HATCH CENTER
POLICY REVIEW

40 Years of Hatch-Waxman: Creating the Generic Drug Industry, Ensuring Its Future Success

ORRIN G. HATCH
FOUNDATION

VOLUME V

DECEMBER 2024

About the Orrin G. Hatch Foundation

Civility and solutions—these are the twin pillars of the Orrin G. Hatch Foundation. They are the ideals that underpinned the senator's service and that guide the organization's mission today.

The Foundation seeks to engender greater civic participation and understanding, to facilitate bipartisan dialogue, and to foster commonsense solutions to our nation's most pressing problems by convening the greatest minds in American public life for high-level discussions on the public policy challenges of the day.

Contact Information

411 E. South Temple
Salt Lake City, Utah 84111
(385) 355-4380
info@orrinhatchfoundation.org
www.orrinhatchfoundation.org

Table of Contents

The Hatch Center encourages vigorous discussion on a variety of pressing policy issues. In that spirit, the essays in this year's Policy Review present a range of views. The views expressed reflect those of the authors and should not be understood as an endorsement by the Hatch Center.

Introduction

For forty years, almost everyone who's taken a prescription drug has benefited from the Drug Price Competition and Patent Term Restoration Act, or Hatch-Waxman. Named for its principal sponsors, Utah Senator Orrin Hatch and California Representative Henry Waxman, the law helped establish the generic drug industry as we know it today by striking a careful balance between promoting innovation and facilitating timely access to affordable generics.

Access to lifesaving generic drugs is crucial to the health of all Americans. Any patient who has a prescription knows that generics are *far* less expensive than name-brand drugs—sometimes less than a tenth, or even a hundredth, of the cost of name-brand alternatives.

Generics do not spring from thin air. They have to be developed and manufactured, just like name-brand drugs. And name-brand medicines come on the market only after many years of research, development, and testing. For the system to work, innovators must find it financially feasible to go through the lengthy, expensive drug development process. Generic manufacturers must also have a secure pathway to bring their cheaper versions to market for patients.

In the years immediately preceding Hatch-Waxman's passage, generics constituted only 13 percent of all prescriptions. Now, they constitute around 90 percent.

I have the privilege of holding the position Senator Hatch once held, the chair of the Senate Health, Education, Labor, and Pensions Committee, better known as the HELP Committee. Senator Hatch strategically chose to work with Representative Waxman. Their bipartisan collaboration, conservative and liberal, was essential to the enduring success of this legislation.

On its fortieth anniversary, Hatch-Waxman has become the example and foundation that other pro-patient policies can follow and improve upon to lower the cost of pharmaceuticals. I commend the Hatch Center for highlighting this in its *Policy Review* and look forward to working with my colleagues to build upon the Hatch-Waxman framework.

– U.S. Senator Bill Cassidy, M.D. (R-Louisiana)

About the Author

Dr. Bill Cassidy is the Senior Senator from Louisiana and Chair of the Senate Health, Education, Labor, and Pensions (HELP) Committee. He is the first physician to hold the position of HELP Chair.

Dr. Cassidy has led Republicans on the HELP Committee since 2023 and spearheaded committee efforts to lower the price of prescription drugs, address the opioid and mental health epidemic, improve our nation's response to natural disasters and public health emergencies, make college more affordable for students and families, protect workers' rights, and ensure Americans have a secure retirement. He has also engaged in extensive government oversight and has sought to improve accountability and transparency in taxpayer-funded programs. In addition to serving as the Chair of the HELP Committee, Dr. Cassidy is a member of the Senate Finance Committee, Energy and Natural Resources Committee, and Veterans' Affairs Committee.

Dr. Cassidy grew up in Baton Rouge, Louisiana and attended Louisiana State University (LSU) for undergraduate and medical school. After his medical residency, Dr. Cassidy worked for over 25 years in the Louisiana charity hospital system to ensure Louisiana families could access quality health care regardless of income. He also joined LSU Medical School teaching medical students and residents.

After serving in the Louisiana legislature, Dr. Cassidy was elected to the U.S. House of Representatives in 2008 to represent Louisiana's Sixth Congressional District, where he served on the House Energy and Commerce Committee.

He is married to Dr. Laura Cassidy, and they have three children. Laura is a retired general surgeon specializing in breast cancer. She also helped found a public charter school in Louisiana specialized in teaching children with dyslexia.

Hatch-Waxman Enters Its Middle Age

By Phil Johnson

September 24, 2024, marked the 40th anniversary of the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, better known as "Hatch-Waxman," offering an excellent opportunity to both reflect on its past successes and to map out its promising future. Hatch-Waxman made sweeping changes to the existing U.S. drug approval statutes to create a modern drug approval pathway for generic drugs. This pathway relies upon a set of time-limited regulatory and patent exclusivities to encourage the development of innovative new drug products while allowing concurrent development of generic versions that may be commercialized as soon as these exclusivities expire. Less well known is that provisions of Hatch-Waxman also encourage the development of Class III medical devices, such as implantable defibrillators, heart stents, and the like, by protecting them from charges of infringement prior to FDA approval and offering post-approval patent term extension ("PTE") to recover some of the time lost during their pre-approval clinical testing and subsequent FDA review.[1]

That Hatch-Waxman has been an outstanding success is beyond question. Since the passage of Hatch-Waxman, the United States has grown to be the largest developer of innovative new drugs, accounting for about half of the new drugs invented worldwide.[2] Hatch-Waxman has similarly enabled the U.S. to take a commanding lead in facilitating the public's access to generic drugs. At the time of Hatch-Waxman's passage, only 19% of the prescriptions filled in the United States were for generic drugs.[3] By 2009, thanks largely to Hatch-Waxman, 75% of the prescriptions dispensed in the United States were for

[1] *See* Alayna Y. Choo et al., MoFo Life Sciences, *Patent Term Extension for Medical Devices* (Dec. 2, 2024), https://lifesciences.mofo.com/topics/patent-term-extension-for-medical-devices. 35 U.S.C. § 156(f)(1) defines the products eligible for extension to include drugs as well as medical device, food additive, or color additive products that are subject to regulation under the Federal Food, Drug and Cosmetic Act.

[2] *See, e.g.*, Derek Lowe, *Where Drugs Come From: By Country*, Science (Nov. 9, 2010), *available at* https://www.science.org/content/blog-post/where-drugs-come-country (for drugs approved between 1998-2007, 118 out of 252 drugs (46.8%) were developed in the U.S.); Avalere, *Majority of API in US-Consumed Medicines Is Produced in the US* (Jan. 31, 2022), https://avalere.com/insights/majority-of-api-in-us-consumed-medicines-is-produced-in-the-us-2020 ("[I]n 2020, the dollar value of API [active pharmaceutical ingredients] made in the US accounted for a majority (53%) of the $86.1 billion of API used in medicines consumed in the US.").

[3] FDA, *Office of Generic Drugs 2022 Annual Report*, at 1 (Jan. 2023) (hereinafter OGD 2022 Report), *available at* https://www.fda.gov/media/165435/download?attachment; IQVIA Inst. for Hum. Data Sci., *Medicines Use and Spending in the U.S. A Review of 2018 and Outlook to 2023*, at 5 (May 2019) (hereinafter IQVIA 2018 Review), *available at* https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023.

generic drugs.[4] And now generics make up over 90% of the prescriptions dispensed in the United States.[5] By contrast, in other Organization for Economic Cooperation and Development countries, on average only 41% of prescriptions are filled using generics.[6]

While Hatch-Waxman's accomplishments to date are universally acknowledged, many things have changed over the past forty years that now affect how well the Hatch-Waxman framework is working and how its operation could be improved were updating legislation to be enacted. To understand how the existing Hatch-Waxman framework came to be and how it might be improved, it's important to look first at the relevant developments in the early 1980s, during which there were significant changes to the drug- and patent-related legal environment that set the stage for the enactment of Hatch-Waxman. These include the creation of the U.S. Court of Appeals for the Federal Circuit, the passage of the Bayh-Dole Act, and the decision in *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.*[7] We then examine recent developments that have impacted the operation and success of the Hatch-Waxman framework and identify opportunities for legislative reforms that could build upon Hatch-Waxman's successes to ensure that the U.S. will maintain its leadership in the biopharmaceutical industry.

Innovation in the life sciences industry is critical for patients in the U.S. as well as for our nation's economy and public health. The U.S. legal and regulatory framework supports collaboration among the private and public sectors and has resulted in the discovery and development of more innovative drugs than any other country.[8] Innovative new medical devices pioneered in the U.S. have similarly revolutionized the treatment of many debilitating and life-threatening conditions and promise to continue to do so if encouraged and protected. U.S. laws should continue to promote such innovation to ensure that patients in the U.S. will have access to innovative new drugs and devices as quickly as possible so that the U.S. will remain the global leader in life sciences research and development. U.S. laws should likewise maintain a robust generic drug pathway that provides patients with additional drug choices and promotes long-term savings across the health-care system.

---

[4] OGD 2022 Report, *supra* note 3, at 1; IQVIA 2018 Review, *supra* note 3, at 5.

[5] OGD 2022 Report, *supra* note 3, at 1; IQVIA 2018 Review, *supra* note 3, at 5.

[6] Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*, 11 RAND Health Q. 5 (2024).

[7] 572 F. Supp. 255 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir. 1984).

[8] *See, e.g.*, Lowe, *supra* note 2 (for drugs approved between 1998-2007, 118 out of 252 drugs (46.8%) were developed in the U.S.).

I. Setting the Stage: Developments Leading Up to the Passage of Hatch-Waxman

A. Creation of the U.S. Court of Appeals for the Federal Circuit

The Federal Courts Improvement Act of 1982 created the U.S. Court of Appeals for the Federal Circuit by merging the U.S. Court of Claims and the U.S. Court of Customs and Patent Appeals into one appellate court with expanded jurisdiction.[9] The Federal Circuit was intended to strengthen the U.S. patent system by enhancing consistency in the application of the federal patent laws, rather than having different controlling precedent applicable in the different regional circuits. The Federal Circuit was intended to "provide nation-wide uniformity in patent law, [to] make the rules applied in patent litigation more predictable and [to] eliminate the expensive, time-consuming and unseemly forum-shopping that characterizes litigation in the field."[10]

When the Act was being considered, witnesses testified before Congress that the creation of the Federal Circuit would help businesses and improve the economy. Former Secretary of Commerce Philip M. Klutznick testified that "[d]ecisions to file patent applications and to invest in commercializing inventions would be improved meaningfully as a result of the greater uniformity and reliability made possible" by the creation of the Federal Circuit.[11] The House of Representatives report similarly acknowledges that "[b]usiness planning becomes easier as more stable and predictable patent law is introduced," which "can have important positive ramifications for the nation's economy."[12] The report also describes patents as "a stimulus to the innovative process, which includes not only investment in research and development but also a far greater investment in facilities for producing and distributing the goods."[13]

---

[9] Federal Courts Improvement Act of 1982, H.R. 4482, 97th Cong.; *see also* H.R. No. 97-312, 97th Cong., at 17 (Nov. 4, 1981).

[10] H.R. No. 97-312, at 20.

[11] *Id.* at 22 (quoting Hearings on the Court of Appeals for the Federal Circuit Before the H. Judiciary Subcomm. on Courts, Civil Liberties and the Administration of Justice, 97th Cong., 1st Sess. 257 (1981)).

[12] *Id.* at 23.

[13] S. Rep. 98-275, 97th Cong., at 3 (Nov. 18, 1981) (testimony of Harry F. Manbeck, Jr., General Patent Counsel of the General Electric Company).

B. The Bayh-Dole Act

The Bayh-Dole Act of 1980[14] ("Bayh-Dole") was enacted with bipartisan support to foster commercialization of federally funded inventions. Prior to the enactment of Bayh-Dole, the U.S. Government retained ownership of patents on federally funded inventions. As a result, only 5% of those patents were ever licensed for use in the private sector,[15] and "not a single drug had been developed when patents were taken from universities [by the federal government]."[16]

Bayh-Dole allows recipients of federal funding agreements, primarily universities and other non-profits, to retain ownership of their federally funded inventions and discoveries, to file and obtain patents for them, and to (exclusively or non-exclusively) license them to private sector companies to develop their potential commercial applications. Net royalties and other payments received by these recipients must be shared with the named inventors and may otherwise be retained by the recipient organizations to subsidize their ongoing activities.

The work needed to transform Government-funded inventions with potential medical application into commercial, FDA-approved products typically takes ten to fifteen or more years. Bayh-Dole licenses to private parties (including start-ups) thus play a critical role in attracting the private funding necessary to support this translational R&D prior to the start of FDA-approved marketing.[17]

C. The Emergence of the Separate Hatch and Waxman Proposals

Before Congress developed what would become Hatch-Waxman, the patent-focused parts of the bill and the drug-focused parts of the bill were put forth separately. In the late 1970s and early 1980s, patent term restoration was supported by the executive branch under Presidents Carter and Reagan.[18] In 1981, the Senate passed S. 255, the Patent Term Restoration Act of 1981, which was cosponsored by Senator Orrin G. Hatch and was aimed at restoring lost patent

---

[14] 35 U.S.C. §§ 200-12.

[15] U.S. Gov't Accountability Off., GAO-09-742, *Information on the Government's Right to Assert Ownership Control over Federally Funded Inventions* (July 2009) (hereinafter GAO, *Information on the Government's Right to Assert Ownership Control*), *available at* https://www.gao.gov/assets/gao-09-742.pdf.

[16] Joseph Allen, *When Government Tried March In Rights to Control Health Care Costs*, IPWatchdog (May 2, 2016), https://ipwatchdog.com/2016/05/02/march-in-rights-health-care-costs/id%3D68816.

[17] *See* GAO, *Information on the Government's Right to Assert Ownership Control*, *supra* note 15, at 6-7.

[18] *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187, 188 (1999).

term due to regulatory reviews.[19] The bill, however, failed to pass with a two-thirds vote in the House of Representatives, which was required due to a suspension of the rules.[20] Despite the bill failing to pass in the House of Representatives, Congress generally remained supportive of patent term restoration.

Representative Henry A. Waxman noticed how close the patent term restoration bill came to passing both houses of Congress and then worked to combine the patent term restoration aspects of the bill with legislation he had developed to establish an expedited pathway for approval of generic drugs.[21] Combining patent term restoration with the proposed pathway for approving generic drugs then became a working compromise intended to garner enough support to pass what became Hatch-Waxman.

D. Roche v. Bolar

The Federal Circuit's April 1984 decision in *Roche v. Bolar* provided a further impetus to merge the separate Hatch and Waxman proposals and prioritize their enactment.[22]

In the *Bolar* case, Bolar sought to conduct testing of a patented compound necessary to submit an application for a generic drug to the FDA. Bolar characterized its activity relating to the patent-protected compound as "limited pre-expiration preparation for post-expiration entry into the market."[23] Bolar argued that if it were not permitted to conduct limited testing prior to patent expiry, the patent owner, Roche, would benefit from an effective extension of its patent term due to Bolar's delay in obtaining regulatory approval from the FDA. The district court concluded that "the limited use of a patented drug for experiments strictly related to FDA drug approval requirements during the last six months of the term of the patent" is not infringement under 35 U.S.C. § 271(a).[24]

On appeal, the U.S. Court of Appeals for the Federal Circuit reversed the district court's decision, finding that "the *use* of a patented invention, without either manufacture or sale, is actionable."[25] The Federal Circuit declined to find that Bolar's proposed use fell within the experimental use exception

---

[19] *See* Patent Term Restoration Act of 1981, S. 255, 97th Cong. (1981).

[20] *See* Patent Term Restoration Act of 1981, H.R. 6444, 97th Cong. (1981).

[21] *See* Ass'n for Accessible Meds., *Thank You, Rep. Henry Waxman*, https://accessiblemeds.org/resources/blog/thank-you-rep-henry-waxman (last visited Nov. 25, 2024).

[22] 572 F. Supp. 255.

[23] *Id.* at 257.

[24] *Id.*; *see also Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958) ("Experimental use does not infringe.").

[25] 733 F.2d at 861.

as Bolar's use "has definite, cognizable, and not insubstantial commercial purposes."[26] The Federal Circuit acknowledged that a patent owner can gain "a *de facto* monopoly of upwards of [an additional] 2 years by enjoining FDA-required testing of a generic drug until the patent on the drug's active ingredient expires."[27] The court reasoned that Congress was presumably aware that the testing requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA") would constructively lengthen the patent term of a pharmaceutical patent and thus declined to apply the patent laws differently to drugs.

The *Bolar* decision added a sense of urgency to ongoing legislative negotiations—now to include a provision to overrule *Bolar*—and spurred adoption of the Hatch-Waxman compromise. By early September, the bills were combined and the House passed the Hatch bill, S. 1538, after amending its text to include the Waxman proposal, H.R. 3605.[28] On September 24, 1984, Hatch-Waxman—i.e., the Drug Price Competition and Patent Term Restoration Act of 1984—was signed into law.[29]

II. The Hatch-Waxman Drug Price Competition and Patent Term Restoration Act of 1984 and Its Initial Successes

A. New Approval Pathways

To advance generic competition, Hatch-Waxman created an accelerated generic drug approval pathway — section 505(j) of the FDCA.[30] Under this section, a generic drug applicant is permitted to rely upon the safety and efficacy testing that has been conducted and submitted to the FDA by the drug's originator in support of its New Drug Application ("NDA"). A generic drug applicant is thus relieved of any requirement to conduct full clinical trials of its generic version as long as the generic applicant submits an Abbreviated New Drug Application ("ANDA") that meets certain other specified requirements, including a showing that the applicant's product is the "same as" the innovator's product in its active ingredient(s), dosage form, route of administration, and strength, and is also "bioequivalent to" the innovator's product.[31] The

[26] *Id.* at 863.

[27] *Id.*

[28] *See* H.R. Rep. No. 98-857, pt. 1, at 45-46 (1984) (explaining the effect of *Bolar* on the bill); *id.*, pt. 2, at 3-4 (1984) (explaining the legislative paths of the patent- and drug-focused bills).

[29] *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[30] *Id.* § 101, 98 Stat. at 1585-92.

[31] FDCA § 505(j)(2)(A)(ii)-(iv) (codified at 21 U.S.C. § 355(j)(2)(A)(ii)-(iv)). This pathway in which an applicant demonstrates sameness is available instead of requiring an applicant to duplicate safety and efficacy testing.

ANDA must further show that the generic drug will be properly manufactured and generally will have the same labeling as the innovator product.[32] Finally, the ANDA applicant must include a certification regarding each relevant innovator patent listed by the innovator in the FDA's "Orange Book" under section 505(j)(2)(A)(ii). This certification must affirm the applicant's belief that the patent: (1) was not listed by the innovator in the Orange Book; (2) has expired; (3) will expire on a given date after which generic marketing is to begin; or (4) is invalid or not infringed by the proposed generic product (this last certification now being commonly referred to as a "Paragraph IV certification").[33]

In enacting Hatch-Waxman, Congress also created section 505(b)(2) of the FDCA. This provision requires an NDA applicant to make the same patent certifications as an ANDA applicant if the NDA applicant submit reports of investigations that "were not conducted by or for [it] and for which [it] has not obtained a right of reference or use."[34] FDA has interpreted section 505(b)(2) to allow a follow-on applicant to rely on a prior finding of safety and effectiveness for a listed drug or published literature to support approval.[35]

B. Hatch-Waxman Exemption from Infringement for R&D

To overrule *Bolar*, the Hatch-Waxman Amendments contained 35 U.S.C. § 271(e)(1), a safe harbor provision to allow an exemption from infringement for research, development, and testing pertaining to the development of information to be submitted to the FDA.[36] Section 271(e)(1) provides that:

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

While originally thought to provide such protection for pre-approval use and testing only of drugs and veterinary biologicals, the breadth of the language used in Section 271(e)(1) is not so restricted and was subsequently held

---

[32] *Id.* § 505(j)(2)(A)(v)-(vi).

[33] *Id.* § 505(j)(2)(vii).

[34] *Id.* § 505(b)(2).

[35] *See id.*; FDA, Draft Guidance for Industry, *Applications Covered by Section 505(b)(2)*, at 2-3 (Dec. 1999), *available at* https://www.fda.gov/media/72419/download.

[36] *See* Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 308 (1985) (explaining that "section 271(e) was intended solely to overrule" *Bolar*).

to pertain to the development and testing of certain types of medical devices as well.[37] By providing a safe harbor for research and development activities, section 271(e)(1) eliminated the "de facto" extension of patent life that resulted from *Bolar* and allowed generic drug developers to make their versions of NDA-approved drugs and to use them as reasonably necessary in bioequivalence testing to obtain FDA approval and to facilitate immediate generic entry upon patent expiration.

C. Resolution of Patent Disputes Without the Risk of Patent Damages

Under Hatch-Waxman, innovator NDA drug sponsors must submit information to the FDA about patents that meet the statutory criteria for listing in the FDA's Orange Book.[38] In general, patents that must be listed in the Orange Book include patents covering the active ingredient of a drug product, patents covering the formulation or composition of a drug product, and patents covering a method of use of the drug. The listing process benefits generic drug applicants by providing notice of the existence of the relevant patents and by identifying the relevance of each patent to the innovator's drug substance, drug product, or method of use via a patent use code. As mentioned above, Orange Book-listed patents are those for which a generic drug applicant must submit a certification to obtain approval of an ANDA.

In addition to requiring the listing of certain patents, Hatch-Waxman also created as an artificial act of infringement the submission of an application under section 505(b)(2) or 505(j) of the FDCA for a drug claimed in a patent, or the use of which is claimed in a patent, and for which the generic applicant seeks to market its product prior to expiration of the patent and challenges the patent via a Paragraph IV certification. The creation of this artificial act of infringement establishes federal jurisdiction enabling innovators to institute patent litigation to resolve infringement disputes prior to the generic entering the market. The 505(b)(2) or 505(j) generic applicant is further required to provide the sponsor of the innovator drug with prompt notice of its Paragraph IV certification alleging and explaining its asserted grounds of invalidity or noninfringement of the sponsor's Orange Book-listed patents, whereupon the sponsor has 45 days from receipt of the notice from the generic applicant to respond to those allegations by commencing patent infringement litigation based upon the Orange Book-listed patent(s) for which the Paragraph IV certification was given. Once such litigation is instituted, the section 505(b)(2) or section 505(j) application becomes subject to a 30-month stay of approval, which is designed to allow for completion of the district court phase

---

[37] *Eli Lilly & Co. v. Medtronic, Inc*, 872 F.2d 402 (Fed. Cir. 1989) (holding that because the infringement exemption applies to "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," and because the same law also covers the manufacture, use, or sale of medical devices, medical devices also fall within this infringement exemption), *aff'd*, 496 U.S. 661 (1990).

[38] *See* FDCA § 505(b)(1)(A)(viii).

of the litigation prior to the grant of FDA approval to market the generic product. During this 30-month period, the FDA generally cannot approve the ANDA application unless in the meantime the federal district court has decided that the patents at issue are invalid or not infringed.[39]

By permitting the early resolution of patent disputes, generic manufacturers avoid the need to launch their generic products "at risk" in order to have a court rule on their invalidity or noninfringement positions. ANDA applicants are thus assured that if they so elect, all the Orange Book-related patent validity and infringement issues may be resolved without subjecting the generic manufacturer to the risk of paying any patent damages. Given typically slim generic profit margins, the guaranteed avoidance of potential patent damages acts as a significant incentive to develop generic drugs. This framework also provides innovators the opportunity to enforce their patents to prevent any generic launch prior to the expiration of the innovator products' patent exclusivities.[40]

D. Restoring Lost Patent Term Due to Regulatory Delay

Hatch-Waxman also provides for restoration of patent term lost due to delays caused by required regulatory reviews for innovative new drugs, veterinary biological products, food additives, and medical devices (including patents directed to methods of manufacturing and using these products). The 1962 amendments to the FDCA had changed the drug approval process to require the FDA to determine that a new drug is safe and effective before its marketing, significantly increasing the time needed for a drug to be developed and approved for marketing.[41] Accordingly, prior to the Uruguay Agreement Amendments Act, the traditional seventeen-year patent term that began on the date of patent grant would leave very few years of patent protection left for a marketed drug after it was finally approved by the FDA.[42] Indeed, as one com-

---

[39] *See id.* § 505(c)(3)(C).

[40] *See* H.R. Rep. No. 98-857, pt. 1, at 28 (1984) (explaining that the artificial act of infringement and related litigation provisions of Hatch-Waxman "fairly balance[] the rights of a patent owner to prevent others from making, using, or selling its patented products and the rights of third parties to contest the validity of a patent or to market a product which they believe is not claimed by the patent").

[41] *See* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962); *see also* Flannery & Hutt, *supra* note 36, at 301.

[42] *See* 130 Cong. Rec. 22,960, 23,058 (Aug. 8, 1984) (statement of Rep. Synar) ("The average effective patent life of a pioneer drug is reduced by 7 years because of FDA review."); *id.* at 23,059 (statement of Rep. Kastenmeier) ("[T]he effective market life of [pharmaceutical firms'] patented inventions was being eroded by excessively long periods of regulatory review—and delay—at the Food and Drug Administration."). A later Government Accountability Office report estimated that it could take ten to fifteen years to meet all requirements for drug approval—including preclinical research, clinical research, and marketing approval. *See* GAO, *Information on the Government's Right to Assert Ownership Control*, *supra* note 15, at 6-7.

mentator observed, it is "not surprising that the erosion of effective patent life for pharmaceutical products . . . coincides with the erosion in pharmaceutical innovation, as measured by the yearly FDA approval of pioneer new drugs."[43]

By adding 35 U.S.C. § 156, which governs the requirements for PTE, Hatch-Waxman sought to restore lost patent term due to regulatory delay at FDA with the aim of incentivizing innovation. 35 U.S.C. § 156 provides that, under certain conditions, the patent term on a product or a method of using or manufacturing a product "that has been subject to a regulatory review period before its commercial marketing or use" may be extended.[44] In addition to applying to drug and veterinary biological products, Section 156 specifically authorizes extensions of patents on any "medical device, food additive or color additive subject to regulation under the Federal Food, Drug and Cosmetic Act."[45]

If an NDA-approved drug and a related patent qualify for PTE, the patent term will generally be extended by a portion of the length of the regulatory review period, as defined in the statute.[46] However, the total effective patent life of the qualifying patent is capped at fourteen years, and only one patent can be extended per active moiety.[47]

With the implementation of PTE, actual effective patent life has generally aligned with the fourteen-year cap. In a cohort of small molecule drugs approved from 1995-2019, the average market exclusivity period—from launch of the innovator drug to launch of the first generic—was between 12.2 and 14.6 years.[48]

---

[43] Flannery & Hutt, *supra* note 36, at 302.

[44] 35 U.S.C. § 156(a).

[45] *Id.* § 156(f)(2)(a).

[46] *Id.* § 156(c) (providing that the term of a patent eligible for extension may be extended by the length of its post-issuance term lost due to regulatory delays in development and review of product, subject to certain limitations and deductions, and then for no more than one patent per product for a total patent term of not to exceed 14 years).

[47] *Id.* § 156(c)(3)-(4).

[48] *See* Henry Grabowski et al., *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, 24 J. Med. Econ. 908, 911 (2021); *see also* Erika Lietzan & Kristina Acri née Lybecker, *Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations*, 33 Fordham Intell. Prop., Media & Entm't L.J. 788, 840 (2023) (finding an average of 11.3 and 13.34 years of market exclusivity for new drug applications and new chemical entities, respectively); USPTO, *Drug Patent and Exclusivity Study*, at 5 (June 2024), *available at* https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf (finding that "the market exclusivity ranged from about 3 to about 16 years" for the drugs studied).

E. 180-Day Generic Drug Exclusivity Incentive

Hatch-Waxman additionally encourages generics to challenge patents through the Paragraph IV process by providing a period of 180 days of market exclusivity to certain first-filing generic applicants who have invested in developing a generic drug and obtained approval of an ANDA that included a Paragraph IV certification. This 180-day period of market exclusivity traditionally allowed these ANDA applicants to introduce their generic products at a higher price than they could have if they were competing against other generics of the same drug, but still at a low enough price to drive conversion of sales from the innovator product to the new generic drug. Even though the 180-day period was relatively short, it was long enough so that the higher margin achieved in this period was generally sufficient to cover the first ANDA filer's development costs, as well as allow a reasonable profit to compensate for the risks entailed in its efforts.

The 180-day exclusivity period remained the same for nearly two decades after Hatch-Waxman passed. As originally developed, 180-day exclusivity was awarded to the first applicant to file an ANDA with a Paragraph IV certification to a listed patent that obtained FDA approval for its generic drug. The original statutory language created a patent-by-patent approach in which there could be multiple first applicants if they each are a "first applicant" with a Paragraph IV certification to different listed patents. The FDA could not approve a subsequent generic application for the same drug during a 180-day period beginning on the date FDA received notice from the applicant of the first commercial marketing of the generic drug by the first applicant or the date of a court decision finding the relevant patent(s) invalid or not infringed, whichever was earlier.[49]

F. The Overall Successes of Hatch-Waxman in Bringing Both Innovative New Drugs and Lower Cost Generic Drugs to U.S. Patients

In 1984, generic drugs accounted for approximately 12% of drug prescriptions, which increased to 22% by 1986, just two years after Hatch-Waxman was passed.[50] Since the passage of Hatch-Waxman, this percentage has been steadily rising. For example, in 1994, generic drugs comprised 36% of all prescriptions dispensed, and this percentage rose to 75% in 2009 and 90% in

[49] *See* Pub. L. No. 98-417, 98 Stat. at 1589.

[50] *See* U.S. Pharmacopeia, *Timeline: Generic Medicines in the US*, https://www.usp.org/our-impact/generics/timeline-of-generics-in-us (last visited Nov. 22, 2024).

2017.[51] Indeed, FDA's Office of Generic Drugs stated that as of 2022, "[i]t is estimated that 91% of all prescriptions in the United States are filled as generic drugs, with more than 32,000 generic drugs approved by the FDA to date."[52]

Forty years after the passage of Hatch-Waxman, the framework continues to balance affordability against the critical need for innovation to meet the unmet needs of patients. The use of generic drugs has saved the U.S. health care system $2.2 trillion between 2010 and 2019.[53] An FDA study published in 2024 revealed that "generic drugs approved in 2022 yielded $18.9 billion in total savings during the 12 months following their approvals, of which $5.2 billion is attributed to first generic approvals."[54] In addition, FDA approved 55 "novel" new drugs in 2023, and 51% of such drugs target rare diseases.[55] Further, 20 of these 55 new drugs are first-in-class, meaning that the drug's mechanism of action is different than that of existing drugs.[56] Thus, Hatch-Waxman continues to incentivize the development and availability of both innovative new drugs and generic drugs, providing U.S. patients with more medicine choices than anywhere else in the world. Such drugs not only improve the availability of quality care, but also reduce the need for care in more costly settings such as in hospitals and continuing care settings while ensuring medicine costs remain a reasonable and stable 14% share of health care system spending.[57] Similar cost containment mechanisms do not exist for other health care services.

---

[51] *See* Off. of Health Pol'y, Issue Brief, *Medicare Part D: Competition and Generic Drug Prices, 2007-2018*, at 2 (Jan. 19, 2021), *available at* https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/198346/medicare-part-d-generic-comp.pdf.

[52] OGD 2022 Report, *supra* note 3, at 1.

[53] FDA, *Office of Generic Drugs 2020 Annual Report*, at ii (Feb. 2021), *available at* https://www.fda.gov/media/145793/download?attachment; Ass'n for Accessible Meds., *2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report*, at 18 (Sept. 2020), *available at* https://accessiblemeds.org/wp-content/uploads/2024/12/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf.

[54] FDA, *Estimating Cost Savings from New Generic Drug Approvals in 2022*, at 2 (Sept. 2024), *available at* https://www.fda.gov/media/182435/download?attachment.

[55] FDA, *Advancing Health Through Innovation: New Drug Therapy Approvals 2023*, at 2-3 (Jan. 2024) (hereinafter FDA, *Advancing Health Through Innovation*), *available at* https://www.fda.gov/media/175253/download?attachment; *see also* Dean G. Brown et al., *Clinical Development Times for Innovative Drugs*, 21 Nature Revs. Drug Discovery 793, at 1 (2022) (FDA approved 440 innovative new drugs between 2010 and 2020).

[56] FDA, *Advancing Health Through Innovation*, *supra* note 55, at 6.

[57] Charles Roehrig & Ani Turner, Altrum, *Projections of the Non-Retail Prescription Drug Share of National Health Expenditures*, at 2 (July 2022), *available at* https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf.

III. Impacts of the Medicare Modernization Act

A. Amendments to Encourage Prompt Generic-Brand Dispute Resolution

Prior to the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[58] ("MMA"), generic companies could, in certain circumstances, be subject to more than one 30-month stay of approval relating to patent litigation. Patents listed after a generic company filed an ANDA could trigger a new 30-month stay. For example, patents covering improvements to approved drugs could be listed after ANDA submission, prompting the possibility of another 30-month stay of approval. These multiple stays of approval could thus prevent FDA from approving the generic company's ANDA within 30 months of the original ANDA filing (in the absence of earlier judicial resolution(s) of all patent infringement).[59] To prevent this from occurring, the MMA generally precludes more than one 30-month stay of approval by preventing a subsequent stay of approval for patents listed in the Orange Book after the date on which an ANDA or 505(b)(2) application was submitted.

B. Amendments to Address Problems with 180-Day Exclusivity

The statutory language in Hatch-Waxman regarding 180-day exclusivity was brief, and it left many interpretative issues up to FDA and the courts.[60] Although FDA first proposed regulations on the 180-day exclusivity provisions in 1989, the agency did not issue any final regulations on these provisions until 1994.[61] FDA's regulations clarified that a first applicant must submit a "substantially complete" application that contains a Paragraph IV certification before any other applicant submits a substantially complete application with the same certification.[62] In addition, a first applicant could lose its exclusivity and FDA could approve any subsequent applications if that applicant did not actively pursue approval of its application. FDA also implemented a rule requiring an applicant to succeed in

---

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

[59] If the patent challenge is started in the fifth year after NDA approval of a new chemical entity, the stay will not be lifted until 7.5 years after NDA approval or litigation is resolved. *See* FDCA § 505(j)(5)(F)(ii).

[60] *See* David E. Korn et al., *A New History and Discussion of 180-Day Exclusivity*, 64 Food & Drug L.J. 335, 355 (2009).

[61] *See* 54 Fed. Reg. 28,872 (July 10, 1989) (proposed rule); 59 Fed. Reg. 50,338 (Oct. 3, 1994) (final rule); 21 C.F.R. § 314.107(c) (1994); *see also* Erika Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 Food & Drug L.J. 287, 294 (2004).

[62] *See* Lietzan, *supra* note 61, at 294.

a patent infringement suit, but that rule was invalidated by a court decision in 1997.[63] A later court case clarified that the first applicant does not need to be sued by the NDA sponsor to be eligible for 180-day exclusivity,[64] and various other cases addressing other aspects of FDA's application of 180-day exclusivity soon followed.[65] These and other issues relating to the 180-day exclusivity provision thus led Congress to consider passing a legislative fix in the form of the MMA.

The MMA revised section 505(j)(5) of the FDCA to make changes to the application and forfeiture of 180-day exclusivity for a first generic applicant. With respect to eligibility as a first applicant, the law was changed such that more than one ANDA applicant may be deemed to be a "first applicant" with respect to a generic drug. Per the MMA, the term "first applicant" now includes more than one first filer if more than one applicant submits a substantially complete ANDA application with a Paragraph IV certification on the first day permitted for doing so.[66] The MMA also replaces the original patent-by-patent approach to determining first applicant status with a product-by-product approach. Accordingly, two or more applicants who first submit substantially complete ANDA applications on the same day, each of which includes a Paragraph IV certification to one or more patents listed in the Orange Book, may share 180 days of marketing exclusivity during which FDA will not approve any further ANDA application for that generic drug. The MMA also revised the provisions describing situations in which a first applicant would forfeit the exclusivity to avoid the situation in which a first applicant delays marketing to prevent final approval of other ANDAs.

Shared 180-day generic exclusivity has been problematic for the generic drug industry, as many generic companies traditionally counted on their company being the only applicant with 180-day exclusivity during which they could introduce their generic drug at a price that was low enough to induce switching to the generic, but high enough to recover its development costs and a reasonable return on its related investments. After passage of the MMA, there was no guarantee of sole generic exclusivity as many ANDA applicants (sometimes as many as 20) could and did achieve first applicant status for popular drugs, leading to immediate, aggressive price competition among them. Although consumers benefited from paying lower prices a few months sooner in such situations, the generic companies who "won" such competitions have often been those who could most cheaply manufacture or

---

[63] *See* 59 Fed. Reg. at 50,354; *see also Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997) (invalidating the successful defense requirement), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998).

[64] *See Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201 (D.C. Cir. 1998).

[65] *See, e.g.*, *Apotex v. Shalala*, 53 F. Supp. 2d 454 (D.D.C. 1999) (allowing grant of exclusivity for lower doses of a drug for which exclusivity was already granted for approval of higher doses), *aff'd*, 1999 WL 956686 (D.C. Cir. Oct. 8, 1999).

[66] *See* FDCA § 505(j)(5)(B)(iv)(II)(bb).

source their active ingredients. Experience has shown, however, that these manufacturers are also less likely to have resilient supply chains. Consumers therefore have suffered in some cases as the generic manufacturers who would have been best able to handle supply chain disruptions and avoid shortages found they could not effectively compete on price and thus have withdrawn from the market.[67]

As explained above, because first applicants must file at least one Paragraph IV certification, they often face litigation in which they are accused of infringing one or more of the sponsor's Orange Book-listed patents. Such litigation is expensive and time consuming,[68] but in cases where there is only one or just a few first applicants, the potential reward of 180 days of marketing exclusivity may remain appealing: 180-day exclusivity "is the only incentive for generic companies to challenge brand patents, [so] it is perhaps the most significant driver of competition—and lower prices—within the pharmaceutical industry."[69] Indeed, successfully challenging the innovator's patents can result in generic drug entry well before the generic drug otherwise would be able to enter the market, allowing patients to obtain access to generic drugs sooner. Nonetheless, the management of ANDA cases involving multiple first applicants that may be charged with infringing different patents and/or patent claims can be challenging for all involved, particularly if the cases must be brought by the innovator company in multiple jurisdictions.[70] In addition, different first applicants are likely to have different litigation priorities, making case management difficult.

---

[67] *See generally* U.S. Dep't of Health & Hum. Servs., *Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States* (Apr. 2, 2024), *available at* https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf ("Key issues include a broad lack of transparency, concentration among middlemen, and prices for generic drugs that are driven to levels so low that they create insufficient incentives for redundancy or resilience-oriented manufacturing, distribution, and purchasing. These market failures lead to pharmaceutical supply chains that are brittle, disruption-prone, and too slow to recover from shortages.").

[68] *See* Ass'n for Accessible Meds., *The Hatch-Waxman 180-Day Exclusivity Incentive Accelerates Patient Access to First Generics* (June 2022), https://accessiblemeds.org/resources/fact-sheets/the-hatch-waxman-180-day-exclusivity-incentive-accelerates-patient-access-to-first-generics (estimating that "[a] patent case may cost each party $1.5 million in legal fees and one study found estimated costs of $10 million per suit").

[69] *Id.*

[70] *See* The Sedona Conference, *WG10 Chapter on Biopharma Patent Litigation*, at 24-26 (Oct. 2021 public comment version), *available at* https://thesedonaconference.org/sites/default/files/basic-page-files/%5B5.1%5D%20Sedona%20WG10%20Biopharma%20Chapter%20%28Mar.%202019%29.pdf (describing additional considerations for ANDA litigation involving multiple generic challengers).

IV. The Biologics Price Competition and Innovation Act

A. An Abbreviated FDA Approval Pathway Is Created for Biosimilars

Inspired in no small part by the success of Hatch-Waxman in expediting the approval of small molecule drugs, the Biologics Price Competition and Innovation Act ("BPCIA") was enacted in 2010 to create an abbreviated pathway for approving products that are "biosimilar" to previously approved biological products. Biosimilar applicants may seek abbreviated approvals through the submission of an abbreviated Biologics License Application under subsection 351(k) of the Public Health Service Act for products that are highly similar to or also interchangeable with a previously approved reference product "notwithstanding minor differences in clinically inactive components" provided there are "no clinically meaningful differences" from the reference product "in terms of safety, purity, and potency of the product."[71]

The BPCIA provides the first licensed biological product a period of 12 years of post-approval regulatory exclusivity, while providing for varying periods of post-approval regulatory exclusivity for the first approved interchangeable biosimilar product, ranging from 1 year up to 42 months, depending on whether the section 351(k) applicant has been sued for infringement.[72] Due largely to the promise of 12 years of regulatory exclusivity, investments in developing these products, as opposed to small molecule drugs that enjoy only a five year period of guaranteed regulatory exclusivity (although measured differently), have substantially increased.

B. A New Statutory Framework Is Provided for Patent Dispute Resolution

The BPCIA also provides a procedure which may be used by subsection 351(k) applicants to resolve patent infringement issues before approval of their applications.[73] This procedure, which has become known as the "Patent Dance," involves disclosures to the reference product sponsor of confidential information relating to the applicant's biosimilar product, including its subsec-

---

[71] 42 U.S.C.§ 262(i)(2), (k). Under 42 U.S.C. § 262(i)(1) a "biological product" is "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."

[72] *Id.* § 262(k)(6)-(7).

[73] *Id.* § 262(*l*).

tion 351(k) application and information "that describes the process or processes used to manufacture the biological product that is the subject of such application."[74] Because a subsection 351(k) application may be filed as soon as 4 years after the reference product's first approval but may not be approved earlier than 12 years after that approval, a period of up to 8 years is provided for the parties to resolve their patent issues prior to FDA approval. Once the "Patent Dance" begins, the BPCIA provides for several exchanges of patent information between the reference product sponsor and subsection 351(k) applicant that may lead to the settlement of their patent disputes or to patent infringement litigation between them.[75]

V. Impacts of the America Invents Act on Hatch-Waxman ANDA litigation

A. Patent Office Patent Invalidity Challenges Made Available to the Public

In 2011, the America Invents Act ("AIA") created two new post-grant proceedings allowing members of the public to challenge a patent's validity within the United States Patent & Trademark Office ("USPTO"). The first of these proceedings, Post-Grant Review ("PGR"), could be instituted based on petitions filed within nine months of a patent's grant. The second of these, Inter Partes Review ("IPR"), could be filed at any time thereafter during the remaining life of the challenged patent. Both proceedings are available to anyone (other than the patent's owner), although IPR petitions must generally be filed no later than one year after the petitioner or its privies has been served with a complaint alleging infringement of the challenged patent.[76] While PGR petitions may raise any ground of invalidity, IPR proceedings are limited to considering anticipation (under 35 U.S.C. § 102) or obviousness (under 35 U.S.C. § 103) and then "only on the basis of prior art *consisting of* patents or printed publications."[77]

The AIA provides that decisions on petitions to institute a PGR or IPR are to be made by the Director of the USPTO.[78] Congress assigned the duty of deciding the merits of instituted PGR or IPR proceedings to the Patent Trial

---

[74] *Id.* § 262(*l*)(2).

[75] *Id.* § 262(l)(2)-(9).

[76] *See* 35 U.S.C. § 314(b) (prohibiting institution "if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent").

[77] *Id.* § 311(b) (emphasis added).

[78] *Id.* § 314(a) ("The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.").

and Appeal Board ("PTAB").[79] As so written, the Director was intended to exercise his or her executive discretion to decide whether a requested PGR or IPR would be instituted, and if so, for which claims of the patent on what alleged grounds. The PTAB was then to be assigned the responsibility of conducting each proceeding instituted by the Director to judge its merits and come to a final written decision confirming the validity or invalidity of each such patent claim. As is typical in administrative law, the AIA made the Director's decision whether to institute a proceeding unappealable but made the PTAB's "judicial" decision on the merits of the proceeding appealable to the Federal Circuit.[80]

Upon implementation by the USPTO, it quickly became apparent that the USPTO designed its IPR trial rules and procedures to strongly favor petitioners. Instead of limiting the PTAB to its assigned role of deciding the merits of IPR proceedings instituted by the Director, during AIA rulemaking the USPTO instead delegated the institution decision to the PTAB itself.[81] This means that for a patentee to prevail, the same PTAB judges who decided to institute the IPR based on a "reasonable likelihood of success" threshold must then reach an opposite conclusion in their Final Written Decision under a preponderance of the evidence standard. Moreover, while district courts typically require patent challengers to make initial disclosures of

---

[79] *Id.* § 6(b) ("The Patent Trial and Appeal Board shall— . . . (4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32."); *see also id.* § 316(c) (stating that the PTAB "shall, in accordance with section 6, conduct each inter partes review instituted under this chapter").

[80] *Compare id.* § 314(b), *and id.* § 324(b) (making institution decisions unappealable), *with id.* §§ 319, 329 (providing the right to appeal).

[81] 37 C.F.R § 42.4(a) ("The Board institutes the [IPR] trial on behalf of the Director."); *see Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016) (affirming the PTAB's authority to institute), *overruled in part by United States v. Arthrex, Inc.*, 594 U.S. 1 (2021). In *United States v. Arthrex, Inc.*, 594 U.S. 1 (2021), the Supreme Court concluded that as inferior officers, PTAB judges were not sufficiently supervised by a principal officer, i.e., the USPTO Director, and that the Federal Circuit "cannot provide the necessary supervision" because PTAB decisions are nonetheless exercises of "'executive Power,' for which the President is ultimately responsible," *id.* at 17. The Court thus held that "[d]ecisions by APJs [administrative patent judges] must be subject to review by the Director." *Id.* at 24. In response, the USPTO promulgated an interim and now final rule allowing a party to request Director Review of decisions on institution, final decisions, rehearing grant decisions, and other decisions "concluding an AIA proceeding" including decisions in derivation proceedings. 89 Fed. Reg. 79,744 (Oct. 1, 2024). During the time when interim Director Review procedures were available, of the 369 requests "completed," 337 (91%) were denied. *Id.* at 79,750. Since July 24, 2023, when Director Review requests were first allowed for institution decisions, over 115 such requests were received. Eileen McDermott, *USPTO Issues Final Rule on Director Review Process, Scraps After Final Consideration Pilot*, IPWatchdog (Sept. 30, 2024), https://ipwatchdog.com/2024/09/30/uspto-issues-final-rule-director-review-process-scraps-final-consideration-pilot/id=181718/.

adverse information and grant robust discovery into their allegedly infringing and pre-infringement activities, IPR petitioners need not disclose information that is adverse to the factual positions being advanced, and adverse party discovery is seldom allowed.[82] A judgment of unpatentability is also easier to obtain because IPR validity challenges are judged under a preponderance of the evidence standard of proof rather than the clear and convincing standard used in the district courts. And in IPRs the PTAB has not limited itself to the consideration of prior art "consisting of" patents and printed publications, but instead often bases its decisions on the credibility of positions advanced in extensive declarations proffered by Petitioners' experts (whose testimony is neither heard or nor cross-examined live before the PTAB).[83]

As a result, between September 16, 2012, and September 30, 2024, 11,272 patents have been challenged by filed PGR or IPR petitions, many times more than the USPTO originally estimated.[84] And the USPTO's statistics show that IPR petitioners are successful in invalidating all or some of the challenged claims in 85% of the PTAB's final written decisions.[85]

PGR and IPR petitions resulting in appeals to the Federal Circuit now represent approximately half of the patent cases on the court's docket. This extra workload has placed a great burden on a court whose docket of complex cases was already very heavy and has led the Federal Circuit to handle them by using procedures that often do not reassure appellants that their contentions have been fully considered. To begin with, the court uses a "substantial evidence" standard for IPR appeals, under which the court looks to whether there is record evidence sufficient to support the PTAB's decision, not whether the weight of the evidence favored the patent challenger. A perception that the court's review was quite limited has

---

[82] Other PTAB rules and practices also made it easier for the PTAB to invalidate challenged patent claims. Under the PTAB's original rules, patent owners were not permitted to submit evidence in opposition to filed IPR petitions and were required to defend their claims as interpreted under a "broadest reasonable interpretation" standard rather than the narrower *Phillips* standard used in the courts. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Currently, patent owners still do not obtain meaningful discovery from petitioners, compel third parties to testify, present inventor testimony, freely make narrowing amendments to their challenged patent claims, or cross examine accusing experts live in front of the PTAB panel deciding the IPR.

[83] In practice, the PTAB routinely institutes and decides patentability on petitioners' expert declarations that range far beyond the content of such patents or printed publications, and the contents of those declarations appears to be routinely accepted by the Federal Circuit as providing substantial evidence sufficient to support the PTAB's final written decisions.

[84] USPTO, *PTAB Trial Statistics FY24 End of Year Outcome Roundup IPR, PGR*, at 15 (2024), *available at* https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2024__roundup.pdf.

[85] *Id.* at 10; *see also* Stephen Schreiner, *The PTAB's 70% All-Claims Invalidation Rate Continues to Be a Source of Concern*, IPWatchdog (Jan. 12, 2025), https://ipwatchdog.com/2025/01/12/ptab-70-claims-invalidation-rate-continues-source-concern/id=184956.

been reinforced by the fact that a substantial percentage of the Federal Circuit's affirmances of patent invalidity in IPR appeals are one word decisions that are not accompanied by any written explanation.[86] As a result, not only are PTAB decisions in IPR appeals rarely overturned, but patent owners are losing faith in a court that appears indifferent as to whether the procedures used by the PTAB in reaching its decisions meet constitutionally mandated due process standards and are otherwise proper. Of the 1,323 IPR appeals that had been decided by the Federal Circuit by June 30, 2024, 932 (74.74%) have been affirmed on every issue, and only 123 (12.27%) have been reversed or vacated.[87]

Due in large part to the recognition that IPRs were (and still are) highly friendly to patent challengers, generic companies who were also engaged in Hatch-Waxman litigation soon began seeking concurrent IPR reviews. These IPR challenges largely duplicated the validity challenges being pressed in their corresponding Hatch-Waxman cases and were intended by the petitioners to create more opportunities for the patent challengers to take advantage of the lower IPR standards and lack of due process protections. This duplication is particularly onerous in the Hatch-Waxman context because the applicable time limitations of these different proceedings effectively require them to proceed concurrently.[88] But even if the generic manufacturer is initially successful in first obtaining a favorable final written decision of unpatentability from the PTAB, this decision is subject to immediate appeal and does not lift the 30-month stay preventing FDA approval of the involved generic product because, as an agency decision, it is not binding on the district court unless and until it is finally affirmed on appeal.

---

[86] Dennis Crouch, *The Silent Circuit: The Growing Backlash Against Rule 36 No Opinion Judgments from the Federal Circuit*, Patently-O (Dec. 11, 2024), https://patentlyo.com/patent/2024/12/circuit-backlash-judgments.html.

[87] Dan F. Klodowski et al., Finnegan, *Federal Circuit Appeal Statistics for June 2024* (Aug. 22, 2024), https://www.finnegan.com/en/insights/blogs/at-the-ptab-blog/federal-circuit-ptab-appeal-statistics-for-june-2024.html (further reporting mixed outcomes in 124 (9.94%) cases and 38 dismissals without rendering a decision on the merits).

[88] In Hatch-Waxman district court proceedings, the parties and the courts seek to complete the proceedings prior to expiration of the 30-month stay, and IPRs need to be completed within 24 to 36 months of the district court infringement case. IPR petitions must be filed by accused infringers within 12 months of being sued for infringement, institution must be decided within 6 months from petition filing, and if instituted, the PTAB must issue its final written decision within 12 to 18 months. With these statutory timelines, judges tend not to stay litigation for an IPR proceeding as it could delay completion of the litigation. PTAB data confirms that the IPR petitions challenging Orange Book patents have most often been filed after the petitioner has been sued in Hatch-Waxman litigation. *See* USPTO, *Orange Book Patent/Biologic Patent Study and District Court Pharma Litigation Study*, at 10 (Jan. 2020), *available at* https://www.aipla.org/docs/default-source/committee-documents/bcp-files/2020/jan28mtg/orange-book-and-biologics-presentation-(2020-01-14)-final-(with-slide-nos).pdf (finding that 95% of Orange Book AIA petitions were filed after litigation started).

B. Prior Uses and Sales as Prior Art Under the AIA

A principal purpose of the AIA was to harmonize U.S. patent law with that of foreign countries, particularly Europe, by replacing the existing U.S. "first-to-invent" system with a "first-to-file" system. While the U.S. had always had a "first-to-invent" system for determining entitlement to a patent, it was and is common outside the U.S. for the entitlement to a patent to be based on being the first person to file a patent application claiming the invention. Downsides of the U.S. "first-to-invent" system are that neither the patent applicant nor the USPTO is likely to know at the time of patent examination that someone else has previously made or was making a commercial use or sale of the invention, meaning that a patent issuing on the invention is subject to later invalidation due to information that was not available to the public at the time of patent examination. This injects considerable uncertainty into decisions to be made about whether to develop a new invention, as the probability that patent protection might fail is an important factor in deciding whether to invest in the needed research, development, and testing needed to bring the invention to market.

To make patent protection more reliable, a goal of the AIA was to switch to a first- to-file system to prohibit the use of evidence of anyone else's prior invention, use, or sale of the claimed subject matter unless that evidence was available to the public as of the effective filing date of the claimed invention. Accordingly, section 102(a) of title 35 was amended by the AIA to prohibit the patenting of any claimed invention that "was patented, described in a printed publication, or in public use, on sale*, or otherwise available to the public* before the effective filing date of the claimed invention."

In the 2019 case, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, the U.S. Supreme Court considered whether "the sale of an invention to a third party who is contractually obligated to keep the invention confidential nonetheless placed the invention 'on sale' within the meaning of the AIA's rewording of § 102(a)."[89] The Court concluded that the AIA's added phrase "otherwise available to the public" did not alter the meaning of the "on sale" language of section 102(a) and that therefore a prior sale that does not make the details of the invention available to the public may still qualify as prior art. [90]

In reaching its conclusion in *Helsinn*, the Court does not appear to have considered the congressional record clearly indicating that the AIA's reworded section 102(a) provisions were designed to limit prior art to information that had previously been disclosed to the public,[91] or to the AIA's creation of a new

[89] *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 586 U.S. 123, 125 (2019).

[90] *Id.* at 125, 132.

[91] *See* 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy) ("[S]ubsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale . . . may be deemed patent-defeating prior art.").

defense to patent infringement based on an accused infringer's prior secret commercial uses or sales. [92] Had Congress intended prior secret uses or sales that were not available to the public to qualify as prior art, the AIA's new prior user defense would have been unnecessary, as such prior uses and sales would already have been prior art available to invalidate the asserted patent. The *Helsinn* decision thus continues to thwart one of the primary objectives of the AIA—to improve patent reliability by ensuring that patents may not later be invalidated by evidence of prior inventions, uses, or sales that were secret and thus unknowable and unknown to the USPTO at the time of the patent's original examination.[93]

VI. Impacts of the Inflation Reduction Act on Biopharmaceutical Innovation

The Inflation Reduction Act ("IRA") was signed into law on August 16, 2022.[94] The IRA created the "Drug Price Negotiation Program" ("Program"). Under the IRA, the Centers for Medicare and Medicaid Services ("CMS") selects drugs for the Program, and these drugs will then be subjected to a government-mandated "maximum fair price." The IRA imposes what some call the "pill penalty," in which a drug approved in an NDA may be selected for negotiation earlier than a biological product—seven rather than eleven years after approval.[95] Selection thus may occur prior to expiration of the average market exclusivity period after which generics enter the market, which is referenced above. Because the IRA allows selection of a product even if it has remaining patent life, it directly undermines the patent system as well as the value of patent term extension provided by Hatch-Waxman. It also creates a situation in which a drug may be selected while the innovator and generic companies may still be conducting Hatch-Waxman patent litigation, thereby disrupting both parties' expectations. The IRA also undermines incentives to develop generic and biosimilar drugs by requiring their manufacturers to compete with an already low government-set "maximum fair price."

---

[92] 35 U.S.C. § 273 (providing an infringement defense under § 282(b) for commercial use of the claimed subject matter in the United States more than a year before the effective filing date (or public disclosure date) of the asserted patent). Such a defense pertains to a person who commercially used the subject matter in the U.S., either in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer or a non-informing useful end result of such a commercial use.

[93] *See Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1344 (Fed. Cir. 2007).

[94] U.S. Dep't of the Treasury, *Inflation Reduction Act*, https://web.archive.org/web/20250103165807/https://home.treasury.gov/policy-issues/inflation-reduction-act (last visited Nov. 20, 2024).

[95] *See* Social Security Act § 1192(e)(1) (codified at 42 U.S.C. § 1320f-1).

The IRA provides that a drug is not eligible for selection if it is the listed drug or reference product for a "marketed" generic drug or biosimilar product,[96] thereby signaling that Congress prefers market-based competition to price setting where available. CMS has undermined this intent, however, by interpreting "marketed" to require "bona fide marketing" and imposing an unpredictable "totality of the circumstances" standard for assessing bona fide marketing.[97]

Moreover, due to the shorter timeframe on the market for small molecule drugs relative to biologics before the implementation of the government-set price, the "pill penalty" especially discourages the development of these critical treatments. The ability for these drugs to cross the blood-brain barrier also makes them critical in the treatment of disease with therapeutic targets inside the brain—including illnesses that impact the central nervous system, mental health conditions, neurodegenerative diseases, and much more. Additionally, given the relatively shorter exclusivity timeframe for small molecules, the pill penalty also particularly jeopardizes the post-approval research and development that is necessary to realize their full therapeutic potential. In fact, one analysis by researchers at the University of Chicago found the IRA's price setting provisions would translate to a total of 79 fewer small molecule drugs and 188 fewer post-approval indications over the next 20 years.[98]

Overall, the IRA significantly damages incentives for pharmaceutical innovation and undermines the Hatch-Waxman compromise for both innovators and generics.

VII. Impacts of Supreme Court Rulings on Life Sciences Innovation

In a series of cases addressing patent-eligible subject matter, the Supreme Court has decided that inventions "directed to" "laws of nature," "natural phenomena," and "abstract ideas" should not be eligible for patenting. Patent cases seeking invalidation based upon the section 101 patent eligibility criteria were virtually unheard of until about 2010, when the Supreme Court began chang-

---

[96] *See id.* (defining a qualifying single source drug as a drug or biological product that is not the listed drug for an approved and marketed generic drug or biosimilar product, respectively).

[97] *See id.* § 1192(c)(1)(B); *see also* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 170 (Oct. 2, 2024), *available at* https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (interpreting "marketing" as meaning "bona fide marketing").

[98] *See* Tomas J. Philipson et al., Univ. of Chi., *Policy Brief: The Potentially Larger Than Predicted Impact of the IRA on Small Molecule R&D and Patient Health*, at 6 (Aug. 25, 2023), *available at* https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2024/06/Small-Molecule-Paper-20240625.pdf.

ing patent eligibility policy in a series of decisions that culminated in *Alice Corporation Party Ltd. v. CLS Bank International*.[99] Together with the decisions in *Bilski v. Kappos*,[100] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[101] and *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[102] the *Alice* decision sparked a firestorm of invalidity challenges based solely on patent eligibility grounds that soon engulfed not only software patents, but also patents covering medical diagnostics, genomic inventions, and many other types of invention that are critical to American innovation and global competitiveness.

Such judicially created exceptions to statutorily-defined patent eligible subject matter are inappropriate because our Constitution vests the responsibility for defining the scope of what is patentable subject matter in Congress alone.[103] Congress fulfilled this responsibility when it enacted 35 U.S.C. § 101 and has not ceded authority to the Supreme Court or to the judiciary more generally to rewrite this definition or create whatever exceptions to it the Court might wish. But the Supreme Court created such exceptions, and experience has shown that it was ill-suited to the task. As the Supreme Court itself recognized in its *Alice* decision:

> At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, "all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.[104]

Yet the courts did not "tread carefully." And while the Supreme Court's exclusionary principles have not yet "swallow[ed] all of patent law," they have expanded them to the point that no one in the IP profession can now predict with certainty whether any given invention that relies in any way upon a law of nature, natural phenomenon, or abstract idea, or that utilizes naturally derived material will be ultimately held patent eligible.[105] Unfortunately, there

---

[99] 573 U.S. 208 (2014).

[100] 561 U.S. 593 (2010).

[101] 566 U.S. 66 (2012).

[102] 569 U.S. 576 (2013).

[103] Article I, section 8 of the U.S. Constitution provides that "[t]he Congress shall have the Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."

[104] *Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 71).

[105] *The State of Patent Eligibility in America: Part I Before the Subcomm. on Intell. Prop. of the U.S. S. Comm. on the Judiciary*, 116th Cong. (June 4, 2019), *available at* https://www.

are now many examples where the confusion created by the Supreme Court has resulted in meritorious discoveries and inventions being held patent ineligible.[106] For example, the International Trade Commission recently found that a composition of matter patent directed to polycrystalline diamond compacts, which are used in drilling applications, is invalid under section 101; this decision is currently on appeal before the Federal Circuit.[107]

The Federal Circuit also continues to find patents covering medical diagnostics to be ineligible for patenting.[108] This worrying trend prompted one judge on that court to remark: "The majority's broad pronouncement of ineligibility of medical treatment that relates to human physiology not only contravenes precedent, but contravenes the national interest in achieving new methods of medical treatment with the assistance of the patent incentive."[109]

VIII. Proposals to Correct or Improve Incentives to Achieve the Hatch-Waxman Objectives of Stimulating Both New Biopharmaceutical Innovation and Generic Drug Utilization

Fortunately, a variety of suggestions and proposals have been advanced for improving our patent system, including the role that Hatch-Waxman plays in current drug and medical device innovation.

A. Senator Hatch's Proposed Hatch-Waxman Integrity Act

The frequent use of IPR petitions used alongside Hatch-Waxman litigation has raised substantial questions about the fairness and appropriateness of such proceedings in the context of Hatch-Waxman and the BPCIA and whether such peti-

judiciary.senate.gov/committee-activity/hearings/the-state-of-patent-eligibility-in-america-part-i (testimony of Paul R. Michel, Former Chief Judge, U.S. Court of Appeals for the Federal Circuit) (stating, at 00:21:40 to 00:22:13: "The most fundamental problem . . . is unpredictability. I spent 22 years on the Federal Circuit and 9 years since dealing with patent cases, and I cannot predict in a given case whether eligibility will be found or not found. If I can't do it, how can bankers, venture capitalists, business executives, and all the other players in the system make reliable predictions and sensible decisions?").

[106] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (stating that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry"); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 757 (Fed. Cir. 2019) (methods for diagnosing neurological disorders by detecting antibodies to a protein called muscle specific tyrosine kinase found ineligible for patenting).

[107] *See U.S. Synthetic Corp. v. ITC*, No. 23-01217 (Fed. Cir.) (oral argument held Oct. 9, 2024).

[108] *See, e.g.*, *CareDx, Inc. v. Natera, Inc.*, 40 F.4th 1371, 1381 (Fed. Cir. 2022) (methods for predicting organ transplant rejection using cell-free DNA found ineligible for patenting).

[109] *INO Therapeutics v. Praxair Distrib. Inc.*, 782 F. App'x 1001, 1017 (Fed. Cir. 2019) (Newman, J., dissenting).

tions alter the balance of the statutory frameworks. Senator Hatch introduced the Hatch-Waxman Integrity Act of 2018 (S. 2738) to address such concerns. The bill would have required generic and biosimilar company patent challengers to choose one pathway for the challenge, not both the district court and the PTAB.

B. Improvements to the PGR and IPR USPTO Patent Challenge Process

1. Restore the Applicability of the 35 U.S.C. § 146 Appellate Process to IPRs and PGRs

As discussed above, serious questions exist about the fairness of PTAB proceedings for patent owners and the ability of any abbreviated and expedited proceeding such as PGR or IPR to adequately provide the due process protections to which a patent owner is entitled. Because subpoenas are not available in PTAB proceedings to compel opposing or third-party witnesses to testify live, patentees are now foreclosed from discovering and introducing important evidence relating to the non-obviousness of their inventions. They are also deprived of having important fact and expert witness credibility determinations made on the basis of live testimony before an independent Article III judge or jury rather than by administrative patent judges who make decisions based on written evidentiary submissions.[110] Finally, and perhaps most importantly, inventors do not feel they are getting their day in court since in IPRs and PGRs where obviousness is an issue, they do not have an opportunity to testify live to an Article III judge (or to a jury of their peers) about secondary considerations of non-obviousness—i.e., the origin of their invention, the long felt need for their invention, the failures of others to satisfy the need for the invention, the invention's commercial success, the copying of the invention by others, or tributes that have been paid to the invention, each of which must be considered in determining obviousness when present.[111]

The traditional way to address due process issues relating to such USPTO board decisions has been to rely on an appeal process that allows any party aggrieved by a final decision of the board to appeal *de novo* to the district courts, where such constitutional concerns may be addressed and additional evidence received, as appropriate.

---

[110] Prior to the AIA, 35 U.S.C. § 146 allowed aggrieved parties in contested USPTO proceedings, such as interferences, to appeal first to a district court, where in addition to the evidence admitted and conclusions reached by USPTO, additional evidence and arguments were routinely considered in finally deciding the matter. Were appeals to be authorized in the 85% of IPR cases where companion infringement cases involving the same patent are already pending, many of these disputes would be resolved at the district court level, substantially reducing the number of appeals now going to the Federal Circuit.

[111] These objective indicia of non-obviousness must be considered in every case where present. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc); *see also Graham v John Deere Co.*, 383 U.S. 1, 16-18 (1966).

Congress could and should modify section 146 of the Patent Act, 35 U.S.C. § 146, to restore the right of a patent owner to appeal *de novo* to the district courts, as they could do for decades in patent interference proceedings (and still may do for other contested proceedings, including prior public use and derivation proceedings). This appeal pathway would not only provide meaningful appellate review but also would lessen the appellate burden on the Federal Circuit and encourage harmonization of the law applied by the PTAB with that used in federal district court proceedings.

2. Pass Legislation to Improve Perceived IPR Unfairness

The Promoting and Respecting Economically Vital American Innovation Leadership Act (the "PREVAIL Act")[112] would further address fairness issues for patentees in any technology. The PREVAIL Act would harmonize the standards, burdens, and presumption of validity in PTAB proceedings with those in district court; address issues of abuse involving serial, duplicative, and parallel petitions; and require petitioners to choose between PTAB and other forums for challenging a patent's validity. It would require the USPTO to establish a code of conduct for PTAB judges and prohibit judges who participated in instituting a proceeding from participating in deciding its outcome. The PREVAIL Act would also establish a standing requirement limiting IPR petitioners to certain commercially independent non-profits, to those willing to certify that due to their ongoing or future planned conduct they may reasonably be accused of infringement, to those who have already been sued for infringement, or to those who would have district court standing corresponding to that required in court when seeking a declaratory judgment of non-infringement. For PGRs, the ability of anyone other than the patent owner to petition to institute a PGR would be maintained. Thus far, the PREVAIL Act has been voted out of the Senate Judiciary Committee, but will need to be reintroduced, likely with amendments, in the next Congress.

3. Pass Patent Eligibility Reform

The Patent Eligibility Restoration Act ("PERA") seeks to clarify and reform the law on patentable subject matter.[113] The bill eliminates all judicial exceptions to patent eligibility while codifying five categories of things that are not patent eligible. These categories include (1) mathematical formulas other than those that are part of a useful invention or discovery; (2) certain processes, e.g., "a process that is substantially economic, financial, business, social, cultural, or artistic, even though not less than 1 step in the process refers to a machine or manufacture";[114] (3) unmodified human genes as they exist in the human body; and (4) unmodified natural materials as they exist in nature.

---

[112] S. 2220, 118th Cong. (2023).

[113] S. 2140, 118th Cong. (2023) ("PERA").

[114] Other excluded processes are any processes that are (i) a mental process performed solely in the human mind, and (ii) processes that occur in nature wholly independent of, and prior to, any human activity. PERA § 101(b)(1)(B)(i)-(iii).

Arguably, the enumeration of these eligibility exceptions is unnecessary, as 35 U.S.C. § 101 already specifies that the patentability of all discoveries and inventions also further requires that to be patentable they must also comply with the other "conditions and requirements of this title." Principal among these are the requirements of novelty, non-obviousness, and written description and enablement.[115] PERA also provides clear procedural rules for considering patentable subject matter challenges, ensures that courts will have the ability to authorize and consider discovery relevant to patent eligibility, and, when there are no genuine issues of material fact, to rule on motions relating to eligibility at any time.[116] The changes proposed in PERA would be welcome steps toward enhancing administrability of patentable subject matter eligibility jurisprudence, increasing predictability and confidence in the U.S. patent system, and incentivizing technological innovations to solve the major problems of the modern world.

4. Other Needed Changes

Other needed legislative changes have not yet been introduced to address the problems discussed above. Among these are the need to provide that Hatch-Waxman infringement cases may be brought in a single jurisdiction against all ANDA applicants who submitted a Paragraph IV certification relating to the drug product involved. Also needed are reversal of the provisions of the Inflation Reduction Act to ensure the practical effects of the full terms of patent and regulatory exclusivity for new drug products and reversal of the Supreme Court's *Helsinn* decision to make it clear that prior secret commercial uses or sales may not be used to invalidate a later-issued patent.

Finally, additional remedial work is needed if PGR and IPR proceedings are to be maintained. Such remedial work would be intended to further balance the fairness of these proceedings so that both sides of these disputes have good reason to believe that they have been treated fairly. To accomplish this, it will be important for the USPTO to reconcile the clear differences between patentability determinations made by patent examiners and those being made by the PTAB. This reconciliation may be accomplished by returning responsibility for PGR and IPR institution to the executive function of the USPTO, i.e., to the Director and the patent examiners. Once *de novo* appeals are reinstated, the PTAB will be in a better position to improve its procedures knowing that any shortcomings caused by short timelines and limited scope may, if needed, be remedied by the district courts on *de novo* appeal.

---

[115] *See* 35 U.S.C. §§ 102, 103, 112.

[116] *See* PERA § 101(c)(1)-(2).

IX. Conclusion

Hatch-Waxman is one of the most important and successful pieces of legislation enacted in the twentieth century. And while the world has changed dramatically since 1984, Hatch-Waxman continues to propel the U.S. to be the world's leader both in the development of important new life sciences inventions and, after appropriate periods of exclusivity, in providing widespread and low-cost access to generic drugs.

Ensuing developments, as discussed above, have nonetheless changed the technological and patent landscape, creating a need to update various aspects of our patent laws and practices to preserve U.S. technological leadership. To maintain our leadership position, it is important to act now, as our foreign competitors are already ahead of us in certain technological areas and will eclipse our position if we do not make needed improvements to our system of drug and medical device discovery, development, and commercialization.

About the Author

Phil Johnson is the Principal of Johnson-IP Strategy and Policy Consulting, which he founded after his retirement in February 2017 as Senior Vice President, Intellectual Property Policy and Strategy at Johnson & Johnson. He is Chair of the Steering Committee of the Coalition for 21st Century Patent Reform and an Emeritus Board Member of the Monell Chemical Senses Center. Prior to April of 2014, he was Senior Vice President and Chief Intellectual Property Counsel at Johnson & Johnson.

Before joining Johnson & Johnson in 2000, Phil was a Partner and Co-chair of IP litigation at Woodcock Washburn in Philadelphia. During his time in private practice, Phil served as trial counsel in countless IP disputes, including cases resolved by arbitration, bench trials, jury trials, and appeals.

Phil previously served as the Chair of the Board of American Intellectual Property Law Education Foundation (now the Foundation for the Advancement of Diversity in IP Law), as President of the Intellectual Property Owners Association, as President of INTERPAT, as President of the Association of Corporate Patent Counsel, as President of the Intellectual Property Owners Education Foundation, as Chair of PhRMA's IP Focus Group, and as a Board Member of the American Intellectual Property Law Association.

Phil's awards include the Woodcock Prize for Legal Excellence, the New Jersey Intellectual Property Law Association's Jefferson Medal, the Philadelphia Intellectual Property Association's Distinguished Intellectual Property Practitioner award, induction into the International IP Hall of Fame by the IP Hall of Fame Academy, the Intellectual Property Owners Association Carl B. Horton President's Distinguished Service Award, an honorary LL.D. from the University of New Hampshire Franklin Pierce School of Law, and the Judge Pauline Newman Award. Phil received a B.S., cum laude with distinction in Biology from Bucknell University and a J.D. from Harvard Law School.

Hatch-Waxman Enters Its Fifth Decade of Balancing Competing Interests

By J. Derek McCorquindale

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, was passed as a grand compromise that balanced the interests of innovating drug developers while also promoting access to affordable generic products.[1] The Hatch-Waxman Act was designed to address two problems that persisted in the pharmaceutical industry.[2] First, because FDA approval is a lengthy process, much of the patent term for a newly discovered drug was spent before it ever came to market, hindering the innovator's ability to recoup significant investments in research and development.[3] Second, efforts by generic drug manufacturers to develop and obtain approval for their own versions of popular drug products were considered acts of patent infringement.[4] The inability to bring generic drugs to market until long after expiration created a de facto patent-term extension and slowed public access to less expensive products.

The Hatch-Waxman Act addressed both problems by granting the branded pharmaceutical companies, after their FDA approval, a restored period of market exclusivity beyond the regular patent term[5] and by creating a "safe harbor" to exempt manufacturers from infringement liability if their activities are for purposes of FDA approval.[6] The Hatch-Waxman Act also provided an easier approval pathway by creating the Abbreviated New Drug Application ("ANDA").[7] If the generic drug candidate has the same active ingredients and is bioequivalent to a previously approved drug, the ANDA filer may rely on the safety and efficacy data of the innovator. The Hatch-Waxman Act's streamlined ANDA process was intended to make it easier for generic drugs to be approved, saving time and resources.[8]

---

[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[2] *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990).

[3] *Id.*

[4] *Id.*

[5] 35 U.S.C. § 156(a).

[6] 35 U.S.C. § 271(e)(1).

[7] 21 U.S.C. § 355(j).

[8] *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (finding that a critical purpose of the Hatch-Waxman Act was to "speed the introduction of low-cost generic drugs to market"); *see also* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48 ("The purpose . . . is to make available more low cost generic drugs by establishing a generic drug approval procedure . . . .").

The statutory solutions devised by the Hatch-Waxman Act have been largely viewed as a success, demonstrated over decades. After forty years, the generic drug market has grown dramatically and 90 percent of U.S. prescriptions filled are now estimated to be for lower-cost generics and biosimilars.[9] On the flipside, hundreds of new drug products continue to be developed and approved because pioneering pharmaceutical companies can still enjoy predictable terms of patent exclusivity.[10]

The Hatch-Waxman framework that seeks to balance these various interests runs, in significant part, through federal courts overseeing ANDA litigations. In 2024, public records showed over 300 complaints commencing ANDA cases—the great bulk of them in New Jersey and Delaware given that so many generic companies are headquartered or incorporated in those states.[11] The concentration of cases into these two venues means that the assigned judges are very experienced with such disputes—they understand the unique procedures of ANDA litigation and are well-versed in patent law. Because these paragraph IV cases are not tried before juries but to judges, this tends to promote more predictable of outcomes, which in turn allows practitioners to better advise clients. Further, the U.S. Court of Appeals for the Federal Circuit—a court with exclusive jurisdiction over patent appeals in the United States—was established by Congress to ensure decisional uniformity.[12] All of this has contributed to the Hatch-Waxman regime remaining stable and successful through nearly a half century. Notwithstanding, a handful of cases every year carry increased significance, and a few examples of hotly debated questions in 2024 are presented below. They highlight the enduring wisdom of the original Hatch-Waxman compromise and the balance still sought today as modifications are suggested and considered.

---

[9] *See* Jocelyn Ulrich, PhRMA, *40 Years of Hatch-Waxman: What Is the Hatch-Waxman Act?* (Sept. 19, 2024), https://phrma.org/Blog/40-Years-of-Hatch-Waxman-What-is-the-Hatch-Waxman-Act.

[10] *See id*. ("[S]ince 2000, biopharmaceutical companies have brought more than 750 new medicines to patients . . . .").

[11] *See TC Heartland v. Kraft Foods Group Brands LLC*, 581 U.S. 258, 261 (2017) (interpreting 28 U.S.C. §1400(b)); *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1119 n.5, 1120-21 (Fed. Cir. 2021); *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374, 1381-82 (Fed. Cir. 2020).

[12] *See* 28 U.S.C. § 1295. In 1982, Congress passed the Federal Courts Improvement Act, Pub. L. No. 97-164, § 165, 96 Stat. 25, 50 (1982), creating the Federal Circuit with the intention of achieving uniformity and reducing forum shopping in patent cases. *See* S. Rep. No. 97-275, at 3-6 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 13-16.

"Skinny" Labeling

A "skinny label" is an FDA-approved label for a generic drug product that covers unpatented indications while "carving out" still-patented methods of use.[13] The Hatch-Waxman Act prescribes the process for obtaining such skinny labels so that generic drugs may be approved by the FDA for uses not protected by patents.[14] If and when the ANDA is approved, the generic applicant will be limited to indications included on its so-called "skinny label" and will be able to launch its product *without infringing* the remaining method patent, where applicable. Recent articles have suggested that "43% of drugs will have generic versions with a skinny label" and that such carve-out approvals "generated nearly $15 billion in Medicare savings from 2015 to 2020 . . . ."[15]

After the Federal Circuit's decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* ("*GSK*"),[16] however, there was widespread concern that the prior practice of skinny labeling pursuant to section viii was in jeopardy.[17] In *GSK*, the Federal Circuit reversed the district court's judgment of non-infringement as a matter of law and reinstated a jury verdict holding—despite a skinny-label carve out—that Teva had induced infringement of GSK's patented method of use under 35 U.S.C. § 271(b).[18] The jury received evidence of Teva's promotional materials and other communications indicating that it intended for the generic drug to be prescribed for use in still-patented methods.[19] The evidence was deemed sufficient to demonstrate that "promotional materials referred to Teva's carvedilol tablets as AB rated equivalents of the [GSK-branded] Coreg® tablets."[20] On appeal, the Federal Circuit found the jury verdict supported by substantial evidence, holding that these promotional

---

[13] *See* 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii").

[14] *Id*.; *see* 21 C.F.R. § 314.94(a)(8)(iv).

[15] *See* Laura Joszt, *Competition from Skinny-Label Generics Saved Medicare Nearly $15B over 5 Years*, Am. J. Managed Care (Apr. 29, 2024) (citing Alexander C. Egilman et al., *Estimated Medicare Part D Savings from Generic Drugs with a Skinny Label*, 177 Annals Internal Med. 833 (2024), and Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181 JAMA Internal Med. 995 (2021)), https://www.ajmc.com/view/competition-from-skinny-label-generics-saved-medicare-nearly-15b-over-5-years; *see also infra* note 25; *cf.* Sara W. Koblitz, *Ding Dong Is the Skinny Label (Effectively) Dead?*, FDA Law Blog (Sept. 7, 2021), https://www.thefdalawblog.com/2021/09/ding-dong-is-the-skinny-label-effectively-dead.

[16] 976 F.3d 1347 (Fed. Cir. 2020), *aff'd in part and vacated in part on reh'g*, 7 F.4th 1320 (Fed. Cir. 2021).

[17] *See supra* note 15.

[18] *GlaxoSmithKline*, 976 F.3d at 1348.

[19] *Id*. at 1350-51.

[20] *Id*. at 1353.

materials induced infringement of GSK's still-active patent.[21] The panel majority rejected Teva's argument that "since it had omitted ('carved out') from its initial (2007) label the indication and prescribing information for treatment of congestive heart failure [i.e., the still-patented method], citing the carve-out authorization in 21 U.S.C. § 355(j)(2)(A)(viii), then Teva could not be found to induce prescribing physicians to infringe the . . . patent."[22] The court disagreed and held that despite the skinny label, Teva still induced infringement through its promotional materials.[23]

In dissent, then–Chief Judge Prost wrote to "reject[] the Majority's nullification of Congress's provision for skinny labels" and reiterated the view that Congress "specifically designed the statutory scheme governing drug approval such that one patented use would not foreclose a generic from marketing a drug for other unpatented uses."[24] Numerous publications following the *GSK* decision suggested that clarification and a statutory fix might be required to save the skinny label.[25] Recent cases, however, have distinguished *GSK* and demonstrate that the perceived threat to skinny labeling is still likely manageable within the current Hatch-Waxman framework.

On December 7, 2023, for example, *H. Lundbeck A/S v. Lupin Ltd.* held that a skinny-label drug manufacturer was not liable for infringing method-of-use claims where the product's promotional and advertising activity did not induce infringement.[26] In that case, the plaintiff obtained NDA approval of the branded drug Trintellix® (vortioxetine) for treating major depressive disorders, as well as U.S. Patent No. 7,144,884 ("the '884 patent") for the compound vortioxetine and U.S. Patent No. 8,476,279 ("the '279 patent") for the method of use to treat depression.[27] After approval of the NDA, the innovator company obtained two additional patents that would expire much later and claimed methods of use for treating depression in patients previously taking

---

[21] *Id.* at 1356 ("We conclude that there was substantial evidence to support the jury's findings of induced infringement, throughout the term of the . . . patent, on the entirety of the documentary and testimonial record concerning liability before and after Teva amended its label.").

[22] *Id.* at 1350.

[23] *Id.* at 1353-57.

[24] *Id.* at 1359-60 (Prost, C.J., dissenting).

[25] *See* S. Sean Tu & Aaron Kesselheim, *Preserving Timely Generic Drug Competition with Legislation on "Skinny Labeling,"* 115 Clinical Pharmacology & Therapeutics 22 (2024); Kevin J. Hickey, Cong. Rsch. Serv., "*Skinny Labels" for Generic Drugs Under Hatch-Waxman* (Dec. 27, 2024), *available at* https://crsreports.congress.gov/product/pdf/IF/IF12700; *see also supra* note 15.

[26] 87 F.4th 1361 (Fed. Cir. 2023).

[27] *Id.* at 1366.

other depression medications but forced to stop due to adverse side effects.[28] Several generic companies subsequently filed ANDAs seeking approval to treat depression using vortioxetine according to the method of the '279 patent upon its expiration. The generic ANDAs also included a skinny label that carved out the methods of use covered by the branded company's two *additional* patents not set to expire for some time. An infringement suit followed, alleging that because physicians would inevitably prescribe generic vortioxetine to treat depression according to the methods of the unexpired patents, there would be indirect infringement under 35 U.S.C. § 271(b)-(c).[29]

On appeal, the Federal Circuit explored the limits of the intent requirement for induced and contributory infringement in Hatch-Waxman litigation.[30] The Federal Circuit found no contributory infringement, affirming the district court's conclusion that "the existence of substantial noninfringing uses," i.e., the uses described in the expiring patents, demonstrated no liability under 35 U.S.C. § 271(c).[31] The court also found that "plaintiffs' inducement case relied solely on defendants' proposed ANDA labels as the inducing conduct"[32] and that the proposed label did not induce infringement. The court further distinguished the case at hand, deeming it fundamentally "unlike *GlaxoSmithKline* . . . and other cases where we have found infringement based on communications outside the ANDA label."[33] The Federal Circuit thus affirmed the district court: "[W]e do not see how, in the normal course, a label required to market the drug for a use covered by expired patents could demonstrate the required specific intent to encourage infringement of new patents covering different uses."[34] At bottom, explained the court, if "a patentee can bar the sale of a drug for a use covered only by patents that will have expired simply by securing a new patent for an additional, narrower use," then "[s]uch an approach to indirect infringement would be inconsistent with the stated purpose of the Hatch-Waxman act—'to enable generic manufacturers to be ready to enter the market once patents expired.'"[35] Thus, as *H. Lundbeck* explains, as long as there are not

---

[28] *Id.*

[29] *See id.*

[30] *See generally id.* at 1368-73.

[31] *Id.* at 1373.

[32] *Id.* at 1370.

[33] *Id.* (citing *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1333 (Fed. Cir. 2021)).

[34] *Id. But see id.* at 1371 (collecting cases) ("If FDA requires, in order to protect patient safety, that the new method of use must be included in the label, the ANDA label may induce infringement of the new safety patents . . . . This is not such a case.").

[35] *Id.* at 1370 (quoting *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1357 (Fed. Cir. 2003)); *see also id.* (adding that "[a] patentee may not use Hatch-Waxman to 'maintain its

communications outside the label itself to demonstrate a generic developer's intent to induce infringement, in most cases a proper skinny label will not lead to a finding of infringement. This analysis has held in subsequent cases.[36]

While some advocate—including in Congress—for more robust inducement protections in skinny-label practice following *GSK*,[37] the recent case law appears to have drawn clear lines and workable distinctions under the current statutory scheme for skinny labeling. In the absence of a legislative fix, litigators must now be aware of and consider intent in various contexts.

"Safe Harbor" Activities

Another core feature of the Hatch-Waxman Act was to offer companies a "safe harbor" against what would otherwise constitute infringing activity, "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 . . . ."[38] This statutory protection was intended to close the gap between the end of patent protection and subsequent FDA approval of other market entrants.[39] The Supreme Court has interpreted section 271(e)(1) to "provide[] a wide berth for the use of patented [inventions] in activities related to the federal regulatory process."[40] Recently, in *Edwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd*, the Federal Circuit rearticulated that "[t]he exemption applies 'as long as there is a reasonable basis for believing' that the use of the patented invention will produce the types of information that are relevant to

exclusivity merely by regularly filing a new patent application claiming a narrow method of use not covered by its NDA'" (quoting *Warner-Lambert*, 316 F.3d at 1359)).

[36] *E.g.*, *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1377-81 (Fed. Cir. 2024) (reversing a threshold rule 12(b)(6) dismissal because the complaint sufficiently alleged induced infringement due to repeated public statements beyond the carve-out label and navigating precedents in *GSK* and *H. Lundbeck*).

[37] Proposed legislation for expanding skinny label protections is in the works, with a bill introduced in December 2024. *See Skinny Labels, Big Savings Act*, *available at* https://www.hickenlooper.senate.gov/wp-content/uploads/2024/12/Skinny-Labels-One-Pager.pdf.

[38] 35 U.S.C. § 271(e)(1).

[39] *See* H.R. Rep. No. 98-857, pt. 1, at 45-46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678-79 ("The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.").

[40] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (explaining further that "it [is] apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Federal Food, Drug, and Cosmetic Act]").

an FDA submission."[41] The Federal Circuit affirmed the district court's determination that the safe harbor applied in *Edwards* and held the court did not err in granting summary judgment under the undisputed facts.[42] There, Meril Life Sciences Ltd. imported two transcatheter heart-valve systems into the United States, and the question was whether this otherwise infringing act was protected under section 271(e)(1). The *Edwards* court noted that Meril had previously taken steps towards obtaining FDA approval for its transcatheter heart valves, communicated with the FDA regarding a proposed clinical study, and hired an FDA consultant to help.[43] Additionally, the court found that "Meril transported the medical device to [the 2019 Transcatheter Cardiovascular Therapeutics Conference in San Francisco], which was attended by a large number of potential clinical trial investigators," but that "no sales or offers for sale were made."[44] Given these facts, the Federal Circuit agreed that "Meril had taken significant steps towards obtaining FDA approval" and that "importation of the transcatheter heart valves constituted another step in the right direction 'on the road to regulatory approval.'"[45] The panel majority deemed that even if the devices were never used upon importation, "our interpretation of § 271(e)(1) applies the safe harbor regardless of the defendant's intent or purpose behind the otherwise infringing act."[46]

Judge Lourie dissented, focusing on the word "solely" to argue that Federal Circuit jurisprudence had strayed from the plain language of section 271(e)(1).[47] Whereas the majority held that "[i]t is not that the use must *only* be reasonably related to the development and submission of information to the FDA," the dissent opined "that 'solely' creates a safe harbor *only* for uses, sales, and importations that solely are for, as the statute says, development of information for the FDA."[48] Judge Lourie concluded that en banc clarification of the law was needed, and that on these particular facts he would have reversed because "the importations occurred, at least partially, for commercial reasons and thus were not entitled to safe harbor."[49] The Supreme Court recently denied certiorari.[50] Courts

[41] 96 F.4th 1347, 1351-52 (Fed. Cir. 2024) (alteration in original) (quoting *Merck KGaA*, 545 U.S. at 207-08), *cert. denied*, No. 24-428, 2025 WL 76453 (U.S. Jan. 13, 2025).

[42] *Id.* at 1353.

[43] *Id.*

[44] *Id.* (citation omitted).

[45] *Id.* (quoting *Merck KGaA*, 545 U.S. at 207).

[46] *See id.* at 1356.

[47] *Id.* at 1357 (Lourie, J., dissenting).

[48] *Compare id.* at 1353 (majority op.) (emphasis in original), *with id.* at 1357 (Lourie, J., dissenting) (emphasis added).

[49] *Id.* at 1362 (Lourie, J., dissenting).

[50] *See Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd.*, No. 24-428, 2025 WL 76453 (U.S. Jan. 13, 2025).

have generally adhered to a broad view of the "safe harbor" under section 271(e)(1)—especially in view of far more limited experimental-use defenses in U.S. law—and such statutory interpretation is well within the expertise of Article III judges given the clear purposes expressed in the Hatch-Waxman Act.

Hatch-Waxman Litigation and Post-Grant Proceedings

Another well-known feature of the Hatch-Waxman Act is the mechanism for triggering patent litigation and the accompanying 30-month stay of ANDA approval.[51] Under the statute's framework, a paragraph IV certification made by an ANDA filer is an artificial act of infringement permitting the patent owner to bring suit within 45 days of receiving notice.

The 30-month stay was once thought a reasonable and even generous amount of time for the average patent litigation to determine validity. However, since the establishment of the Hatch-Waxman framework, post-grant proceedings at the Patent Trial and Appeal Board ("PTAB") have also become commonplace pursuant to the Leahy-Smith America Invents Act ("AIA") of 2011.[52] These new AIA proceedings allow patentability to be challenged and have a statutory timeline of 18 months. And although post-grant proceedings, such as *inter partes* review ("IPR"), occur in conjunction with Hatch-Waxman litigation less frequently than with traditional patent cases, it can still happen. District court cases are often stayed while PTAB matters are pending, but the clock on the 30-month stay provided by the Hatch-Waxman framework keeps ticking.

Courts have addressed whether the 30-month stay should be extended due to a stay for IPR and have decided against tolling this litigation deadline pending an IPR. In *Eli Lilly & Co. v. Accord Healthcare, Inc.*, the district court denied the plaintiff's request for an extension of the 30-month stay after the court decided to stay the case pending IPR.[53] The court explained that the only justification for extension of the 30-month stay provided in the Hatch-Waxman Act is an extension under 21 U.S.C. § 355(j)(5)(B)(iii), which allows the court to grant an extension if a party has "failed to reasonably cooperate in expediting the litigation."[54] The court found that the filing of an IPR did not amount to a failure to reasonably cooperate and denied the request for an extension of the 30-month stay, noting that "Congress did not tie resolution of the patent litigation to approval of the product."[55]

---

[51] *See* 21 U.S.C. §355(j)(5)(B)(iii) (providing for a 30-month stay).

[52] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

[53] No. 1:14-cv-00389-SEB-TAB, 2015 U.S. Dist. LEXIS 166106 (S.D. Ind. Dec. 11, 2015).

[54] *Id.* at 11 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

[55] *Id.* at 10-11.

Congress could consider, due to the rise of AIA post-grant proceedings at the PTAB, whether the Hatch-Waxman Act—designed as a balanced and comprehensive system for litigating in this space—should be amended to either exempt patents implicated in ANDA disputes from the competing regime, or at least allow the possibility of extending or tolling the 30-month stay during PTAB proceedings.[56] Additional proposals have suggested that the Director of the USPTO could simply use administrative discretion to decline institution in such complicated co-pending cases. But there is little consensus and only sparse need for action at present.

Conclusion[*]

As the Hatch-Waxman Act enters its fifth decade, courts still frequently look to the drafters' original intent to simultaneously promote innovative drug development and provide more affordable generics. That clear vision continues to guide federal courts as they decide cases under this framework forty years later and strive to balance competing interests.

[56] For example, the proposed Hatch-Waxman Integrity Act of 2018 would have required generics to choose between these paths when challenging branded pharmaceuticals. *See* Hatch-Waxman Integrity Act of 2018, H.R. 7251, 115th Cong. § 2(d) (2018).

[*] The author thanks P. Michael Nielsen for his assistance with this essay. The opinions expressed in this essay are personal and do not reflect the position of Finnegan LLP. This essay is not intended to be a source of solicitation or legal advice from Finnegan attorneys and is for informational purposes only. This information is not intended to create, and receipt of it does not constitute, an attorney-client relationship. Therefore, readers should not take any actions, or refrain from acting, based on information contained herein without first consulting their own attorneys and seeking legal counsel for individualized legal advice.

About the Author

J. Derek McCorquindale is a Partner at the global law firm Finnegan LLP, focusing his practice on patent and other intellectual property litigation at both the trial and appellate levels. He has experience in cases before federal district courts, the Patent Trial and Appeal Board, and the U.S. Court of Appeals for the Federal Circuit, where he has contributed to dozens of appeals and argued successfully as lead counsel. Derek works on cases in a wide range of industries, including pharmaceutical and Abbreviated New Drug Application litigations.

Toward the Next 40 Years of Generic Drugs

By Dan Liljenquist, Maryll Toufanian, and Allan Coukell

Introduction

The Drug Price Competition and Patent Term Restoration Act of 1984—commonly known as "Hatch-Waxman"—was enacted to achieve the complementary goals of ensuring that developers of innovative medicines enjoy a period of market exclusivity to profit from their inventions and supporting the development of a robust generic drugs marketplace to foster competition that will limit high drug prices and expand access to patients. Hatch-Waxman is considered a grand balance of these critically important needs and a durable hallmark of successful bipartisanship.

Other pieces in this volume address the impact of Hatch-Waxman on innovator medicines. This essay focuses on the current generic medicines landscape and on potential Hatch-Waxman updates and other federal policy changes to maintain the law's balance and support a robust and reliable generic medicines industry into the future.

There are two necessary legs of any policy effort to ensure sustained patient access to generic medicines in the U.S.: 1) ensuring Hatch-Waxman statute is modernized to reflect the current and future landscape of generic drug development and review; and 2) addressing key dynamics outside of the Food and Drug Administration ("FDA" or the "Agency") that directly risk the economic viability of the generic marketplace.

Inside FDA: The Need for Hatch-Waxman Modernization

The breadth of the current Hatch-Waxman generic program would be unrecognizable to the statute's drafters in 1984. In FY2024 alone, 740 abbreviated new drug applications ("ANDAs") and 11,809 supplements were submitted to the Agency, and FDA issued 2,270 action letters approving, tentatively approving, or issuing a "complete response."[1] For every such action, FDA must apply both the scientific and intellectual property provisions of the statute. In addition, last year generic drug developers requested 184 meetings or teleconferences and submitted over 3,424 "controlled correspondence" inquiries related to specific aspects of generic drug development. Additional activities to support the generic drug review program include, but are not limited to, inspections, review of Drug Master Files for drug substances, and guidance and regulation development.

[1] FDA, *Generic Drugs Program Activities Report – FY 2024 Monthly Performance*, https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-fy-2024-monthly-performance (last visited Jan. 6, 2025).

The scale of the program should inform policymakers seeking to ensure efficient decision-making and sustained access to generic medicines. Policies aimed at facilitating approval have to be considered in light of their practical impact to the whole program, i.e, whether they can be operationally scaled. Conversely, policies that seem purely administrative could nevertheless have significant positive impact on generic access by freeing up agency resources to redirect into other elements of the program due to the sheer numbers involved. Although generic drug access has been significantly enhanced by resources provided by user fees, there are policy solutions that would add to that access.

To further this end, policymakers should pay particular attention to policies proposed by the FDA each year in the President's annual budget.[2] Because these proposals have been developed by the experts who administer the statute on a daily basis, these recommendations frequently are targeted to make the daily administration of the statute more efficient, rebalance incentives that have been distorted, and directly free up resources to utilize in other priority parts of the generic drug program. These policies, if enacted, would result in more expedient generic drug approvals, broader access for patients, and lower healthcare costs for the U.S.

For example, Hatch-Waxman does not explicitly identify the data and information required to demonstrate sameness for drug-device combination products (of which few existed in 1984). Today, a sizable and growing number of new drug products are drug-device products. FDA has requested explicit authority to ensure that the Agency can efficiently review and approve these products, including authority to approve generics with slight device differences that do not impact the safety or efficacy of the proposed generic product.[3] Congress should provide FDA with the authority to request the scientific data it requires to evaluate drug-device product sameness, similar to the authority Congress provided in 1984 to demonstrate bioequivalence or drug product quality. This will make the requirements for approval transparent, ensure that FDA is asking for data and information as contemplated by Congress, and, as described in more detail below, avoid legal ambiguity that could directly impact FDA's authority to request the necessary scientific information and approve these generic products.

Another FDA proposal that would alleviate burden on both the new and generic drug programs is to streamline FDA's authorities regarding the "three-year" new drug exclusivity afforded to brand companies that conduct clinical

[2] *See, e.g.*, FDA, *FY2025 Legislative Proposals*, *available at* https://www.fda.gov/media/176924/download (last visited Jan. 6, 2025).

[3] *Id.*

studies in support of new uses of previously approved moieties.[4] This is an important incentive in Hatch-Waxman, but the current statute requires FDA to conduct exclusivity analyses for *every* new drug application ("NDA") or supplement that contains clinical data supporting new uses that were essential to approval, regardless of whether the NDA applicant has requested that exclusivity.[5] Removing this burden would free up FDA resources and expedite generic access, as these new drug exclusivity decisions must be made before a generic version of the drug product can be approved.

In addition, the law is unclear whether new safety risk data can qualify a product for additional exclusivity. The same goes for new clinical data that fails to demonstrate efficacy. In keeping with the original intent of the exclusivity provisions,[6] Congress should clarify that neither of these are a qualification for exclusivity. Such a change would again improve patient access to generic drugs.

Notably, in late 2024, Congress signaled its willingness to embrace operational fixes to Hatch-Waxman when lawmakers reached bipartisan agreement to streamline the generic development and review process by providing FDA with explicit authority to disclose confirmatory formulation information to generic drug developers.[7] Under the current law, brand companies have asserted that such information constitutes trade secret disclosure—even though that information is required to be on the drug product labeling. This results in generic drug manufacturers having to submit cycles of proposed formulations through the "controlled correspondence" process that FDA rejects without comment until the generic applicant

---

[4] *Id.*

[5] In FY2023 alone, NDA sponsors submitted 105 efficacy supplements, which represents a rough subset of applications for which a three-year exclusivity analysis would be required. FDA, *Performance Report to Congress: Prescription Drug User Fee Act FY2023*, at 77-78 (2003), *available at* https://www.fda.gov/media/177976/download?attachment. In addition, FDA conducts three-year exclusivity analyses for stand-alone and "505(b)(2)" NDAs for new uses supported by clinical data.

[6] *See* Amend. of Sen. Hatch, No. 3707, Cong. Rec. Aug. 10, 1984, at S10505 ("[T]he amendment clarifies the data release provision and 3-year moratorium for ANDAs [Abbreviated New Drug Applications]. It would protect only those new drug applications which involve new clinical investigations. The effect on changes to existing NDA's would be to restrict coverage to only those alterations, like some changes in strength, indications, and so forth, which require considerable time and expense in FDA required clinical testing.") (second alteration in original); Remarks of Rep. Waxman, Cong. Rec. Sept. 6, 1984, at H9113-14 ("[A] 3-year period of exclusive market life is afforded to nonnew chemical entities. . . . This provision will encourage drugmakers to obtain FDA approval for significant therapeutic uses of previously approved drugs.").

[7] Further Continuing Appropriations and Disaster Relief Supplemental Appropriations Act of 2025, § 903, *available at* https://docs.house.gov/billsthisweek/20241216/CR.pdf.

finally submits the precise formulation. This wastes FDA resources and slows the development and approval process for generic drug manufacturers—counter to Hatch-Waxman's intent. Since 1984, the Agency has confirmed formulation sameness for these products upon ultimate approval, to which the innovator industry cannot object. The new legislation would allow FDA to conduct these sameness evaluations in an efficient and logical manner. This will result in faster development of new generic therapies and significant savings to the American public. This legislation should quickly be reintroduced and enacted in 2025.

In addition to these important operational refinements to Hatch-Waxman, Congress also should act to restore the intellectual property balance between new drug innovation and generic drug access through policies that will reduce gaming by brand manufacturers in efforts to delay generic competition. Take, for example, "skinny labeling." For nearly 40 years, generic manufacturers enjoyed a "safe harbor" under Hatch-Waxman from patent infringement liability for generics that include some approved uses of a drug but "carve out" other patented approved uses from the generic label. However, recent court decisions have brought significant uncertainty to carve-outs by concluding that general statements by generic companies could constitute evidence of induced infringement for a carved-out use even though the generic is marketed with FDA-approved generic labeling without that use. Without explicit authority like that proposed in the *Skinny Labels, Big Saving Act*,[8] generic drug applicants face litigation risk with each carve-out decision. The resulting uncertainty already has caused generic manufacturers not to carve out conditions of use that previously were permitted, directly delaying competition.

Another element of the Hatch-Waxman balance that is primed for recalibration is the intersection of FDA's regulatory decision-making and brand-generic patent litigation in response to the proliferation of patents brand companies obtain years after the original drug substance, drug product, or method-of-use patents are issued. Later-issued patents for drug product formulation changes and for new uses reflect a monopoly-extending strategy commonly referred to as "patent thicketing." Currently, when a generic drug application is submitted, all patents listed by the brand manufacturer can provide a basis of the 30-month stay of the generic application. Congress should amend the statute to provide that only a single patent may be the basis of the 30-month stay, as proposed in S. 4878, *The Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act*.[9] Other listed patents still could be grounds for a patent infringement claim, but would not prevent the generic applicant from obtaining FDA approval and making a decision to market

[8] *Available at* https://www.hickenlooper.senate.gov/wp-content/uploads/2024/12/Skinny-Labels.pdf (last visited Jan. 6, 2025).

[9] *Available at* https://www.congress.gov/bill/118th-congress/senate-bill/4878/text (last visited Jan. 6, 2025).

"at risk" during patent litigation. This approach would maintain the option of a 30-month stay, thus not overturning the apple cart, and would not impact the brand manufacturer's intellectual property protections, which could still be litigated. It would result in faster access to generic drugs and, similar to the operational policies discussed above, would free up related FDA resources for other Hatch-Waxman activities.

Hatch-Waxman recalibration is not limited to provisions that impact brand manufacturers. Hatch-Waxman provides an incentive (180 days of market exclusivity) to the first generic manufacturers that submit a substantially complete ANDA that includes a certification of intent to challenge a related brand patent. Historically, instances arose in which generic manufacturers awarded 180-day exclusivity improperly blocked subsequent generic products from approval. In 2003, Congress narrowed the circumstances under which such blocking can occur by establishing six scenarios under which a 180-day holding applicant "forfeits" their eligibility for exclusivity. Under one of these provisions, 180-day holders that are successful on the merits in patent litigation must market their product within 75 days of the court's decision. Since 2003, however, fewer and fewer patent litigations end with a court decision on the merits; more often, the litigation is settled with the parties agreeing on the date (or event) after which the generic manufacturer can commence marketing.[10] In the President's budget, FDA proposed to expand this "failure to market" forfeiture provision to require the 180-day exclusivity holder to market within 75 days of the market-entry date or event identified in a settlement agreement.[11] This aligns with the original intent of both Hatch-Waxman and the forfeiture provisions: when nothing is stopping market entry by a 180-day exclusivity holder, those applicants should gain the benefit of that exclusivity in a timely fashion. There are additional proposals to amend the forfeiture provisions already before Congress that similarly address gaps, including the BLOCKING Act,[12] which addresses instances in which a first applicant fails to obtain tentative approval[13] after an extended period of time.

[10] Settlements between brand and generic companies can serve a pro-competition purpose by allowing the generic to come to market more quickly. In some circumstances in which the parties settle, generics would not be successful on the merits of their patent challenges. In other instances, it is not economically viable for generic manufacturers to litigate the patent claims fully due to the sheer number of listed patents (the "patent thicket") that would have to be cleared in order to market the product. Therefore, we do not recommend a blanket presumption that such settlements have anticompetitive effect as has been proposed in recent legislation. *See* Preserve Access to Affordable Generics and Biosimilars Act, S.142, 118th Cong. (2023), *available at* https://www.congress.gov/bill/118th-congress/senate-bill/142/text.

[11] FDA, *FY2025 Legislative Proposals*, *supra* note 2.

[12] Bringing Low-Cost Options and Competition while Keeping Incentives for New Generics Act, *available at* https://www.thefdalawblog.com/wp-content/uploads/2024/12/TAM22B68_Final.pdf (last visited Jan. 6, 2025).

[13] "Tentative approval" signals FDA's determination that an ANDA meets the scientific requirements for approval but cannot be approved due to blocking patents or exclusivity.

In all of these instances, explicit statutory authority, including for what might appear to be permissible under the current statute, is more critical than ever. The pharmaceutical marketplace is fiercely competitive, and brand manufacturers are litigious. FDA routinely is approached directly or through citizen petitions by parties seeking to delay generic competition, as each day of delay can mean millions of dollars in revenue. If there is a question of FDA's authority to approve a generic drug, brand manufacturers have and will continue to challenge Agency decisions to prevent or forestall generic competition.

This dynamic will only heighten under the recent Supreme Court decision in *Loper Bright Enterprises v. Raimondo*[14]—which overturned so-called "Chevron" deference to agency interpretations of a statute—after which FDA will be afforded less deference to its interpretations of Hatch-Waxman than previously.[15] The more explicit the authority for FDA to request certain data or information or to make regulatory decisions, the stronger the ground on which FDA can stand in its scientific decision-making and, in turn, the more efficiently the Agency can get to generic approvals.

Outside of FDA: When Hatch-Waxman Succeeds Too Well

Generic drug approvals lead to competition and lower prices. However, in some respects Hatch-Waxman—and associated market forces—may have been *too* successful, leading to generic drug prices so low that they threaten the future of the sector and cause drug shortages.

Since enactment of Hatch-Waxman, generic drugs have generated trillions of dollars in societal savings. The Association for Accessible Medicines, the generic industry trade association, calculates savings of $445 billion from generics and biosimilars in 2023 and $3 trillion over the prior decade alone.[16] While the generic drug industry accounts for over 90 percent of medicines used in the United States, they account for 13.1 percent of the total drug spend.[17]

---

[14] 144 S. Ct. 2244 (2024).

[15] *Id.* (holding that the Administrative Procedure Act requires courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority and that courts may not defer to an agency interpretation of the law simply because a statute is ambiguous).

[16] Ass'n for Accessible Meds, *The U.S. Generic & Biosimilar Medicines Savings Report* (Sept. 2024), *available at* https://accessiblemeds.org/resources/blog/2024-savings-report.

[17] *Id.*

In general, increasing numbers of generic entrants correlate with greater savings.[18] For products with a single generic producer, the generic average manufacturer price ("AMP") is 39 percent lower than the brand AMP before generic competition. With two competitors, generic prices are 54 percent lower than before generic competition. Price reductions continue as the number of generic entrants increases. With six or more competitors, generic prices are 95 percent below pre-competition brand prices. In a healthy market, such robust competition is welcome. However, the U.S. generics market is not healthy, as a result of consolidation and contracting practices of supply chain participants that have created outsized purchasing power and market instability for individual manufacturers. According to recent studies, three hospital and clinical group purchasing organizations represent 90 percent of the hospital and clinical market,[19] and in the retail market, three entities comprised of wholesaler and retail chains control 90 percent of the retail market.[20] The three entities in each market successfully negotiate low prices and other purchaser-favorable contracting terms among many more than three producers of fully substitutable products. As a result, in the United States, generic drug prices sometimes fall to, or even below, what it costs to manufacture the product.[21] Counterintuitively, when the number of market participants shrinks, prices usually remain low because of artificial ceilings imposed by the consolidated purchasers and the Medicaid Price Inflation Rebate.[22] This dynamic has been termed "the race to the bottom."

---

[18] Ryan Conrad & Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (2019), *available at* https://www.fda.gov/media/133509/download?attachment.

[19] Elizabeth Seeley, The Commonwealth Fund, *The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending* (July 20, 2022), *available at* https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending.

[20] Adam J. Fein, Drug Channels Inst., *The 2022-23 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors* (Oct. 2022), *available at* https://drugchannelsinstitute.com/products/industry_report/wholesale.

[21] U.S. generic drug prices are substantially lower than in comparator countries—a contrast with price trends for branded products. For example, generic prices in the United States are 39 percent of those in Canada, 53 percent of prices in France, 56 percent of those in Germany, and 47 percent of generic drug prices in the United Kingdom. Andrew W. Mulcahy et al, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data RAND Corporation* (2024), *available at* https://www.rand.org/content/dam/rand/pubs/research_reports/RRA700/RRA788-3/RAND_RRA788-3.pdf.

[22] For additional information on the inflationary Medicaid rebate and its negative impact on generic market sustainability, see Kirsten Axelsen et al., Charles River Assocs., *An Analysis of Medicaid CPI Rebates and the Sustainability of U.S. Generic Markets* (May 2024), *available at* https://media.crai.com/wp-content/uploads/2024/05/10094459/CRA-Viatris-Generic-Sustainability-Medicaid-CPI-Rebate-May2024.pdf.

This race to the bottom on generic drug pricing has unintended consequences—most importantly, the problem of drug shortages, which, after 13 years of persistent shortages, remains near an all-time high.[23]

This market dynamic has a two-fold impact: first, manufacturers not selected by the consolidated purchasers are forced to leave the market. Second, low prices are widely acknowledged to be the root cause of manufacturing quality problems that often precipitate a shortage.[24] (Indeed, more than half of shortages occur in products that cost $1 per unit or less.[25]) Low prices reduce the ability of manufacturers to invest in quality or in newer manufacturing facilities. This also has pushed production offshore to low-wage markets where quality problems proliferate and the FDA presence is less consistent. Manufacturers that maintain a quality culture in the U.S. or abroad will leave a market rather than lower the quality of their manufacturing processes. These realities in turn shrink the number of market participants, lessening the resiliency of the supply chain and exacerbating the impact when something occurs to interrupt the supply of the remaining manufacturers due to quality issues, natural disasters, or disruptions resulting from geopolitical events.

So what can policy makers do to provide a lasting solution to ensure a sustainable generic market? There are a number of critical elements. First, there are the targeted revisions to Hatch-Waxman discussed above. Second, and potentially more critical, there are policies that directly can resolve the instability of the generic marketplace and ensure these safe and effective, lower-costs medicines are available to patients.

For example, the Senate Finance Committee in a recent discussion draft proposed financial incentives to providers that make long-term purchase com-

---

[23] Am. Soc'y Health-Sys. Pharmacists, *Drug Shortages Statistics*, https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly (last visited Jan. 6, 2025).

[24] *See, e.g.*, FDA, *Drug Shortages: Root Causes and Potential Solutions* (2019), *available at* https://www.fda.gov/media/131130/download?attachment; Marta E. Wosinska & Richard G. Frank, Brookings Inst., *Federal Policies to Address Persistent Generic Drug Shortages* (June 2023), *available at* https://www.brookings.edu/wp-content/uploads/2023/06/20230621_ES_THP_GSI_Report_Final.pdf; Stephen Colvill et al., Duke-Margolis Ctr. for Health Pol'y, *Advancing Federal Coordination to Address Drug Shortages* (Sept. 2023), *available at* https://healthpolicy.duke.edu/sites/default/files/2023-09/Advancing%20Federal%20Coordination%20to%20Address%20Drug%20Shortages.pdf; *see also* FDA, *Agency Drug Shortages Task Force*, https://www.fda.gov/drugs/drug-shortages/agency-drug-shortages-task-force (last visited Jan. 6, 2025).

[25] IQVIA Inst. for Hum. Data Sci., *Drug Shortages in the U.S. 2023: A Closer Look at Volume and Price Dynamics*, (Nov. 2023), *available at* from www.iqviainstitute.org.

mitments and take into account quality and buffer inventory when procuring generic medicines.[26] Similar elements have been incorporated into rules proposed by the Centers for Medicare and Medicaid Services.[27] Such changes would help to stabilize the generic medicines sector and create a market for manufacturers that are less likely to experience a failure to supply.

In a similar vein, the "Project 2025" presidential transition report proposes that the FDA make available information from "a graded system that recognizes manufacturers that exceed minimum standards by investing in improving production reliability" as a signal to the market.[28] Such an approach, which the FDA has described as "quality maturity" ratings, would indeed be a valuable signal to the market. However, all available evidence suggests that the current system drives purchasing behavior that overwhelmingly favors the lowest-cost generic, irrespective of other factors.

A novel approach to ensuring supply resiliency in hospital settings is Civica Inc. (Civica Rx), which was established by hospitals to supply drugs that are in shortage or at high risk of shortage. The "Civica model" includes multi-year purchase commitments, maintenance of a targeted six-month buffer inventory of every drug on behalf of participating hospitals, an emphasis on U.S. manufacturing, and robust and ongoing quality oversight of suppliers. This approach has been shown both to be a more reliable supply than the traditional wholesaler model and to reduce net spending on already low-cost drugs.[29] Wider adoption of this type of approach to procurement by public and private purchasers would both reduce chronic drug shortages and bring greater financial stability to the wider generic drugs industry.

One element of the Civica approach is that it does not rely on contracts through Group Purchasing Organizations, which Federal regulators are examining for their role in causing drug shortages.[30] In comments to the Federal

---

[26] S. Comm. on Fin., *Medicare Drug Shortage Prevention and Mitigation Program* (May 3, 2024 discussion draft), *available at* https://www.finance.senate.gov/imo/media/doc/050124_sfc_drug_shortages_discussion_draft_legislative_text.pdf.

[27] Such as a proposal that was included in the 2024 Medicare Inpatient Prospective Payment rule but that was not finalized.

[28] Heritage Found., *Project 2025 Presidential Transition Project* (2023), *available at* https://static.project2025.org/2025_MandateForLeadership_FULL.pdf.

[29] Carter Dredge & Stefan Scholtes, *Vaccinating Health Care Supply Chains Against Market Failure: The Case of Civica Rx*, NEJM Catalyst (Sept. 2023), *available at* https://catalyst.nejm.org/doi/full/10.1056/CAT.23.0167.

[30] Fed. Trade Comm'n, *FTC, HHS Seek Public Comment on Generic Drug Shortages and Competition Amongst Powerful Middlemen* (Feb. 14, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/02ftc-hhs-seek-public-comment-generic-drug-shortages-competition-amongst-powerful-middlemen.

Trade Commission, the Association for Accessible Medicines has recommended additional marketplace solutions emphasizing longer-term contracts and stabilizing contracting practices, as well as revisions to the Anti-Kickback Statute safe harbor provisions to exclude anticompetitive fees and charges imposed by such buying groups.[31] Policymakers should continue to think critically about what policy solutions can be enacted to ensure resiliency of U.S. essential medicines. In all of these options, the key is not providing policy "handouts" to generic manufacturers or nationalizing any elements of the market. Rather, these policy solutions seek to ensure a robust and stable market in which high-quality manufacturers fairly can compete.

Summary

Hatch-Waxman gave rise to a dynamic generic medicines industry that produces lower-cost, quality medicines that benefit patients. The Act creates a balance that protects innovation and establishes a free market that reduces health care costs. To ensure the continuation of these benefits, Congress should enact targeted reforms to ensure efficient generic drug approvals. Additional policy change beyond the scope of Hatch-Waxman will be necessary to ensure a reliable and sustainable supply of essential medicines for the next 40 years.

[31] Comment of David R. Gaugh, Ass'n for Accessible Meds., FTC-2024-0018, *Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices That May Be Contributing to Drug Shortages* (May 30, 2024), https://www.regulations.gov/comment/FTC-2024-0018-6371.

About the Authors

Dan Liljenquist is Chief Strategy Officer, Intermountain Health, where he is responsible for helping Intermountain's Enterprise Leadership Team in setting and achieving the organization's strategic priorities. He oversees Intermountain's Strategy, Corporate Development, Government Relations, Consumer Experience, Strategic Partnerships and Integration, and Digital Technology Services teams. He is the chief architect and Board Chair of nonprofit Civica Inc. (Civica Rx), and also chairs the Board of CivicaScript, a public benefit company that aims to lower the price of select high-cost, generic medications at pharmacies. Dan also chairs the Board of Graphite Health, a member-led, nonprofit company dedicated to making healthcare data interoperability easy and affordable and facilitating the rapid adoption of digital health solutions. Dan previously served in the Utah State Senate and was nationally recognized for his work on Medicaid and public-sector pension reforms. He began his career as a consultant at Bain & Company. Dan earned a J.D. from The University of Chicago Law School and a B.A. in Economics from Brigham Young University.

Maryll Toufanian is Senior Vice President, Regulatory Strategy and Government Affairs at Amneal Pharmaceuticals, LLC, where she leads the company's efforts to develop top-level regulatory strategies. She also leads Amneal's government relations and public policy interface with state and federal policymakers. Prior to her work at Amneal, Maryll held senior leadership roles at the FDA, including Director of the Office of Generic Drug Policy and Associate Chief Counsel for Drugs in FDA's Office of Chief Counsel. Her early career also included time as a litigator in private practice focused on FDA regulatory matters and white-collar criminal defense. Maryll holds a J.D. from New York University School of Law, an M.A. in English Literature from the University of Texas at Austin, and a B.A. from the University of Michigan in Afro-American and African Studies and English.

Allan Coukell is Chief Government Affairs and Public Policy Officer for Civica Inc. Allan also leads government relations for CivicaScript. He previously served as Senior Director, Health Programs, at the Pew Charitable Trusts and has been a Board Member and Secretary for the Reagan-Udall Foundation and a founding Board Member and Vice Chair of the Medical Device Innovation Consortium. He practiced clinical pharmacy, specializing in oncology, at Victoria Hospital in London, Ontario and served as a medical writer and editor at Adis International in Auckland, New Zealand. He also spent nearly a decade as a health and science reporter, including for WBUR, Boston. He holds a B.Sc. degree from the University of Manitoba in Pharmacy and completed his hospital pharmacy residency at the Winnipeg Health Sciences Centre.

A Bipartisan Success: Celebrating 40 Years of the Hatch-Waxman Act

By Stephen Ezell and Leah Kann

The 1984 Hatch-Waxman Act revolutionized the U.S. pharmaceutical industry, successfully balancing the interests of pharmaceutical innovation and affordability by creating legal pathways for accelerated generic drug competition while extending patent protections and introducing data exclusivities that preserved incentives for novel pharmaceutical innovation.

Introduction

September 24, 2024 marked the 40th anniversary of the landmark Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act (HWA).[1] Promoted on a bipartisan basis by Senator Orrin Hatch and Congressman Henry Waxman, the legislation sought to create a more competitive generic pharmaceutical market, using market-based solutions of increasing competition to help drive down the price of drugs while preserving incentives and mechanisms supporting pharmaceutical innovation.[2] The HWA created a comprehensive legal framework that streamlined the process for approval of generic pharmaceutical drugs while also creating effective procedures to manage patent litigation involving generic pharmaceuticals, and it did this all while preserving incentives and rewards for pharmaceutical innovation. Over the past four decades, the Act has played a catalytic role in transforming America from an "also-ran" into the global biopharmaceutical innovation leader.

The facts bear clear testament to the Hatch-Waxman Act's success. Prior to the passage of the HWA, only 35 percent of top-selling pharmaceutical drugs had generic competition, a number that now exceeds 80 percent.[3] Likewise, prior to the passage of the legislation, only 19 percent of prescriptions were filled with generic drugs, a figure that now exceeds 90 percent.[4]

The increased availability of generic drugs has led to tremendous savings for individual patients and the broader U.S. healthcare system alike. Individually, the average co-pay of generic drugs (drugs that have the same active ingredient as brand-name drugs but can be sold at lower prices) in the United States is

[1] FDA, *Hatch-Waxman Letters* (Feb. 2022), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters.

[2] PhRMA, *What is Hatch-Waxman* (2018), *available at* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf.

[3] *Id.*

[4] IQVIA, *The Use of Medicines in the U.S. 2023* (Apr. 2023), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2023/the-use-of-medicines-in-the-us-2023.pdf.

$6.16, and 92 percent of all generics have a co-pay of less than $20.[5] Nationally, over the past 10 years alone, generic and biosimilar competition (inspired by the HWA) has saved over $3.1 trillion, and in 2023 alone it saved $445 billion for American consumers.[6] The HWA has also managed to slow increases in drug prices compared to overall healthcare costs, with drug prices increasing 10 percent between 2010 and 2020 while overall healthcare costs increased over 30 percent.[7]

The real genius of the HWA lies in effectively balancing the interests of the innovative and generic drug industries in the United States, as well as balancing additional competition with incentives for companies to continue to undertake the lengthy, expensive, and risky research and development (R&D) efforts that enable creation of the next generation of drugs. The Hatch-Waxman Act's effectiveness has been borne out in the reality that the United States alone leads the world in innovating new drugs and getting them to patients first, while also sustaining a globally competitive industry and over time making drugs broadly affordable by incentivizing competition and creating generic pathways.

It's absolutely imperative to emphasize that no other nation can "square the circle" like this. Patients certainly pay less for drugs in Europe than Americans do. However, stringent price controls have contributed to Europe's loss of its biopharmaceutical industry and the economic and employment opportunities the sector generates. Indeed, European firms' share of global new drug development has fallen by more than half over the past two decades, whereas U.S. biopharmaceutical enterprises now annually invest almost three times more in R&D than their European counterparts.[8] Likewise, Japan's share of global value added in the pharmaceutical industry declined by 70 percent from 1995 to 2018, from 18.5 to 5.5 percent, in large part through excessive drug price controls.[9] Similarly, Canadians pay less for their drugs; but the availability of

---

[5] Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* (Sept. 2023), *available at* https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[6] *Id.*

[7] Matthew McGough et al., Peterson-KFF, *How Much Is Health Spending Expected to Grow?* (Oct. 7, 2024), https://www.healthsystemtracker.org/chart-collection/how-much-is-health-spending-expected-to-grow; Matthew McGough et al., Peterson-KFF, *How Has U.S. Spending on Healthcare Changed over Time?* (Dec. 15, 2023), https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time.

[8] Stephen Ezell, Info. Tech. & Innovation Found., *Going, Going, Gone? To Stay Competitive in Biopharmaceuticals, America Must Learn From Its Semiconductor Mistakes* (Nov. 22, 2021), *available at* https://itif.org/publications/2021/11/22/going-going-gone-stay-competitive-biopharmaceuticals-america-must-learn-its.

[9] Stephen Ezell, Info. Tech. & Innovation Found., *How Japan Squandered Its Biopharmaceutical Competitiveness: A Cautionary Tale* (July 25, 2022), *available at* https://itif.org/publications/2022/07/25/how-japan-squandered-its-biopharmaceutical-competitiveness-a-cautionary-tale.

the most-innovative new drugs in Canada is less than half what it is in the United States, while the innovative Canadian biopharmaceutical sector has shriveled over the past decade. In short, the United States is the only country in the world that has figured out how to support the world's leading innovative biopharmaceutical industry, and a competitive generic one, while creating mechanisms to get innovative drugs to patients first while fostering those medicines' affordability and availability over time through generic competition.

That the United States has been able to uniquely accomplish this is largely thanks to the Hatch-Waxman Act. However, it's important to start by turning the page back 40 years, because the state of America's pharmaceutical industry looked much different then.

Pre-Hatch-Waxman Act

America's Pharmaceutical Industry Before 1984

Before the passage of the Hatch-Waxman Act, the U.S. pharmaceutical industry was governed mainly by the Food, Drug, and Cosmetic Act of 1962. This Act, also known as the Kefauver-Harris Amendments, greatly increased the regulatory authority of the U.S. Food and Drug Administration (FDA) and required all drugs, including generics, to demonstrate the same safety and efficacy requirements though clinical trials. Additional provisions of the Kefauver-Harris Amendments increased manufacturing standards, mandated informed consent for patients in clinical trials, and regulated drug advertising.[10] Much of this came in response to the devastation caused by thalidomide, a sedative that was used to treat morning sickness for pregnant women that later was found to cause birth defects.[11]

In the 1960s and 1970s, the U.S. pharmaceutical industry was characterized by promoting innovation at the expense of affordability. Brand-name drug companies dominated the market, and minimal generic competition was present due to strict regulations that made entry difficult. Drug prices continued to rise steadily, driven by a lack of competition in the market, in part itself driven by the complicated process for securing generic approvals.[12] Regulatory inefficiencies and a lack of personnel led to slow drug approvals and regulatory difficulty in staying abreast of the latest technological innovations in the field.

---

[10] FDA, *Kefauver-Harris Amendments Revolutionized Drug Development* (Oct. 2023), *available at* https://www.gvsu.edu/cms4/asset/F51281F0-00AF-E25A-5BF632E8D4A243C7/kefauver-harris_amendments.fda.thalidomide.pdf.

[11] *Id.*

[12] Wendy H. Schacht & John R. Thomas, Cong. Rsch. Serv., *The Hatch-Waxman Act: A Quarter Century Later* (Mar. 13, 2012), *available at* https://www2.law.umaryland.edu/marshall/crsreports/crsdocuments/R41114_03132013.pdf.

Moreover, the simple reality was that, in the decades pre-Hatch-Waxman, the United States was a mere "also-ran" in global pharmaceutical innovation. As Shanker Singham of the Institute of Economic Affairs observed, "Europe was the unquestioned center of biopharmaceutical research and development for centuries, challenged only by Japan in the post-war period."[13] For instance, between 1960 and 1965, European companies invented 65 percent of the world's new drugs, and in the latter half of the 1970s, European-headquartered enterprises introduced more than twice as many new drugs as U.S.-headquartered enterprises (149 to 66).[14] And well throughout the 1980s, fewer than 10 percent of new drugs launched in the world were first introduced in the United States.[15] (See Figure 1.) Even as recently as 1990, the global biopharmaceutical industry invested 50 percent more in Europe than in the United States.[16]

---

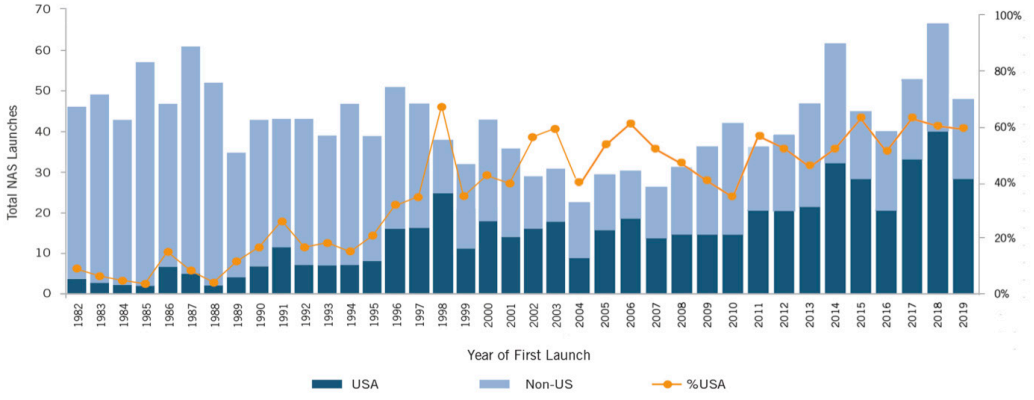
[13] Shanker Singham, Int'l Roundtable on Trade & Competition Pol'y, *Improving U.S. Competitiveness; Eliminating Anti-Competitive Market Distortions*, at 10 (Nov. 15, 2011), *available at* https://shankersingham.com/wp-content/uploads/2021/10/Paper_on_Improving_US_Competitiveness_Eliminating_ACMDs_15NOV11.pdf.

[14] Neil Turner, *What's Gone Wrong with the European Pharmaceutical Industry*, The Pharma Letter (Apr. 29, 1999), https://www.thepharmaletter.com/article/what-s-gone-wrong-with-the-european-pharmaceutical-industry-by-neil-turner; David Michels & Aimison Jonnard, U.S. Int'l Trade Comm'n, *Review of Global Competitiveness in the Pharmaceutical Industry*, at 2-3 (Apr. 1999), *available at* https://www.usitc.gov/publications/332/pub3172.pdf.

[15] John K. Jenkins, FDA, *CDER New Drug Review: 2015 Update* (Dec. 14, 2015).

[16] Eur. Fed'n Pharm. Indus. & Ass'ns, *The Research Based Pharmaceutical Industry: A Key Actor for a Healthy Europe* (2006).

Figure 1: Share of new active substances on the world market launched first in the United States, 1982–2019[17]



However, the United States would subsequently flip the script so thoroughly that by 2014 nearly 60 percent of new drugs launched in the world were first introduced in the United States (a figure that stands at 65 percent today). (See Figure 1.) Moreover, over the past two decades, U.S.-headquartered biopharmaceutical enterprises have accounted for almost half of the world's new drugs developed. As this essay will elaborate, that's in significant part thanks to the world created by the Hatch-Waxman Act.

The Challenge for Generic Drug Manufacturers

Generic drug manufacturers faced their own set of challenges prior to Hatch-Waxman. Perhaps the most significant obstacle they faced was that they were required to complete the same duplicative clinical trials as the brand-name drug they were mimicking. The intent of those trials was to prove that the safety and efficacy of the generic matched those of the brand drug, but these were unnecessary and increased costs and time.[18] Then-existing laws also prohibited early development of generic drugs and required manufacturers to

[17] Jenkins, *supra* note 15, at 23; Ian Lloyd, PharmaIntelligence, *Pharma R&D Annual Review 2020 NAS Supplement*, at 3 (Apr. 2020); *see also* PhRMA, *Global Access to New Medicines Report* (Apr. 2023), *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/2023-04-20-PhRMA-Global-Access-to-New-Medicines-Report-FINAL-1.pdf.

[18] Susan Haigney, PharmTech, *Hatch-Waxman Amendments Turn 40* (Sept. 25, 2024), https://www.pharmtech.com/view/hatch-waxman-amendments-turn-40.

wait until the original patent fully expired before initiating their production.[19] The combination of these dynamics underscored the need for drastic pharmaceutical regulatory change to help ensure innovation was not occurring at the expense of affordability.

Overview of the Hatch-Waxman Act

Key Provisions

The Hatch-Waxman legislation represents a well-conceived integrated whole, a comprehensive piece of legislation that simultaneously balances the interests of the innovator and generic industries, hence why it was called "The Drug Price Competition *and* Patent Term Restoration Act." When he signed the Act into law, President Ronald Reagan proclaimed in the White House Rose Garden that "[The Hatch-Waxman] bill will provide regulatory relief, increased competition, economy in government, and best of all, the American people will save money and yet receive the best medicine that pharmaceutical science can provide."[20]

It's critical to emphasize that the HWA incorporates mechanisms that actively seek to encourage generic entry and competition with brand-name drugs. The Hatch-Waxman Act has been able to accomplish this through six major components: 1) the abbreviated new drug application (ANDA) process; 2) "safe harbor" provisions; 3) a market exclusivity period for the first generic manufacturer; 4) data exclusivity periods for innovative drugs; 5) patent term extension; and 6) connection with the FDA Orange Book.[21]

Abbreviated New Drug Application Process

The Abbreviated New Drug Application (ANDA) provision of the HWA streamlined the approval process for generic drugs, addressing key barriers that had previously impeded their market entry. Unlike a full New Drug Application (NDA), which requires extensive and costly clinical trials to demonstrate safety and efficacy, the ANDA allows generic manufacturers to rely on the safety and efficacy data of the already-approved brand-name drug (known as the reference-listed drug).[22] To gain approval, generic manufacturers must demonstrate that their drug delivers the same active ingredient, at the same rate and extent,

---

[19] Joanna T. Brougher, *Patent Battles Part I: The Hatch-Waxman Act and Small-Molecule Drugs*, *in* Intellectual Property and Health Technologies ch. 1 (Jan. 1, 2013), *available at* https://link.springer.com/chapter/10.1007/978-1-4614-8202-4_7.

[20] Ronald Reagan, *Remarks on the Signing of the Drug Price Competition and Patent Term Restoration Act of 1984* (Sept. 24, 1984), *available at* https://www.reaganlibrary.gov/archives/speech/remarks-signing-drug-price-competition-and-patent-term-restoration-act-1984.

[21] FDA, *Hatch-Waxman Letters*, *supra* note 1.

[22] FDA, *Abbreviated New Drug Application (ANDA)* (Dec. 16, 2022), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.

and thus performs the same in the body as the brand-name counterpart.[23] The ANDA eliminated the need for the previously required duplicative clinical trials—that is, the generic company could use the innovators' clinical trial data validating the safety and efficacy of the drug—significantly reducing both development costs and time to market for the generic drug.

The anticipated impact of this provision was profound: it enabled faster availability of lower-cost medications while ensuring safety and effectiveness. By encouraging competition through the easier path to market entry, the provision's architects expected to reduce prescription drug costs for consumers and the healthcare system, as the supply would increase, forcing producers to decrease prices to stay competitive. Additionally, the ANDA provision addressed public demand for affordable medications while preserving innovation incentives for brand-name manufacturers through other Hatch-Waxman provisions, such as patent term extensions.

Safe Harbor

Accompanying the expedited development and approval timeline under the HWA is the Bolar Provision, another important clause that allows generic manufacturers to prepare for FDA submissions during patent protection, expediting their market entry. This provision, working in line with the ANDA, helps to increase competition and incentivize brand-name companies to develop new therapies, supporting innovation.[24] This essentially represents a "safe harbor" provision that exempts generic manufacturers from patent infringement liability for their development work on the generic drug before its patent term expires.

Market Exclusivity for First Generic Manufacturer

To actively encourage generic entry, the HWA grants 180 days of market exclusivity to the first generic manufacturer to file an ANDA with a Paragraph IV certification asserting that the brand-name drug's patent is invalid, unenforceable, or will not be infringed by the generic product.[25]

---

[23] FDA, *Bioequivalence* (Jan. 14, 2025), https://www.fda.gov/animal-veterinary/abbreviated-new-animal-drug-applications/bioequivalence.

[24] Lisa L. Mueller, *Understanding Bolar and Bolar-Like Exceptions in U.S. and Abroad – Part 1*, Nat'l L. Rev. (July 20, 2017), https://natlawreview.com/article/understanding-bolar-and-bolar-exceptions-us-and-abroad-part-1.

[25] Allucent, *Types of Marketing Exclusivity in Drug Development*, https://www.allucent.com/resources/blog/types-marketing-exclusivity-drug-development (last visited Jan. 16, 2025).

Once the generic drug is approved and launched, the manufacturer has a 180-day period as the exclusive generic competitor to the brand-name drug. During this time, no other generic versions of the same drug making a Paragraph IV certification can enter the market, allowing the first filer to benefit from a temporary "monopoly." Note that the law allows for multiple generic manufacturers to obtain "first filer" status should additional generic manufacturers file Paragraph IV certifications on the same first day. This incentive helps offset the legal and financial risks involved in challenging patents, such as costly litigation with brand-name companies.

This exclusivity period benefits consumers by accelerating the introduction of generic drugs, which are typically priced lower than their branded counterparts. However, the provision has faced criticism for potential misuse, such as "pay-for-delay" agreements where the first filer delays launching its product in exchange for payments from the brand-name company.[26]

Data Exclusivity Periods for Innovators

The Hatch-Waxman Act included data exclusivity protections for innovators. This data exclusivity is based on the proprietary nature of the data supporting the innovator's approval; given that, generics cannot rely on the data for FDA approval for certain defined periods. In particular, the Hatch-Waxman Act incentivized innovators to develop new pharmaceuticals through a five-year data exclusivity period during which generic manufacturers cannot submit FDA applications for new generic versions of the pharmaceutical using the innovator's clinical trial data. It also established a three-year exclusivity period for improved versions of brand pharmaceuticals that required additional clinical studies for FDA approval.

Patent Term Extension

The HWA also included a patent term extension provision that addressed a major concern of brand-name pharmaceutical manufacturers: the loss of effective patent life (time when the drug is on the market) due to the lengthy FDA approval process. Drug development often involves years of research, clinical trials, and regulatory review, during which manufacturers are unable to market their products, shortening the period of market exclusivity granted by patents. Due to the time required to complete R&D and subsequent clinical trials, patents covering certain inventions contained within a drug product (e.g., the active ingredient) can be granted well before FDA approval and subsequent marketing; therefore, the average term of market exclusivity is far less than the full 20-year standard patent term.[27]

---

[26] Robin Feldman, *The Price Tag of 'Pay-for-Delay'*, Sci. & Tech. L. Rev. (Mar. 7, 2022), *available at* https://journals.library.columbia.edu/index.php/stlr/article/view/9389.

[27] FDA, *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program* (Feb. 4, 2020), https://www.fda.gov/drugs/cder-small-business-industry-assistance-

Under this provision, companies can apply for a patent term extension to compensate for some of the time lost during the clinical research and FDA approval process. The extension is calculated based on the time spent in clinical trials and regulatory review, with certain limits. It essentially is available for only one patent on a product. In addition, the maximum extension allowed is 5 years, and the total effective patent life from the patent, including the extension, cannot exceed 14 years from the date of FDA approval.

This provision aimed to strike a balance between continuing to incentivize innovation and promoting competition. By restoring a portion of the effective patent life, the Hatch-Waxman Act provided drug manufacturers with a fair opportunity to recoup their investments. At the same time, it ensured that the extension was limited, allowing for eventual market entry by generic competitors.

Orange Book

The Orange Book, officially called the Approved Drug Products with Therapeutic Equivalence Evaluations, is a pivotal component of the U.S. biopharmaceutical intellectual property framework. The Orange Book constitutes an essential complement to the HWA, helping the U.S. biopharmaceutical industry achieve maximum innovation and affordability.

The Orange Book provides comprehensive information on FDA-approved drugs, including associated patents and exclusivities. When a pharmaceutical company submits a new drug application to the FDA, they are required to include details on pertinent patents covering the drug's substance, product, or specific uses. Upon approval, this patent information is published in the Orange Book, ensuring transparency and facilitating the resolution of patent disputes prior to the marketing of generic versions.

The Orange Book offers several key benefits. It helps to incentivize patent challenges as it encourages generic manufacturers to challenge existing patents. It ensures transparency, allowing for clear information to be consolidated into one regulatory location. Lastly, it facilitates patent resolution, as it enables orderly resolution of patent disputes.[28]

Complementary Legislation to the Hatch-Waxman Act

The Hatch-Waxman Act undoubtedly played a pivotal role in transforming America into the world's life-sciences innovation leader. But it should be noted that the HWA represented one component of a comprehensive suite

sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program.

[28] PhRMA, *What is the Orange Book?* (n.d.), *available at* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/What-is-the-Orange-Book_3.pdf.

of legislation introduced on a bipartisan basis in the 1980s and 1990s that also played catalytic roles in reviving U.S. industrial competitiveness and establishing U.S. biopharmaceutical leadership. They're worth briefly mentioning here, both because they're complementary to the Hatch-Waxman Act and because without them Hatch-Waxman wouldn't have become the extraordinary success it has.

The Bayh-Dole Act

Like the Hatch-Waxman Act, another vital piece of legislation toward establishing U.S. leadership in biopharmaceutical innovation was the Patent and Trademark Law Amendments Act of 1980. Commonly known as the Bayh-Dole Act, the legislation permitted universities, nonprofit research institutions, and small businesses to own, patent, and commercialize inventions developed under federally funded research programs. The legislation played a catalytic role in transforming American universities into engines of innovation, especially in life sciences.[29]

Prior to the Bayh-Dole Act the federal government had licensed less than 5 percent of the up to 30,000 patents it owned.[30] Likewise, throughout the 1960s and 1970s, many American universities shied away from direct involvement in the commercialization of research.[31] Indeed, before the passage of Bayh-Dole, only a handful of U.S. universities even had technology transfer or patent offices.[32] And one investigation found that "not a single drug had been developed when patents were taken from universities [by the federal government]."[33]

But the Bayh-Dole Act turbocharged American universities' innovation capacity. It led to a ten-fold increase in academic patenting in the first 20 years alone, and whereas just 55 U.S. universities had been granted a patent in 1976; by 2006, 240 had. The Bayh-Dole Act is often credited as a key driver of the

---

[29] Stephen Ezell, Info. Tech. & Innovation Found., *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System* (Mar. 4, 2019), *available at* https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system.

[30] Bradley Graham, *Patent Bill Seeks Shift to Bolster Innovation*, Wash. Post (Apr. 8, 1978), *available at* https://www.washingtonpost.com/archive/business/1979/04/08/patent-bill-seeks-shift-to-bolster-innovation/db14f277-ec0e-4ca5-9aeb-ce2cad86e25b; Ashley J. Stevens et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, New Eng. J. Med., Feb. 2011, at 1, *available at* https://www.nejm.org/doi/full/10.1056/NEJMsa1008268.

[31] Naomi Hausman, U.S. Census Bureau Ctr. for Econ. Studies, *University Innovation, Local Economic Growth, and Entrepreneurship*, at 5 (July 2012), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2097842.

[32] Louis G. Tornatzky & Elaine C. Rideout, State Sci. & Tech. Inst., *Innovation U 2.0: Reinventing University Roles in a Knowledge Economy*, at 165 (2014), *available at* https://ssti.org/report-archive/innovationu20.pdf.

[33] Joseph P. Allen, *When Government Tried March In Rights to Control Health Care Costs*, IPWatchdog (May 2, 2016), http://www.ipwatchdog.com/2016/05/02/march-in-rights-health-care-costs/id=68816.

United States' "competitive revival" in the 1990s and beyond. As *The Economist* observed, the law "helped to reverse America's precipitous slide into industrial irrelevance." From 1996 to 2020, academic technology transfer inspired by the Bayh-Dole Act has led to the issuance of over 140,000 patents, helped seed the formation of over 18,000 startup companies, and led to the development of over 200 novel drugs and vaccines through public-private partnerships.[34] University technology licenses play a crucial role in fostering innovation, with the majority—73 percent—granted to startups and small companies. This support is particularly significant in the biotech sector, where nearly 70 percent of drugs in Phase III clinical trials originate from small biotech firms.[35]

The Prescription Drug User Fee Act (PDUFA)

A major challenge for America's pharmaceutical industry in the 1980s was the slow regulatory environment for reviewing the safety and efficacy of new drugs.[36] In fact, during that decade, the median FDA review approval time for new medicines exceeded 28 months.[37] (See Figure 2.) At the time, it was not uncommon for pharmaceutical companies to have to wait more than two years for their submissions regarding the clinical trial data and efficacy studies for novel drugs to even be opened and examined. The FDA simply lacked the resources it needed to handle the caseload, particularly when a flood of applications arrived in response to the AIDS crisis of the late 1980s and early 1990s. Accordingly, Congress passed the Prescription Drug User Fee Act in 1992, recognizing that industry user fees could supplement limited general-funds appropriations to ensure the FDA had the needed resources at its disposal to review new drug applications in a timely manner. By 2015, even while maintaining the FDA's high standards for patient safety, the median drug approval time at the FDA had fallen by more than a year-and-a-half (from 1992 levels) to under 10 months. That expediency has persisted: in 2024, the typical review period for drugs was 10 months after the drug application has been accepted by the FDA, while for drugs that receive a priority review, the review period has been reduced to 6 months.[38]

---

[34] Ass'n of Univ. Tech. Managers, *Driving the Innovation Economy: Academic Technology Transfer in Numbers* (2023), *available at* https://autm.net/AUTM/media/SurveyReportsPDF/AUTM-Infographic-23-DIGITAL.pdf.

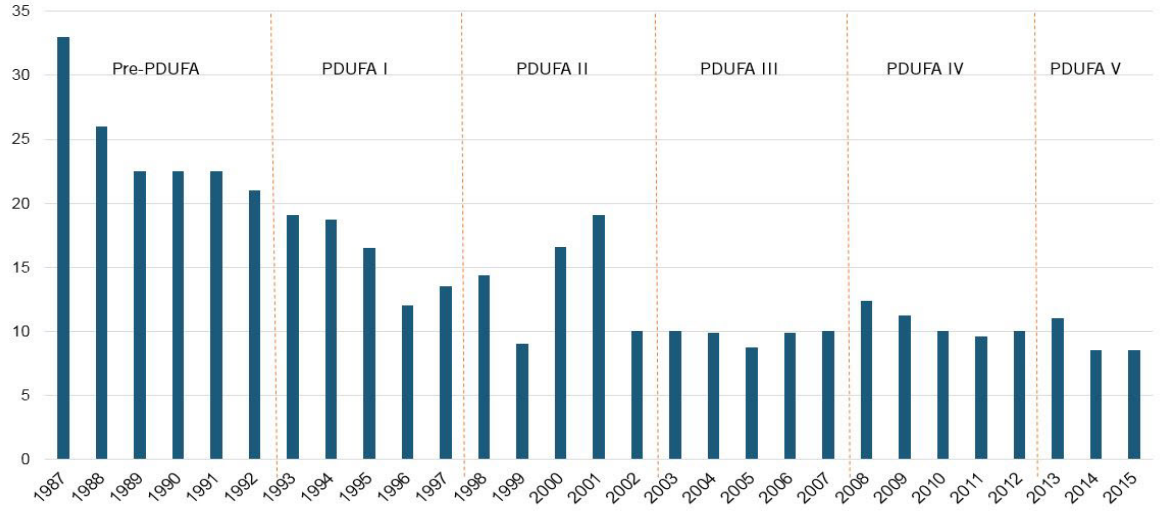
[35] Cong. Budget Off., *Research and Development in the Pharmaceutical Industry*, at 4-5 (Apr. 2021), *available at* https://www.cbo.gov/publication/57025.

[36] Stephen Ezell, Info. Tech. & Innovation Found., *How the Prescription Drug User Fee Act Supports Life-Sciences Innovation and Speeds Cures* (Feb. 2017), *available at* https://itif.org/publications/2017/02/27/how-prescription-drug-user-fee-act-supports-life-sciences-innovation-and.

[37] Amanda Kronquist, Heritage Found., *The Prescription Drug User Fee Act: History and Reauthorization Issues for 2012* (Dec. 2011), *available at* https://www.heritage.org/health-care-reform/report/the-prescription-drug-user-fee-act-history-and-reauthorization-issues.

[38] Diane Ernst, *FDA Drug Approval Decisions Expected in October 2024*, Med. Prof'ls Reference (Sept. 5, 2024), https://www.empr.com/news/fda-drug-approval-decisions-expected-in-october-2024.

Figure 2: Median approval time for new medicines, in months (CDER NME NDAs/BLAs)[39]



The R&D Tax Credit and Orphan Drug Tax Credit

In 1983, the United States became the first country in the world to introduce an R&D tax credit, stimulating corporate levels of R&D investment closer to societally optimal levels. America's introduction of the R&D tax credit played a vital role in catalyzing the growth of research-driven industries, such as pharmaceuticals. Also in that year, Congress passed the Orphan Drug Tax Credit to incentivize investment in new treatments for rare diseases (those that afflict patient populations of 200,000 individuals or less). Since the law's enactment, over 500 orphan products have been approved by the U.S. FDA, whereas prior to the law's introduction fewer than 40 drugs were approved in the United States to treat rare diseases and on average only two new orphan drugs were produced each year.[40] A 2015 study by the National Organization for Rare Disorders found that at least one-third fewer new orphan drugs would have been developed to treat rare diseases over the preceding 30 years had the act not been implemented.[41]

---

[39] The chart refers to New Molecular Entities (NMEs) in the form of New Drug Applications (NDAs) or Biologics License Applications (BLAs) using data from the Center for Drug Evaluation and Research (CDER). U.S. Gen. Acct. Off., *FDA Drug Approval: Review Time Has Decreased in Recent Years* (Oct. 20, 1995), *available at* http://www.gao.gov/assets/230/221919.pdf; Jenkins, *supra* note 15.

[40] Jennifer Huron, Nat'l Org. for Rare Disorders, *Impact of the Orphan Drug Tax Credit on Treatments for Rare Diseases* (June 17, 2015), *available at* https://rarediseases.org/assets/files/white-papers/2015-06-17.nord-bio-ey-odtc.pdf.

[41] *Id.*

These complementary pieces of legislation are worth mentioning because they've also played important roles in turbocharging the growth of America's innovative biopharmaceutical industry—which provides the seed corn for the generic industry—and because they help inform the following assessment of the impact of the Hatch-Waxman Act after 40 years.

Post-Hatch-Waxman Act

As noted, the United States leads the world in innovating new drugs and getting them to patients first while sustaining a globally competitive industry and over time making drugs broadly affordable, especially through incentivizing competition by creating generic pathways. Indeed, over the past 40 years, the Hatch-Waxman Act has done a remarkable job at balancing the interests of innovation and affordability and sustaining both a competitive innovative and generic drug industry.

Increased Generic Competition and Generic Drug Availability

Since the enactment of the Hatch-Waxman Act, generic drug competition in the United States has increased significantly, leading to substantial changes in the pharmaceutical market. In 1984, only 35 percent of top-selling pharmaceuticals experienced generic competition after their patents expired, and generic drugs accounted for only about 19 percent of all prescriptions filled. By 2007, this latter figure had risen to 63 percent, and by 2024, generics were filled in 90 percent of all prescriptions.[42] (Pharmacies dispense generics 97 percent of the time when they're available as an option.) The United States clearly leads the world in generic uptake, with only 41 percent of prescriptions filled using generics on average in other Organization for Economic Cooperation and Development (OECD) countries.

This surge in generic drug utilization has resulted in considerable cost savings, for both patients at the pharmacy counter and for the U.S. healthcare system overall. For patients, the average generic copay costs only $6.16, and 92 percent of all generics have a copay of less than $20.[43] A 2019 FDA report estimated that the median generic drug was 60 percent cheaper than its branded counterpart, with that figure rising to nearly 80 percent less expensive for products with four or more generic competitors.[44]

---

[42] U.S. Pharmacopeial Convention, *Timeline: Generic Medicines in the US*, https://www.usp.org/our-impact/generics/timeline-of-generics-in-us (last visited Jan. 16, 2025).

[43] Ass'n for Accessible Meds., *2023 U.S. Generic and Biosimilar Medicines Savings Report* (2023), https://accessiblemeds.org/resources/reports/2023-savings-report-2.

[44] Ryan Conrad & Randall Lutter, FDA Ctr. for Drug Evaluation & Rsch., *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (Dec. 2019), https://www.fda.gov/media/133509/download.

Generic competition has also produced significant U.S. healthcare systems cost savings. In 2023, generic and biosimilar prescription medicines saved $445 billion for the U.S. healthcare system overall, with more than $3.1 trillion saved over the past 10 years.[45] Overall, generics account for 13.1 percent of U.S. expenditures on prescription drugs and 1.2 percent of total U.S. healthcare spending.[46]

Both the volume and complexity of generic drugs have grown since the HWA's passage, and patients continue to benefit from both the decreased prices and continued innovation. Additionally, the approval process for new medications has become more efficient. Between 2013 and 2018, the median annual number of generic drug approvals increased to 588, up from 284 between 1985 and 2012, reflecting efforts to expedite the availability of generic medications.[47]

Accelerating Growth of the U.S. Generic Drug Industry

The U.S. generic industry has experienced significant growth in recent years, another successful result of the Hatch-Waxman Act. In 2023, the industry's market size reached approximately $133 billion, with analysts projecting the market will expand to $188.4 billion by 2033.[48] The continued widespread adoption of generics highlights the success and importance of the HWA in making drugs more affordable and accessible to patients, and the growth of the generics market itself shows that the HWA has achieved great success in accomplishing that goal. Between 2010 and 2019, the FDA approved a total of 8,706 ANDAs, including both first-time generics and existing generic applications.[49] In 2023 alone, 956 ANDAs and 90 first generic medicines were approved. Investment in generic drug research and discovery is critically important, and the FDA's Office of Generic Drugs allocated $20 million in funding for generic drug science and research projects in 2023.[50] Two notable first generics in 2023

---

[45] Ass'n for Accessible Meds., *State Advocacy*, https://accessiblemeds.org/advocacy/state-advocacy (last visited Jan. 16, 2026).

[46] *Id.*

[47] Jonathan J. Darrow et al., *FDA Approval and Regulation of Pharmaceuticals, 1983-2018*, JAMA Network (Jan. 14, 2020), *available at* https://jamanetwork.com/journals/jama/article-abstract/2758605.

[48] BioSpace, *U.S. Generic Drugs Market Size to Surpass USD 188.44 Bn by 2032*, BioSpace (May 9, 2024), https://www.biospace.com/u-s-generic-drugs-market-size-to-surpass-usd-188-44-bn-by-2032.

[49] U.S. Dep't of Health & Hum. Servs., Off. of the Assistant Sec'y for Plan. & Evaluation, *Number of US FDA ANDA Approvals Per Fiscal Year*, https://aspe.hhs.gov/number-us-fda-anda-approvals-fiscal-year (last visited Jan. 16, 2025).

[50] FDA, *Office of Generic Drugs 2023 Annual Report* (Feb. 2024), *available at* https://www.fda.gov/media/176440/download.

were multiple forms of Vyvanse, a treatment for attention deficit hyperactivity disorder, and of Tofacitinib, a treatment for rheumatoid arthritis.[51] The prospering of the U.S. generics industry, and its continued benefit for patients, is directly the effect of successful implementation and execution of the HWA.

Promoting the Affordability of Medicines in the United States

There's a narrative that prescription drug prices are rising radically out of control in the United States. And while it's certainly true that some drugs can be quite expensive—especially new ones treating small populations, such as drugs for rare cancer diseases, some of which can cost over $1 million—the reality is that on net this is not the case, particularly when compared to what Americans pay for other healthcare services. Again, Americans have Hatch-Waxman to thank for this.

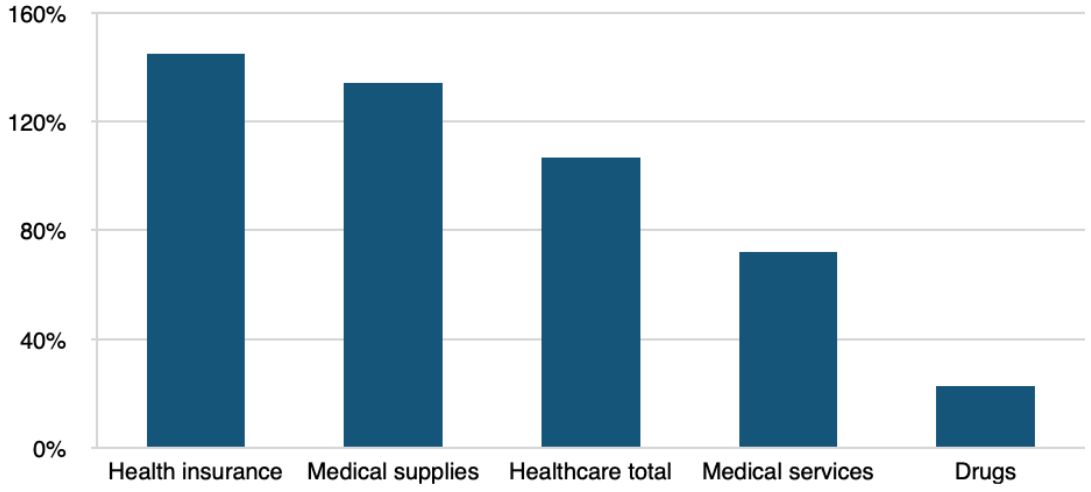
Consider that, as calculated by the U.S. Bureau of Labor Statistics, from 2008 to 2023, Americans' reported expenditures on health insurance increased by over 140 percent, and their total healthcare expenditures increased 107 percent, while consumer expenditures on drugs increased only 23 percent. (See Figure 3.) This startling statistic can be attributed to the fact that no similar type of cost containment mechanism exists for other health care services in the United States. For example, the cost of a medicine commonly used to prevent cardiovascular disease decreased by 95 percent from 2007 to 2017, while the average charge for a surgical procedure to treat cardiovascular disease increased by 94 percent over that same period.[52] In fact, relative to total health expenditures, U.S. drug spending fell from 10.5 percent to 8.4 percent over the past 15 years.

---

[51] *Id.*

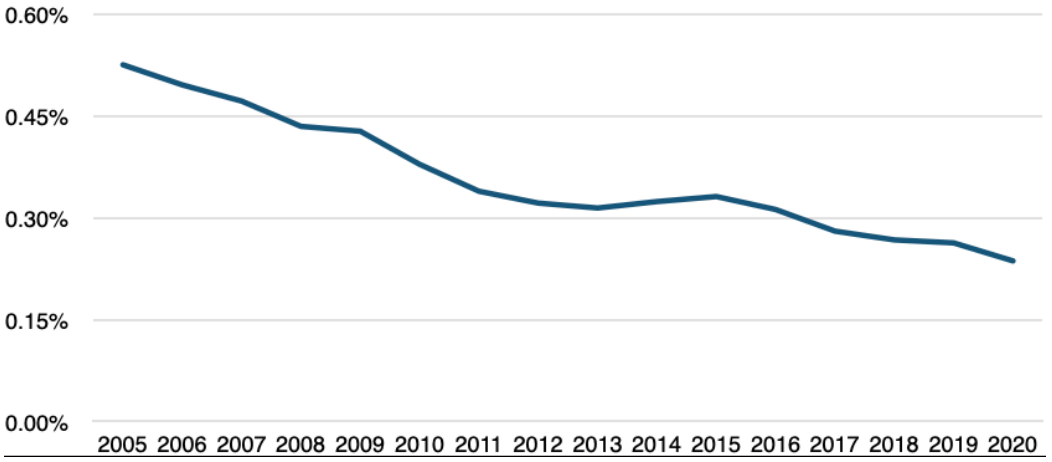
[52] Agency for Healthcare Rsch. & Quality, Healthcare Cost & Utilization Project, *National (Nationwide) Inpatient Sample (NIS) Database 2007, 2017*, *available at* https://www.ahrq.gov/research/data/hcup/index.html (last accessed July 2020); *see also* IQVIA, *National Sales Perspectives Data for 2007 and 2017* (June 2020) (invoice price data for atorvastatin 10mg; 2007 branded data, 2017 generic data).

Figure 3: Percent change in American consumers' reported healthcare expenditures, 2008–2023[53]



Moreover, American consumers have paid a generally declining share of their personal incomes toward out-of-pocket drug costs since 1960. In 1960, out-of-pocket drug costs accounted for 9.5 percent of total healthcare expenditures; that number today is only 1.1 percent. And the share of personal income in the United States paid toward out-of-pocket drug costs actually halved from 2005 to 2020, from 0.53 percent in 2005 to 0.24 percent in 2020. (See Figure 4.)

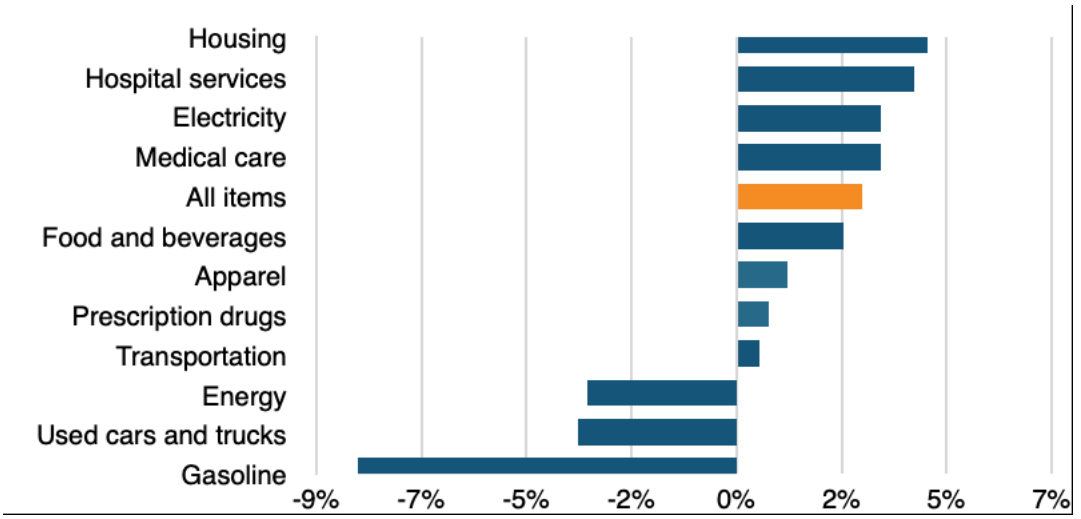
Figure 4: U.S. out-of-pocket drug expenditures, as share of personal income, 2005–2020



[53] Bureau of Lab. Stat., *Consumer Expenditure Survey (Healthcare Expenditures, 2008-2023)*, *available at* https://www.bls.gov/cex (last visited Jan. 16, 2025).

Further, prescription drugs are in no way a significant contributor to the increased inflation the United States is presently experiencing. In fact, over the past 12 months, prescription drug prices increased just 1 percent—one-third the 3 percent increase for all items in the CPI, and less than other parts of the U.S. healthcare system, such as hospital services, which experienced a 4.1 percent increase. (See Figure 5.)

Figure 5: Consumer price index by sector, 12-month change ending in November 2024[54]



In fact, over the past five years (the full years 2020 to 2024), the overall U.S. consumer price index rose four times faster overall than it did for drugs, with the overall CPI rising 23 percent and prescription drugs only 6 percent.[55] Indeed, over the past five years, changes in prescription drug prices rank in the bottom 10 percent of price changes for all products in the CPI Index.

Elsewhere, a 2022 IQVIA report found that over the past 10 years, net per capita spending on medicines has remained effectively flat, increasing just 1.8 percent, on average, per year, even with the introduction of many new treatments and cures.[56] Similarly, the Congressional Budget Office found in its

[54] Bureau of Lab. Stat., *Consumer Price Index*, https://www.bls.gov/cpi (last visited Dec. 17, 2024).

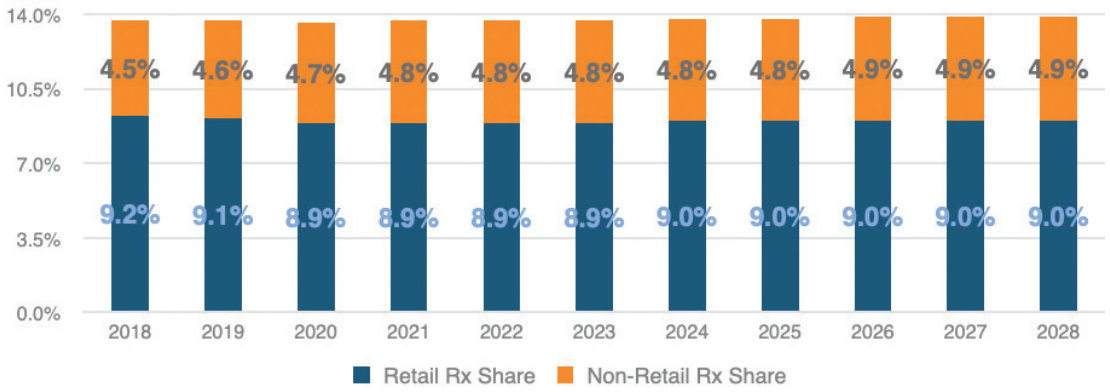
[55] Bureau of Lab. Stat., *Consumer Price Index for All Urban Consumers (CPI-U)*, https://data.bls.gov/pdq/SurveyOutputServlet (last visited Jan. 7, 2025).

[56] IQVIA, *The Use of Medicines in the U.S. 2022* (Apr. 21, 2022), *available at* https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2022.

January 2022 report "Prescription Drugs: Spending, Use, and Prices" that the average net price per prescription fell from $57 in 2009 to $50 in 2018 in the Medicare Part D program and from $63 to $48 in the Medicaid program.[57]

Moreover, the retail prescription drug share of national health expenditures is expected to remain stable and consistent going forward—just as it has over the past two decades. In fact, in a 2020 report, the research firm Altarum found that the share would remain roughly stable in the 9 percent range through most of this decade, with non-retail expenditures also roughly stable in the 4.5 to 4.9 percent range over that period.[58] (See Figure 6.) For 2023, analysts estimate that prescription drugs accounted for 9.2 percent of total U.S. health care spending.[59] That share has remained remarkably consistent over the past half decade.

Figure 6: Projected prescription drug share of national health expenditures, 2018–2028[60]



Lastly, it should be noted that while Americans do in general pay more for drugs than peers in OECD nations, America's overall expenditures on pharmaceutical drugs as a percentage of total healthcare spending stands right in line with that of OECD peers. For 2021, this figure (as calculated by the OECD's methodology) stood at 11.8 percent for the United States, just slightly more than Austria and Switzerland's 11.4 percent, but well below Japan's 17.8 per-

[57] Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* (Jan. 2022), *available at* https://www.cbo.gov/publication/57050.

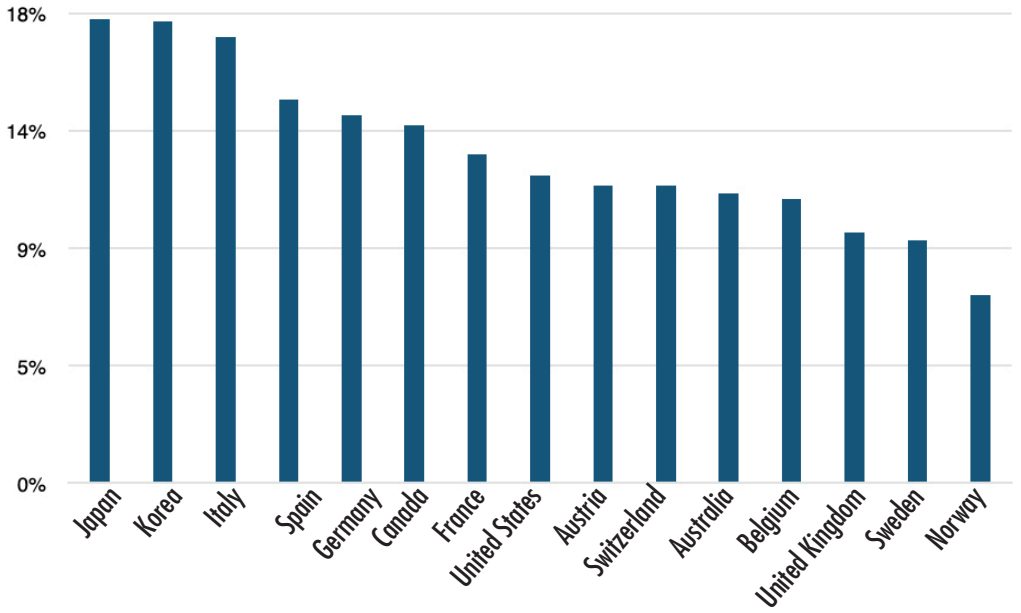
[58] Altarum, *Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail* (June 29, 2018), https://dev.altarum.org/publications/projections-prescription-drug-share-national-health-expenditures-including-non-retail.

[59] McGough et al., *How Has U.S. Spending on Healthcare Changed Over Time?*, *supra* note 7.

[60] Altarum, *supra* note 58.

cent, Korea's 17.7 percent, Germany's 14.1 percent, Canada's 13.7 percent, and France's 12.6 percent.[61] (See Figure 7.) This certainly does not paint a picture of rampantly out of control drug prices in the United States.

Figure 7: Pharmaceutical spending as a percentage of total healthcare spending, 2021[62]



It's also important to note that the system America has devised gets innovative drugs to patients faster than anywhere else in the world.[63] Indeed, a broad range of research suggests that Americans enjoy access to innovative medicines earlier than citizens in other nations do.[64] For instance, considering the availability of 460 new medicines launched globally from 2012 through year-end 2021, 85 percent were available in the United States, a wide gap over Germany

[61] Note that the OECD uses a slightly different accounting methodology to compare countries' prescription drug health expenditures. The point here is meant to be illustrative.

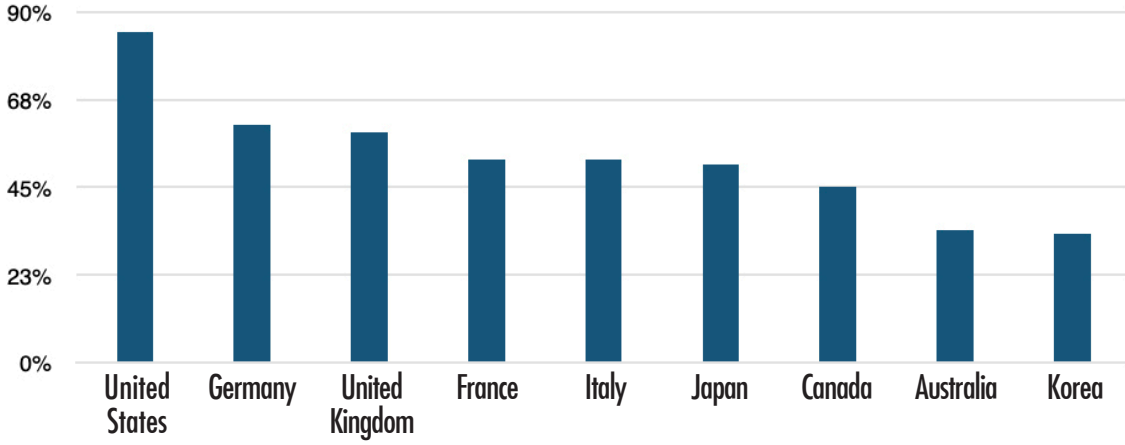
[62] OECD, *Pharmaceutical Spending*, https://www.oecd.org/en/data/indicators/pharmaceutical-spending.html (last visited Jan. 16, 2025).

[63] Andrew W. Mulcahy, *Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries*, RAND Health Q., June 2024, at 4, *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC11147638.

[64] Kevin Haninger, PhRMA, *New Analysis Shows that More Medicines Worldwide Are Available to U.S. Patients* (June 5, 2018), https://phrma.org/en/Blog/new-analysis-shows-that-more-medicines-worldwide-are-available-to-us-patients; Patricia M. Danzon & Michael F. Furukawa, *International Prices and Availability of Pharmaceuticals In 2005*, Health Aff., Jan.-Feb. 2008, at 221, *available at* https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.27.1.221.

and the United Kingdom, at 61 and 59 percent respectively, with percentages declining to as low as 45 percent in Canada, 34 percent in Australia, and 33 percent in Korea. (See Figure 8.) In other words, for Canadian citizens, their medicine cabinet is less than half as full as an American citizen's.

Figure 8: National availability of new medicines first launched globally from 2012 to year-end 2021[65]



Lastly, it should be noted that the expenditures Americans make on drugs deliver tremendous value for society. For instance, a 2020 study in *Health Affairs* found that 35 percent of the 3.3-year increase in Americans' life expectancy at birth (from 75.4 to 78.7 years of age) from 1990 to 2015 resulted directly from pharmaceutical innovation.[66] Elsewhere, in analyzing the value added by biopharmaceutical innovation compared with its cost, Columbia University professor Frank Lichtenberg found that, for pharmaceutical drugs launched post-1981 on citizens before 85 years of age, the cost was $2,837 of pharmaceutical expenditure per life-year saved. As Lichtenberg noted, this amounts to "about 8% of per capita GDP, indicating that post-1981 drugs launched were very cost-effective overall."[67] In other research, Lichtenberg found that, from 1997 to 2010, "the value of reductions in work loss days and hospital admis-

[65] PhRMA, *Global Access to New Medicines Report* (2023), *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/2023-04-20-PhRMA-Global-Access-to-New-Medicines-Report-FINAL-1.pdf.

[66] Jason Buxbaum et al., *Contributions of Public Health, Pharmaceuticals and Other Medical Care to US Life Expectancy Changes, 1990-2015*, Health Aff., Sept. 2020, at 1546, *available at* https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00284.

[67] Frank R. Lichtenberg, *How Many Life-Years Have New Drugs Saved? A 3-Way Fixed-Effects Analysis of 66 Diseases in 27 Countries, 2000-2013*, Int'l Health, Sept. 2019, at 403, *available at* https://academic.oup.com/inthealth/article/11/5/403/5420236.

sions attributable to pharmaceutical innovation was three times larger than the cost of new drugs consumed."[68] The point is that innovative drugs produce tremendous value for society, and the United States continues to lead at creating them, thanks in no small part to the Hatch-Waxman Act.

World-Leading American R&D and Innovation in Biopharmaceuticals

The transformation from America's status as a global "also-ran" in biopharmaceutical innovation into the world's leader has been truly profound. That leadership is reflected in both the world-leading amounts of biopharmaceutical R&D being conducted in the United States and the world-leading numbers of new drugs being developed.

To the first point, the U.S. biopharmaceutical industry is both America's and the world's most R&D-intensive industry, of any kind. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), over the last decade its member companies have invested more than $800 billion in the search for new treatments and cures.[69] In 2023, the top 20 global pharmaceutical companies collectively invested $145 billion in R&D, marking a 4.5 percent increase from 2022.[70] Internationally, one 2024 study found that global biopharmaceutical R&D investment in 2021 reached $276 billion across 4,191 companies. That study further found that U.S. public companies reinvest 30 percent of their revenues, on average, back into R&D.[71] Moreover, America's biopharmaceutical sector accounts for 18 percent of total U.S. business R&D investment. Further, the U.S. biopharmaceutical industry alone employs over one-quarter of America's total R&D workforce, while approximately 23 percent of the industry's workforce toils at the science bench developing innovative cures.

Unsurprisingly, America's world-leading investment in biopharmaceutical research leads directly into America's world-leading production of biopharmaceutical innovation. In the 2000s, U.S.-headquartered biopharmaceutical

---

[68] Frank R. Lichtenberg, *The Impact of Pharmaceutical Innovation on Disability Days and the Use of Medical Services in the United States, 1997–2010*, J. Hum. Capital, Summer 2014, at 432, *available at* https://www.jstor.org/stable/10.1086/679110.

[69] PhRMA, *Research and Development Policy Framework*, https://phrma.org/en/policy-issues/Research-and-Development-Policy-Framework (last visited Jan. 16, 2025).

[70] Deloitte, *Deloitte's 14th Annual Pharmaceutical Innovation Report: Pharma R&D Return on Investment Rebounds After Record Low* (Apr. 30, 2024), https://www2.deloitte.com/us/en/pages/about-deloitte/articles/press-releases/deloittes-14th-annual-pharmaceutical-innovation-report-pharma-rd-return-on-investment-rebounds-after-record-low.html.

[71] Amitabh Chandra et al., *Comprehensive Measurement of Biopharmaceutical R&D Investment*, Nature Revs. Drug Discovery, Aug. 2024, at 652, *available at* https://www.nature.com/articles/d41573-024-00131-2.

enterprises generated more new-to-the-world drugs than companies from the next five nations combined.[72] Indeed, in every five-year period since 1997, the United States has produced more new chemical or biological entities than any other country or region. And from 1997 to 2016, U.S.-headquartered enterprises accounted for 42 percent of new chemical or biological entities introduced throughout the world, far outpacing relative contributions from European Union (EU) member countries, Japan, China, or other nations.[73] Put simply, over the past two decades, U.S.-headquartered biopharmaceutical enterprises accounted for almost half of the world's new drugs developed.[74]

Indeed, pharmaceutical innovation has experienced significant growth in the past four decades, marked by an increase in new drug approvals and advancements in R&D. In 1984, the FDA approved 22 new molecular entities (NMEs). This number has generally trended upward, with the FDA's Center for Drug Evaluation and Research (CDER) approving 55 novel drugs in 2023.[75] And while there is a yearly ebb and flow to the number of new FDA drug approvals, overall the trend has been significantly up since the 1984 passage of the Hatch-Waxman Act. Since 1985, nearly 1,300 new medicines have been approved by the FDA. (See Figure 9.) Currently, there are some 8,000 innovative drugs under development.[76] These innovative drugs are crucially important as treatments and cures in their own right, but also in no small part because they constitute the generic pipeline of the future.

---

[72] Ross C. DeVol et al., Milken Inst., *The Global Biomedical Industry: Preserving U.S. Leadership*, at 5 (Sept. 2011), *available at* https://www.pacificresearch.org/wp-content/uploads/2017/05/CASMIFullReport.pdf.

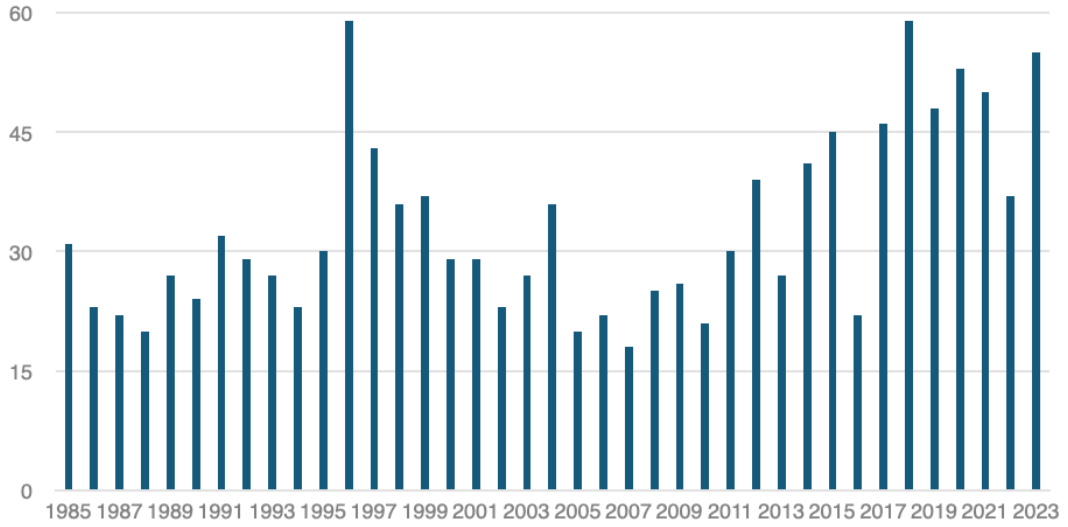
[73] Joe Kennedy, Info. Tech. & Innovation Found., *How to Ensure that America's Life-Sciences Sector Remains Globally Competitive*, at 37 (Mar. 2018), *available at* https://itif.org/publications/2018/03/26/how-ensure-americas-life-sciences-sector-remains-globally-competitive; Eur. Fed'n of Pharm. Indus. & Ass'ns, *The Pharmaceutical Industry in Figures, Key Data 2017*, at 8 (2017), *available at* https://www.efpia.eu/media/219735/efpia-pharmafigures2017_statisticbroch_v04-final.pdf.

[74] Stephen Ezell, Info. Tech. & Innovation Found., *Testimony to the Senate Finance Committee on Prescription Drug Price Inflation* (Mar. 2022), *available at* https://itif.org/publications/2022/03/16/testimony-senate-finance-committee-prescription-drug-price-inflation.

[75] Enrique Seoane-Vazquez et al., *Analysis of US Food and Drug Administration New Drug and Biologic Approvals, Regulatory Pathways, and Review Times*, Sci. Reps. (Feb. 9, 2024), *available at* https://www.nature.com/articles/s41598-024-53554-7.

[76] PhRMA, *Medicines in Development*, https://phrma.org/en/Scientific-Innovation/In-The-Pipeline/Medicines-in-Development (last visited Jan. 16, 2025).

Figure 9: FDA new drug approvals, 1985–2023[77]



Inspiring the BPCIA

The HWA also inspired the framework for the future legislation that enabled biosimilar competition in the biologics space, preserving the interests of innovation and affordability there as well. Unlike so-called "small molecule" drugs, which are chemically synthesized, biologic drugs are derived from (and generally manufactured within) living tissues.[78] (For this reason, it's not possible to develop an exact copy of them.) The Biologics Price Competition and Innovation Act (BPCIA), passed by Congress in 2010, helped carry on the HWA's goals and continued to abbreviate regulatory pathways for so-called "biosimilars." Essentially, the BPCIA requires that the biosimilar drug be shown to be "highly similar" to the reference product and that there be "no clinically meaningful differences . . . [from] the reference product in terms of safety, purity, and potency."[79] Like the Hatch-Waxman Act, the BPCIA also created a process for patent litigation, resolving previous disputes, and provided 12 years of reference product data exclusivity from date of first licensure until biosimilar approval.[80]

---

[77] FDA, *Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals* (Apr. 22, 2024), https://www.fda.gov/drugs/drug-approvals-and-databases/compilation-cder-new-molecular-entity-nme-drug-and-new-biologic-approvals.

[78] Huy X. Ngo & Sylvie Garneau-Tsodikova, *What Are the Drugs of the Future?*, MedChemComm, Apr. 2018, at 757, *available at* https://pubs.rsc.org/en/content/articlelanding/2018/md/c8md90019a.

[79] 42 U.S.C. § 262(i)(2).

[80] PhRMA, *Research & Development: Biologics & Biosimilars*, https://phrma.org/en/policy-issues/Research-and-Development-Policy-Framework/Biologics-Biosimilars (last visited Jan. 16, 2025).

Preserving the Spirit, Intent, and Effect of the Hatch-Waxman Act

As this essay has argued, the Hatch-Waxman Act represents a finely tuned, integrated system that effectively preserves and maintains incentives and rewards for novel pharmaceutical innovation while promoting affordability by creating pathways for generic competition. But such finely balanced systems are precarious and prone to disruption in the face of significant policy changes. Unfortunately, the continuing success of the system the Hatch-Waxman Act created is under threat from several directions, including government drug price controls and intermediary management of drug formularies.

On average in the years since the introduction of the Hatch-Waxman Act, innovative small molecule drugs have enjoyed about 13 years on the market before they face generic competition.[81] This has afforded companies adequate time to recoup their investments and earn sufficient profits to reinvest in future generations of innovation. It's this dynamic that produced the great successes this essay has documented in positioning the United States as the world leader in pharmaceutical innovation while keeping prescription drugs, on net, broadly affordable.

Yet, as noted, a narrative persists that U.S. drug prices remain too high. In 2022, Congress passed the Inflation Reduction Act (IRA), which became the first law in American history to grant the Centers for Medicare & Medicaid Services (CMS) the authority to control the price of drugs. Specifically, it allowed CMS to set prices for approved drugs covered under Medicare Part B, outpatient care, and Medicare Part D prescription drug coverage. The IRA drew a distinction between small molecule and biologic drugs, allowing small molecules to be sold at market prices for only 9 years, compared to 13 years for large molecules, before they become subject to IRA price setting.[82] In August 2023, Medicare released a list of the first 10 drugs to become subject to price setting. The drugs target a wide range of diseases, including diabetes, heart disease, and cancer, and are used by 8 million people on Medicare.[83]

---

[81] Henry Grabowski et al., *Continuing Trends in U.S. Brand-Name and Generic Drug Competition*, J. Med. Econ., Jan.-Dec. 2021, at 908, *available at* https://pubmed.ncbi.nlm.nih.gov/34253119.

[82] Emily Michiko Morris & Joshua Kresh, George Mason Univ. Ctr. for Intell. Prop. & Innovation Pol'y, *Pharmaceutical 'Nominal Patent Life' Versus 'Effective Patent Life,' Revisited* (May 20, 2024), https://cip2.gmu.edu/2024/05/20/pharmaceutical-nominal-patent-life-versus-effective-patent-life-revisited.

[83] Ctrs. for Medicare & Medicaid Servs., Medicare Drug Price Negot. Program, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), *available at* https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf; PhRMA, *Access to Medicines*, https://phrma.org/access-to-medicines (last visited Jan. 16, 2025).

Some have contended that government drug price controls would have a limited impact on future pharmaceutical innovation. For instance, a 2022 Congressional Budget Office report concluded that only 15 potential drugs would be lost over the next 30 years due to lost revenues from drug price controls.[84] Other assessments reached differing conclusions. A 2021 study found that the impact of price controls as outlined in the IRA would result in a nearly 45 percent decrease in pharmaceutical R&D investment and 254 fewer new drugs introduced between 2021 and 2039.[85]

Unfortunately, the market reality since the IRA's introduction has been much closer to the less-sanguine assessment: indeed, the IRA is already exerting significantly deleterious impacts on innovation, especially in small molecules. In a study of PhRMA member companies, 78 percent reported they expected to cancel early-stage small molecule pipeline projects, preventing these drugs from even reaching the end of their research stages, as they are no longer economically viable.[86] An additional 82 percent of companies with current projects in the pipeline focused on "cardiovascular, mental health, neurology, infectious disease, cancers and rare diseases" stated that there would be substantial impacts on future R&D decisions, likely discontinuing projects.[87]

The negative effects of the IRA on small molecule development are already being felt. Novartis, for example, recently announced the discontinuation of several early-stage cancer drugs, as their development is no longer financially viable due to the IRA.[88] Other pharmaceutical companies, such as AstraZeneca, have also announced delayed releases of cancer drugs in response to the IRA, and have even reported further reprioritization of small drugs more generally.[89] Treatments are being removed from the market even before they have the

---

[84] Cong. Budget Off., *Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14* (Sept. 7, 2022), *available at* https://www.cbo.gov/publication/58455.

[85] Tomas Philipson & Troy Durie, Univ. of Chi., Becker Friedman Inst. for Econ., *The Evidence Base on the Impact of Price Controls on Medical Innovation* (Sep. 14, 2021), *available at* https://bfi.uchicago.edu/working-paper/the-evidence-base-on-the-impact-of-price-controls-on-medical-innovation.

[86] PhRMA, *Inflation Reduction Act Already Impacting R&D* (Jan. 9, 2023), *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Infographics/Infographic--Inflation-Reduction-Act-Already-Impacting-RD--010923-FINAL.pdf.

[87] *Id.*

[88] Josh Nathan-Kazis, *Novartis CEO: Some Cancer Drugs Dropped From Pipeline Because Medicare Price Negotiations*, Barron's (May 19, 2023), *available at* https://www.barrons.com/articles/novartis-stock-price-ceo-cancer-drug-medicare-e9b0fcb7.

[89] Steve Usdin, *AstraZeneca May Defer U.S. Cancer Drug Launches in Response to IRA*, BioCentury (Nov. 10, 2022), https://www.biocentury.com/article/645834/astrazeneca-may-defer-u-s-cancer-drug-launches-in-response-to-ira.

chance to save lives. Bristol Myers Squibb's CEO announced that the company was conducting a thorough review of its portfolio, with the expectation that it will have to cancel some programs to make financially sound decisions.[90] Elsewhere, an informal survey conducted by Steve Potts, CEO of SLAM Biotherapeutics, found that out of 100 venture capital firms, over 75 percent are planning on divesting from small molecule companies, as the return on investment in the wake of the IRA has become too unpredictable.[91] This matters greatly for the future of Hatch-Waxman, for an innovative drug not made today can never become a generic drug in the future.

A separate challenge to preserving the intent and effect of the Hatch-Waxman Act pertains to the intermediary management of formularies, especially by pharmacy benefit managers (PBMs). That's because a generic drug that never makes it onto a formulary may as well not even exist at all, because patients don't have access to the cheaper generic option. As a growing share of PBM compensation is tied to the list prices of medicines, they are incentivized to prefer medicines with higher list prices and large rebates.

Unfortunately, the reality is that PBMs consistently delay adoption of new generics into health insurance policies, and it currently takes over 1,000 days before first generics are covered on more than half of Medicare Part D formularies.[92] Further, a January 2022 Avalere analysis found that Medicare Part D plans were placing a growing number of generic medicines on Tier 4 (non-preferred) and Tier 5 (specialty) lists over time. Specifically, the share of generic drugs placed on preferred generic (Tier 1) or generic (Tier 2) tiers declined from 65 percent in 2016 to 43 percent in 2022, and the percentage of these products placed on non-preferred or specialty tiers rose from 20 percent to 37 percent over the same period.[93]

---

[90] James Waldron, *Bristol Meyers CEO Already Reassessing Portfolio in Wake of US Pricing Law: Repor*t, Fierce Biotech (Nov. 21, 2022), https://www.fiercebiotech.com/biotech/bristol-myers-already-reassessing-portfolio-wake-ira-ceo-tells-ft.

[91] Vital Health Podcast, *The Future of Biotech: Steven Potts on Innovation, Policy, and the Impact of the IRA* (Oct. 7, 2024), https://podcasts.apple.com/us/podcast/the-future-of-biotech-steve-potts-on-innovation/id1412765237?i=1000672143305.

[92] Ass'n for Accessible Meds., *New Evidence Shows Medicare Part D Plans Continue to Fail to Get New Generics to Seniors*, https://accessiblemeds.org/resources/reports/new-evidence-shows-medicare-part-d-plans-continue-fail-get-new-generics-seniors (last visited Jan. 16, 2025).

[93] Avalere, *57% of Generic Drugs Are Not on 2022 Part D Generic Tiers* (Jan. 24, 2022), https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers.

As an example, consider the case of Tecfidera (dimethyl fumarate), a blockbuster multiple sclerosis treatment manufactured by Biogen that went generic in late 2020. Within months of Tecfidera going off-patent, more than 10 generic drug makers brought competing versions of dimethyl fumarate to market with "deeply discounted prices to Tecfidera."[94] Roughly one year post-generic launch, aggressive competition from generic manufacturers drove prices for a 60-count bottle of the generic equivalent down to "a 99%+ discount to the brand's list price."[95] However, by Q3 2021, Medicare Part D plans covering the majority of U.S. seniors didn't even make the generic equivalent available to their members, instead only offering them brand-name Tecfidera.[96] Moreover, when the generic was made available to seniors, it was largely done so at "negotiated prices" that far exceeded the lowest-cost generic's price.[97]

Or consider the case of insulin, which shows how misaligned supply chain dynamics drive affordability challenges for patients. A bipartisan 2021 report by the Senate Finance Committee (SFC) on the insulin market found "PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs retain at least a portion of what they negotiate."[98] Manufacturers often sell insulin, an essential medicine, to insurers and PBMs at deep discounts. In fact, as the SFC report noted, some PBMs have secured rebates on insulin as high as 70 percent in recent years.[99] Yet, PBMs paid $52 for an insulin product that had a list price of more than $350.[100]

Unfortunately, many patients are forced to make out-of-pocket payments based on insulin's irrelevant list price.[101] For instance, one study found that list prices for Sanofi's insulins have grown by 140 percent over the past eight

---

[94] Antonio Ciaccia, *New Drug Pricing Report Showcases Highs, Lows, Distorted Incentives, and Brokenness of Medicare Part D*, 46Brooklyn (Dec. 1, 2021), https://www.46brooklyn.com/news/2021/12/1/wreckfidera-now-streaming.

[95] *Id.*

[96] *Id.*

[97] *Id.*

[98] Staff of S. Comm. on Fin., 117th Cong., *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 2021), *available at* https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

[99] *Id.*

[100] Adam J. Fein, *Five Top Drugmakers Reveal List vs. Net Price Gaps (Plus: The Trouble With Insulin Prices)*, Drug Channels (Aug. 11, 2020), https://www.drugchannels.net/2020/08/five-top-drugmakers-reveal-list-vs-net.html.

[101] *Id.*

years, while net prices have declined by 41 percent.[102] Similarly, over the past five years, the list price of Eli Lilly's Humalog insulin increased by 27 percent, while its net price declined by 10 percent.[103] But as Adam Fein notes, "[formulary plan] benefit designs often mask these declining net prices."[104] Fein explains, "Payers' drug costs and manufacturers' revenues have been dropping for the past four years. Despite this decline, patients' out-of-pocket costs have been rising."[105] That is because increasing use of high-deductible health plans and coinsurance means that patients are increasingly exposed to undiscounted list prices, thus enabling PBMs to increasingly shift costs on to patients. As Fein concludes, "Third-party payers' benefit designs remain a significant barrier to addressing drug costs. Many continue to use the ever-growing rebate dollars of the gross-to-net bubble to offset overall plan costs rather than reducing patients' out-of-pocket spending."[106]

Generic drugs help drive down healthcare system costs, but they can't if they don't reach patients. For these reasons, the Information Technology and Innovation Foundation (ITIF) has supported proposals calling for the imposition of greater fiduciary obligations on the activities of PBMs. ITIF also supports other proposals to increase drug price transparency, including removal of pharmacy gag clauses and requiring plan sponsors to provide patients with information about drug price increases and lower cost-options.[107]

Conclusion

On September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche's Avastin, a then-breakthrough anti-cancer drug for lung, cervical, and colorectal cancer[108]. In other words, a drug for forms of cancers that scarcely existed 20 years before in 1997 was now available as a biosimilar. That's

---

[102] *Id.*

[103] *Id.*

[104] Adam J. Fein, *Drug Channels News Roundup, July 2020: Diabetes Costs, Regeneron's Copay Support, MA Rethinks Coupons, My Favorite Chart Updated, and ABC's Steve Collis*, Drug Channels (July 29, 2020), https://www.drugchannels.net/2020/07/drug-channels-news-roundup-july-2020.html.

[105] *Id.*

[106] *Id.* (spelling corrected).

[107] Neeraj Sood et al., *Do Companies in the Pharmaceutical Supply Chain Earn Excess Returns?*, Int'l J. Health Econ. & Mgmt., Jan. 2021, at 99, *available at* https://doi.org/10.1007/s10754-020-09291-1.

[108] FDA, *FDA Approves First Biosimilar for Cancer Treatment* (Dec. 21, 2017), https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-first-biosimilar-cancer-treatment.

emblematic of an effective system of U.S. life-science innovation that promotes breakthrough innovation and then facilitates generic competition to help manage drug prices.

As Jack Scannell, a senior fellow at Oxford University's Center for the Advancement of Sustainable Medical Innovation framed the issue (in a 2015 *Forbes* interview), "I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995."[109] He continued, "Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good."[110]

It's that dynamic that explains why anti-lung cancer and multiple sclerosis drugs that simply didn't exist 20 years ago are available on the market at generic prices today. And it's that dynamic that enables us to envision a future where drugs that do not even exist today (or that are only just now starting to exist) for heretofore-intractable diseases such as Alzheimer's, Parkinson's, or pancreatic cancer may well be available at generic prices in 2045 or 2050.

That's certainly the most important legacy of the Hatch-Waxman Act. However, the other essential legacy of the Hatch-Waxman Act (and the Bayh-Dole Act as well) is that it exemplifies how effective, well-designed public policy can be made when policymakers come together on a bipartisan basis to develop elegant solutions for vexing societal challenges.

[109] Jack Scannell, *Four Reasons Drugs Are Expensive, of Which Two Are False*, Forbes (Oct. 13, 2015), http://www.forbes.com/sites/matthewherper/2015/10/13/four-reasons-drugs-are-expensive-of-which-two-are-false/#257708d948a5.

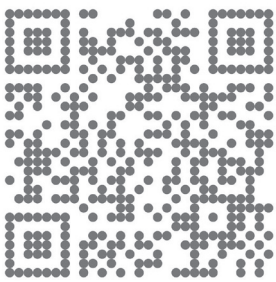
[110] *Id.*

About the Authors

Stephen Ezell is Vice President, Global Innovation Policy at the Information Technology and Innovation Foundation (ITIF) and Director of ITIF's Center for Life Sciences Innovation. He also leads the Global Trade and Innovation Policy Alliance. His areas of expertise include science and technology policy, international competitiveness, trade, and manufacturing. Ezell is the coauthor of Innovating in a Service-Driven Economy: Insights, Application, and Practice (Palgrave Macmillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale, 2012). Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown's Landegger International Business Diplomacy program.

Leah Kann is a Policy Fellow at ITIF's Center for Life Sciences Innovation. She is a senior at the University of North Carolina at Chapel Hill pursuing a B.S. in Biology and a B.A. in Public Policy, with a minor in Spanish for Business.

Support Our Efforts



@senatororrinhatch @orrinhatch @orrinhatchcenter


HATCH CENTER
CIVILITY & SOLUTIONS