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The Hatch-Waxman Act: A Primer

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Summary

Congress has for many years expressed interest in both medical innovation and the growing cost of health care. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, addressed each of these concerns. Through amendments to both the patent law and the food and drug law, the Hatch-Waxman Act established several practices intended to facilitate the marketing of generic pharmaceuticals while providing brand-name firms with incentives to innovate.

The Hatch-Waxman Act established an expedited pathway for generic drug companies to obtain Food and Drug Administration (FDA) approval for their products. It also created a statutory "safe harbor" that shields generic applicants from charges of patent infringement until such time as they request approval to market their products from the FDA.

The legislation also encourages brand-name firms to identify to the FDA any patents that cover their products. If they do so, the patents are listed in the "Orange Book"—a publication that identifies approved drugs and the intellectual property rights associated with them. When a generic firm seeks marketing approval from the FDA, it must account for any Orange Book-listed patents—typically by delaying marketing of its products until they expire, or by asserting that the patents are invalid or do not cover the generic's proposed product. This latter assertion exposes the generic drug company to charges of patent infringement by the brand-name firm.

The Hatch-Waxman Act also created periods of "regulatory exclusivity" that protect an approved drug from competing applications for marketing approval under specified conditions. These FDA-administered regulatory exclusivities typically operate alongside patents to block generic competition for a period of time. Generic firms may sell their own versions of brand-name drugs once these intellectual property rights expire.

Several issues relating to the Hatch-Waxman Act remain of interest to Congress. One of them pertains to the legitimacy of "authorized generics," pharmaceuticals that are marketed by or on behalf of a brand-named drug company, but are sold under a generic name. Although authorized generics may be pro-consumer in that they potentially increase competition and lower prices, some observers argue that such products may discourage independent generic firms both from challenging drug patents and from selling their own generic products.

In addition, the Hatch-Waxman Act requires generic drug companies to prove that their proposed products are bioequivalent to the brand-name drug. Bioequivalence testing therefore requires that the generic firm use the brand-name product as a basis for comparison. Some generic firms have expressed concerns, however, that certain brand-name firms have refused to sell them samples of their drugs for use in developing competing products.

Cases litigated under the auspices of the Hatch-Waxman Act have often ended with a settlement between the parties. In some of these cases, a generic firm agrees to neither challenge the brand-name company's patents nor sell a generic version of the patented drug for a period of time. In exchange, the brand-name drug company agrees to compensate the generic firm, often with substantial monetary payments over a number of years. Because the payment flows counterintuitively, from the patent owner to the accused infringer, this compensation has been termed a "reverse" payment. While some observers believe that this outcome results from the structure of the Hatch-Waxman Act, others believe that these settlements are anti-competitive and harmful to consumers.

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Introduction

Congress continues to focus attention upon both medical innovation and the growing cost of health care. The Drug Price Competition and Patent Term Restoration Act of 1984,[1] commonly known as the Hatch-Waxman Act,[2] addresses each of these concerns. Through amendments to both the patent law and the food and drug law, the Hatch-Waxman Act established several practices intended to facilitate the marketing of generic pharmaceuticals while providing brand-name firms with incentives to innovate. Although Congress has since modified the basic framework of the Hatch-Waxman Act, both through direct amendments and the enactment of related legislation, potential legislative issues remain for congressional consideration.

This report provides an overview of the Hatch-Waxman Act and identifies potential legislative issues. It begins by explaining the fundamentals of the patent acquisition process at the U.S. Patent and Trademark Office (USPTO) and patent litigation in the federal courts. The drug approval process at the Food and Drug Administration (FDA) is described next. The report then describes the 1984 judicial ruling in *Roche Products, Inc. v. Bolar Pharmaceutical Co*.,[3] a case that called attention to the relationship between pharmaceutical innovation and competition.

The report then describes the principal features of the Hatch-Waxman Act. These features include an expedited generic regulatory approval procedure; a patent term extension to compensate for regulatory approval delays; and a statutory exemption from patent infringement for firms seeking regulatory approval. The Hatch-Waxman Act also established specialized infringement litigation procedures with respect to certain pharmaceutical patents. The statute further created periods of "regulatory exclusivity" that protect an approved drug from competing applications for marketing approval under specified conditions. The report then reviews significant legislative amendments impacting the Hatch-Waxman Act. It closes with an identification of proposed amendments and other issues that may potentially be of legislative interest.

Patent Law Fundamentals

Under the nation's patent laws, inventors may obtain patents on processes, machines, manufactures, and compositions of matter that are useful, novel, and nonobvious.[4] An invention is judged as useful if it is minimally operable toward some practical purpose. To be considered novel within the patent law, an invention must differ from existing references that disclose the state of the art, such as publications and other patents. The nonobviousness requirement is met if the invention is beyond the ordinary abilities of a skilled artisan knowledgeable in the appropriate field.

In order to be awarded a patent, an inventor must file a patent application with the USPTO.[5] A patent application must include a specification that so completely describes the invention that skilled artisans are enabled to practice it without undue experimentation. The patent application

[1] P.L. 84-417.

[2] Shasank Updahye, "There's a Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filing," *William Mitchel Law Review*, vol. 40 (2014), p. 1307.

[3] 733 F.2d 858 (Fed. Cir. 1984).

[4] 35 U.S.C. §§101, 102, 103.

[5] 35 U.S.C. §111.

must also contain distinct, definite claims that set out the proprietary interest asserted by the inventor.[6]

Trained personnel at the USPTO, known as "examiners," review all applications to ensure that the invention satisfies the pertinent requirements of the patent law.[7] If the USPTO believes that the application meets the statutory standards, it will allow the application to issue as a granted patent.[8] At that time, the USPTO will assemble and publish the corresponding patent instrument, which includes the complete specification, claims, and prior art references considered during prosecution. Each patent ordinarily enjoys a term of 20 years commencing from the date the patent application was filed.[9]

Granted patents give the patentee the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[10] Parties who engage in those acts without the permission of the patentee during the term of the patent can be held liable for infringement. The patentee may file a civil suit in federal court in order to enjoin infringers and obtain monetary remedies.[11] Although issued patents enjoy a presumption of validity, accused infringers may assert that the patent is invalid or unenforceable on a number of grounds.[12] Patents have the attributes of personal property and may be assigned or licensed to others.[13]

Introduction to the FDA Drug Approval Process

Since the 1962 Kefauver-Harris Drug Amendments,[14] the Federal Food, Drug, and Cosmetic Act has prohibited the marketing of a "new drug" unless that drug meets certain safety and efficacy standards.[15] A showing that a new drug is sufficiently safe and effective to allow it to be marketed ordinarily requires manufacturers to conduct clinical investigations of drugs. Such investigations generally occur over several stages, commencing with preclinical evaluation. The testing process begins in the company's laboratory, where scientists perform preliminary tests to determine whether the drug has any effect on a disease or its symptoms.

For those compounds that merit further consideration following preclinical evaluation, the next step is the filing of an Investigational New Drug application (IND), at the FDA.[16] The FDA evaluates the pre-clinical data and the proposed clinical trial design to determine whether to allow the IND and testing in humans. Clinical trials are ordinarily carried out in three phases that gather further evidence of the drug's safety and effectiveness.

Once a new drug's clinical testing is complete, the sponsor prepares a New Drug Application (NDA) and submits it to the FDA for evaluation.[17] An NDA includes the clinical trial results

[6] 35 U.S.C. §112.

[7] 35 U.S.C. §131.

[8] 35 U.S.C. §151.

[9] 35 U.S.C. §154(a)(2).

[10] 35 U.S.C. §271(a).

[11] 35 U.S.C. §§283, 284.

[12] 35 U.S.C. §282.

[13] 35 U.S.C. §261.

[14] P.L. 87-781.

[15] CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Susan Thaul.

[16] 21 C.F.R. §312.23.

[17] 21 C.F.R. §314.50.

along with a description of the drug's manufacturing process and facilities. The agency considers three broad questions when reviewing an NDA:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[18]

As the agency has explained, an NDA "is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."[19] FDA approval of an NDA allows the drug to be marketed to the public.

The Hatch-Waxman Act: An Overview

The *Roche v. Bolar* Litigation

The award of marketing approval by the FDA and the grant of a patent by the USPTO are formally distinct events that depend upon different criteria.[20] For example, the USPTO could issue a patent on a drug that the FDA ultimately decides not to approve for marketing due to deleterious side effects. As well, the FDA could grant marketing approval to a safe and effective drug that was already described in the published literature and therefore not patentable. However, because brand-name firms ordinarily seek both marketing approval and patent protection, the practical relationship between these procedures was the subject of policy debate for many years.[21]

Many observers believe that the 1984 judicial decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co*.[22] hastened the pace of discussion in Congress. As noted previously, patent proprietors possess the right to exclude others from practicing the patented invention. Accused infringers may offer several defenses to avoid liability for patent infringement.

One potential patent infringement defense consists of the so-called experimental use privilege.[23] One nineteenth century court explained that it was "well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere

[18] FDA, *New Drug Application (NDA)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/.

[19] Ibid.

[20] See, e.g., *In re Krimmel*, 292 F.2d 948 (C.C.P.A. 1961) ("There is nothing in the patent statute or any other statutes called to our attention which gives the Patent Office the right or the duty to require an applicant to prove that compounds or other materials which he is claiming and which he has stated are useful for 'pharmaceutical applications,' are safe, effective, and reliable for use with humans.").

[21] Alfred J. Engelberg, "Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?," *IDEA*, vol. 39 (1999), p. 389.

[22] 733 F.2d 858 (Fed. Cir. 1984).

[23] Rochelle Cooper Dreyfuss, "Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?," *Arizona Law Review*, vol. 46 (2004), p. 457.

amusement is not an infringement of the rights of the patentee."[24] Most patent attorneys observe that few infringers have successfully pled an experimental use defense, however.[25] As a practical matter, infringement charges are only rarely brought against philosophers or amusement seekers.

The venerable experimental use defense suggested an interesting possibility with the advent of marketing approval procedures before the FDA. When a competitor grew interested in marketing the generic equivalent of a drug patented by another, it might have wished to commence clinical trials and other procedures needed to obtain commercial marketing approval during the term of the other's patent. This procedure would allow the generic firm to market the drug as soon as possible—and ideally upon the date the patent expired. Whether the regulatory compliance activities of a generic drug manufacturer amounted to patent infringement or were exempted by the experimental use defense was an open legal question for many years.

The 1984 decision of the Court of Appeals for the Federal Circuit in *Roche v. Bolar* resolved this question conclusively in favor of a finding of patent infringement. In that case, Roche Products, Inc. (Roche) marketed a prescription sleeping pill and owned a patent covering its active ingredient. During the term of Roche's patent, Bolar Pharmaceutical Co. (Bolar) began using the active ingredient to obtain data needed to file an NDA with the FDA.

When Roche brought a patent infringement suit, the federal courts agreed that Bolar should be enjoined from using the active ingredient until Roche's patent expired. The courts explained that:

> Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use ... to derive FDA required test data is thus an infringement of the [Roche] patent. Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use *de minimis*. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair.... We cannot 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.[26]

The ruling in *Roche v. Bolar*, in combination with the requirement of marketing approval for new drugs under the Food, Drug, and Cosmetic Act, was perceived as leading to two distortions of the statutory patent term. First, patent term would continue to run whether or not the FDA had approved the claimed pharmaceutical for marketing. As a result, the period of time that the proprietor of a patent claiming a regulated drug actually could enjoy exclusivity could be quite significantly reduced. In effect, each day of delay associated with the FDA approval process amounted to a lost day of patent term. Second, under *Roche v. Bolar*, competitors that commenced activities necessary for regulatory approval before a patent had expired could be enjoined as patent infringers. This possibility was seen as a *de facto* period of exclusivity that the patent proprietor enjoyed beyond the actual term of the patent.[27]

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[24] *Poppenhausen v. Falke*, 110 F. Cas. 1048, 1049 (C.C.S.C.N.Y. 1861).

[25] *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (noting that the common law experimental use privilege is "narrow and strictly limited.")

[26] *Roche v. Bolar*, 733 F.2d at 863.

[27] Erik K. Steffe and Timothy J. Shea, Jr., "Drug Discovery Tools and the Clinical Research Exemption from Patent Infringement," *Biotechnology Law Report*, vol. 22 (August 2003), pp. 369, 370.

Enactment of the Hatch-Waxman Act

The *Roche v. Bolar* decision was widely seen as the impetus for congressional enactment of the Drug Price Competition and Patent Term Restoration Act of 1984.[28] Signed into law on September 24, 1984, that law has come to be known as the Hatch-Waxman Act. The new law was subsequently codified in Titles 15, 21, 28, and 35 of the U.S. Code.

The Hatch-Waxman Act includes elaborate provisions governing the mechanisms through which a potential generic manufacturer may obtain marketing approval on a drug that has been patented by another. Although the Hatch-Waxman Act is a complex statute, observers have frequently noted that it presents a fundamental trade-off: In exchange for permitting manufacturers of generic drugs to gain FDA marketing approval by relying on safety and efficacy data from the brand-name firm's NDA, the brand-name firms receive a period of regulatory exclusivity and patent term extension.[29] A review of the legislation's significant provisions follows.

The Statutory Experimental Use Exception

The Hatch-Waxman Act created a statutory exemption from certain claims of patent infringement. As codified in 35 U.S.C. §271(e)(1), this provision mandates: "It shall not be an infringement to make, use, offer to sell, or sell within the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal Law which regulates the manufacture, use or sale of drugs or veterinary biological products." This provision effectively overturned the *Roche v. Bolar* decision.[30] As a result, generic manufacturers may commence work on a generic version of an approved drug any time during the life of the patent, so long as that work furthers compliance with FDA regulations.

Abbreviated New Drug Applications

Prior to the introduction of the Hatch-Waxman Act, the federal food and drug law contained no separate provisions addressing generic versions of drugs that had previously been approved. The result was that a would-be generic drug manufacturer had to file its own NDA in order to market its drug.[31] Some generic manufacturers could rely on published scientific literature demonstrating the safety and efficacy of the drug. Because these sorts of studies were not available for all drugs, however, not all generic firms could file these so-called paper NDAs.[32] Further, at times the FDA requested additional studies to address safety and efficacy questions that arose from experience with the drug following its initial approval. The result is that some generic manufacturers were

[28] Shasank Updahye, "There's a Hole in My Bucket Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filing," *William Mitchell Law Review*, vol. 40 (2014), p. 1307.

[29] Andrew E. Podgorny, "Supporting the Rationale Behind the Hatch-Waxman Act and Patent Law: How Reverse Payment Settlements Under FTC v. Actavis Can Be Procompetitive," *Indiana Health Law Review*, vol. 12 (2015), p. 423.

[30] Kate Y. Jung, "Hatch-Waxman's Safe-Harbor Provision for Pharmaceutical Development: A Free Ride for Patent Infringers?," *John Marshall Review of Intellectual Property Law*, vol. 13 (2014), p. 445.

[31] D. Christopher Ohly and Sailesh K. Patel, "The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines," *University of Baltimore Intellectual Property Law Journal*, vol. 19 (2011), p. 107.

[32] Kristin E. Behrendt, "The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest?" *Food and Drug Law Journal*, vol. 57 (2002), p. 247.

forced to prove independently that the drugs were safe and effective, even though their products were chemically identical to previously approved drugs.

Some commentators believed that the approval of a generic drug was a needlessly costly, duplicative, and time-consuming process prior to the Hatch-Waxman Act.[33] These observers noted that although patents on important drugs had expired, manufacturers were not moving to introduce generic equivalents for these products due to the level of resource expenditure required to obtain FDA marketing approval.[34] As the introduction of generic equivalents often causes prices to decrease, the interest of consumers was arguably not being served through these observed costs and delays.

The Hatch-Waxman Act created a new type of application for market approval of a pharmaceutical. This application, termed an "Abbreviated New Drug Application" (ANDA), may be filed at the FDA.[35] An ANDA may be filed if the active ingredient of the generic drug is the bioequivalent of the approved drug. An ANDA allows a generic drug manufacturer to rely upon the safety and efficacy data developed by the original manufacturer. The Hatch-Waxman Act also continued the FDA's earlier "paper NDA" practice by establishing what has come to be known as a Section 505(b)(2) application.[36] Such an application relies, at least in part, upon safety and efficacy data that the applicant did not itself develop, but rather is available in the published literature.

ANDAs and Section 505(b)(2) applications may allow a generic manufacturer to avoid the costs and delays associated with filing a full-fledged NDA. These two expedited marketing approval pathways also allow a generic manufacturer, in many cases, to place its FDA-approved bioequivalent drug on the market as soon as any relevant patents expire.[37]

Certifications for Orange Book-Listed Patents

All approved drug products, both brand name and generic, are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*. This publication is commonly known as the "Orange Book" due to the color of its cover,[38] although today most individuals likely view its contents through use of the Internet or the smartphone "Orange Book Express" app.[39] The Orange Book uses a coded lettering system to identify those approved drugs the FDA considers therapeutically equivalent. The FDA considers those drugs with an "A" code to be therapeutically equivalent, while those with a "B" code have a documented bioequivalence problem. The Orange Book provides physicians, pharmacists, and patients with information to help them decide when therapeutically equivalent generic drugs can be substituted for brand-name products.

The Orange Book also plays a role in the resolution of patent disputes. The Hatch-Waxman Act requires each holder of an approved NDA to list pertinent patents it believes would be infringed if

[33] Justina A. Molzon, "The Generic Drug Approval Process," *Journal of Pharmacy and Law*, 1996, p. 275.

[34] Emily Michiko Morris, "The Myth of Generic Competition Under the Hatch-Waxman Act," *Fordham Intellectual Property, Media, and Entertainment Law Journal*, vol. 22 (2012), p. 245.

[35] 21 U.S.C. §355(j)(1).

[36] 21 U.S.C. §355(b)(2).

[37] *Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 345 (D.C. Cir. 2006).

[38] Jane F. Djung, "Insufficient Mechanisms for Orange Book Corrections and the FDA's Ministerial Role: A Need for Reform," *Connecticut Law Review*, vol. 47 (2014), p. 229.

[39] The Orange Book is available on the Internet at http://www.accessdata.fda.gov/scripts/cder/ob/.

a generic drug were marketed before the expiration of these patents.[40] Would-be manufacturers of generic drugs must then engage in a specialized certification procedure with respect to Orange Book-listed patents. An ANDA applicant must state its views with respect to each Orange Book-listed patent associated with the drug it seeks to market.

In particular, the generic applicant must either file a so-called section viii statement or a patent certification. Section viii statements are appropriate when the applicant is seeking approval for a method-of-use that is not claimed in a patent listed in the Orange Book.[41] Alternatively, the generic applicant must provide one of four certifications:

1. the brand-name firm has not filed any patent information with respect to that drug;
2. the patent has already expired;
3. the date on which the patent will expire; or
4. the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA is submitted.[42]

These certifications are respectively termed paragraph I, II, III, and IV certifications.[43] An ANDA certified under paragraphs I or II is approved immediately after meeting all applicable regulatory and scientific requirements.[44] A generic firm that files an ANDA including a paragraph III certification must, even after meeting pertinent regulatory and scientific requirements, wait for approval until the drug's listed patent expires.[45] A paragraph IV certification leads to additional possibilities, as described next.

Patent Infringement Proceedings

Under 35 U.S.C. §271(e)(2), the filing of an ANDA with a paragraph IV certification constitutes a "somewhat artificial" act of patent infringement.[46] The Hatch-Waxman Act requires the ANDA applicant to notify the proprietor of the patents that are the subject of a paragraph IV certification.[47] The patent owner may then commence patent infringement litigation against the ANDA applicant in federal district court. This charge of infringement under 35 U.S.C. §271(e)(2) is technical in nature. At this stage the generic manufacturer has done nothing more than request FDA approval to market a drug. If the patentee's charge of infringement is successful, however, it may prevent the marketing of that generic equivalent until the date the patent expires.[48]

If the patent owner brings a patent infringement charge against the ANDA applicant within 45 days of receiving notice from the ANDA applicant, then the Hatch-Waxman Act provides the patentee with a significant benefit. Under these circumstances the FDA must suspend approval of the ANDA until one of the following times:

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[40] 21 U.S.C. §355(c)(2).

[41] 21 U.S.C. §355(j)(2)(A)(viii).

[42] 21 U.S.C. §355(j)(2)(A)(vii).

[43] Vincent J. Roth, "Will FDA Data Exclusivity Make Biologic Patents Passé?," *Santa Clara Computer and High Technology Law Journal*, vol. 29 (2013), p. 249.

[44] 21 U.S.C. §355(j)(5)(B)(i).

[45] 21 U.S.C. §355(j)(2)(B)(i).

[46] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

[47] 21 U.S.C. §355(j)(2)(B)(i).

[48] 35 U.S.C. §271(e)(4).

- the date of the court's decision that the listed drug's patent is either invalid or not infringed;
- the date the listed drug's patent expires, if the court finds the listed drug's patent infringed; or
- subject to modification by the court, the date that is 30 months from the date the owner of the listed drug's patent received notice of the filing of a Paragraph IV certification.[49]

Congress intended that this latter, 30-month period would give the parties sufficient time to resolve their patent dispute before the ANDA applicant introduced its generic product to the market. This period of time, commonly called the "30-month stay," is effectively the equivalent of a preliminary injunction that is awarded against the generic drug company for the stipulated period of time. The 30-month stay is awarded automatically by statute, however, provided that the brand-name drug company has timely followed the appropriate procedures. In particular, the brand-name drug company need not make any of the usual showings required for a preliminary injunction.[50]

Patent Term Extension

The Hatch-Waxman Act also provides for the extension of patent term. Ordinarily, patents may last as long as 20 years from the date the patent application is filed.[51] The Hatch-Waxman Act provides that for pharmaceutical patents, the term of one patent may be extended for a portion of the time lost during clinical testing.[52] If, as is often the case, the patent proprietor owns more than one patent covering a drug, it must choose one to be eligible for term extension.

In particular, the patent holder is entitled to have restored to the patent term one-half of the time between the IND application and the submission of an NDA, plus the entire period spent by the FDA approving the NDA. The statute sets some caps on the length of the term restoration. The entire patent term restored may not exceed five years. Further, the remaining term of the restored patent following FDA approval of the NDA may not exceed 14 years. The Hatch-Waxman Act also provides that the patentee must exercise due diligence to seek patent term restoration from the USPTO, or the period of lack of diligence will be offset from the augmented patent term.

As a simplified example, suppose that four years passed between the filing of the IND and NDA, and another two years passed between the filing of the NDA and its approval. The period of extension would be $(4 \div 2) + 2 = 4$ years.

Patent term extension under the Hatch-Waxman Act does not occur automatically. The patent owner must file an application with the USPTO requesting term extension within 60 days of obtaining FDA marketing approval.[53]

[49] 21 U.S.C. §355(j)(5)(B)(iii).

[50] Gregory Dolin, "Reverse Payments as Patent Validity Signals," *Harvard Journal of Law and Technology*, vol. 24 (2011), p. 281.

[51] 35 U.S.C. §154(a)(2).

[52] 35 U.S.C. §156.

[53] 35 U.S.C. §156(d).

Regulatory Exclusivities

The Hatch-Waxman Act includes provisions that create regulatory exclusivity for certain FDA-approved drugs.[54] The FDA administers these provisions by issuing approval to market a pharmaceutical to only a single entity. Stated differently, during the statutorily stipulated period of time, the FDA protects an approved drug from competing applications. A grant of regulatory exclusivity does not depend on the existence of patent protection. Indeed, it is possible that two completely different entities may own USPTO-granted patent rights, on one hand, and FDA-issued regulatory exclusivity, on the other.

The Hatch-Waxman Act was not the first legislation to provide for a regulatory exclusivity. Two years earlier, Congress had approved the Orphan Drug Act[55] in order to encourage firms to develop pharmaceuticals to treat rare medical conditions. Such drugs are called "orphan" drugs because firms may lack the financial incentives to "adopt," or sponsor, products to treat small patient populations.[56] The Orphan Drug Act established a seven-year term of market exclusivity for drugs determined to treat rare disease and conditions. Orphan drug exclusivity prevents the FDA from approving another marketing approval application for the same drug and same orphan indication.[57]

Expanding upon this concept, the Hatch-Waxman Act established a five-year exclusivity that is available to drugs that qualify as a new chemical entity (NCE).[58] A drug is judged to be an NCE if the FDA has not previously approved that drug's active ingredient. During that five-year period of NCE exclusivity, the FDA may accept neither a Section 505(b)(2) application nor an ANDA for a drug product containing the same active moiety protected under the NCE exclusivity. The term of NCE exclusivity may be reduced to as little as four years if a generic firm files a paragraph IV ANDA.

The Hatch-Waxman Act also provided for a three-year new clinical study exclusivity period.[59] New clinical study exclusivity may be awarded with respect to either an NDA or a supplemental NDA that contains reports of new clinical studies conducted by the sponsor that are essential to FDA approval of that application. In contrast to NCE exclusivity, new clinical study exclusivity applies only to the use of the product that was supported by the new clinical study.

The Hatch-Waxman Act further provided prospective manufacturers of generic pharmaceuticals with a reward for challenging the patent associated with an approved pharmaceutical.[60] The reward consists of a 180-day generic drug exclusivity period awarded to the first generic applicant to file a paragraph IV certification. Congress hoped that this entitlement would encourage generic applicants to challenge a listed patent for an approved drug product.

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[54] CRS Report R44032, *Patents and Regulatory Exclusivities: Issues in Pharmaceutical Innovation and Competition*, by John R. Thomas.

[55] P.L. 97-414.

[56] David C. Babaian, "Adopting Pharmacogenomics and Patenting Repurposed Molecules Under the Orphan Drug Act: A Cost Dilemma?," *John Marshall Review of Intellectual Property Law*, vol. 13 (2014), p. 667.

[57] 21 U.S.C. §360cc.

[58] 21 U.S.C. §355(j)(5)(F)(ii).

[59] 21 U.S.C. §355(j)(5)(F)(iii, iv).

[60] 21 U.S.C. §355(j)(5)(B)(iv).

Subsequent Legislation

The Generic Animal Drug and Patent Term Restoration Act

As originally enacted, the term extension provisions of the Hatch-Waxman Act did not apply to patents claiming new animal drugs and veterinary biological products. The result was that although these products were subject to FDA marketing approval delays, patents claiming these products did not receive the benefit of term extension. Through the Generic Animal Drug and Patent Term Restoration Act,[61] which became effective on November 16, 1988, Congress decided to open the term-restoration provisions of the Hatch-Waxman Act to veterinary drugs and biological products as well. Animal drug products primarily derived from recombinant DNA technology are expressly denied the benefit of patent term restoration, however.

The FDA Modernization Act

Section 111 of the Food and Drug Administration Modernization Act of 1997,[62] titled the Better Pharmaceuticals for Children Act, aimed to increase the number of pharmaceuticals available for children. This statute provided for a six-month "pediatric exclusivity" to encourage drug manufacturers to conduct research concerning the effectiveness of their drugs in children.[63] Pediatric exclusivity attaches to any children's drug products with the same "active moiety"—that portion of the drug that causes its physiological or pharmacological reaction—as the previously approved drug.

The effect of the pediatric exclusivity is, in essence, to add six months to the term of any patent or regulatory exclusivity that exists at the time the pediatric exclusivity is obtained.[64] For example, the term of an NCE exclusivity would be extended to five years, six months. However, if the pediatric exclusivity is awarded later than nine months prior to the expiration of a particular intellectual right, its term is not extended. Although initially subject to a sunset provision, Congress made the pediatric exclusivity permanent in 2012 with the FDA Safety and Innovation Act.[65]

The product must be one for which studies on a pediatric population are submitted at the request of the Secretary of Health and Human Services. Note that the law does not require that a study be successful in demonstrating safety and effectiveness in a pediatric population in order to trigger the added six-month exclusivity period. The statute instead creates incentives for drug companies to conduct research and submit their results.

[61] P.L. 100-670.

[62] P.L. 105-115.

[63] Karena J. Cooper, "Pediatric Marketing Exclusivity—As Altered by the Best Pharmaceuticals for Children Act of 2002," *Food and Drug Law Journal*, vol. 58 (2002), p. 519.

[64] 21 U.S.C. §355a(b).

[65] P.L. 112-144.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[66] titled "Access to Affordable Pharmaceuticals," introduced several changes to the original Hatch-Waxman Act. This law was designed to further decrease the time needed to bring generic pharmaceuticals to the marketplace. Congress principally crafted many of the new provisions for the purpose of discouraging perceived strategic behavior upon the part of both brand-name and generic drug companies said to delay the availability of generic drugs in the U.S. market.[67]

In particular, the MMA generally permits no more than one 30-month stay on FDA approval of drugs for which patents are listed in the Orange Book at the time of a paragraph IV ANDA or 505(b)(2) filing.[68] Second, the MMA stipulates that in a situation where a patent holder does not file an infringement action within 45 days of notification of a paragraph IV ANDA, the ANDA applicant may request that a district court issue a declaratory judgment regarding the validity of the patent.[69]

Further, if the brand-name drug company launches a patent infringement suit against an ANDA applicant, the generic firm may file a counterclaim requesting that the patent holder modify or delete patent information listed in the Orange Book. The usual ground for such suits is that the listed patents do not claim the drug for which the NDA was approved. The MMA stipulates that no monetary damages are to be awarded in such suits.[70]

The MMA also provides that the 180-day generic exclusivity commences with the first commercial marketing of the generic drug. This exclusivity can be forfeited under specified circumstances, including the failure to market under specific time constraints, withdrawal of the ANDA, amendment of the ANDA's patent certification, the failure to obtain marketing approval from the FDA, the expiration of all patents, or the determination by the Federal Trade Commission (FTC) or the Assistant Attorney General that an agreement between the brand-name and generic firms violates antitrust laws.[71] Multiple generic firms may qualify for the 180-day market exclusivity if they file a substantially complete ANDA on the same day.[72]

Finally, the MMA requires that certain agreements reached between brand-name companies and generic firms concerning the production, sale, or marketing of a pharmaceutical or a 180-day market exclusivity must be filed with the FTC and the Department of Justice within 10 days of the agreement.[73] This measure was intended to allow these agencies to track "reverse payment" or "pay-for-delay" settlements, a subject that this report discusses below.

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[66] P.L. 108-173

[67] John R. Thomas, *Pharmaceutical Patent Law*, 3rd ed. (Arlington, VA: Bloomberg BNA, 2015), p. 23.

[68] 21 U.S.C. §355(c)(3)(C).

[69] 21 U.S.C. §355(c)(3)(D)(i)(I)(bb).

[70] 21 U.S.C. §355(c)(3)(D)(ii).

[71] 21 U.S.C. §355(j)(5)(B)(iv)(I).

[72] 21 U.S.C. §355(j)(5)(B)(iv)(II)(bb). In these cases, each firm is considered to meet the definition of "first to file."

[73] MMA at §§1111-1113.

The Food and Drug Administration Amendments Act of 2007

The Food and Drug Administration Amendments Act (FDAAA) of 2007[74] incorporated provisions that allowed the FDA to grant NCE exclusivity to enantiomers of previously approved racemates.[75] This legislation overturned the agency's previous view that a single enantiomer of a previously approved racemate contained a previously approved active moiety and was not a new chemical entity. The FDAAA only allows exclusivity to be awarded if the non-racemic drug is approved for a different use than the previously approved racemic one. In addition, approval of the non-racemic drug must be based upon different studies than the racemic one for exclusivity to be awarded.[76]

The Biologics Price Competition and Innovation Act of 2009

Following years of debate concerning the introduction of competitive biotechnology medicines, Congress approved the Biologics Price Competition and Innovation Act (BPCIA). The statute appears as Title VII of the Patient Protection and Affordable Care Act.[77]

Biologics, which are sometimes termed biopharmaceuticals or biotechnology drugs, have begun to play an increasingly important role in U.S. health care.[78] Observers expressed concern that patent expirations on certain biologics might not be accompanied by the introduction of competing, lower-cost biologics in the marketplace. Of course, a similar analysis prompted the enactment of the Hatch-Waxman Act over a quarter-century ago. Many observers believed that the Hatch-Waxman's Act accelerated marketing approval provisions did not comfortably apply to biologics, due to those drugs' greater complexity, structural complexity, and method of manufacture.[79]

The BPCIA included three principal components. First, it created an expedited regulatory pathway for two sorts of follow-on products—"biosimilars" and "interchangeable" biologics.[80] Second, Congress established regulatory exclusivities that are available to brand-name and follow-on firms. Third, the legislation stipulates intricate procedures for identifying and resolving patent disputes with respect to follow-on biologics.[81]

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[74] P.L. 110-85.

[75] "A racemate consists of equal amounts of spatial isomers called enantiomers, molecules that are mirror images of each other. Due to their spatial orientation, enantiomers are optically active and are characterized by whether they rotate plane-polarized light clockwise (dextrorotatory) or counter-clockwise (levorotatory). Although enantiomers and their racemates have the same chemical composition, they may differ in their physical, chemical, or biological properties." Ortho-McNeil Pharmaceutical, Inc. v. Lupin Pharmaceuticals, Inc., 603 F.3d 1377, 1378 (Fed. Cir. 2010).

[76] Kyle Faget, "Why FDCA Section 505(u) Should Not Concern Us Greatly," *Michigan Telecommunications and Technology Law Review*, vol. 15 (2009), p. 453.

[77] P.L. 111-148.

[78] CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*, by Judith A. Johnson.

[79] See Ude Lu, "Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility," *Minnesota Journal of Law, Science, and Technology*, vol. 15 (2014), p. 613.

[80] Rather than use the term "generic" as is done in the context of comparatively simple drugs, the term "follow-on" is used in the context of biologics.

[81] See CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*, by Judith A. Johnson; and CRS Report R44173, *Follow-On Biologics: Intellectual Property Issues*, by John R. Thomas.

The GAIN Act of 2012

Congressional concern over the spread of antibiotic-resistant "superbugs" led to the enactment of the Generating Antibiotic Incentives Now (GAIN) Act, enacted as Title VIII of the FDA Safety and Innovation Act.[82] That statute allows the FDA to designate a drug as a "qualified infectious disease product" (QIDP) if it consists of an antibacterial or antifungal drug intended to treat serious or life-threatening infections. The GAIN Act stipulates that QIDPs include drugs that address drug-resistant tuberculosis, gram negative bacteria, and Staphylococcus aureus.

Along with other measures intended to provide pharmaceutical and biotechnology companies with incentives to develop innovative antibiotics, the GAIN Act adds five years to the term of the new chemical entity, new clinical study, and orphan exclusivities for any QIDP.[83] The statute stipulates that the five-year QIDP extension is cumulative with the pediatric exclusivity. As a result, a QIDP that qualified as a new chemical entity, and was also awarded a pediatric exclusivity, would be entitled to a data exclusivity period of ten years and six months.

Issues for Congress

Since enacting the Hatch-Waxman Act, Congress has maintained a consistent interest in the role intellectual property rights play in the development of new pharmaceuticals and biologics. Congress frequently reconsiders whether the appropriate balance has been struck between providing financial incentives to innovators and encouraging the development of competition to limit economic cost to the public. This section addresses select legislation in the 114th Congress. Similar themes are likely to be considered by future Congresses as well.

Authorized Generics

The 2016 announcement that a brand-name firm would produce a generic version of its EpiPen® auto-injector renewed discussion of so-called "authorized generics."[84] An "authorized generic" is a pharmaceutical that is marketed by or on behalf of a brand-named drug company, but is sold under a generic name.[85] The brand-name firm may distribute the drug under its own auspices or via a license to a generic drug company. The price of this "authorized copy" is ordinarily lower than that of the brand-name drug. Some sources refer to authorized generics as "branded," "flanking," or "pseudo" generics.

Authorized generics may be pro-consumer in that they potentially increase competition and lower prices, particularly in the short-term. They have nonetheless proven controversial. Authorized generics ordinarily enter the market at about the time the brand-name drug company's patents are set to expire. Some observers argue that such products may decrease the value of the potential 180-day market exclusivity for the first approved generic. This in turn may discourage independent generic firms both from challenging drug patents and from selling their own generic products.[86]

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[82] P.L. 112-144.

[83] 21 U.S.C. §355f(a).

[84] Carolyn Y. Johnson, "Mylan to introduce a half-price generic version of EpiPen," *Washington Post,* August 29, 2016.

[85] CRS Report RL33605, *Authorized Generic Pharmaceuticals: Effects on Innovation*, by John R. Thomas.

[86] Aaron S. Kesselheim and Jonathan J. Darrow, "Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for

Competitor Access to Medications

The Hatch-Waxman Act requires generic drug companies to prove that their proposed products are bioequivalent to the brand-name drug. Bioequivalence testing therefore requires that the generic firm use the brand-name product as a basis for comparison. Some generic firms have expressed concerns, however, that certain brand-name firms have refused to sell them samples of their drugs for use in developing competing products.[87]

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016, S. 3056, addresses access to reference product samples when a brand-name product is subject to limited distribution channels—either voluntarily or via FDA-imposed "Risk Evaluation and Mitigation Strategies (REMS)" procedures. The bill would allow a generic or biosimilar firm to commence litigation in federal court in order to obtain a sample of a drug or biologic that is subject to a restricted distribution scheme so that it may obtain FDA approval of its competing product.

Parallel Importation

At least six bills have been introduced in the 114th Congress that would allow individuals to import lower-cost prescription drugs from foreign jurisdictions. The bills differ on the jurisdictions from which imports are permissible. H.R. 2228 and S. 122, each titled the Safe and Affordable Drugs from Canada Act of 2015; along with H.R. 3513 and S. 2023, each titled the Prescription Drug Affordability Act of 2015; would allow U.S.-approved drugs to be imported from approved Canadian pharmacies. H.R. 2623, the Personal Drug Importation Fairness Act, would allow U.S.-approved drugs to be imported from Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, a member state of the European Union, or a country in the European Economic Area, as well as any other country determined by the Commissioner of Food and Drugs to have safety and efficacy standards at least as protective as the United States. Finally, S. 1790, the Safe and Affordable Prescription Drugs Act of 2015, would allow U.S.-approved drugs to be imported from approved pharmacies located anywhere in the world.

Regulatory Exclusivities

Congress continues to express interest in regulatory exclusivities.[88] In the 114th Congress, the Curb Opioid Misuse By Advancing Technology (COMBAT) Act of 2016, H.R. 5127, would extend the three-year new clinical study exclusivity by 12 months if the new study was related to clinical abuse potential and the product's labeling characterized the drug's abuse-deterrent potential. The COMBAT Act would similarly extend the 180-day generic exclusivity by 60 days in such circumstances. On the other hand, the period of biologics exclusivity would be reduced from 12 to 7 years by the Price Relief, Innovation, and Competition for Essential Drugs (PRICED) Act, introduced as both H.R. 5573 and S. 3094.

Over the past 35 years, FDA-administered regulatory exclusivities have been growing in numbers, scope, complexity, and duration. The long history of congressional lawmaking has

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the Modern Era?," *Yale Journal of Health Policy, Law, and Ethics*, vol. 15 (Summer 2015), p. 293.

[87] Robin Feldman and Evan Frondorf, "Drug Wars: A New Generation of Generic Pharmaceutical Delay," *Harvard Journal on Legislation*, vol. 53 (Summer 2016), p. 499.

[88] For additional information, see CRS Report R44032, *Patents and Regulatory Exclusivities: Issues in Pharmaceutical Innovation and Competition*, by John R. Thomas.

given rise to three types of patents: utility patents in 1790,[89] design patents in 1842,[90] and plant patents in 1930.[91] In contrast, since 1982 Congress has established 15 sorts of regulatory exclusivity.[92]

Encouraging innovation through regulatory exclusivities, rather than through the patent system, arguably possesses certain advantages. The large number of industries affected by patents may make patent reform politically difficult. Fine tuning drug regulation rules may be more feasible.[93] In addition, U.S. membership in the World Trade Organization requires that "patents shall be available and patent rights enjoyable without discrimination as to the ... field of technology...."[94] This requirement of technological neutrality appears to prevent discrimination both against and in favor of drug patents. On the other hand, increasing reliance upon regulatory exclusivities may require greater legislative oversight and hold less regard for the public domain.[95]

Reverse Payment Settlements

Cases litigated under the auspices of the Hatch-Waxman Act have often ended with a settlement between the parties. In some of these cases, a generic firm agrees to neither challenge the brand-name company's patents nor sell a generic version of the patented drug for a period of time. In exchange, the brand-name drug company agrees to compensate the generic firm, often with substantial monetary payments over a number of years. Because the payment flows counterintuitively, from the patent owner to the accused infringer, this compensation has been termed a "reverse" payment.[96]

For over two decades, a number of courts of appeal have been called upon to analyze the antitrust implications of patent settlements between brand-name and generic firms within the shadow of the Hatch-Waxman Act. Facing somewhat different case specifics, the courts developed varying approaches to the issue. These distinctions were laid to rest by the 2013 Supreme Court opinion in *Federal Trade Commission v. Actavis, Inc*.[97] The watershed *Actavis* decision ushered in a new era for antitrust review of reverse payment settlements. There, the Court held that the legality of reverse payment settlements should be evaluated under the "rule of reason" approach. However, the Court declined to hold that such settlements should be presumptively illegal under a "quick look" analysis. The *Actavis* opinion resolves a long-standing circuit split regarding the approach that should be taken toward settlement of pharmaceutical patent cases under the antitrust laws. The lower courts have now been left with the potentially complex task of applying the rule of reason to reverse payment settlements going forward.[98]

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[89] Patent Act of 1790, 1 Stat. 109 (1790).

[90] Patent Act of 1842, 5 Stat. 543 (1842).

[91] Townsend-Purnell Plant Patent Act, 46 Stat. 376 (1930).

[92] John R. Thomas, "The End of 'Patent Medicines'? Thoughts on the Rise of Regulatory Exclusivities," *Food and Drug Law Journal*, vol. 70 (2015), p. 39.

[93] Rebecca S. Eisenberg, "The Role of the FDA in Innovation Policy," *Michigan Telecommunications and Technology Law Review*, vol. 13 (2007), p. 345.

[94] Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), 33 I.L.M. 81 (1994), art. 27, ¶ 1.

[95] John R. Thomas, "The End of 'Patent Medicines'? Thoughts on the Rise of Regulatory Exclusivities," *Food and Drug Law Journal*, vol. 70 (2015), p. 39.

[96] CRS Report R44222, *Pharmaceutical Patent-Antitrust: Reverse Payment Settlements and Product Hopping*, by John R. Thomas.

[97] *Federal Trade Commission v. Actavis, Inc.*, 133 S.Ct. 2223 (2013).

[98] See, e.g., Michael A. Carrier, "Why a "Large and Unjustified" Payment Threshold Is Not Consistent with Actavis," *Washington Law Review*, vol. 91 (March 2016), p. 109.

In the 114th Congress, a number of bills deal with reverse payment settlements. The Fair and Immediate Release of Generics Act, S. 131, would make a number of changes to the Hatch-Waxman Act in order to discourage reverse payments settlements. In particular, S. 131 would grant any generic firm the right to share the 180-day regulatory exclusivity if it wins a patent challenge in the district court or is not sued for patent infringement by the brand company. The legislation would also oblige generic firms to abide by any deferred entry date agreed to in their settlements with brand-name firms, even if relevant patents were struck down previously. Finally, brand-name firms would be required to make a decision to enforce their patents within 45 days of being notified of a patent challenge by a generic firm under the Hatch-Waxman Act.

Another bill, S. 2019, the Preserve Access to Affordable Generics Act, would declare that certain reverse payment settlements constitute acts of unfair competition. In particular, that bill would amend the Federal Trade Commission Act to provide that an agreement "shall be presumed to have anticompetitive effects and be unlawful if—(i) an ANDA filer receives anything of value; and (ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time." Certain exceptions apply—for example, the payment of reasonable litigation expenses not exceeding $7.5 million would not be unlawful. That "quick look" presumption would not apply if the parties to the agreement demonstrate by clear and convincing evidence that the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement. S. 2019 includes a list of factors to be weighed by the courts in such circumstances.

A third bill, S. 2023, the Prescription Drug Affordability Act of 2015, would act similarly to S. 2019. It would also create a presumption that reverse payment settlements violate the Federal Trade Commission Act, subject to certain exceptions. However, unlike S. 2019, the parties to the agreement would not be able to overcome this presumption by showing that its procompetitive benefits outweigh the anticompetitive harms.

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