The Hatch-Waxman Act:
Prescriptions for Innovative and Inexpensive Medicines

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The Drug Price Competition and Patent Term Restoration Act of 1984,[2] commonly known as the Hatch-Waxman Act, was legislatively negotiated to strike "a balance between two potentially competing policy interests—inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term."[3] The Hatch-Waxman Act was, at least according to two economists, the first change in patent terms since 1861.[4]

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[1] The views expressed in this article are those of the author alone and do not necessarily reflect the views of Schiff Hardin, LLP, or of its other attorneys, or of any of its clients.

[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (collectively, the "Hatch-Waxman Act").

[3] *See Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al.*, No. 2010- 1001 (Fed. Cir., April 14, 2010), at 2, *citing Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). *See also Caraco Pharmaceutical Laboratories, Ltd., et al. v. Forest Laboratories, Inc., et al.* , No. 2007-1404 (Fed. Cir., April 1, 2008); and B. Randall, *The U.S. Drug Approval Process: A Primer* (Congressional Research Service, June 1, 2001), Summary and CRS-1, http://www.thememoryhole.org/crs/more-reports/RL30989.pdf (hereinafter "CRS I"). The purpose of the Act was "to make available more low cost generic drugs by establishing a generic drug approval process for pioneer drugs first approved after 1962." H.R. Rep. No. 98-957, Pt. 1, at 14 (June 21, 1984). As stated in a recent *amicus* brief filed by Rep. Henry Waxman, in *Federal Trade Commission v. Schering-Plough Corporation, et al.*, No. 05-273 (S.Ct. 2005), the "Act reflected the concern that then-existing FDA procedures, which required generic drug manufacturers to complete the lengthy procedures for new drug approval once patents protecting the name-brand drug expired, "had serious anti-competitive effects," the result of which was "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent. H.R. Rep. No. 98-857, Pt. 2, at 4 (Aug. 1, 1984)."

[4] See H. Grabowski and J. Vernon, Longer Patents for Increased Generic Competition: The Hatch-Waxman Act After One Decade, SSRN 40940 (Duke Univ., June 1995).

Some commentators have said that the Hatch-Waxman Act has played a "critical role" in the development of the United States pharmaceutical industry.[5] The Congressional Research Service, in a 2004 report to Congress, after enactment of the most recent Hatch-Waxman amendments in the 2003 MMA, stated:

> Many experts agree that the Act has had a significant effect on the availability of generic substitutes for brand name drugs. Generics generally are rapidly available after patent expiration and at lower prices. Concurrently, given the increasing investment in research and development (R&D) and the gains in research intensity of the pharmaceutical industry, it appears that the 1984 Act has not deterred the search for and the development of new drugs.[6]

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[5] *See* G. Glover, M.D., *"Hatch-Waxman" Law Has Played A Critical Role in Medical Advances*, ISBN 1056 3059 (Washington Legal Foundation2002). Dr. Glover, then a partner in a law firm, commented that the "U.S. pharmaceutical market is robust, competitive, and working to the benefit of consumers, exactly as Congress intended when it passed the Hatch-Waxman Act," that the "U.S. pharmaceutical industry continues to lead the world in innovation," and that

> The Hatch-Waxman Act has played a critical role in this. On the one hand, the generic industry has flourished since the law eliminated major barriers to market entry and made it much easier, far less costly, and quicker for low-cost generic drug manufacturers to get their copies of innovator medicines to market following patent expiration. On the other hand, the Hatch-Waxman Act provided the research-based pharmaceutical industry — the source of virtually all new drugs in the U.S. — incentives to innovate. The law restored part of the patent life lost by pioneer medicines as a result of regulatory review by the Food and Drug Administration (FDA), and provided litigation procedures to decrease the likelihood of patent infringement when generic drug products entered the market. As a result, consumers are receiving the benefits of both an expanding stream of ever more effective, precise, and sophisticated medicines, as well as early access to low-cost generic copies.

See also R. Epstein and B. Kuhlik, *Navigating the Anticommons for Pharmaceutical Patents: Steady the Course on Hatch-Waxman*, http://ssrn.com/abstract_id=536322, at 14 ("Whatever one thinks of the recent changes to Hatch-Waxman, the legal institutions now in place are not in need of any major repair."), and Note, *The Hatch-Waxman (Im)Balancing Act,* http://leda.law. harvard.edu/leda/ data/551/Paper1.html (the Act was, in large part, successful at meeting its goals). *And see* Ernst R. Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parcee, and Edward Tuttle, *Authorized Generic Drugs, Price Competition and Consumers' Welfare*, www.aei.org/docLib/20051103_GenericsDraft.pdf (Oct. 2005).

[6] W. Schacht and J. Thomas, *The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents*, http://www.ipmall.fplc.edu/hosted_resources/crs/IB10105.pdf (2004), at CRS-1.

On various occasions surrogates for both generic and branded pharmaceutical manufacturers have been more critical of the effects and effectiveness of the Act, each arguing that the other had exploited provisions of the Act to their benefit, and that timely introduction of lower cost drugs or that truly innovative research and development ("R&D") of new drug products had suffered as a result.[7]

The Hatch-Waxman Act is again under attack or, at minimum, alteration, by agency, legislative and judicial actions. The FTC has asserted that its terms have been abused by both branded and generic manufacturers, which have entered into settlements of litigation that the FTC regards as anticompetitive. Authorized generics have been introduced into the marketplace by branded companies, in an effort to retain a portion of the sales lost at introduction of generic products into a particular pharmaceutical product market. With

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[7] *See, e.g.*, G. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process,* 54 Food and Drug L. J. 187 (1999)(" For those who ask whether Hatch-Waxman was a good deal or a bad deal for the research-based pharmaceutical industry, the most learned response is: It was not a good deal, unless one believed that FDA was going to go forward with its plans to implement abbreviated new drug applications (ANDAs) through regulation. If one thought that was going to happen — and FDA was working on it — then Hatch-Waxman probably was a good balance. If one did not think that would ever happen, Hatch-Waxman probably was not a good balance, at least at the time."). *See also* M. Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 Hastings L.J. 171 (2009); Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions,* http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf (January 2010); T. Chen, *Authorized Generics: A Prescription for Hatch-Waxman Reform*, 93 Va. L. Rev. 459 (2007); D. Reiffin and M. Ward, *"Branded Generics" As a Strategy to Limit Cannibalization of Pharmaceutical Markets,* www.uta.edu/faculty/mikeward/ brandedgenerics.pdf (May 2005); Comment, *The Dubious Value of Hatch-Waxman Exclusivity*, 45 Houston L. Rev. 555 (2008).

significant justification, generics have labeled this practice as anti-competitive and a gross distortion of the "delicate balance" struck in the Hatch-Waxman Act.

Members of Congress have recently introduced legislation to ban settlements that include so-called "reverse payments" and to prohibit "authorized generics."[8] At the same time, the Congress has recently enacted a "pathway" for "follow-on biologics" that greatly expand the data exclusivity granted to branded biological product manufacturers, making future generic competition increasingly difficult, if not economically infeasible.

The Federal Circuit has recently determined that induced infringement may be proven by a showing of "deliberate indifference" to the existence of a patent.[9] Although the decision was made in a non-Hatch-Waxman case, it may well affect cases brought under the Act, especially against foreign generic pharmaceutical manufacturers.[10] In *Exergen Corp. v. Wal-Mart Stores, Inc.*,[11] the

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[8] *See, e.g.*, Fair Prescription Drug Competition Act, S. 438, 110th Cong. (2007); S. 3695, 109th Cong. (2006) (authorized generics); Preserve Access to Affordable Generics Act, S. 316 (2007)(prohibiting brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market).

[9] *See SEB., S.A. v. T-Fal Corporation*, No. 2009-1009 (Fed. Cir., February 5, 2010).

[10] See, e.g., *AventisPharmaceuticals, etc. v. Lupin, Inc.,* 403 F.Supp. 2d 484, 495 (E.D.Va. 2005)("In ANDA litigation, an action for induced infringement may be brought pursuant to Section 271(e)(2). Under Section 271(b), [w]hoever actively induces infringement of a patent shall be liable as an infringer. *See* 35 U.S.C. § 271(b). In order to be liable for inducement, the inducing party must knowingly act and specifically intend to aid the infringement. *Pfizer, Inc. v. Ranbaxy Lab. Ltd.,* 321 F.Supp.2d 612, 616 (D.Del.2004)*Allergan, Inc. v. Alcon Lab., Inc.,* 324 F.3d 1322, 1331 (Fed.Cir.2003)*Geneva,* 287 F.Supp.2d at 585. While "active inducement" requires "an affirmative act of some kind," *see id.,* the majority of courts have held that allegations of activities done in the preparation of an ANDA application are not enough; rather, the claim must include aiding and abetting infringement so that the primary question of the suit may be resolved, namely: "whether, if a particular drug were put on the market, it would infringe the relevant patent.")

Federal Circuit held that to plead the "circumstances" of inequitable conduct with the requisite particularity" a pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. [12] The seemingly heightened pleading requirements set forth in *Exergen*, when introduced in Hatch-Waxman litigation, may well make it far more difficult for generic pharmaceutical manufacturers to invalidate patents procured through fraud on the PTO or, at least, inequitable conduct.

And, in *Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al.*,[13] the Federal Circuit held that the amendments to the Act made in the MMA, in 2003, to recognize a counterclaim by a generic manufacturer for de-listing of a patent improperly listed in the FDA's Orange Book, "on the ground that the patent does not claim either (aa) the drug for which the application was approved; or (bb) an approved method of using the drug,"[14] lies "only if the listed patent does not claim *any* approved methods of using the listed drug."[15]

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[11] 573 F.3d 1312 (2009).

[12] A pleading that alleges inequitable conduct must "include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.*, 573 F.3d at 1328 – 29.

[13] *See* Note 3, *supra*.

[14] 21 U.S.C. § 355(j)(5)(C)(ii)(I).

[15] Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al., supra, Note 3, at 10.

The *Novo Nordisk* decision permits branded pharmaceutical manufacturers to engage in practices, through changes in listings in the Orange Book, designed to defeat a generic manufacturer's "carve-outs" from labeled indications to avoid costly patent litigation, raising a specter that practices described in *Mylan Pharms., Inc. v. Thompson,*[16] that the Congress intended to remedy in the MMA amendments in 2003, may well again be abusively employed by branded pharmaceutical manufacturers.

All of these recent trends and developments raise the question whether the terms of the Hatch-Waxman Act should be revisited again, or whether, even with its perceived flaws, it is best to leave things as they are.[17]

Hatch-Waxman Act History and Basic Provisions

Although there is a "paucity of legislative history,[18] it is clear from the accounts of those who participated in the "congressionally supervised" process of negotiating the legislation,[19] that the Act was always a compromise intended designed to interfere with and change the "free market" for patented

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[16] 268 F.3d 1323, 1332-33 (Fed. Cir. 2001).

[17] Be careful what you wish for, you might get it.

[18] *See* G. Mossinghoff, *supra* Note 7.

[19] *See* A. Engelberg, *Special Provisions for Pharmaceuticals: Have They Outlived Their Usefulness*, 39 J. L. & Tech. 389 (1998), http://ipmall.org/hosted_resources/IDEA/39_IDEA/39-3_IDEA_389_Engelberg.pdf for a detailed account of the "congressionally supervised negotiation between the generic and brand-name pharmaceutical industries in which the parties were compelled to reach a compromise by the legislature." *Compare* G. Mossinghoff, *supra* Note 7.

pharmaceutical products that existed prior to its enactment. In 1984, when the Hatch-Waxman Act was passed, the pharmaceutical market was essentially devoid of generic competition. No "pathway" existed for approval of generic drugs by the FDA.[20] Each pharmaceutical manufacturer was required to conduct full clinical trials to demonstrate the safety and effectiveness of its drug product, even if an "innovator's" product had been marketed for years. More than 150 products existed without any patent protection and without any generic competition.[21] Hence, prior to enactment of the Hatch Waxman Act, although it may have been "to society's benefit to introduce generic versions of as many drugs as possible as quickly as possible, to maximize consumer savings,"

> … there was little incentive for the generics to do so. If they attempted to prematurely research a competing product, challenging the validity of a patent, they would be subject to an infringement suit, an expense they could ill afford when the potential return on their investment was so far in the future. And once they finally brought a

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[20] *See* A. Engelberg, *supra* Note 9, at 396 (the 1962 amendments to the Food and Drug Act, "contained no provisions for a separate approval process for drugs which were identical to drugs which had been previously approved. Thus, a party seeking approval to market a generic version of an existing drug was compelled to file a New Drug Application ("NDA") and to independently prove that the drug was safe and effective. Many drugs were approved based on a so-called "paper" NDA in which the applicant relied upon published data concerning the safety and efficacy of the previously approved drug as the proof that its own, identical product was safe and effective. However, such data were not readily available for all approved products. Moreover, nothing in the FDA regulations prevented the Agency from requesting additional, expensive clinical studies to deal with safety or efficacy questions that may have arisen from adverse reaction reports or other published information pertaining to the approved product between the time of its approval and the time of the paper NDA filing. Often, the paper NDA applicant lacked the financial resources or expertise required to respond to such requests.")

[21] *See* G. Mossinghoff, *supra* Note 7 ("After 1962, there was congressional testimony that there were 150 drugs that were off-patent, but for which there were no generics because generic companies simply would not spend the time and money doing the clinical trials to get to market, and that there were only fifteen "paper NDAs," for post-1962 generics.")

> product to market, price competition would have dramatically lowered their profit margins relative to those enjoyed by brand name drug companies, despite the generics' having undergone a significant outlay of expenditures on expensive human clinical trials, almost comparable to the brand name drug companies' clinical studies and research and development expenses, before being able to bring their product to market. Only the most truly altruistic or delusional would have been able to remain in the industry, which is why, prior to 1984, only 36% of top-selling brand name drugs had a competing generic product on the market, and generic drugs accounted for only 19% of prescription drug volume.[22] All of this was made more complicated by the 1983 decision in *Roche*

Products, Inc. v. Bolar Pharmaceutical Co.,[23] in which the Federal Circuit held that the ultimate commercial purpose underlying generic pharmaceutical manufacturers' efforts to develop bioequivalent products in order to seek FDA approval was a "use" of a patented invention and an act of infringement that could be enjoined under the patent laws as they existed at that time. The Court said that it could not "construe the "experimental use" rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[24]

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[22] Note, *The Hatch-Waxman (Im)Balancing Act*, http://leda.law.harvard.edu/leda/data/551/Paper1.html, *citing* CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xii (1998), (hereinafter "CBO Competition Study"). According to the CBO Competition Study, prior to 1984, "competition from generic drugs in terms of price and market share was limited primarily to antibiotics." CBO Competition Study at 29.

[23] 733 F.2d 858 (Fed. Cir. 1984).

[24] 733 F.2d at 363.

The changes made in the Hatch-Waxman Act were intended to reverse the decision in *Bolar,* to permit generic manufacturers to develop bioequivalent products and request FDA approval without instantly infringing a patent, and to create a new regime for rapid FDA approval of generic bioequivalents of branded pharmaceuticals.[25] The principal *quid pro quo* for enactment of the *Bolar* exception to the Patent Act,[26] was the addition of provisions "allowing for the extension of the normal term of a patent for up to five years to compensate a patent owner for the marketing time allegedly lost in [the FDA drug approval process],"[27] and for a total patent term extension of up to 14 years.[28]

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[25] One of the architects of the legislatively supervised negotiated Hatch-Waxman Act, Representative Waxman recently stated that the "ultimate goal of all of these provisions was to 'provide low-cost, generic drugs for millions of Americans,' resulting in 'a significant savings to people who purchase drugs.' 130 Cong. Rec. 24427 (Sept. 6, 1984) (statement of Rep. Waxman)." He stated that the "legislators who voted for the Act anticipated that it 'will do more to contain the cost of elderly care than perhaps anything else this Congress has passed, because it will bring about lower priced generic alternatives to brand name drugs once the patent has expired or if there is no valid patent and the courts decide there is no valid patent in order to give that monopoly protection.' *Id.* (statement of Rep. Waxman)." *See* Amicus Brief of Rep. Henry Waxman, *Federal Trade Commission v. Schering-Plough Corporation, et al.*, No. 05-273 (S.Ct. 2005), at 5, http://www.citizen.org/documents/waxman amicus.pdf (hereinafter "Waxman Amicus").

[26] 35 U.S.C. § 271(e)(1)(1994).

[27] This process is briefly described in B. Randall, *The U.S. Drug Approval Process: A Primer*, *supra*, Note 3 (CRS I). It is summarized as follows: "To begin clinical testing, drug companies or sponsors must file an Investigational New Drug (IND) application with the FDA. The INDs must include information about the study protocol, the qualifications of the lead investigator, the trial's location, and assurances that the welfare of the study participants will be protected." *Id.*, Summary and CRS-4 to CRS-11. So-called "Phase I studies focus on assessing the drug's safety in a group of healthy volunteers, usually at very small doses in fewer than 100 patients." *Id.*, at CRS-9. "Phase II trials are randomized, well-controlled, double-blind clinical investigations," designed to "verify further a drug's safety," and primarily "to find out whether the drug is effective or not." *Id.* Lastly, "Phase III clinical trials can involve both controlled and uncontrolled studies and may include as many as several thousand patients. These trials produce additional information about safety and effectiveness, help define the drug's overall benefit-to risk ratio, and determine how its official labeling will be worded. The larger studies are intended to provide more information on the drug's side effects, whether it interacts with foods and/or other medications, and whether certain patient populations should avoid its use altogether." *Id.*

As consideration for their agreement to the Hatch-Waxman compromise, branded pharmaceutical companies also received a novel additional protection, *not* based on any patents, for "data exclusivity."[29] Under the Hatch-Waxman Act, a generic manufacturer is permitted to file an Abbreviated New Drug Application that relies on data acquired during a branded company's clinical trials conducted prior to approval of an NDA, without conducting all such trials again.[30] Instead, the Act permits filing of an ANDA based upon more limited tests, demonstrating the "bioequivalence" of a proposed generic product to an FDA approved branded product.[31]

After completion of such clinical studies, "the sponsor submits a New Drug Application (NDA) for FDA evaluation. During the application's review, agency officials examine the drug's safety and efficacy data, assay samples, and conduct factory inspections to be sure the finished product will be manufactured properly. FDA also checks the drug's labeling to be sure that it is accurate and comprehensive. Typically, when FDA finishes its review, it notifies the applicant by letter stating that its NDA is either approved, would be approved if changes are made, or cannot be approved due to unresolved problems. Once a new drug is approved, its safety is monitored through FDA's post-marketing surveillance system, MedWatch. …" *Id.*, Summary and CRS-4 to CRS-11.

[28] 35 U.S.C. § 156(c)(3).

[29] This five-year non-patent exclusivity was a "key" to the Hatch-Waxman compromise. *See* A. Engelberg, *supra* Note 9, at 406.

[30] 21 U.S.C. § 355(j)(1) and (2).

[31] 21 U.S.C. § 355 § 355(j)(2)(A)(iv). *See National* Institute for Health Care Management Research and Educational Foundation, *A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace,* at 4 (2002), http://www.nihcm.org/~nihcmor/pdf/GenericsPrimer.pdf. A "bioequivalent drug" is defined as one for which

> (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

The novel "data exclusivity" provision included in the Hatch-Waxman Act as a *quid pro quo* for permitting generic company reliance on previous clinical trials, grants the NDA holder a period of five years after the date of FDA approval of a New Chemical Entity (NCE),[32] during which the FDA is not permitted to approve an ANDA that relies upon such trials.[33] The Hatch-Waxman "data exclusivity" provisions also create a period of three years after the date of any FDA approval of a new use of an existing and previously approved chemical entity, or new dosage form using that chemical entity, that was based on clinical tests, during which the FDA is not permitted to approve an ANDA that relies upon such trials.[34] The effect of these data exclusivity

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> (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355(j)(8).

[32] 21 CFR 314.108(b) defines a "New Chemical Entity" as "a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the act." An "active moiety" is "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other non-covalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance."

[33] 21 U.S.C. §§ 355 (c)(3)(D)(ii). *See* W. Schacht and J. Thomas, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, RL30756, http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL307560 1102005.pdf, and W. Schacht and J. Thomas, *The Hatch-Waxman Act: Legislative Changes Affecting Pharmaceutical Patents*, RL32377 http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/IB10105.pdf.

[34] 21 U.S.C. §§ 355 (c)(3)(D)(iii).

provisions is to create an effective monopoly for the innovators that conducted clinical trials, insulating them from *any* generic competition during the "data exclusivity" period.

Hence, under the Hatch-Waxman Act, pharmaceutical innovators may be entitled to (1) a patent term extension of up to five years, based upon delays in FDA approval of an NDA,[35] (2) a 30 months as a result of the "automatic stay" of final FDA approval during Hatch-Waxman litigation,[36] and up to five years of data exclusivity,[37] or 12.5 years of protection from generic competition after FDA approval of an innovator's drug product. This period, it has been argued, is necessary, according to industry advocates, in order to afford and NDA holder an "opportunity to earn a positive return on the new therapeutic candidates that successfully complete the lengthy and costly R&D process."[38]

As a general matter, the Hatch-Waxman Act requires the FDA to list the official and proprietary name of each drug which has been approved by the FDA

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[35] 35 U.S.C. § 156(c) and (g)(6).

[36] 21 U.S.C. § 355 (c)(3)(C) .

[37] 21 U.S.C. § 355 (c)(3)(D)(ii).

[38] *See* H. Grabowski, *Follow-on biologics: data exclusivity and the balance between innovation and competition,* 7 Nature Reviews Drug Discovery 479 (June 2008). *Compare* A. Brill, *Proper Duration of Data Exclusivity for Generic Biologics: A Critique*, http://www.tevadc.com/Brill_Exclusivity_in_Biogenerics.pdf; and M. Pugatch, *Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access,* http://www.iprsonline.org/unctadictsd/ bellagio/ docs/Pugatch_Bellagio3.pdf.

for sale (reference listed drugs).[39] Branded companies are required to identify all patents that claim the drug or a method of using the drug, by patent number and expiration date.[40] These drug names and list of patents are published in what has become known as the "Orange Book."[41]

Under the Act a generic pharmaceutical manufacturer may file an ANDA no earlier than one year prior to the expiration of the five-year data exclusivity period for newly approved NCEs[42] (the NCE-1 date).[43] The application must contain information that demonstrates that the active ingredient of the generic drug is the same as that of a drug that been previously approved by the FDA,

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[39] 21 USC 355(j)(7). "Not surprisingly, the opportunity to extend market exclusivity by merely listing a patent in the Orange Book has encouraged brand- name drug companies to seek, obtain, and, ultimately list a great variety of patents of little scope or merit except for their ability to delay legitimate competition. A cursory inspection of the FDA Orange Book's patent and exclusivity listings will reveal that most approved products have more than one listed patent. Sometimes, there are five or six listed patents for a single product. Some of these patents claim unapproved uses, special crystalline forms of the active ingredient, specific formulations, tablet shape or other subject matter which can easily be circumvented while still producing an equivalent generic version of an approved drug. These patents nevertheless prevent competition for at least thirty months." *See* A. Engelberg, *supra*, Note 9, at 415. *See also Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al.*, *supra*, Note 12.

[40] 21 U.S.C. § 355(b)(1)(G).

[41] *See* www.fda.gov/cder/ob/default.htm.

[42] 21 USC 355(j)(5)(F)(ii).

[43] Under the present structure, the FDA does not regard any single generic ANDA applicant as the sole-first filer, when several such ANDA applications are made on the NCE-1 date. The result has been that, in many cases, 10 or more generic manufacturers file ANDAs on an NCE-1 date, often with different invalidity and non-infringement positions. In these cases, the ensuing Hatch-Waxman litigation is often joined in a single judicial district, forcing these generic manufacturers together, even if they have separate and different interests. While such joinders may well yield efficiencies and frequently result in cooperative teams of generic company lawyers that may outnumber their branded counterparts, the economics of the product may well render lengthy and costly litigation unaffordable, because the ultimate market, after price discounts attendant to introduction of multiple generic competitors, will shrink to levels of marginal profitability for some, most or even all of the ANDA applicants. These economic conditions often produce strong tendencies to settle Hatch-Waxman litigation, simply to avoid further litigation costs.

listed in the Orange Book, and that the proposed generic product is "bioequivalent" to the Orange Book listed product.[44] The generic manufacturer must also certify, in its ANDA, with respect to each Orange Book listed patent, that "(I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)."[45] The last and the most important of these certifications, commonly known as a "Paragraph IV Certification," spawns Hatch-Waxman litigation between generic and branded pharmaceutical companies. It is the most important because, when making a Paragraph IV certification:

> … a generic firm is seeking market entry prior to patent expiration, whereas the other certifications simply confirm there are no extant patent rights that would prevent generic entry. Generic applicants making Paragraph IV certifications must notify the pioneer firm, which then has forty-five days to initiate a patent infringement lawsuit. Pioneers typically pursue litigation, automatically triggering a thirty-month stay that prevents FDA approval of the ANDA until the earliest of the following dates: patent expiration, a final resolution of the patent litigation, or expiration of the thirty-month period.[46]

In 2002, an FTC study found that generic pharmaceutical manufacturer that issued Paragraph IV certifications "prevailed in 73% of the patent litigation

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[44] 21 U.S.C. § 355(j)(2)(A)(iv).

[45] Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al., No. 2010- 1001 (Fed. Cir., April 14, 2010), at 3 – 4.

[46] *See* T. Chen, *supra* Note 7, at 465.

ultimately resolved by a court decision between 1992 and June 2002."[47] If this figure is correct, then generic manufacturers have a significant reason to make a Paragraph IV certification.

A generic manufacturer that is a "first applicant"[48] and that prevails in a Paragraph IV challenge to a patent is rewarded in the Hatch-Waxman scheme with 180 days of marketing exclusivity, during which the FDA is not authorized to issue a final ANDA approval to any other generic pharmaceutical manufacturer.[49] This 180-day marketing exclusivity period effectively "creates a period of duopoly," in which the branded NDA holder and successful ANDA first-filer are the only two entities permitted to manufacture and sell the Orange Book listed product, even if all of the patents on that product have been invalidated.[50]

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[47] *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Exec. Summary at viii (July 2002), www.ftc.gov/os/2002/07/genericdrugstudy.pdf, cited in Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions*, *supra*, Note 7, at 3. These rates of success for generic manufacturers may well be different from the success rates of defendants in patent litigation generally. A PriceWaterhouse Coopers study, entitled *2008 Patent Litigation Study: Damages awards, success rates and time-to-trial*, www.pwc.com/us/en/forensic-services/publications/2008-patent-litigation-study.jhtml, studied 1,282 final decisions issued at two stages of the litigation life cycle: summary judgment (666 decisions) and trial (616 decisions) between 1995 and 2007. The study reported that patent holders were only successful 37 - 40% of the time (that is, "instances where a liability and damages (if included) decision was made in favor of the patent holder"), with success rates at trail increasing significantly in the last several years, to as high as 63% for patent holders. It reported that, where alleged infringers (like generic manufacturers) were the plaintiffs , in declaratory judgment actions (9% of the cases studied), the alleged infringers were successful at trial 52% of the time. *Id.*¸ at 8, 9, 19.
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[48] A "first applicant" is defined by 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) as "an applicant that, on the first day on which a substantially complete application containing a [Paragraph IV] certification … is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV] certification … for the drug."

[49] 21 U.S.C. § 355(j)(5)(B)(iv).

[50] Comment, *The Dubious Value of Hatch-Waxman Exclusivity*, *supra*, Note 7, at 558 (duopoly).

The 180-day marketing exclusivity period was created in the Hatch-Waxman Act to encourage Paragraph IV challenges by rewarding the first filing applicant for undertaking the costs and risks of patent litigation, in which weak or improperly obtained patents are challenged, or in which appropriate non-infringing products are defended.[51] The 180-day exclusivity was, at one time, "very valuable to generic manufacturers, as they can sell product at a price significantly higher than they could if multiple generics were on the market."[52]

As Senator Hatch has noted, "Perhaps no single provision of the 1984 law has caused so much controversy as the 180-day marketing exclusivity rule."[53] Following enactment of the Hatch-Waxman Act, the FDA and litigants disagreed over what necessary for a first-filer to be entitled to exclusivity.[54] The Hatch-Waxman Act "originally provided for two events that would trigger the 180-day

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[51] See, e.g., W. Schacht and J. Thomas, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act"), RL30756, at CRS-24 and CRS-26; A. Mehl, The Hatch-Waxman Act and Market Exclusivity for Generic Drug Manufacturers: An Entitlement or an Incentive?, 81 Chicago-Kent L. Rev. 649, 651 (2006). The 180 day exclusivity period was included "to encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer drug makers' patents." Mylan Pharmaceuticals, Inc. v. Shalala, 81 F. Supp. 2d 30, 33 (D.D.C. 2000). See also A. Engelberg, supra, Note 9, at 403 – 404 (provision included to allow first-filer to recoup its litigation costs); and J. Thomas, Authorized Generic Pharmaceuticals: Effects on Innovation, RL 33605 , at CRS-6 and CRS-7.

[52] M. Avery, *supra,* Note 7, at 178. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998).

[53] *See* Sen. Orrin Hatch, Committee Statement, *Revising Hatch-Waxman Act*, May 8, 2002, at 4, http://hatch.senate.gov/newsite/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=182648&Month=5&Year=2002.

[54] *See* A. Mehl, *supra*, Note 48, at 657.

exclusivity period: (1) commercial marketing of the drug, or (2) a final court decision holding the relevant drug patent(s) invalid or not infringed."[55] Prior to amendment of the Act in 2003, settlements of Hatch-Waxman litigation were concluded that included an agreement by "the first Paragraph IV applicant to refrain from entering the market to exploit its 180-day exclusivity in return for substantial monetary payments." The "result was that a pioneer could block all subsequent generic competitors, whose market entry was contingent upon the triggering and expiration of 180-day exclusivity, which had now been 'parked' indefinitely."[56]

After challenges by the FTC,[57] ample criticism by others,[58] and complex litigation in the courts,[59] the 180-day exclusivity provisions were amended by the

[55] *See* T. Chen, *supra* Note 7, at 465 - 466.

[56] *See* T. Chen, *supra* Note 7, at 466; A. Engelberg, *supra*, Note 9, at 416 - 418.

[57] See, e.g., Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, supra, Note 44.

[58] See, e.g., Note, Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now in Exchange for Less Pharmaceutical Innovation Later?, 81 Wash. Univ. L. Q. 829 (2002); N. Derzko, The Impact of Recent Reforms on Orange Book Strategic Behavior and Pharmaceutical Innovation, 45 J. of Law & Tech. 165, 195 – 203 (2005); and J. Bulow, The Gaming of Pharmaceutical Patents, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=412123 (May 2003).

[59] *See, e.g., Teva Pharmaceutical Industries v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005); and *Mylan Pharm. v. FDA*, 454 F.3d 270, 276 (4th Cir. 2006)

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MMA.[60] The effects of these amendments were described in a paper by the Biotechnology Industry Organization (BIO):

> Under the new provisions, a generic applicant gains 180 days of exclusivity beginning on the date of first commercial marketing unless one of the following forfeiture events occurs:
>
> - The applicant fails to market the drug within 75 days of approval or within 30 months after submission of the ANDA;
> - The applicant fails to market the drug within 75 days after any court decision (from which no appeal can be taken) on each of the patents that earned the applicant eligibility for the exclusivity;
> - The applicant withdraws the ANDA or amends each of the paragraph IV certifications;
> - The applicant fails to obtain a tentative approval within 30 months;
> - The applicant enters into an agreement found to be in violation of the antitrust laws; or
> - All the patents that earned the applicant eligibility for the exclusivity expire.
>
> Under the new law the first generic drug applicant to file a paragraph IV certification on any patent receives exclusivity regardless of certifications that might be made by other applicants to different patents.[61]

The 2003 MMA amendments have not cured all problems with the 180-day period of exclusivity provided in the Hatch-Waxman Act. Significant problems remain with authorized generics, which may be deployed by branded

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[60] Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[61] *See* BIO, *Hatch-Waxman Reform Provisions,* at 2 (December 2003), http://bio.org/healthcare/archive/medicare/HatchWaxman_120303.pdf; and N. Derzko, *supra*, Note 55, at 243 – 245.

pharmaceutical manufacturers to deprive successful generic litigants of a significant portion of the "reward" conferred by the 180-day exclusivity provisions. Settlement agreements are still made that have the effect of delaying market competition, even after enactment of the 2003 MMA exclusivity forfeiture provisions. The lawfulness of "reverse payments" in exchange for a first-filer's agreement to refrain from marketing a generic product until a future date, continues to be challenged by the FTC and is without final determination by the courts or Congress.[62]

In addition, as the recent decision in *Novo Nordisk* has shown, even after enactment of the MMA amendments in 2003, which explicitly authorized counterclaims by aggrieved generic manufacturers seeking "an order requiring the holder to correct or delete the patent information submitted by [an NDA] holder" for inclusion in the Orange Book, "on the ground that the patent does not claim either … the drug for which the application was approved; or … an approved method of using the drug."[63]

Where We Are Now: Statistics

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[62] *See, e.g.*, C. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 Santa Clara Computer & High Tech L.J. 489 (2007), http://www.chtlj.org/sites/default/files/media/articles/v023/v023.i3.Holman.pdf; Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions, supra*, Note 7.

[63] 21 U.S.C. § 355(j)(5)(C)(ii)(I).

However successful the Hatch Waxman Act has been, staggering statistics will likely define inquiry into future changes to the Act. As Representative Waxman succinctly put it, "The escalating cost of health care in the United States — and, in particular, of prescription drugs — is an enormous, nationwide problem."[64] The tendency to look for ways to control health care expenditures may well lead to efforts to change the "delicate balance" struck in the Hatch Waxman Act, to promote the manufacture and sale of lower cost drug products, without sacrificing our nation's leadership role in pharmaceutical innovation.

In 2008, national health expenditures in the United States totaled $2.33 trillion, or 16.2% of our Gross Domestic Product.[65] Our population of 304 million people spent some $7,681 per capita on health care. In 1980, shortly before the Hatch-Waxman Act was enrolled into law, when our country was a mere 230 million souls, our national health expenditures were $253.4 billion, a mere 9.1% of our GDP, amounting to $1,100 per capita.[66] In the next 10 years, by 2019, when our population is expected to rise to 335 million, the national bill for health

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[64] *See* Waxman Amicus, at 2.

[65] http://www.cms.gov/NationalHealthExpendData/25_NHE_Fact_Sheet. asp#TopOfPage. *See also* http://www.oecd.org/document/16/0,3343,en_2649_34631_2085200_1_1_1_1, 00.html, and http://www.cdc.gov/nchs/hus/healthexpenditures.htm

[66] In comparison, between 1980 and 2007, national health care expenditures in Canada rose from 7.0% to 10.1% of GDP. In Germany, they rose from 8.4% to 10.4% of GDP; in France, from 7.0% to 11.0% of GDP; in the United Kingdom, from 5.6% to 8.4% of GDP; and in Japan, from 6.5% to 8.1% of GDP (2006). http://www.oecd.org/document/16/0,3343,en_2649_34631_2085200_1_1_1_1, 00.html.

care in expected to rise to nearly $4.5 trillion, comprising 19.3% of GDP, and about $13,387 per capita.

During the period from 1980 to 2008, expenditures on prescription drugs rose from $12 billion (4.7% of total health care expenditures) to $234.1 billion (10%). "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures."[67] By 2019, prescription drug expenditures are projected to increase to $457.8 billion (10%), an increase from $769 per capita in 2008 to $1,367 per capita in 2019.

The GAO study, cited in representative Waxman's *amicus* brief in *Schering Plough*, analyzed "the prices of 96 of the most commonly used prescription drugs" in the period between January 2000 and December 2004. The GAO study "showed that average prices for a one-month supply increased by 24.5%" in that period, an "annual rate of increase was nearly double that of consumer prices generally over the same period."[68] Representative Waxman's description of the current state of economic conditions in the pharmaceutical marketplace continued:

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[67] Waxman Amicus, *supra*, Note 62, at 2, *citing* Government Accountability Office, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* 1 (Aug. 2005), at www.gao.gov/new.items/d05779.pdf (GAO Study).

[68] Waxman Amicus, *supra*, Note 62, at 2, *citing* GAO Study, at 7.

> Brand-name drugs, many of which claim patent protection, account for most of the increase in drug costs. Generic drugs—chemically and pharmacologically identical but lacking the brand-name—are typically much less costly, on average about half the price of comparable brand-name drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 9 (2002), at www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The GAO found, for example, that the price of brand-name drugs in its sample increased by 28.9% over the five-year period covered by its study, while the price of the generic drugs surveyed increased by an average of only 9.4% over the same time. *GAO Study* at 4. The annual rate of increase for the generic drugs was significantly less than the overall inflation rate for consumer goods, which was approximately 2.5% annually, *id.* at 7, meaning that the generic drugs studied actually *declined* in price in real terms. The tremendous savings associated with generic drugs are illustrated by the fact that, in 2001, generic drug spending accounted for only $11 billion of the approximately $130 billion spent on prescription drugs, yet that $11 billion "bought 45 percent of the total prescription drugs purchased in 2001." 149 Cong. Rec. S8187 (June 19, 2003) (statement of Sen. Kohl).[69]

The major manufacturers of pharmaceutical products, the "innovators," have done very well. In the year ending September 2009, the 19 largest pharmaceutical manufacturers (other than Proctor & Gamble, whose reporting differs from others) reported consolidated revenues of some $558 billion, an average of $29.39 billion. These 19 companies had net income of $96 billion, or an average of $5.08 billion, some 16.5% of revenues. They had assets totaling $972 billion, averaging $51 billion. Shareholder equity amounted to nearly $470 billion, or an average of $24.7 billion. Net income thus represented an average return of 16.48% on assets, and 21.23% on shareholder equity.

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[69] Waxman Amicus, *supra,* Note 62, at 2 – 3.

In the same year, these 19 largest manufacturers spent a total of $88.9 billion on research and development, or an average of $4.681 billion, representing 16.28% of the average total revenues.[70] These are all substantial amounts, in both absolute and relative terms. By any measure, the risk born by these 19 manufacturers in making these expenditures yielded a healthy return on assets, and a healthier return on equity.

A great deal was spent on advertising. In the calendar year 2009, Pfizer, Inc. spent $1.4 billion on direct-to-consumer advertising; Johnson & Johnson spent more than $1.25 billion.[71] At least one study, based on analysis of industry standard IMS and CAM data, reported that in 2004, including samples, detailing, meetings, mailings, journal advertising and direct-to-consumer advertising, at least $27.7 billion (IMS data) and as much as $57.5 billion (combined IMS and CAM data) was spent by pharmaceutical manufacturers on promotion of their products. The same study reported, based on IMS data that, in the same year, those pharmaceutical manufacturers spent $29.6 billion on R&D.[72]

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[70] *See* Table 1, attached (based on data available in Med Ad News, September 2009).

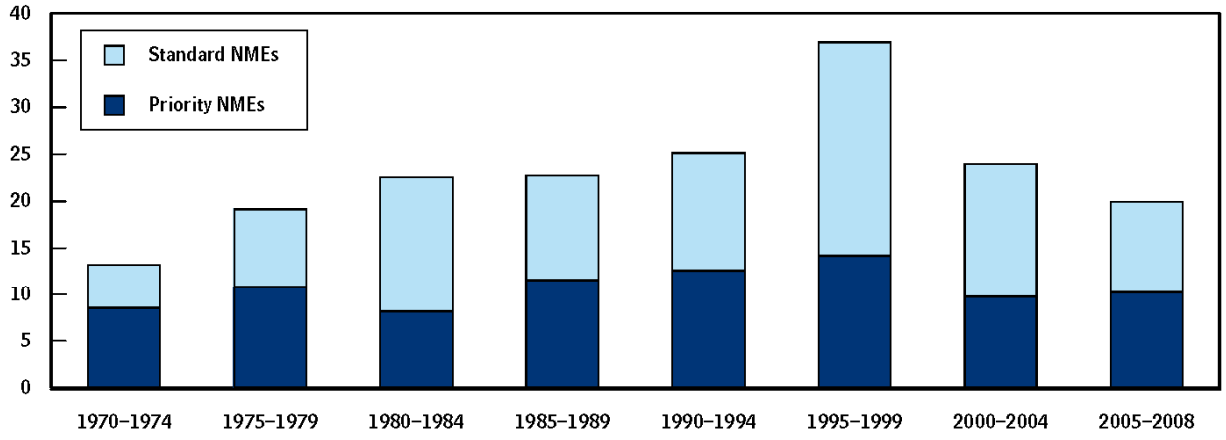
[71] *See* Kantar Media Reports U.S. Advertising Expenditures Declined 12.3 Percent in 2009, http://finance.yahoo.com/news/Kantar-Media-Reports-US-bw-699808888. html?x=0&.v=1

[72] *See* Gagnon and Lexchn, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, http://www.plosmedicine.org/ article/ info:doi/10.1371/journal.pmed.0050001 (*PLoS* Medicine, January 2008).

During the period since 1970, for many reasons, the number of new chemical entities approved by the FDA for marketing in the United States has significantly slowed.

Average Annual Approvals of New Drugs by the Food and Drug Administration, 1970 to 2008

(Number)



Source: Congressional Budget Office based on data from the Food and Drug Administration.

Notes: The data, which are for new molecular entities (NMEs) only, exclude extensions and new approved uses of existing drugs. New molecular entities are drugs based on a molecule not used before in any pharmaceutical product. Priority drugs are those that, according to the Food and Drug Administration, provide a "significant therapeutic or public health advance."

Beginning in 2004, approvals include those for biologics (large-molecule drugs such as monoclonal antibodies, growth factors, and recombinant proteins). The Food and Drug Administration approved five such drugs in 2004 (four given priority status); two in 2005 (both priority drugs); four in 2006 (all priority drugs); two in 2007 (one priority drug); and three in 2008 (two priority drugs). See www.fda.gov/cder/rdmt/default.htm.

A recent study by the Congressional Budget Office reported that "Drug introductions spiked in the mid- to late 1990s but have declined since 2000 — in most years, back to levels not seen since the 1980s. The introduction of priority drugs — drugs that, according to the Food and Drug Administration (FDA), provide a 'significant therapeutic or public health advance' — has also slowed, from an average of more than 13 a year in the 1990s to about 10 a year in the

2000s."[73] In part, this is attributable to the complexity of new products, or to the shift from "small molecules" to biologics. In part, it is also due to the FDA's quality standards. Drug approval standards in the United States are considered by many to be the most demanding in the world.[74] Part may have been due to changing economics of research and development. Whatever the specific reasons, the introduction of NCEs has slowed, even while "innovator" company profitability has been maintained or improved.

The generic industry has also done well. In the period between 2000 and 2008, the FDA reported having received an average of 587 ANDAs per year, or a total of 5284 generic drug applications.[75]

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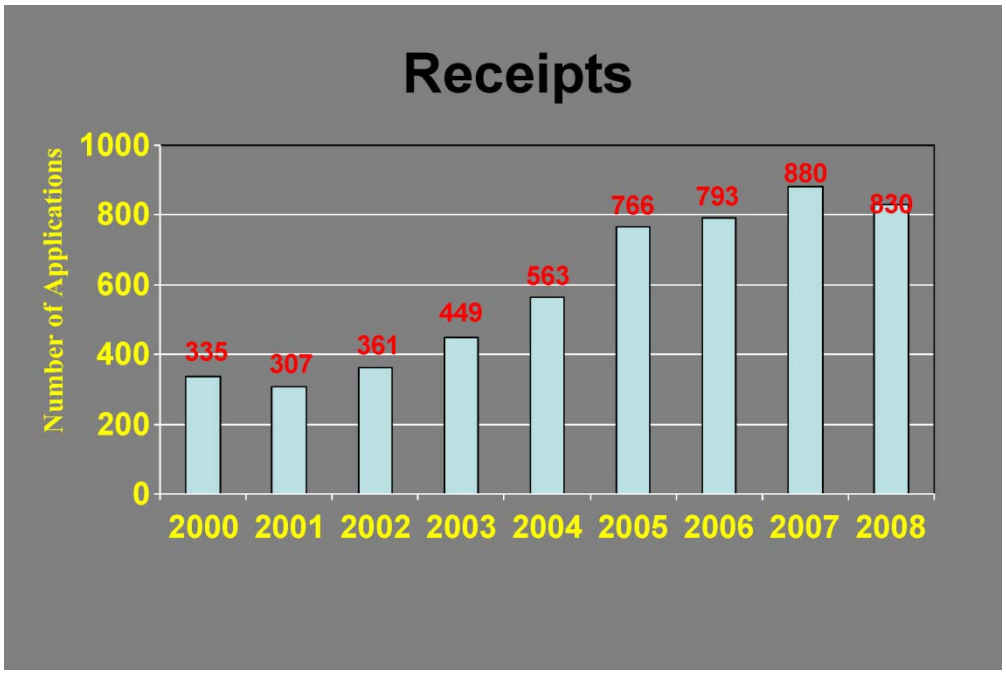
[73] See Congressional Budget Office, Research and Development in the Pharmaceutical Industry, at 20 (2006) (hereafter, "CBO R&D Study"), at 11. See also Congressional Budget Office, Pharmaceutical R&D and the Evolving Market for Prescription Drugs, at 2 (October 2009)(chart in text reproduced from this report), http://www.cbo.gov/ftpdocs/106xx/doc10681/10-26-DrugR&D.pdf (hereafter "CBO 2009 R&D Study"). According to IMS Health, the FDA approved 28 NCEs in 2009. http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=b523257373a96210VgnVCM100000ed152ca2RCRD&vgnextfmt=default.

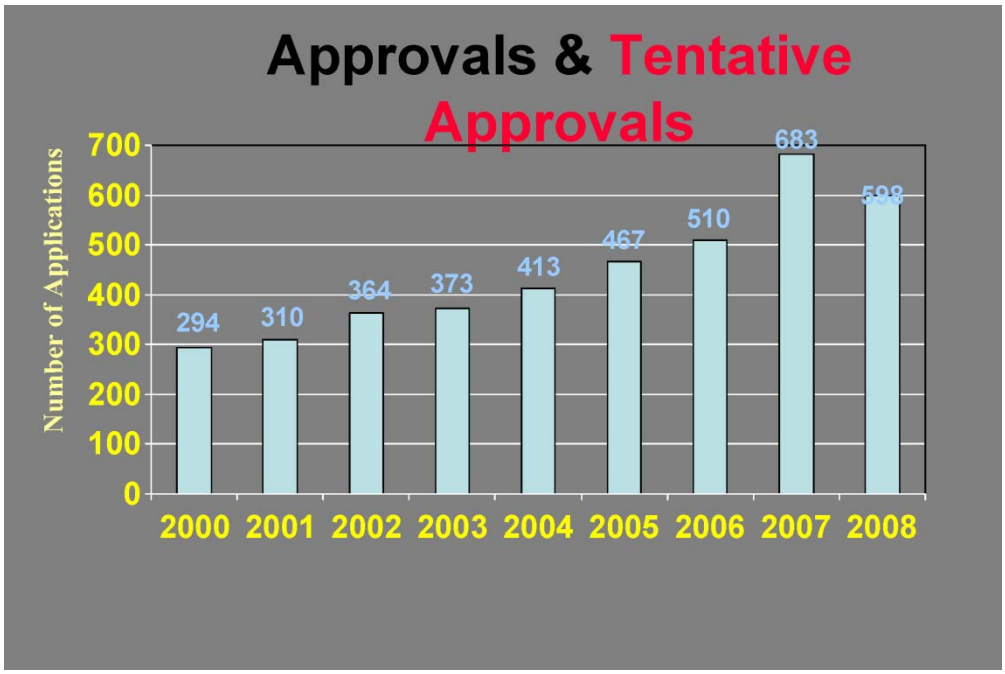
[74] CRS I, at CRS-2.

[75] *See* Food and Drug Administration, Office of Pharmaceutical Science, *Generic Drugs: Overview of ANDA Review Process*, http://www.fda.gov/downloads/Drugs/NewsEvents/ UCM182553.pdf (chart at slide 43).



In the same period, the FDA reported having approved or tentatively approved some 4012 ANDAs, or an average of 446 per year.[76]

[76] *Id.* (chart at slide 45).



In FY 2009, according to FDA data in its 2011 budget request, "CDER approved, or tentatively approved, 599 applications, the equivalent of more than two approvals and tentative approvals made each business day of the year."[77] As of February 2010, more than 2000 ANDAs were awaiting FDA action.[78]

IMS Health, an industry standard source for pharmaceutical industry data, reported in February 2010 that "unbranded generics" drove growth in the number of "prescription transactions" in 2009, accounting for 65.9% of all prescriptions, but only 10.7% of pharmaceutical revenues from prescription sales.

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[77] Food and Drug Administration FY 2011 Congressional Budget Request, at 103 (2010), http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM202321.pdf .

[78] *See Generic Drug Approvals Languish at FDA*, http://www.fiercepharma.com/story/ generic-drug-approvals-languish-fda/2010-02-22; and http://www.nytimes.com/2010/02/20/ business/20generics.html?ref=health.

"Branded generics accounted for 8.6% of all prescriptions and 12.4% of revenues from prescription sales. Branded pharmaceuticals accounted for 25.6% of all prescriptions and 76.9% of revenues from prescription sales.[79] Total *US* pharmaceutical sales surpassed $300 billion for the first time in 2009,[80] with *global* generic sales exceeding $78 billion in 2008.[81]

Moreover, the increasing presence of generic pharmaceuticals in the marketplace has benefitted consumers with lower prices, a factor that may also account for increasing pharmaceutical sales overall. The Congressional Budget Office has noted that "As generic drugs are substituted for their more expensive brand-name counterparts, the average price of a prescription falls."[82]

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[79] *See* D. Long, *2009 U.S. Pharmaceutical Market Trends: A Picture of Increasing Trends,* http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=b523257373a96210VgnVCM100000ed152ca2RCRD&vgnextfmt=default.

[80] *Id*.

[81] *See IMS Health Reports Annual Global Generics Prescription Sales Growth of 3.6 Percent, to $78 Billion,* http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=2943d52288d1e110VgnVCM100000ed152ca2RCRD&vgnextfmt=default.

[82] The CBO Competition Study commented that, in its retail pharmacy data set, "the average retail prescription price for a brand name drug with generic substitutes was $37 in 1994. However, including prescriptions that were filled with a generic drug, the average prescription price for a multiple-source drug was only $26. Thus, generic substitution lowered the average cost for a multiple source prescription by $11. That result is only a rough estimate, however, since prescriptions may somewhat misrepresent the relative quantities of brand-name and generic drugs sold." CBO Competition Study at 28. The report continued to state: "Several economists have studied what happens to the prices of innovator drugs when generic copies enter the market." The CBO Competition Study reported that "All of the studies agree that the effect on innovators' prices is very small, although there is some dispute about the direction of that effect. … Overall, brand-name prices frequently continue to rise after generic entry. Whether they rise more quickly or more slowly than would be the case without competition from generic drugs, however, is unclear based on these studies." CBO Competition Study, at 30.

The Hatch Waxman Act has encouraged continued innovation by branded pharmaceutical companies, with some generic manufacturers recently entering the market with their own new drug products. It has facilitated the growth of a robust generic pharmaceutical manufacturing industry, both in the US and around the globe. It has resulted in lower drug prices and wider availability of prescription pharmaceutical products. While there are certainly aspects of the Hatch-Waxman legislative scheme that cause interested participants to complain, viewed in historical context and as a whole, it is reasonable to say that the Act has played a "critical role" in the development of the United States pharmaceutical industry.[83]

It is reasonable to suggest that major changes to the Act should occur with great caution, based upon empirical evidence of current and historical economic effects, and based upon sound analysis of potential future economic effects of any proposed revisions. That economic evidence may be available. Careful economic analysis of that evidence may not yet exist. Whether such evidence and analysis has been employed in policy making about additions and changes to the Hatch-Waxman legislative compromise, including recent legislation to clarify or create a "pathway" for follow-on biologics, is unclear.

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[83] *See* Note 5, *supra*.

What Should Be Changed?
What Should be Left Alone?

We are a country dedicated to innovation, especially in health care. We are also a country in search of ways in which to control extraordinary increases in health care expenditures. The same two urgent objectives motivated the enactment of the Hatch-Waxman Act; they are the impulse for further reforms today. Not all those impulses should be followed. Some aspects of the Hatch-Waxman compromise are best left as they are.

1. *Data Exclusivity – Should be Left As-Is*

In 1984, when negotiating the terms of legislation that became the Hatch-Waxman Act, "innovator" companies asked for additional protections against competition from generic pharmaceutical manufacturers arguing that such measures were necessary to attract and make investment in pharmaceutical research and development by providing greater certainty that significant investments taken in new drug development would be repaid with a return on investment commensurate with the risk. Then, as now, they argued that, in order to ensure that innovation would continue, an expansion of the monopoly granted in patents was required, both in the life of issued patents and in legislative requests for "data exclusivity."

A widely circulated study estimated that in 2000, the average cost of developing an "innovative new drug" was "more than $800 million, including expenditures on failed projects and the value of forgone alternative investments."[84] More recent comments have suggested that the average cost of developing and bringing an NCE to market may now be as much as $1.2 billion.[85] Half of this amount, the study concluded, was for the direct costs of drug development, and, assuming a capital cost of 11% per annum and an average period of about 12 years to bring a new drug to market, half was for opportunity costs, that is, "indirect, financial costs of tying up investment capital for years in research projects."[86] In its comments about that study, in 2006, the Congressional Budget Office noted:

> Although that average cost suggests that new-drug discovery and development can be very expensive, it reflects the research strategies and drug-development choices that companies make on the basis of their

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[84] Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics, vol. 22, no. 2 (March 2003), pp. 151-185 (hereafter ÐiMasi"). *See* CBO Competition Study, at 20.

[85] *See, e.g.*, PHARMA, *Profile 2008*, http://www.phrma.org/files/attachments/2008%20 Profile.pdf ($1.3 billion); and K. Kaitin, *Creating a Policy Environment for Dynamic R&D Getting R&D Working for Growth*, http://www.law.gwu.edu/Academics/research_centers/ciec/Documents/roundtables/Rd_Table_Kenneth%20 Kaitin. pdf (Tufts study, $1.2 billion). The "average R&D cost of developing an incrementally modified drug was probably much lower than that amount. Available data indicate that, roughly speaking, spending to modify existing drugs accounts for less than one-third of total R&D expenditures, although modified versions of existing drugs make up about two thirds of all new drug products." CBO R&D Study, at 21.

[86] CBO R&D Study, at 19. DiMasi's study reported that, the average successful new molecular entity (new drug) in its sample "required 4.3 years for discovery and preclinical development and another 7.5 years for clinical trials and FDA approval," or a total of 11.8 years. CBO Study, at 19. FDA Approval, at that time, took an average of 1.5 years (part of the 7.5 years). *Id.*

> expectations about future revenue. If companies expected to earn less from future drug sales, they would alter their research strategies to lower their average R&D spending per drug. Moreover, that estimate represents only NMEs developed by a sample of large pharmaceutical firms. Other types of drugs often cost much less to develop (although NMEs have been the source of most of the major therapeutic advances in pharmaceuticals).
>
> * * * * *
>
> Research and development costs vary widely from one new drug to the next. Those costs depend on the type of drug being developed, the likelihood of failure, and whether the drug is based on a molecule not used before in any pharmaceutical product (a new molecular entity, or NME) or instead is an incremental modification of an existing drug.[87]

Branded pharmaceutical companies' apparent calls for increased time of data exclusivity are based, in large part, upon an analysis of the "ideal" time for delay of approval of any abbreviated new drug application "until innovators have had the opportunity to earn a return on the new therapeutic candidates that successfully complete the lengthy and costly R&D process."[88] The model employed in the analysis relies upon the assumption that the "capitalized R&D costs for a representative NBE [will] range from $1.24 billion to $1.33 billion when the real cost of capital is 11.5–12.5%," with data derived from "a capital asset pricing model analysis for a small set of biotechnology firms with a history of profitability based on multiple marketed products," which "companies also

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[87] CBO Study, at 1 - 2.

[88] *See* Grabowski, *supra*, Note 38, at 1. It is worth noting that the Grabowski study was "supported in part by grants from the Pharmaceutical Research and Manufacturers of America."

had an extensive portfolio of new biological product candidates over the period 1990–2003."[89]

The "break-even" analysis featured in the study "combines data from analysis of research and development (R&D) costs and cash flows from this cohort of 1980–1984 introductions," that is, NCEs, many *prior* to the enactment of the Hatch-Waxman Act.[90] The study defines the "break-even" point as the time when "the net present values (NPV) of inflow just equals outflows," that is, the "point at which a firm recovers its R&D investment and earns a risk-adjusted rate of return."[91] The study states that the "break-even lifetime for the mean drug in this [1980-1984] portfolio is just over 16 years," adding that a "similar analysis for the 1990–1994 portfolio of NCEs gives a break-even lifetime of 15 years."[92] The study concludes that in the model portfolio, the "break-even" point occurs "at 12.9 years in the case of an 11.5% real cost of capital," or at 16.2 years when a 12.5% real cost of capital is used.

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[89] *Id.*, at 480 – 481. "The key assumptions are that pre-approval R&D costs are based on post-approval out-of-pocket costs equal to 35% of pre-approval costs; post-approval R&D costs are spread evenly over the first 8 years after launch; sales are based on historical distribution of successful biotechnology market introductions; a pre-tax contribution margin of 50%; and all sales are measured in constant 2005 US dollars." *Id.,* at 486 (Figure 6).

[90] *Id*., at 483 (Figure 3).

[91] *Id.,* at 486 (Figure 6).

[92] Id.

The results of the study have been often repeated, without significant review of its underlying assumptions. The study *was* subjected to academic review a few months after its initial publication.[93] Using the same data as the "branded" study, and the same "simple" cumulative Net Present Value "break-even" model, but varying only the cost of capital (10%, instead of 11.5% or 12.5%), and the "contribution margin,"[94] from 50% to 60%, both of which alternative assumptions were said to be "more plausible," the "generic" study concluded that the "break-even" duration ranges from less than 9 years to 12 years.[95] The later study strongly suggested that "great care" be taken in interpreting the study results, "for public policy applications related to the optimal duration of data exclusivity rules."[96] Importantly, the study continued, the "break-even duration will always be greater than the optimal duration of data exclusivity in a market such as biologic drugs, where it can be expected that the innovator drug will continue to earn economic profits following the entrance

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[93] *See* A. Brill, *supra*, Note 38. The Brill study was supported by a generic pharmaceutical manufacturer, Teva Pharmaceuticals.

[94] The "contribution margin" was defined in the Grabowski study as "sales minus the costs of goods sold (including depreciation charges for plant and equipment), marketing, promotion and administrative costs in the numerator. This is expressed as a percentage of sales in the denominator." *See* Grabowski, *supra*, Note 38, at 483. The Brill study used the same definition. *See* A. Brill, *supra*, Note 38, at 9. The "contribution margin" is the numerator used in these net present value calculations; the "cost of capital" is used in the denominator as the discount rate.

[95] *See* A. Brill, *supra*, Note 38, at 9.

[96] *Id.*, at 10.

of biogeneric competition." It noted that "As a result of the fact that economic profits can be earned beyond the break-even point, optimal data exclusivity will be at a time prior to the break-even point," adding

> Grabowski (2008) and the variations to that model presented here are stylized approximations of the market for biologics. Important other factors, including other patent protection issues and the aforementioned evergreening issue, not modeled here will affect incentives to innovate and affect the ability of biogeneric competition to improve access to drugs. Nevertheless, a critical factor in any legislation creating a pathway for follow-on biologics will be the duration granted for data exclusivity. Results presented here indicate that seven years is a reasonable duration to balance incentives for innovators with the market benefits of competition.[97]

What is clear from these studies, used to lobby Congress in the course of the recent debates about Health Care Reform and, in particular, about the need for a lengthy period of data exclusivity for follow-on biologics, is that real-world conclusions about investment behavior, including the behaviors of branded pharmaceutical companies in making investments in research and development of both NCEs and new biological entities (NBEs), can only be seen partially through the lens of academic economic research. The real-world data, set forth above, strongly suggests that branded companies and their shareholders continue to make substantial investments in research and development, and that they realize significant returns on those investments. Although this recent real-

[97] *Id.,* at 10, 11.

world data is available, at least in the aggregate manner displayed in corporate audited financial statements, none of the economic analyses used in recent legislative debates has been based upon such recent data. Whether the models used in the Grabowski and Brill studies, described above, are even sensitive enough to changing business environments, including lowered interest rates for borrowing, low inflation, rapid technological innovation, cost-cutting through outsourcing, rationalization through mergers and acquisitions, altered patterns of payment for both medicines and medical research, and other variables, may also be questioned. Whether the branded pharmaceutical industry will continue to thrive on the "blockbuster" model that has driven its research investments, or will be replaced by another model, will undoubtedly also be dependent upon a number of variables, and not merely on data exclusivity.

At least with respect to "small molecule" NCEs, the evidence strongly suggests that investment in research and development of new products will continue, although it may be changed in character and efficiency. If patents on small-molecule NCEs that are obtained by "innovators" are not sufficiently strong to withstand novelty challenges, or not sufficiently broad to preclude later designs that avoid infringement, greater protection for what, in the end, is not real innovation or invention, is not in the interests of our society. While real innovation should be protected and rewarded, and while investments in research

and development should be compensated, it is not economically wise or efficient to provide an alternative form of monopoly power, to prevent introduction of generic competition, through altered or enlarged data exclusivity, to products that are neither innovative nor real inventions.

Until greater evidence is provided of a need to change, the data exclusivity provided to NCEs in the Hatch-Waxman Act should not be enlarged.[98]

2. *180-day Exclusivity – Should be "Rolling"*

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[98] A great deal more can be said about arguments that rely upon the notion that a "data-centric" regime, instead of a "patent-centric"regime, should be adopted and should govern introduction of generic medicines. These arguments suggest that "patent- linkage" should *not* determine the date upon which the FDA may approve a generic pharmaceutical product fro marketing in the United States.

Many of the same arguments were recently considered by the High Court of Delhi, in *Bayer Corporation & Ors. V. UOI & Ors. (Cipla)*, WP(C) No. 7833/2008 (August 18, 2009), http://lobis.nic.in/dhc/SRB/judgement/18-08-2009/SRB18082009MATC78332008.pdf. Some large branded pharmaceutical manufacturers argue, in the United States, that "patent-centricity" should be abandoned, because the "patent-linkage" inherent in the Hatch-Waxman bargain creates a large and expensive litigation burden, creates unnecessary uncertainties, increases risk and the commensurate cost of capital, and results in distortions. In India, in the *Bayer* case, other large branded pharmaceutical manufacturers argued *for* "patent linkage," claiming that the Indian Drugs Act, read together with the Indian Patents Act, "have an in-built provision of 'patent linkage.'" *Id*., Opinion at 10.

The FDA "has consistently held the position that its role in listing patents in the Orange Book is 'ministerial,' and that establishing an administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are beyond its expertise and authority. See, e.g., Report and Order Accompanying the Patent Listing Rule, 68 Fed. Reg. at 36,683." *See Novo Nordisk*, *supra,* Note 3 (Dyk, dissenting), at n.3. The *Bayer* court similarly found that the Indian Drug Act did not create "patent linkage," because the Indian Drug authorities lack "institutional expertise to deal with complex patent issues." *Bayer Corporation,* Opinion at 17 – 18.

What can be gleaned from these varying positions is that, as might be predicted, branded pharmaceutical manufacturers will take positions about issues, like "patent linkage," depending upon their perceptions of what may yield the greatest protection for their franchises and the greatest economic reward for their investors.

Even after enactment of the MMA amendments in 2003, problems remain with the 180-day Hatch-Waxman exclusivity provisions. Some have suggested that they should be repealed.[99] Others have taken a less extreme view and have suggested that problems with "blocking" and consequent potentially anti-competitive litigation settlements can be ameliorated through amendments that would create a "rolling" exclusivity.[100]

The Act should be amended, in the view of this writer, to provide 180-day exclusivity to a second ANDA applicant that is successful in invalidating an asserted Orange Book patent, or that successfully demonstrates that its product is non-infringing, in the event the NDA holder settles with the first-filer and the first filer does not enter the market within 180 days after such settlement. An exclusivity grant to a successful second-filer could be crafted to be "shared" with the first-filer, if only to avoid litigation between the first- and second-filers and to avoid potential distortions that may be generated in settlements if such "sharing" did not occur. Such "rolling" exclusivity" would likely deter "reverse payments," because it would be "less feasible for the patent holder to enter such settlements with multiple generic challengers."[101] Moreover, such "rolling

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[99] *See, e.g.,* A. Engelberg, *supra* Note 9, at 423 – 425.

[100] *See* M. Avery, *supra,* Note 7, at 194. *But see*, *See* Sen. Orrin Hatch, Committee Statement, *supra*, Note 53, at 4 (do not favor "rolling exclusivity").

[101] *See* M. Avery, *supra,* Note 7, at 194.

exclusivity," especially if "shared" would restore a significant portion of the incentive or "bounty" that Congress intended for generic manufacturers when it originally enacted the Hatch-Waxman act; it would reduce or eliminate the rush to the FDA by NCE-1 applicants, which now have an incentive to be first-filers, even if jointly; it would likely result in fewer "bottlenecks" and faster introduction of multiple generic competitors; and it would, in the long run, lower consumer prices for needed pharmaceutical products.[102] At the same time, it would ensure that patent holders could recover their investments in R&D, in a manner unchanged from the present legal regime.

While such "rolling exclusivity" may not solve all problems, and may create new ones, the purpose of the Hatch-Waxman Act, to encourage generic companies to contest weak and invalid patents, to ensure that lower cost generic products are marketed at an earlier time, and to compensate successful generic patent challengers, would be furthered.

3. Orange Book Delisting Provisions Should be Strengthened

The recent decision in *Novo Nordisk* strongly suggests that further amendment of the Hatch-Waxman Act, to permit the FDA or generic patent

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[102] *Id.* *See also* A. Mehl, *supra,* Note 48, at 674, 676. "As explained by Senator Hatch himself," the article notes, "the rationale behind the 180-day provision is to create an incentive for challenges to the pioneer's patents, not to create an entitlement to the first applicant to file a patent challenge with the FDA in the Parklawn Building." *Id.*, *citing* 149 CONG. REC. at 16105 – 06.

litigants to prevent manipulation of the Orange Book,[103] are necessary. The "counterclaim provision" of the Hatch-Waxman Act[104] was added by Congress in the MMA, "in order to prevent manipulative practices by patent holders with respect to the Orange Book listings." These manipulative practices "were designed to delay the onset of competition from generic drug manufacturers." [105] Congressional concern with proper listing of Orange Book patents, expressed in the MMA, "does not remotely suggest a myopic congressional focus on situations where the patent belonged nowhere in the Orange Book," as the majority opinion in *Novo Nordisk* suggests.[106] Instead, the legislative history of the MMA "makes clear that Congress was concerned with correcting Orange Book information generally." It "suggests a broad concern with preventing brand manufacturers from manipulating the patent listing system in the Orange Book in order to delay entry of generics into the market."[107]

The holding in *Novo Nordisk,* that "the Hatch-Waxman Act authorizes a counterclaim only if the listed patent does not claim any approved methods of using

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[103] *Compare*N. Derzko, *supra*, Note 55, at 212 – 221.

[104] *See* 21 U.S.C. § 355(j)(5)(C)(ii).

[105] Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al., supra, Note 3 (Dyk, dissenting).

[106] *Id*., Dissenting Op. at 10.

[107] *Id*., Dissenting Op. at 15 (quoting Sen. Schumer, one of the MMA sponsors, at 149 Cong. Rec. 31,200 (2003))/.

the listed drug,"[108] may or may not misconstrue the MMA "counterclaim amendments." It is, until reversed, the law. It should be modified by further amendment to the Hatch-Waxman Act that specifically endows generic litigants with a cause of action, for a declaratory judgment, by claim or counterclaim, to review the appropriateness of *any* patent listing in the Orange Book. If the FDA is correct in its consistent assertion that "that its role in listing patents in the Orange Book is 'ministerial,' and that establishing an administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are beyond its expertise and authority,"[109] then there is no means of review vide of such listings, to prevent their abuse, other than in the courts. The Act should be amended to clearly provide for jurisdiction, in the United States District Courts, over declaratory judgment actions brought by generic ANDA applicants who seek to review the propriety of listing of any patent in the Orange Book. If the standards for such listings are not sufficiently precise, or are too precise, because they require NDA holders to list "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application 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," then those standards

[108] *Id*., Majority Op. at 10.

[109] *Id*., Dissenting Op. at 4, n.3.

should also be amended, to ensure that only those patents are listed that actually be asserted against any generic applicant, and that patents that have only tangential relationships to the reference listed drug will be removed.

4. Standards for Measuring Intent Should be Uniform

As noted above, in *Exergen Corp. v. Wal-Mart Stores, Inc.,*[110] the Federal Circuit applied Rule 9(b) of the Federal Rules of Civil Procedures and held that to plead the "circumstances" of inequitable conduct with the requisite particularity" a pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. The decision held that a pleading asserting inequitable conduct must "include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." [111]

Exergen applied 37 C.F.R. § 1.56 (2008), which provides that "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [PTO] ...," and which

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[110] 573 F.3d 1312 (2009).

[111] *Id., surpa*, Note 11, 573 F.3d at 1328 – 29.

imposes a" duty to disclose to the Office information" of which such individuals "are aware" and that "is material to the examination of the application." [112]

The PTO regulation on which an assertion of inequitable conduct is based is, in turn, founded generally on the Patent Act. Nothing in the Patent Act explicitly provides for unenforceability of a patent based upon a finding of inequitable conduct, and nothing in the Patent Act expressly provides a level of intent that must be found before imposition of inequitable conduct remedies. In its current form, the judicially crafted inequitable conduct doctrine permits a judge to render a patent unenforceable, even if it is valid and infringed, if the patent was obtained by misleading statements or omissions of material information which were intended to deceive the USPTO.[113]

Some commentators have observed that allegations of inequitable conduct can unnecessarily draw out the time and increase the cost of litigation, since such allegations require analysis of the knowledge and intent of the patent

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[112] *Id.*, 573 F.3d at 1329, *citing* 37 C.F.R. § 1.56(a) and (c)(identifying classes of individuals); and Manual of Patent Examining Procedures § 2001.01 (8th ed., rev. 2, May 2004) (explaining that "the duty applies only to individuals, not to organizations"). These PTO regulations provide that information is "material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent," and that the duty of disclosure "is commensurate with the degree of involvement in the preparation or prosecution of the application." 37 C.F.R. § 1.56(a). The words "are aware" might be equated with mere "knowledge." The words are not the same as "knowingly" or "willfully," which are well known in the law. *See In re Seagate Technology, LLC*, 497 F.3d 1360, 1365 (Fed. Cir. 2007) (en banc)(decided under 35 U.S.C. §284, and recognizing that this enhanced damages provision is "devoid of any standard for awarding them," and that, in the absence of any statutory guide, the Federal Circuit has "held that an award of enhanced damages requires a showing of willful infringement."

[113] *See Dippin' Dots, Inc., v. Mosey*, 476 F.3d 1337, 1345 (Fed. Cir. 2007).

applicants.[114] Based on their perceptions of these potential burdens, some commentators and advocacy groups have called for the elimination of the

[114] *See, e.g.*, Scott D. Anderson, "Inequitable Conduct: Persistent Problems and Recommended Solutions," 82 *Marquette Law Review* (1999), 845.

inequitable conduct defense.[115] Others have defended the doctrine as necessary to the proper supervision and functioning of the patent acquisition process.[116]

Recently, amendments have been proposed in the Patent Reform Act, relating to inequitable conduct, motivated by the perceived failure of the Federal

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[115] Lynch, *supra*, Note 69, at 44. *See also* http://www.patentsmatter.com/; and National Academy of Sciences, *A Patent System for the 21st Century* (2004). The NAS argues that elimination of the inequitable conduct defense would "reduce the cost and increase the predictability of patent infringement litigation outcomes, and … avoid other unintended consequences," *id*., at 143, "without substantially affecting the underlying principles that these aspects of the enforcement system were meant to promote." *Id*., at 198. It argues hat deterrence of inequitable conduct, especially outright fraud on the Patent Office, can be and is achieved by "other civil and even criminal remedies" such as actions for "antitrust, unfair competition, common law fraud, and tortious interference." *Id*., at 206. It suggests that "third-party- and USPTO-initiated re-examination on withheld prior art, publication of pending applications, and third-party access to pending prosecution papers and the ability to submit material information," *id*., at 206 – 07, provide systemic protection against inequitable conduct, and that the inequitable conduct defense in patent litigation is unnecessary and costly. It states that elimination of the defense or changes in its implementation "would almost certainly simplify litigation and curb unproductive discovery and thereby reduce its expense." *Id*., at 207.

The AIPLA has supported the NAS's recommendation "that the 'inequitable conduct' defense to the enforceability of a patent be removed from patent litigation," conditioning its support, however, "on enactment of a new administrative enforcement mechanism providing that determinations of inequitable conduct would be undertaken by an adequately funded (and otherwise fully capable) office in the U.S. Patent and Trademark Office and that the USPTO would impose appropriate sanctions for misconduct, including – in the case of an actual fraud on the USPTO – canceling the patent." AIPLA, *Response to the National Academies Report entitled "A Patent System for the 21st Century"*, at 33, found at http://www.promotetheprogress.com/ptpfiles/patentreform/misc/ AIPLA_response_to_NAS_report.pdf. It suggests that an adjudication of misconduct by the USPTO, which others would argue is already overburdened and inefficient, "would provide a predicate for possible liability in situations other than a patent infringement case," since "[c]auses of action based upon adjudicated misconduct … would not be preempted under [the AIPLA] proposal … based upon invalid patent claims that were obtained as a consequence of the adjudicated misconduct," i*d*., at 34, and that the "administrative process [suggested by the AIPLA] would provide a fully effective deterrent to … misconduct." *Id.*

[116] *See, e.g.*, GPhA, *Position on Patent Reform*, http://www.gphaonline.org/issues/patent-reform ("it is critical that generic drug companies be able to use the inequitable conduct doctrine as a defense in patent infringement suits filed by innovators under the provisions of Hatch-Waxman.")

Circuit "to establish one clear standard of materiality for inequitable conduct purposes."[117] Drafts of a proposed Patent Reform Act introduced in the current session of Congress omit previously suggested language relating to inequitable conduct.[118] None of these current proposals included language that would establish a clear statutory basis for the doctrine, or that would clearly define the level of corporate or individual intent that is required for application of the doctrine.

In *SEB., S.A. v. T-Fal Corporation*, the Federal Circuit determined that induced infringement may be proven by a showing of "deliberate indifference"

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[117] *See* Report of the Senate Judiciary Committee on S. 1145 (Patent Reform Act of 2007), at http://thomas.loc.gov/cgi-bin/cpquery/T?&report=sr259&dbname=110&, at 32. The Report cited *Digital Control v. Charles Machine Works,* 437 F.3d 1309 (Fed. Cir. 2006), where the Federal Circuit held there is no single standard to define ''materiality'' for inequitable conduct," and, instead, "discussed five different standards for materiality."

The Judiciary Committee Report continued: "Having multiple materiality standards," the Report concluded, "is hardly helpful to the district courts that are charged with making inequitable conduct determinations in the first instance, and patent holders are left with less than clear guidance about what they should disclose to the USPTO. The Report noted that "direct evidence of an intent to deceive is uncommon, so some courts collapse the issue of intent into the issue of materiality, so that intent to deceive is often inferred from materiality." And, if stated that "if inequitable conduct is found, judges have no discretion as to the remedy—no claim of the patent can ever be enforced against anyone." *Id*. As a practical matter, the Committee stated, this lack of clarity "has led to two types of conduct that frequently occur during patent prosecution. Either patent holders (i) ''dump'' everything they have on the USPTO (sometimes many boxes of printed documents), or (ii) do not search the prior art, and thus in turn have little or nothing to give the USPTO. Neither approach is helpful to the patent examiner or the patent system in general." *Id*., at n. 152.

[118] *See* S. 515 (2010), at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:s515rs.txt.pdf, *and* Manager's Amendment, http://judiciary.senate.gov/legislation/upload/PatentReform Amendment.pdf.

to the existence of a patent.[119] The holding in *SEB* was based on the Federal Circuit's reading of 35 U.S.C. § 271(b), which simply provides "Whoever actively induces infringement of a patent shall be liable as an infringer." Like other parts of the Patent Act, this section is devoid of any standard of intent. Nevertheless, in *SEB* the Federal Circuit reiterated its previously holding that, under this section, "the plaintiff must show that the alleged infringer knew or should have known that his actions would induce actual infringements."[120]

The absence of clear standards for assessment of intent has lead or may lead to confusing and inconsistent results. There is no valid reason for applying different standards of intent in Hatch-Waxman cases involving different portions of Patent Act, or applying a PTO regulation based on the Act generally, when none of those provisions contain any legislative standard. Instead, a single standard should apply.

In the view of the author, the Hatch-Waxman Act should be amended to provide that, in cases arising under the Act, in any case in which a provision of the Patent Act is applied, where no other standard is provided in the Patent Act, the level of intent that should be required is "willfulness." Hence, in future Hatch-Waxman cases, any action that relies upon the induced infringement

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[119] See *SEB., S.A. v. T-Fal Corporation, supra*, Note 9.

[120] *Id.*, at 22, *citing DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc).

provision of 35 U.S.C. § 271(b) should, as is now the law in cases under 35 U.S.C. § 284, demand proof of "willfulness," as that term has been and may be applied in the courts, generally.

Further, in the view of the author, the Hatch-Waxman Act should be amended to provide a clear statutory basis for the doctrine of inequitable conduct that, in cases arising under the Act, should be applied based upon a showing of "knowing" statements or omissions of material information which were or had the effect of misleading the USPTO. Liability for such inequitable conduct, in the view of the author, should *not* be limited, in Hatch-Waxman cases, to "individuals" involved in the prosecution of a patent, but should extend to corporate "knowledge," as in cases of fraud under other statutes that prohibit false statements to the Federal government.[121]

5. *Authorized Generics Should be Abolished*

[121] *See, e.g.*, 31 U.S.C. § 3729 (False Claims Act)("Any person who - knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval … is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person …")

Authorized generics contravene the purposes of the Hatch-Waxman legislatively supervised, negotiated compromise. They "disrupt the 'bounty' system established by the Hatch-Waxman Act.'"[122]

> Neither the Hatch-Waxman Act, nor the Medicare Modernization Act addressed the issue of authorized generics directly. Because Congress has remained silent on this issue, courts cannot effectively deal with this problem since the statutes make it clear that the exclusivity provisions only apply to generic manufacturers who enter the market via ANDA applications. The market exclusivity provisions do not prohibit pioneers from marketing authorized generics during the first ANDA applicant's 180-day exclusivity period.[123]

The presence of authorized or "branded" generics in the marketplace is keenly felt. As noted above, in 2009 branded generics accounted for 8.6% of all prescriptions and 12.4% of revenues from prescription sales. Were it not for the "loophole" in the Hatch-Waxman scheme that permits the introduction of authorized generics even during the 180-day exclusivity period, a significant portion of these sales would be realized by a successful generic challenger. It may also be true that authorized generics "help consumers by lowering short-term prices." As a result, even authorized generics might have social utility *after* expiration of the Hatch-Waxman 180-day exclusivity period, because they will simply permit a patent holder to exercise, albeit in a delayed manner, rights that it might otherwise possess, and to compete on equal footing with all of the

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[122] See J. Thomas, *Authorized Generic Pharmaceuticals: Effects on Innovation, supra,* Note 57, at CRS-21.

[123] *See* M. Avery, *supra,* Note 7, at 196.

potential generic entrants, thus reducing consumer prices more rapidly to an optimum level.

Nevertheless, it cannot be doubted that allowance of authorized generics, especially during the 180-day exclusivity period, "will negatively affect the incentive given to generic manufactures to challenge drug patents."[124] Authorized generics created and operated by branded companies may also be used as a vehicle to force generic manufacturers into unfavorable dispositions of litigation, since the threat of such authorized generic competition further reduces the incentives for generic manufacturers to risk loss of potential revenues even after a successful challenge to a weak or invalid patent.

Authorized generics should thus "be banned as a strategic *response* to impending Paragraph IV entry but should be allowed in their absence or after 180-day exclusivity expiration."[125] The Hatch-Waxman Act should be amended to prohibit the introduction of a generic equivalent to a branded product, either directly or indirectly, by an NDA holder, during the 180-day Hatch-Waxman exclusivity period.

Conclusion

[124] *See* M. Avery, *supra,* Note 7, at 197; and T. Chen, *supra* Note 7, at 511 (Prohibiting authorized generics during 180-day exclusivity period "would assure potential ANDA IV applicants of first-mover advantages and an adequate economic prize in return for bearing the risks and costs of patent litigation.")

[125] *See* T. Chen, *supra* Note 7, at 512.

The Hatch-Waxman Act should be revisited again, but with a careful and deliberate approach. Even with its perceived flaws, the Act has functioned well, as a general matter, producing both continued innovation and lower cost drugs. Reforms may occur in other areas, such as in a more comprehensive Patent Reform Act, that may well impact the "delicate balance" struck in the Hatch-Waxman compromise. Limited reforms to Hatch-Waxman are desirable, to restore the balance to its original equilibrium and to eliminate incentives for anti-competitive behaviors. The next visit to the Hatch-Waxman Act should not effect a major alteration in the structure of the Act: efforts to change its "patent-centricity," to eliminate its "patent linkage," and to create a "data-centric" regime, should be rejected. The Act has been and will, absent major change, remain an effect prescription for pharmaceutical innovation and for inexpensive medicines.