being proposed<sup>39</sup> that would attempt to plug some of the “loopholes” in Hatch-Waxman. This proposed legislation, commonly referred to as the Greater Access to Affordable Pharmaceuticals (“GAAP”) Act,<sup>40</sup> was passed by the U.S. Senate last year, and, at the

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<sup>32</sup> THE HENRY J. KAISER FOUNDATION, PRESCRIPTION DRUG TRENDS, A CHARTBOOK UPDATE 7 (2001) <<http://www.kff.org/content/2001/3112/>>.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> CONSUMERS UNION, CONSUMERS UNION SUPPORTS THE “GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS (GAAP) ACT” (2002) <<http://www.consumersunion.org/health/gaap2dc402.htm>>.

<sup>37</sup> AARP, AARP BULLETIN ONLINE: BRANDS VS. GENERICS (2002) <[http://www.aarp.org/bulletin/departments/2002/medicare/0405\\_medicare\\_1.html](http://www.aarp.org/bulletin/departments/2002/medicare/0405_medicare_1.html)>.

<sup>38</sup> Generic Pharmaceutical Association, <<http://www.gphaonline.org>>.

<sup>39</sup> S. 812, 107th Cong. (2002).

<sup>40</sup> *Id.*

time of this writing, is awaiting action by the House.<sup>41</sup> While Hatch-Waxman certainly provided for the explosive growth in the generic drug industry the past two decades, thus paving the way for lower-cost drug options for consumers, some aspects of Hatch-Waxman remain a sore spot for advocates of affordable drugs.

One such trouble spot in Hatch-Waxman is what is known as the “30 month stay,”<sup>42</sup> which allows a patent owner to obtain a 30 month preliminary injunction against a generic manufacturer by claiming that the generic drug would infringe the patent. Patent owners are required under Hatch-Waxman to list all pharmaceutical patents in the FDA’s “Orange Book.”<sup>43</sup> Manufacturers interested in marketing a generic equivalent of a patented drug before the patent’s expiration must provide notice to the patent owner, triggering the automatic 30 month stay.<sup>44</sup> The premise of the 30 month stay is to allow the patent owner to protect its patent by giving it the opportunity to file an infringement action. Allegations have arisen concerning abuse by some patent owners who list frivolous patents with the FDA to exclude competitors from development of certain drugs.<sup>45</sup> Since an innovator drug is often protected by several patents, the manufacturer can fire off numerous requests for stays, keeping the competition in limbo due to the uncertainty of whether

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<sup>41</sup> PUBLIC CITIZEN, CONSUMER GROUP CRITICAL OF HOUSE FOR FAILING TO TAKE UP LEGISLATION EASING ACCESS TO LOWER-PRICED GENERIC DRUGS (2002) <[http://www.citizen.org/pressroom/print\\_release.cfm?ID=1238](http://www.citizen.org/pressroom/print_release.cfm?ID=1238)>.

<sup>42</sup> 21 U.S.C. § 355(c)(3)(C), 21 U.S.C. § 355(j)(5)(B)(iii) (2003).

<sup>43</sup> NATIONAL INSTITUTE FOR HEALTH CARE MANAGEMENT, *supra* note 21, at 6.

<sup>44</sup> *Id.*

<sup>45</sup> Alfred B. Engelberg, Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?, PTC Res. Found. Franklin Pierce Law Center 39 J.L. & Tech 389 (1999).

any other parties are free to develop a competitive product. After an extensive study into alleged anticompetitive conduct in the pharmaceutical industry,<sup>46</sup> The Federal Trade Commission has reported that multiple 30 month stays prevented FDA approval of generic equivalents for 4 to 40 months beyond the initial 30 month period.<sup>47</sup> That the 30-month stay is so easily abused is indication that it has become contrary to the goals of Hatch-Waxman to promote competition by generic manufacturers. Indeed, Representative Henry Waxman, co-sponsor of the 1984 Act, expressed his doubts by asking the FTC in 2001 to launch its study.<sup>48</sup> The proposed GAAP bill would limit the ability of patent owners to invoke the 30 month stay.<sup>49</sup> However, industry groups representing the patent pharmaceutical manufacturers assert that the bill is unnecessary, that such procedural rights are necessary ensure continued research and development of new drugs.<sup>50</sup>

Another bone of contention involves frivolous filings of “citizen” petitions with the FDA. The premise of citizen petitions has been to provide an important feedback mechanism from the public to raise concerns about FDA-regulated products. However there have been allegations of abuse in that some citizen petitions have been filed by the patent owners or their representatives as a

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<sup>46</sup> FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* (2002) <<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>>.

<sup>47</sup> *Id.*, at iv.

<sup>48</sup> FEDERAL TRADE COMMISSION, *supra* note 46, at 1.

<sup>49</sup> S. 812, 107th Cong. (2002). Under the Senate bill, patent owners would be limited to one automatic 30 month stay per drug product, rather than the current provision allowing multiple stays.

<sup>50</sup> PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *supra* note 30.

tactic for delaying approval of a generic drug.<sup>51</sup> Proponents of GAAP believe that the bill's full-disclosure requirement for citizen petitions will help shed light on what interest is truly behind the petition.<sup>52</sup> The GAAP bill proposes requiring, inter alia, the source and amount of any compensation received by the petitioner, and a declaration by the petitioner stating that the petition "is not submitted for any improper purpose, such as to harass or cause unnecessary delay."<sup>53</sup> However, in its study of anticompetitive conduct among pharmaceutical manufacturers, the FTC found that such petitions did not affect the timings of generic entry.<sup>54</sup>

Alleged anticompetitive activity by some pharmaceutical manufacturers, both innovator and generic, is an area that has drawn the full attention of the FTC.<sup>55</sup> Indeed, a full quarter of the agency's anticompetition investigative resources has been focused on the pharmaceutical industry.<sup>56</sup> In addition to investigating abuses of the 30 month stay provision, discussed supra, the FTC has directed a substantial portion of these resources toward the investigation of cases where innovator pharmaceutical manufacturers have allegedly colluded with generic manufacturers to

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<sup>51</sup> GENERIC PHARMACEUTICAL ASSOCIATION, GPhA LEGISLATION: MCCAIN-SCHUMER BILL (2002) <<http://www.gphaonline.org/legislation/mccain-schumer.phtml>>. One provision of the bill would require disclosure of who actually paid for the petition and any accompanying briefs that are filed.

<sup>52</sup> *Id.*

<sup>53</sup> S. 812, Sec. 5, 107th Cong. (2002).

<sup>54</sup> FEDERAL TRADE COMMISSION, *supra* note 46, at 68.

<sup>55</sup> FEDERAL TRADE COMMISSION, PREPARED STATEMENT OF THE FEDERAL TRADE COMMISSION BEFORE THE COMMITTEE ON THE JUDICIARY SUBCOMMITTEE ON ANTITRUST, COMPETITION, AND BUSINESS AND CONSUMER RIGHTS UNITED STATES SENATE (Sep. 19, 2002) <<http://www.ftc.gov/os/2002/09/020919overviewtestimony.htm>>.

<sup>56</sup> *Id.*

prevent or delay the latter from developing a generic equivalent. As of September 2002, the FTC had settled three such cases where the generic company was paid to not compete.<sup>57</sup>

### III. CONCLUSION

Much of what the Hatch-Waxman Act had set out to accomplish in 1984 has become reality today. The market has been enriched with greater competition, creating options for consumers. Providing patent term extensions for innovators of new drugs has balanced well with the ability of generic manufacturers to begin testing of equivalent drugs prior to the expiration of the innovators' patents, an opportunity available to no other industry. Still, the cost of innovator prescription drugs continues its ascent, and the public's outcry for reform becomes more and more vocal. The U.S. patent system becomes an easy target for consumer backlash. However this is not the root of the problem. If anything, the patent system has fostered competition.

The symbiotic relationship between the innovators and generics has been marred by instances of anticompetitive trade practices. In an era of corporate hijinks by the likes of Enron and Worldcom, the public's dismay for such abuses by drug manufacturers can do nothing but fuel the fire of populist backlash. Some legislators are tuned in to this sentiment and may seek to appease their constituents' needs. Legislative response so far seems to address a few glaring inequalities

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<sup>57</sup> FEDERAL TRADE COMMISSION, *supra* note 46 (noting one particular case involving a settlement with American Home Products (AHP), which resolved charges that AHP entered into an agreement with Schering Plough Corporation to delay AHP's introduction of a generic potassium chloride supplement in exchange for millions of dollars).

that exist in the drug development landscape, particularly the “30-month stay” provision, the citizen petition process, and certain antitrust activities.

Nevertheless it is this author’s belief that a strong intellectual property protection system is necessary to foster continued development of novel and effective medicines. The U.S. patent system not only encourages new medical developments, it provides others with the opportunity to compete in these areas, resulting in more, not fewer choices. Erosion of patent protections would only hinder incentive for product research and development. Current legislation recognizes this and has wisely left patent term extensions in place. The proposals to close procedural “loopholes” in Hatch-Waxman may help ensure a more level playing field and promote fair play between drug companies. Unfortunately it will likely result in minimal cost reduction to consumers.