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THE HATCH-WAXMAN ACT: A PATH FORWARD FOR MAKING IT MORE MODERN

Robert A. Armitage[†]

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INTRODUCTION

The Hatch-Waxman Act¹ is perhaps the most significant single piece of consumer legislation of all time.² By creating a pair³ of simplified regulatory pathways for approval of copied versions⁴ of

1. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. While this Act today is universally known and cited as the Hatch-Waxman Act, in earlier years it was more commonly known as the Waxman-Hatch Act. See Henry Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PHARMACOECONOMICS (ISSUE 2 SUPPLEMENT) 110 (1996).

2. A recent study characterized the consumer benefit from the Act. It sought to determine the “total savings that have accrued to the U.S. health care system from substituting generic drugs for their brand-name counterparts,” and the study concluded “that from 1999 through 2010 doing so saved more than \$1 trillion.” See U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE (2012).

3. These pathways are commonly known as the “paper NDA” and “ANDA,” or “abbreviated new drug application,” options that became available through the Hatch-Waxman Act and are discussed in detail *infra* Parts I, III.C.

4. The reference in this article to a “copied version” of a medicine refers to a product that was developed by someone other than the originator of the medicine. The originator of the medicine refers to the entity that originally developed the medicine and secured regulatory approval to market the medicine. As will be explained *infra* Part I, entities that develop copied versions of new medicine typically make use of abbreviated regulatory filings—for example, the ANDA pathway—to secure marketing approval for their copied versions.

new drugs,⁵ the Act provided a legal and economic framework for creating an entirely new industry: today's generic drug industry. As a result of the Hatch-Waxman Act, generic drug manufacturers now supply American consumers with a wide spectrum of high-quality, low-cost copies of an array of important medicines. The economics of this new industry were made possible by dramatically abbreviating the otherwise demanding requirements⁶ imposed on the originators of new medicines to secure regulatory approval for marketing of their innovations.⁷

5. As used herein, the terms "drug" and "biologic product" have the same meanings as in the MODERN Cures Act of 2013. *See* H.R. 3116, 113th Cong. § 4 (2013) ("The term 'biological product' has the meaning given to that term in section 351 of the Public Health Service Act (42 U.S.C. 262)" and "[t]he term 'drug' has the meaning given to that term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)."). The more generic term "medicines" is used herein to reference both drugs and biologic products.

6. Before a new medicine can come to market, three phases of clinical trials—that is, trials involving human subjects—must follow the preclinical or animal studies required to ethically justify proceeding to test an experimental medicine in human beings. The last of the three phases of human trials (Phase III) is the point at which substantial evidence of safety and effectiveness must be established for a new medicine to be approved for marketing. *See Clinical Trial Phases*, U.S. NAT'L LIBR. MED., <http://www.nlm.nih.gov/services/ctphases.html> (last visited Mar. 3, 2014).

7. The past one hundred years have brought about nothing short of a revolution in the regulatory requirements to bring new medicines to market. Following enactment of the Pure Food and Drug Act, ch. 3915, 34 Stat. 768 (1906), Congress created the U.S. Food and Drug Administration (FDA) to oversee the safety of drugs under the Federal Food, Drug, and Cosmetic Act of 1938 (FDC Act), ch. 675, 52 Stat. 1040. Subsequently, biologic products came under federal regulation with the Public Health Service Act (PHSA), ch. 373, 58 Stat. 682 (1944), but it was not until the Kefauver-Harris Amendments to the FDC Act, Pub. L. No. 87-781, 76 Stat. 780 (1962), that the current requirements for safety and effectiveness for new drugs were put into place as a result of the thalidomide tragedy. *See* Walter Mattli & Ngaire Woods, *In Whose Benefit? Explaining Regulatory Change in Global Politics*, in *THE POLITICS OF GLOBAL REGULATION* 23 (Walter Mattli & Ngaire Woods eds., 2009). Today, a New Drug Application (NDA) filed to secure FDA approval must contain "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" before it can be given regulatory approval for marketing. 21 U.S.C. § 355(b)(1)(A) (2012).

The path a drug travels from a lab to your medicine cabinet is usually long, and every drug takes a unique route. . . .

....

Since enactment of the Hatch-Waxman Act in 1984, the generic drug industry has come to dominate quantitatively the U.S. prescription drug market.⁸ The unqualified success of the Hatch-Waxman Act in this respect helped pave the way for, indeed made inevitable, the enactment of the Biosimilars Act in 2009.⁹ This law was intended by its proponents to accomplish for copied versions of biologic medicines¹⁰ what the Hatch-Waxman Act had accomplished for drugs.¹¹

Most drugs that undergo preclinical (animal) testing never even make it to human testing and review by the FDA. The drugs that do must undergo the agency's rigorous evaluation process, which scrutinizes everything about the drug—from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured.

The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> (last visited Mar. 3, 2014).

8. Approximately eighty-four percent of prescriptions in the United States are for generic drugs. IMS INST. FOR HEALTHCARE INFORMATICS, DECLINING MEDICINE USE AND COSTS: FOR BETTER OR WORSE? 15 (2013) (citing IMS HEALTH, NATIONAL PRESCRIPTION AUDIT (2012)). At the turn of the century, these copied versions of new medicines had less than fifty percent of the U.S. prescription drug market.

9. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, subtit. A, 124 Stat. 119, 804–21 (2010). The Biosimilars Act was passed as a separate title of the same act that contained the provisions of law often referred to as “Obamacare.”

10. Biologic products include medicines made through modern biotechnological processes, rather than largely chemical ones. During the past thirty-five years, microbes have been turned into medicine-making machines capable of churning out a remarkable spectrum of new-era biologics. Working in partnership with Genentech, Eli Lilly and Company launched the era of recombinant DNA medicines made from microbes with the 1978 launch of its human insulin product, Humulin. See Suzanne White Junod, *Celebrating a Milestone: FDA's Approval of First Genetically-Engineered Product*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SelectionsFromFDLIUpdateSeriesonFDAHistory/ucm081964.htm> (last updated Apr. 10, 2009).

11. “Drugs” are medicines that are mostly the product of chemical synthesis. These chemically-based medicines today are used in the treatment of a wide spectrum of diseases. Nothing demonstrates the revolution in treatment made possible through “new drugs” more than the emerging treatments for HIV/AIDS. Stribild, Atripla, and Complera are one-pill-a-day oral medicines for the treatment of HIV/AIDS. See ARTIPLA, <http://www.atripla.com> (last visited Feb. 1, 2014); COMPLERA, <http://www.complera.com> (last visited Feb. 1, 2014); STRIBILD, <http://www.stribild.com> (last visited Feb. 1, 2014).

While the Biosimilars Act and the Hatch-Waxman Act addressed fundamentally the same challenge (i.e., how to best craft the regulatory/intellectual property (IP) interface¹² under which copied versions of new medicines might come to market through abbreviated regulatory approval processes), the Biosimilars Act was no clone of the Hatch-Waxman Act. As will be detailed later in this article, key aspects of the regulatory/IP interface contained in the Biosimilars Act differ in highly significant ways from the analogous provisions in the Hatch-Waxman Act. In a nutshell, while the Hatch-Waxman Act is highly patent-centric and effectively provides that generic drug entry is determined by the expiration of the innovator's relevant patents, the Biosimilars Act is nearly patent-agnostic and permits biosimilar products to be approved for marketing only after an extended IP protection period that Congress justified based on the heft of the required data package containing the reports of the preclinical and clinical studies needed for the original version of a new medicine to be approved for marketing.

In making these two laws materially different, Congress was no doubt signaling that, were it inclined to rewrite the Hatch-Waxman Act from scratch today, it might well ground a twenty-first century incarnation of the Hatch-Waxman law on concepts for a regulatory/IP interface found in the Biosimilars Act. Given the contemporary economics for bringing innovative new medicines to market, the Biosimilars Act's provisions were apparently regarded by Congress as better reflecting the modern economic reality for the originators of new medicines.

The brutality of biopharmaceutical innovators' economics is something that Congress could hardly ignore. Some current

12. As noted above, copied versions of new medicines gain access to the market under abbreviated regulatory approval pathways specifically designed for reviewing and approving such versions. However, there are limitations on the availability of marketing approvals under these abbreviated regulatory pathways. Approval to begin marketing under an abbreviated approval pathway is typically based upon a set of intellectual property rules designed to protect the investment of the originator of the new medicine. The limitations can include both access limitations, e.g., moratorium provisions that prevent filing for regulatory approval under the abbreviated pathway, and direct approval limitations (i.e., provisions that define that date upon which a regulatory approval can become effective so that the marketing of the copied version can commence). As will be discussed in detail *infra* Part III.D., the limitation on the ability to approve a copied version of a new medicine represents what is commonly called "data package protection."

estimates suggest that a \$4–5 billion research and development (R&D) investment¹³—and decades of concerted effort¹⁴—is now required to bring a single new medicine to market. While much of the biopharmaceutical industry R&D spending relates to experimental medicines that fail to produce a commercial product,¹⁵ among the R&D projects that do reach the market, only about one out of every five to six new medicines ever earns back the investment needed to create it.¹⁶ Additionally, many of the new

13. While the R&D investment needed to bring a single new medicine to market varies depending upon the method used to make the calculation, the industry R&D investment per new medicine coming to market is roughly \$4 billion simply using the ratio between \$135 billion in annual R&D investment, *see infra* note 21, and actual number of new medicines being approved from marketing lying somewhere in the mid-30s. Both lower and higher figures can be found. Dr. Francis Collins recently opined, “Developing a drug takes time and money: on the average, around 14 years and \$2 billion or more. More than 95 percent of the drugs fail during development.” Francis Collins, *Crowdsourcing Therapeutic Molecules for Drug Discovery*, NAT’L INST. HEALTH (June 18, 2013), <http://directorsblog.nih.gov/2013/06/18/crowdsourcing-therapeutic-molecules-for-drug-discovery> (last visited Mar. 23, 2014). Other estimates place the figure on the order of \$5 billion in R&D costs for every new medicine that comes to market, a figure largely based on taking full account of the failed efforts noted by Dr. Collins.

A company hoping to get a single drug to market can expect to have spent \$350 million before the medicine is available for sale. In part because so many drugs fail, large pharmaceutical companies that are working on dozens of drug projects at once spend \$5 billion per new medicine.

Matthew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013 11:10 AM), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine>. Whether the best representation of the magnitude of the R&D investment required to bring a new medicine to market is \$2 billion or \$5 billion, or somewhere in between, the implications for the IP protection that is necessary to make the investment a viable one are substantially unchanged.

14. The time from the initiation of a research program to getting a new medicine to a patient is measured not in days or months or years, but decades. PHARM. RESEARCH & MFRS. OF AM., 2013 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE 32 (2013) (citing Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REVIEWS: DRUG DISCOVERY 417, 417–29 (2004)).

15. Failed efforts directed to the creation of new medicines may now consume at least ninety percent of a biopharmaceutical company’s R&D expenditures. *See* Herper, *supra* note 13.

16. PHARM. RESEARCH & MFRS. OF AM., *supra* note 14 (citing John A. Vernon et al., *Drug Development Costs When Financial Risk Is Measured Using the Fama-French*

medicines reaching the market today find themselves competing with copied versions of earlier-generation medicines that are sold by generic manufacturers—and available to patients—at nominal prices.¹⁷

It seems doubtful that the ying of the Hatch-Waxman Act regime and the yang of the Biosimilars Act provisions will forever coexist with one another. It cannot be good policy that copying drugs is to be subject to one set of IP rules and copying biologic products is to be governed by a materially different set of IP provisions.

What may be the best next-generation thinking on defining a common regime for copied versions of all new medicines to be able to come to market can be found in a bill that is now pending before Congress. This latest congressional effort is the MODDERN Cures Act.¹⁸ The MODDERN Cures Act, according to its proponents, has the potential to be a quantum improvement over both the Hatch-Waxman Act and the Biosimilars Act in terms of meeting the needs and expectations of patients for access to low-cost, high quality medicines—while spurring greater industry focus on the development of new medicines of the greatest potential

Three-Factor Model, 19 HEALTH ECON. 1002, 1002–05 (2009)) (“Only 2 of 10 marketed drugs return revenues that match or exceed R&D costs.”); see also JIM GILBERT ET AL., REBUILDING BIG PHARMA’S BUSINESS MODEL 1–2 (2003), available at http://www.fredreichheld.com/bainweb/PDFs/cms/Public/rebuilding_big_pharma.pdf (“Declining R&D productivity, rising costs of commercialization, increasing payor influence and shorter exclusivity periods have driven up the average cost per successful launch to \$1.7 billion and reduced average expected returns on new investment to the unsustainable level of 5%. . . . [This is] significantly lower than the industry’s risk-adjusted cost of capital. Only one out of six new drug prospects will likely deliver returns above their cost of capital, an unattractive prospect for investors.”).

17. The nominal cost from many generic drug prescriptions is reflected in a CVS Pharmacy promotion, which allows consumers to enroll in its Health Savings Pass program that advertises “\$11.99 for 90 days—hundreds of generic medications.” See *CVS Pharmacy Health Savings Pass*, CVS PHARMACY, <http://www.cvs.com/promo/promoLandingTemplate.jsp?promoLandingId=healthsavingspass> (last visited Mar. 3, 2014). In addition, the retail giant Walmart advertises “\$4 Prescriptions—Choose from hundreds of generic drugs.” See *\$4 Prescription Program*, WALMART, <http://www.walmart.com/cp/1078664?povid=cat5431-env198764-moduleB120712-lLinkFC44DollarPrescriptions> (last visited Mar. 3, 2014).

18. Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2013 (“MODDERN Cures Act of 2013”), H.R. 3116, 113th Cong. (2013).

benefits for patients (i.e., those addressing unmet medical needs). Compared to the IP interface provisions of either the Hatch-Waxman Act or the Biosimilars Act, the MODDERN Cures Act is a virtual paragon of simplicity and directness.

This article offers some commentary on the economic and regulatory environment that led to the development of the MODDERN Cures Act. It reviews the key provisions of the Act. It then lays out the rationale that proponents of the legislation have offered for its enactment into law.

I. THE REGULATORY JOURNEY FROM HATCH-WAXMAN TO THE BIOSIMILARS ACT TO THE MODDERN CURES ACT

No one questions that the medicines that have come to market since the end of World War II have been revolutionary in what they have contributed to human health. These modern medicines, including the approximately three-dozen new such medicines being approved each year, stand wholly without precedent throughout all of human history.¹⁹ The benefits to human health, longevity, and productivity due to access to modern medicines, were those benefits to be quantified in purely economic terms, would certainly be in the trillions of dollars. Many more such medicines may be on their way to market,²⁰ driven by the massive,

19. The difference an innovative medicine can make can be seen in the fate of Arthur Ashe, who was infected with the HIV/AIDS virus in June 1983, diagnosed with HIV/AIDS in 1988, and died from complications of the disease in February 1993, as contrasted with Earvin (“Magic”) Johnson who was diagnosed with HIV/AIDS in 1991 and, more than 20 years later, continues to lead a full and active life. Robin Finn, *Arthur Ashe, Tennis Champion, Dies of AIDS*, N.Y. TIMES, Feb. 7, 1993, at 11, available at 1993 WLNR 3412281; Allison Samuels, *Magic Johnson: I Survived*, DAILY BEAST (May 15, 2011), <http://www.thedailybeast.com/articles/2011/05/16/magic-johnson-20-years-of-living-with-hiv.html>. The difference in prognosis as between the two men was defined by an experimental combination of new antiretroviral drugs that Mr. Johnson was prescribed in 1994. Samuels, *supra*. Within two years, these experimental medicines would be approved by the FDA and become the benchmark for HIV/AIDS therapies.

20. The number of new biologic medicines alone under development by biopharmaceutical companies exceeds 900. PHARM. RESEARCH & MFRS. OF AM., *supra* note 14, at 44.

continuing R&D investments (currently \$135 billion annually²¹), being made by the biopharmaceutical industry.

Most of the medicines being prescribed to U.S. consumers today are, however, not sold by the companies that originally created them. Rather, the vast majority are supplied by generic drug manufacturers. Today, copying of new medicines is accomplished within a relatively few years from the time a new medicine first reaches the market. The protection period for new medicines is short enough to assure that the overwhelming majority of all of the innovative drugs that reached the market before the end of the twentieth century are, today, sold by copiers—not the originators of those medicines. As noted earlier, copying new medicines in this manner has been made possible because of new regulatory approval pathways that have been put in place under the Hatch-Waxman Act and the Biosimilars Act. Copied versions of new medicines can be developed and regulatory approval sought under the abbreviated approval pathways based upon a truncated set of filing requirements that relate to the otherwise required testing of new medicines for safety and effectiveness.

The abbreviated regulatory filing requirements are complemented with a companion set of IP rules that are unique to each of the two laws. The IP-related provisions, among other aspects, define the point in time at which regulatory approval can be granted to the copied versions of a medicine under an abbreviated regulatory approval pathway. The Hatch-Waxman Act, as noted briefly above, established two separate abbreviated regulatory approval pathways for copied versions of new drugs to come to market. By far, the more important of the two pathways is the “abbreviated new drug application” (ANDA) pathway.²² Under the

21. Over the past six years, the Pharmaceutical Research and Manufacturers of America (branded as “PhRMA”) reports that its members’ expenditures on R&D into new medicines have run between \$46.4 billion and \$50.7 billion. PHARM. RESEARCH & MFRS. OF AM., *supra* note 14, at 2. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) puts the global pharmaceutical R&D number at \$135 billion. INT’L FED’N OF PHARM. MFRS. & ASS’NS, THE PHARMACEUTICAL INDUSTRY AND GLOBAL HEALTH: FACTS AND FIGURES 2012, at 5 (2012), *available at* http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf.

22. 21 U.S.C. § 355(j) (2012) affords copiers the right to file “abbreviated new drug applications” that effectively treat the abbreviated application as though it contained all the reports of investigations that were required to secure approval

ANDA pathway, a generic drug can be approved without repeating *any* of the testing for safety and effectiveness that was required in order for the original version of the new medicine to be approved.²³

The IP-related provisions of the Hatch-Waxman Act tightly intertwine regulatory approval of copied medicines with the patent rights of the originator. The Act dictates detailed procedures for both the originator and the copier to follow in order to precisely establish when a generic version of a new medicine might be approved under one of the regulatory pathways for copied versions of new medicines. These procedures are, under any measure, as complex as they are prodigious.²⁴ The Hatch-Waxman Act dictates that the originator of a new drug cannot seek regulatory approval for a new medicine without providing in its new drug application²⁵ (NDA) a listing of its relevant patents and their respective expiration dates.²⁶ Anyone seeking to copy a medicine using one of the abbreviated regulatory pathways is required to make a certification with respect to each of the relevant patents listed in the originator's NDA.²⁷ Thereafter, regulatory approval of the copier's generic drug is tied to the expiration of the originator's patents, at least for those not successfully challenged under the patent-challenge provisions of the Hatch-Waxman Act.²⁸ For a

of the original version of the new medicine, even if those investigations were maintained as trade secrets.

23. See 21 U.S.C. § 355(j)(2) (setting out all the requirements for a complete nontesting of a generic drug for safety and effectiveness and bars any additional requirements from being imposed on the copier). No requirements for either safety or effectiveness testing are imposed on an ANDA applicant.

24. See DONALD O. BEERS & KURT R. KARST, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS* ch. 4 (8th ed. 2013).

25. 21 U.S.C. § 355(b).

26. The term "relevant patents" is used in this article to reference the patents that are described in 21 U.S.C. § 355(b)(1) ("[A]ny patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.").

27. *Id.* § 355(j)(2)(vii).

28. When patents are challenged, the regulatory approval of the copied version can take place immediately unless the sponsor brings a patent infringement action within forty-five days from receipt of the challenge notice, or another generic drug manufacturer has an unexpired, nonforfeited generic drug marketing monopoly period. *Id.* § 355(j)(5)(B)(iii), (iv).

patent challenge to arise, the copier's patent certification needs to state that the patent in question is not valid or otherwise will not be enforceable against the copier's product. If the originator then undertakes to enforce the challenged patent—within a required time period set by the Hatch-Waxman Act—the copied version of the medicine in most situations cannot be approved unless the patent expires or the challenge to the patent succeeds.²⁹ As for the originator's patents, a single patent of the originator is entitled to an extension of its term under the "patent term restoration" provisions of the Hatch-Waxman Act.³⁰ The patent term restoration provisions allow the selected patent to be extended to expire up to fourteen years from the original approval date of the new medicine.³¹

As outlined earlier, the Biosimilars Act took a different approach from the Hatch-Waxman Act's patent-centric IP interface. The Biosimilars Act does require a "patent dialogue"³² of sorts

29. The full complexity of these provisions of the Hatch-Waxman Act are set out in 21 U.S.C. § 355.

30. 35 U.S.C. § 156 (2006).

31. *Id.* § 156(c)(3).

32. The "patent dialogue" provisions appear at 42 U.S.C. § 262(l) (2006). Among the applicable provisions, within twenty days of seeking regulatory approval for the copied version of a biologic product, the copier must provide the originator "a copy of the [biosimilar] application . . . and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." *Id.* § 262(l)(2)(A). The provision of this information by the copier then triggers a sixty-day period during which the originator must provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted" and "an identification of the patents on such list that the reference product sponsor would be prepared to license" to the copier. *Id.* § 262(l)(3)(A). The patent listing then triggers another sixty-day period in which the copier may elect to supply to the originator a listing of the patent for which the copier "believes a claim of patent infringement could reasonably be asserted" against the copied product, but in any event must provide, with respect to each patent identified by the originator, a representation that the copier "does not intend to begin commercial marketing of the [copied] biological product before the date that such patent expires" or "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [copier] that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the [copied] biological product." *Id.* § 262(l)(3)(B). A third sixty-day period then commences during which the originator must provide, for each patent asserted to be invalid, unenforceable or not infringed, "on a claim by claim basis, the factual and legal basis . . . that such patent will be infringed . . . and a response to the statement

to take place between the originator and a would-be copier of a new biologic medicine. That dialogue, however, is mostly a sideshow. Approval of the copier's abbreviated regulatory filing is made independently from any patent considerations. The patent dialogue's only effects are in the context of subsequent patent litigation, should that litigation materialize.³³ Instead of tying the approval of biosimilars to patent rights, the Biosimilars Act bases approval of these copied versions on the originator's right to protect its data package of preclinical and clinical investigations that formed the basis for concluding that the original version of the biologic product could be approved for marketing.³⁴ Since the existence and sufficiency of such data would be critical to any conclusion that the copied version of the new biologic medicine merits approval under the abbreviated approval pathway, the Biosimilars Act protects the originator's rights to the exclusive regulatory benefit of its data package for a period of twelve to twelve-and-a-half years from the original approval of the biologic product.³⁵

concerning validity and enforceability." *Id.* § 262(l)(3)(C). This set of exchanges then sets the stage for a fifteen-day period of "good faith" negotiations over which of the originator's patents should be the subject of a patent infringement action. *Id.* § 262(l)(4)(A). If there is agreement with the fifteen-day period, then the originator has a thirty-day period in which to bring a patent infringement action on each of the agreed patents. *Id.* § 262(l)(6)(A). If there is no such agreement within the fifteen-day period, then the copier must provide to the originator the number of patents the copier believes to be in dispute and for which a patent infringement action would be appropriate to resolve the dispute. *Id.* § 262(l)(5)(A). Thereafter, a period of up to five days ensues when the copier and the originator must exchange lists of patents that each believes would be appropriate for patent infringement litigation. *Id.* § 262(l)(5)(B)(i). The originator is entitled to list at least one patent but cannot list more patents than the number provided initially by the copier. *Id.* § 262(l)(5)(B)(ii). Within thirty days from the exchange, the originator is obliged to bring a patent infringement action on each patent that has been listed. *Id.* § 262(l)(6)(B).

33. See generally *id.* § 262(l).

34. See 42 U.S.C. § 262(k)(6), (7). While the regulatory approval of a copied version of a new biologic product under the Biosimilars Act is not linked to the patents that might exist on the new medicine, the ability to market the copied version, once approved, is subject to patents that might be infringed by the manufacture, use, or sale of the copied version. If such a patent is successfully enforced, the marketing of the infringing copy may be enjoined until the patent has expired.

35. 42 U.S.C. § 262(k)(7)(A), (m)(2)(A).

The MODDERN Cures Act, at least in one sense, picks up where the Biosimilars Act left off. It clearly does so in terms of the policy for crafting a regulatory/IP interface. Like the Biosimilars Act, the MODDERN Cures Act disconnects regulatory approval for copied versions of new medicines from patents and provides marketing approval for copied versions of new medicines entirely based upon a data package protection period.³⁶

For the MODDERN Cures Act, the data package protection period is fifteen years.³⁷ This period was intentionally made longer than both the fourteen-year patent term restoration period under the Hatch-Waxman Act and the twelve- to twelve-and-a-half-year data package protection period under the Biosimilars Act.³⁸

36. House Bill 3116, unlike its predecessor House Bill 3497 from the 112th Congress, contains a so-called “registration exclusivity” provision that operates independently from either data package protection or the protection accorded under any relevant patents. The registration exclusivity provision prohibits the approval of a second original version of an approved medicine unless the clinical testing for the other original version of the new medicine commenced before the approval of the medicine accorded protection under the MODDERN Cures Act. An exception to such regulatory exclusivity is made for a second original version of a new medicine that exhibits greater effectiveness on a clinically meaningful endpoint, greater safety in a substantial portion of the target populations, or otherwise makes a major contribution to patient care. H.R. 3116, 113th Cong. § 201(e)(1)(C)(ii) (2013). The registration exclusivity provision does not appear to play any significant role in the MODDERN Cures legislation, because it is difficult to posit a scenario under which the registration exclusivity provisions would be of any relevance. While there have been historical examples of two originators seeking to develop the same medicine, each utilizing a nonabbreviated approval process, there are no such examples that have arisen where one of the originators commences its clinical studies after the other originator has already secured regulatory approval to market. Were a second originator to do so, its independent work would almost certainly be grounded on the exception—the prospect of a significant clinical benefit for patients.

37. H.R. 3116 § 201(i)(4)(B).

38. The longer IP protection period in the MODDERN Cures Act, at least compared to either the fourteen-year Hatch-Waxman Act patent term restoration period or the Biosimilars Act’s twelve to twelve-and-a-half-year data package protection period, is driven by the proponents’ desire to make the provision a viable option for the originator of a new medicine. The actual protection period for new medicines under the Hatch-Waxman Act or the Biosimilars Act can be highly variable, as discussed *infra* Part III. The actual period of protection from copied versions coming to market can exceed the fourteen-year patent term restoration period, or fall short of the fourteen-year mark. The Biosimilars Act’s twelve- to twelve-and-a-half-year protection period offers only a floor on protection from copying a new biologic product. The biologic’s available patent life renders

A second (and in some respects a much more profound) feature of the MODDERN Cures Act is that, when its provisions apply to a new medicine, they supersede all the patent term restoration provisions of the Hatch-Waxman Act.³⁹ In their place, the MODDERN Cures Act resets the term of each of the relevant patents of the originator of the new medicine to the same fifteen-year period that applies to data package protection.⁴⁰ The MODDERN Cures Act does so by extending the term of any patents that would expire earlier and, if required, mandating a waiver⁴¹ of protection under other patents that would otherwise expire later.

Thus, there is perfect alignment under the MODDERN Cures Act between the data package protection period and the patent protection period.⁴² This revolutionary feature of the MODDERN Cures Act was specifically designed to eliminate the possibility for patent litigation as an adjunct to market entry of copied versions of the new medicine. In these key respects, therefore, the MODDERN Cures Act would turn the litigation-laden Hatch-Waxman Act's regulatory/IP interface on its head. It would likewise moot the

the actual protection period variable; periods of protection from copied versions of new medicines coming to market in excess of the fourteen-year patent term restoration period remain possible. In contrast, the fifteen-year IP protection period under the MODDERN Cures Act operates not just as a floor, but also as a ceiling. Were this ceiling on protection to be materially lowered, this IP-based incentive to direct new R&D investments into unmet medical needs would quickly vanish. Thus, an IP protection period of fourteen years or less could render the MODDERN Cures Act a far less effective incentive. All in all, the fifteen-year period was crafted to represent the minimum period for effectiveness. As will be discussed *infra* Part V, a lesser ceiling on protection would be difficult to justify—on the basis of policy or economic considerations.

39. See H.R. 3116 § 201(e)(2).

40. *Id.* § 201(e)(2)(C).

41. The “patent waiver” provisions of House Bill 3116 are contained in section 201(c). They provide that the originator of the new medicine must provide “a waiver of the right to enforce or otherwise assert any [relevant] patent . . . which may expire after the end of the [fifteen-year IP] protection period . . . against any applicable product.” *Id.* § 201(c)(1)(A). The “applicable products” are any copied versions of new medicines seeking approval under abbreviated approval pathways of the Hatch-Waxman Act or the Biosimilars Act. The patents to which the waiver provisions apply otherwise remain in full force and effect.

42. House Bill 3116, section 201(i)(4)(B) sets the protection period at fifteen years from the date of the initial approval for marketing of a new medicine, which applies to both approval for marketing of copied versions of new medicines under section 201(e)(1) and patent term extensions under section 201(e)(2).

need for the elaborate “patent dialogue” interface provisions of the Biosimilars Act.

Finally, the MODDERN Cures Act seeks neither to amend nor otherwise modify the Hatch-Waxman Act or the Biosimilars Act. The provisions of the bill were crafted so as to sit atop these laws, but not change either of them.⁴³ It is an Act that can only be applied to some, but not all, new medicines—its applicability is limited to medicines being investigated to address unmet medical needs.⁴⁴ It is an Act that does not automatically apply to all new medicines addressing unmet medical needs—the originator of the medicine must request that the new medicine be subject to the provisions of the MODDERN Cures Act,⁴⁵ and the U.S. Food and Drug Administration (FDA) must then approve that request by determining that the “unmet medical need” test has been met by the studies for the experimental medicine on which the request was based.⁴⁶ This unique approach to a regulatory/IP interface comes from a surprising source. It is not the product of a trade group or industry initiative. It is the product of direct patient advocacy for regulatory/IP policies that will result in creating better medicines.

43. H.R. 3116 § 201(e)(1) (superseding the timing provisions on approvals under Hatch-Waxman Act and Biosimilars Act with respect to access to abbreviated approval pathways); *id.* § 201(e)(2) (superseding the patent restoration provisions for new medicines under the Hatch-Waxman Act).

44. House Bill 3116, section 201(i)(1) defines when a new medicine addresses “unmet medical needs.”

45. House Bill 3116, section 201(a)(1) requires the developer of a new medicine (the “sponsor”) to submit a request for designation of the new medicine as a “dormant therapy.” The requirements for the request are set out in section 201(b) and include a listing of the relevant patents and the provision of an appropriate patent waiver of enforceability beyond the fifteen-year “protection period.” *Id.* § 201(b). The developer needs to submit a clinical plan for the development of the new medicine, and the request must be filed before seeing regulatory approval for the new medicine. *Id.* § 201(b), (d)(1).

46. *Id.* § 201(a)(1). The requester of a designation may withdraw the request up to the time the new medicine is approved for marketing. *Id.* § 201(d)(1). Under this same provision, the FDA can revoke a designation if the developer fails to provide periodic certification that the development of the new medicine for an unmet medical need is continuing or if the developer fails to provide a sufficient waiver of the right to enforce each relevant patent after the end of the fifteen-year protection period.

II. THE MODDERN CURES ACT: A PATIENT-LED REGULATORY REFORM INITIATIVE

A. *The Congressional Origins of the Bill; Who Is Not Among Its Proponents?*

The MODDERN Cures Act, House Bill 3116, was introduced by Representative Leonard Lance on September 17, 2013.⁴⁷ The bill superseded a bill with the same title, House Bill 3497, that Representative Lance introduced in 2011.⁴⁸ Like many bills introduced in recent years, its title is acronymic. The “MODDERN” in “MODDERN Cures” asserts that it is about “Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network.”⁴⁹ Its provisions are more ambitious than the acronym would suggest. As noted above, the legislation’s target is not limited to just the traditional drugs, but its provision would affect the approval of both drugs and biological products.⁵⁰

In the 112th Congress, the original Lance bill garnered no less than four dozen congressional sponsors, nearly equally divided as between Democrats and Republicans.⁵¹ This bipartisan support represented an auspicious start for this effort. Thus far at least, the

47. Press Release, Representative Leonard Lance, Lance Legislation Designed to Help Patients with Chronic Diseases and Disabilities (Sept. 12, 2013), <http://lance.house.gov/press-releases/lance-legislation-designed-to-help-patients-with-chronic-diseases-and-disabilities>.

The bipartisan ‘Modernizing Our Drug and Diagnostics Evaluation and Regulatory Network (MODDERN) Cures Act’ would update the Nation’s drug evaluation process to encourage the discovery and development of new treatments for chronic and rare diseases. The measure would provide a pathway to bring promising new compounds to market and establish a predictable timeline for the introduction of generic equivalents. In addition, it will advance creative solutions for developing companion diagnostic tests and create a system that rewards efficiency and effectiveness to the benefit of all people with chronic diseases.

Id.

48. H.R. 3497, 112th Cong. (2011).

49. H.R. 3116, 113th Cong. § 1 (2013).

50. *See id.* § 4.

51. *See H.R. 3497 Bill Summary & Status: 112th Congress (2011–2012)*, LIBR. CONGRESS, <http://thomas.loc.gov/cgi-bin/bdquery/z?d112:H.R.3497>: (last visited Mar. 3, 2014) (noting that there were forty-eight cosponsors for the original bill).

bill has all the hallmarks of becoming a serious legislative enterprise.

Unlike most bills that focus on medicines and their regulation by the FDA, the usual trade association suspects—GPhA,⁵² PhRMA,⁵³ and BIO⁵⁴—are not to be found among its early proponents. Notwithstanding that lack of visible biopharmaceutical industry backing for the bill, an impressive listing of nongovernmental entities endorsed the bill in the last Congress.⁵⁵ According to the bill's proponents, its focus lies in enhancing patient access to medicines and diagnostic tools that can address serious diseases. Title I of the bill (not addressed in this article) deals with diagnostic products, and Title II of the bill, "Capturing Lost Opportunities for Patients," provides the changes that would impact the regulatory/IP interface for medicines.⁵⁶

52. Generic Pharmaceutical Association, or "GPhA" as it is now known, is the trade association for the generic drug manufacturers. Its website indicates that it is "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." *The Association*, GENERIC PHARMACEUTICAL ASS'N, <http://www.gphaonline.org/about/the-gpha-association> (last visited Mar. 3, 2014). It is an amalgamation of the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance. *Id.*

53. Pharmaceutical Research and Manufacturers of America, or "PhRMA" as it is typically branded, is the leading trade association for the biopharmaceutical industry, headquartered in Washington, D.C. Its website describes its mission as "to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical and biotechnology research companies." *About PhRMA*, PhRMA, <http://www.phrma.org/about> (last visited Mar. 3, 2014).

54. Biotechnology Industry Organization, or "BIO" as it is universally known, describes its mission as providing advocacy, business development, and communications services for more than 1100 members worldwide. "It is our mission to be the champion of biotechnology and the advocate for our member organizations—both large and small." *About BIO*, BIOTECHNOLOGY INDUSTRY ORG., <http://www.bio.org/articles/about-bio> (last visited Jan. 25, 2014).

55. The organizations sponsoring the bill were among the best-known patient groups in the United States. For the listing of organizations that agreed to be listed as sponsoring organizations, see Letter from Acad. of Physicians in Clinical Research et al. to Representatives Leonard Lance and Jay Inslee, U.S. House of Representatives (Feb. 14, 2012), *available at* http://www.nationalhealthcouncil.org/NHC_Files/Pdf_Files/MODDERNCuresSign-on-SupportLetter.pdf.

56. While Title I of House Bill 3116, "Advancing Diagnostics for Patients," contains provisions that would provide enhanced incentives for work on important

B. *The “Grass Roots” Origin of the Bill; What Is the National Health Council?*

Both House Bill 3497 and House Bill 3116 represent initiatives developed and advanced by the National Health Council (NHC).⁵⁷ The NHC’s mission is to be an advocate for the work of so-called “patient advocacy” organizations.⁵⁸ Once the bills were introduced in Congress, the NHC became the bills’ chief proponent.⁵⁹

The NHC statement on the introduction of House Bill 3116 was succinct in summarizing its views on the great promise for the bill. It implicitly noted the role of the bill in providing a novel interface between the intellectual property protection accorded to a new medicine and the entry of copied versions into the marketplace when that IP protection gives way, calling its novel provisions “game changing legislation.”⁶⁰ While the NHC call to

new diagnostic tests and capabilities, it contains only a single section—section 103—that would provide enhanced incentives to promote the development of new diagnostic products and techniques. These incentives would, unlike the Title II provision, enhance—rather than replace—the protection periods for new medicines currently available under law. H.R. 3116, 113th Cong. tit. I–II (2013).

57. See generally NAT’L HEALTH COUNCIL, <http://www.nationalhealthcouncil.org> (last visited Jan. 26, 2014).

58. See *About the National Health Council*, NAT’L HEALTH COUNCIL, <http://www.nationalhealthcouncil.org/pages/page-content.php?pageid=53> (last visited Mar. 3, 2014)

Founded in 1920, the National Health Council is the only organization of its kind that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, the NHC’s core membership includes the nation’s leading patient advocacy organizations, which control its governance.

Id.

59. Exemplary of the NHC’s work is the Capitol Hill briefing for House Bill 3497 on February 28, 2012, providing a link to its Twitter conversation: #modmodern. Nat’l Health Council, Briefing on the MODDERN Cures Act (Feb. 28, 2012), available at http://www.nationalhealthcouncil.org/NHC_Files/Pdf_Files/NHC_MODDERNCuresActBriefing.pdf.

60. See *March 2013 Council Currents*, NAT’L HEALTH COUNCIL, <http://www.nationalhealthcouncil.org/pages/page-content.php?pageid=154> (last visited Jan. 26, 2014).

legislative action on these types of reform measures is not unique,⁶¹ it and its patient advocacy affiliates have now accomplished things that truly are unprecedented—by providing an innovative regulatory/IP interface for congressional consideration, a specific legislative proposal, and a cadre of supporters dedicated to bringing profound changes to the way in which research on new medicines is undertaken and copied versions of these new medicines come to market.

Title II of House Bill 3116 would offer a dramatic simplification of the intellectual property framework that provides the economic rationale for investments to discover and develop new medicines.⁶² That novel framework would remove inadequate IP protection as a reason not to move forward to develop a new agent that appears to have promising potential as a new medicine. Additionally—and in a revolutionary departure from current law—it would afford greater predictability, and vastly lower transaction costs, for securing regulatory approval for marketing copied versions of new medicines.⁶³ An army of patent litigation lawyers could be put to pasture, were innovators able to make widespread use of the MODDERN Cures interface.

The remainder of this article sets out the case for proceeding with the MODDERN Cures Act framework for defining—at least in relevant part—a future regulatory/IP interface for copied versions

The NHC is again advocating for passage of the MODDERN Cures Act during this Congress. This game-changing legislation was initially crafted by the NHC and encourages the development of better diagnostic tools and the co-development of diagnostics and drugs to predict the safe, effective, and efficient use of medicines. The bill also creates a new class of drugs called ‘dormant therapies’—medicines that address conditions with limited or no treatment options—and establishes a predictable timeline for the introduction of low-cost generic equivalents.

Id.

61. See Robert A. Armitage, *Creating the Best Medicines for Patients, Making Medicines More Affordable, but Not Limiting Research to Medicines with the Best Patents* (2010), http://djf.typepad.com/files/armitage_paper.pdf (paper); Robert A. Armitage, *Creating the Best Medicines for Patients, Making Medicines More Affordable, but Not Limiting Research to Medicines with the Best Patents* (May 2010), http://www.aipla.org/committees/committee_pages/Biotechnology/Committee%20Documents/Committee%20Presentations/2010.Spring/Ohly.ppt (presentation).

62. See *infra* Part III.

63. See *infra* Part III.

of new medicines. That case begins with a background setting out the manner in which IP protection for new medicines has evolved in the Hatch-Waxman era.⁶⁴ It then continues with the case to be made for sufficient IP protection to sustain a viable, research-based biopharmaceutical industry.⁶⁵ The article concludes with the case for defining a common IP protection period of fifteen years.⁶⁶

III. A PRIMER ON THE POST-HATCH-WAXMAN EVOLUTION OF IP PROTECTION FOR NEW MEDICINES

The “game-changing” nature of the MODDERN Cures Act regulatory/IP framework cannot be fully appreciated without an understanding of how IP protection for new medicines has operated historically and why the historically most important forms of IP protection for medicines—patents and trade secrets—have become increasingly problematic, even perverse, over the past two decades.

A. *An Overview of the Evolution of IP Protection for New Medicines*

As noted above, the most important forms of IP protection for new medicines have historically come from patents and trade secrets. The concept of data package protection as an additional and distinct form of IP protection for new medicines did not exist until it first emerged as a consequence of the Hatch-Waxman Act. Its existence—indeed importance—was validated in the Biosimilars Act, where data package protection plays a much more central and essential role.

In the debates that led to the enactment of the Hatch-Waxman Act, the consensus view was that the “gold standard” for IP protection for new medicines should reside in patents.⁶⁷ Through a

64. See *infra* Part III.

65. See *infra* Part IV.

66. See *infra* Part V.

67. The importance of patents is apparent from the debates that led up to the patent term restoration provisions in the Hatch-Waxman Act. Originally, Congress considered a separate bill that would have simply provided patent term restoration—without the Hatch-Waxman Act provisions that were responsible for the creation of the generic drug industry. S. 255, 97th Cong. (1981); S. 2892, 96th Cong. (1980). These separate efforts began by noting the unfairness of according the holders of medicine patents less than a full seventeen years of patent protection.

number of provisions, the economics of investing in the creation of new medicines was entrusted to the patent system. The underlying—but never tested—premise of the Hatch-Waxman Act was that patents on new medicines could be routinely—and successfully—invoked to prevent making and selling copies of a patented medicine.⁶⁸ The premise was that such protection would suffice to sustain the innovative industry from what otherwise would be the onslaught of price competition from copiers, which could come within a few years from the time the original version of the new medicine came onto the market.⁶⁹

Thirty years of experience under the Hatch-Waxman Act would suggest that the patent system was never fully up to this task. Moreover, in recent decades, patent protection has taken on an increasingly perverse character when it comes to protecting new medicines from premature generic competition. Patent protection becomes perverse when some of the best candidates for development as new medicines are left with some of the worst

[Senate Bill 255] . . . merely corrects the anomaly under which the government grants a 17-year term of patent protection, but prohibits the patented product from being marketed while the patent life ticks away. There is no valid reason for a better mousetrap to receive 17 years of patent protection and a lifesaving drug less than ten years.

S. REP. NO. 97-138, at 2 (1981).

68. Prior to the Hatch-Waxman era, there were few reported cases that addressed the issues of validity and infringement of patents covering new medicines. Generic drug entry seldom occurred until years after all relevant patents on a medicine had expired. The originators of new medicines only very rarely were involved in enforcing patent rights against one another. The vast majority of new medicines coming to market, thus, never spawned even a single patent infringement lawsuit.

69. Under Hatch-Waxman, absent patent protection, the only bar to immediately seeking approval to market of a generic copy is found in 21 U.S.C. § 355(j)(5)(F)(ii) (2012). This provision sets up a five-year period in which such filings would be barred. The five-year period corresponds, roughly, to the period of time after the original version of a new medicine reaches the market during which a would-be copier can discern whether the new medicine is successful enough in the marketplace to merit developing a copy of the medicine, be able to secure a source of supply for the active ingredient, complete any research needed to develop a copied formulation that would behave similarly in a patient being administered the copied drug, complete the required testing needed to experimentally confirm the equivalence, and then pursue FDA approval for the copied version. During this nominal period of protection, few new medicines could ever hope to pay back to the originator the cost of creating them before generic drug entry could occur.

prospects for securing adequate patent protection. Patent perversity sits alongside other features inherent in the patent system that have exposed its frailty, at least when patents must stand as the exclusive vehicle for providing protection of the investments needed to create new medicines. The exact nature of the perversity and frailty is detailed below.

Trade secret protection—in the pre-Hatch-Waxman era at least—constituted an effective adjunct to patenting as a protection for investments in innovation. As the originator of a new medicine conducts expansive testing of an experimental medicine, it can acquire trade secret protection with respect to the massive compilation of data on the experimental medicine's effects.⁷⁰ That protection can be perpetual; it can be sustained at least so long as such data remains unpublished and is otherwise maintained in secrecy.

The rise of abbreviated approval pathways for biopharmaceutical products, however, effectively trumps traditional notions of trade secret rights that most other industry sectors enjoy. If a generic competitor can come to market without repeating the work that produced the compiled trade secret information, the economic value of the trade secret is nullified.

In addition, growing requirements for data transparency with respect to an experimental medicine's effects, once approved for marketing, inevitably diminish the effectiveness of trade secret protection. If all but the details of a new medicine's effects are subject to public disclosure as a condition for gaining regulatory approval for the new medicine, there is little room left for trade secrecy to serve its traditional protective role. As patent protection

70. Under 21 U.S.C. § 355(b)(1)(A), the originator of a new medicine must amass, before seeking regulatory approval for a new drug, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." These "full reports" of investigations exist at a level of detail, including patient-level detail, that typically and historically are not made publicly available—either by the sponsors of the studies or by regulatory agencies that are charged with reviewing the reports. Absent repeating the underlying clinical trials, there is no way such reports can be duplicated and—absent some abbreviated approval pathway—no way in which a competing product can come to market. Thus, the preclinical and clinical studies on a new medicine have historically met the definition for a valuable trade secret. They are compilations of information that produce economic value from not being generally known by competitors and derive significant economic value from access to the information.

has increasingly taken on a perverse character, and trade secrecy has been trumped by abbreviated approval pathways and demands for greater data transparency, data package protection has taken on a much greater significance as a means for protecting new medicines from copied versions obtaining regulatory approval to market.⁷¹ Even if this ascendant role for data package protection had not arisen by design, it would have come by default.

The MODDERN Cures Act can be seen as an effort to optimize data package protection, obliterate any possible patent perversity, and obviate any need for reliance on trade secret protection of a new medicine's safety and effectiveness data. By applying a common fifteen-year IP protection period to the originator's relevant patents and its data package, the Act wholly eliminates the perversity with which the patent system can otherwise operate and assures protection from copying, whether the data package is held as a trade secret or fully available to the public.

Given the common IP protection period for patents and the data package, the patent waiver requirements of the Act—a novel and unprecedented derogation from the originator's patent rights—can be seen as a provision that is nonetheless fair to the originator of the new medicine. The waiver arises, if at all, only when the innovator requests the application of the Act. By securing the protection under the Act, the originator has the assurance of an extended period for IP protection. This voluntary waiver imposed only on those originators who elect the MODDERN Cures protection regime can be seen for what it is—a boon to the creator

71. Heroic efforts have been undertaken in recent years, especially in the United States, to reform elements of the patent system to make it more transparent, objective, predictable, and simple. The aim of the reforms, in part, has been to make the patent system a more reliable source of protection for new medicine for which patents have been secured. See Robert A. Armitage, *The America Invents Act: Will It Be the Nation's Most Significant Patent Act Since 1790?*, in PATENTS IN THE 21ST CENTURY: THE LEAHY-SMITH AMERICA INVENTS ACT (Deborah Nathan & Phyllis Skuplen eds., 2012), available at <http://www.mofo.com/files/Uploads/Images/120206-Patents-21st-Century.pdf>; Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 133 (2012), available at http://www.uspto.gov/aia_implementation/armitage_pdf.pdf. Even with the success of patent reform efforts in recent years, there remain numerous legal hurdles that need to be surmounted before a patent can be found both valid and infringed and invoked to stop a copied version of a new medicine from entering the market.

and copier alike, neither of which will need to calibrate possible patent enforceability risks as part of its business planning.

With this IP overview in hand, it is worth taking the above perspectives and drilling down into somewhat greater detail on IP protection for medicines, particularly the details of the evolution from the pre-Hatch-Waxman era to the post-Biosimilars Act era.

B. Patent Protection and Patent Perversity

The world of biopharmaceutical patenting changed in a significant manner on June 8, 1995. That was the date on which a new law, the Uruguay Round Agreements Act (URAA), took effect and changed the measure for the term of protection for a patent. It replaced a standard that had been in operation for more than two hundred years⁷² and constituted a foundational premise for how the patent term restoration provisions of the Hatch-Waxman Act operated.

Under the URAA, the term of protection for all new U.S. patent filings was set at a fixed term of years from the original, nonprovisional application date.⁷³ In the post-URAA world, U.S. patents would expire at twenty years from the original, nonprovisional filing for the patent. What this meant, of course, was that the new twenty-year patent term would start to run down the date the patent was initially sought.⁷⁴ Under the pre-URAA patent law, a seventeen-year patent term existed under which the

72. See Act of Apr. 10, 1790, ch. 7, § 1, 1 Stat. 109 (authorizing “letters patent to be made out in the name of the United States . . . granting to such petitioner or petitioners, his, her or their heirs, administrators or assigns for any term not exceeding fourteen years”). The use of a fixed term from the date of grant of letters patents as the temporal measure of patent protection continued until 1995.

73. The Uruguay Round Agreements Act, Pub. L. No. 103-465, § 101, 108 Stat. 4809, 4809 (1994), amended 35 U.S.C. § 154(a)(2) (2006) to provide a twenty-year term of protection from the original filing date of an application for patent. Section 154(a)(3) provides that a provisional patent filing date is excluded from the twenty-year term, allowing a patent term to extend to twenty-one years from the earliest provisional patent filing date. The URAA implemented the Trade Related Aspects of Intellectual Property Rights (TRIPS) text agreed as part of the 1986-1994 Uruguay Round of the General Agreement on Tariffs and Trade (GATT). *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Mar. 23, 2014).

74. See also 35 U.S.C. § 154(b), which in some situations can result in the adjustment of the patent term to account for delays in granting a patent.

date a patent eventually granted was used as the start of the seventeen-year protection period.⁷⁵ The longer a patent took to be issued, the later in time the patent would expire. If a patent took ten to fifteen years to be processed, the patent would expire twenty-seven to thirty-two years after the patent was initially sought.

In most technology sectors—and under many fact situations—there is little discernable economic consequence between the pre- and post-URAA patent term measures. However, given the manner in which biopharmaceutical patent filings must take place, and the manner in which the marketing of new medicines is regulated, the biopharmaceutical industry was uniquely—and negatively—impacted by the URAA change in the measure of the patent term.

As noted above, patent protection, when at its theoretical best, can be impeccable as a form of IP protection. This applies to almost any product in any technology sector. Patenting has the potential to provide effective and long-lived marketplace exclusivity for a patent-protected product, including all manner of copied versions of that product. For many innovative nonmedicinal products, patent protection can be initially sought as the product being engineered for commercialization. When the relevant patents on the new product are issued at or near the time the new product comes to market, it matters little how the patent term is calculated—pre-URAA seventeen years from grant or post-URAA twenty years from initial patent filing. Under either measure of patent term, the originator of the product may well secure no less than seventeen years of post-commercialization patent protection.

The key to securing a long-lived patent in such situations is that the time between patent filing and commercialization ranges from a few months to a few years. For many nonmedicinal products, thus, the patent life under either measure of patent term will prove not only longer than seventeen years from the initial commercialization, but may typically be longer than the actual commercial lifespan of the patented product. In these situations, there is nothing perverse about patenting. Rather, patenting can form the full and complete economic predicate for proceeding to invest in the commercialization of the new product.

The same potential for categorical, long-lived protection from copying through patents is—*theoretically at least*—available for new

75. Patent Act of 1952, ch. 950, § 154, 66 Stat. 792, 804 (codified as amended at 35 U.S.C. § 154).

medicines, just as it is for other technology sectors. For a medicine incorporating a novel active ingredient, patents on the active ingredient can prevent any and all copied version of the medicine from coming to market. In a similar manner, patents can protect the methods of using a new medicine for its approved uses, thereby holding at bay the ability of a copyist to market a copied version of the medicine for the patented uses.

However, in practice, much can go awry in perfecting adequate protection through patents. Patents on a medicine's active ingredient and approved uses, even though they are theoretically capable of providing absolute protection from copying during the term of the patent, may fail to so operate in practice. A patent—no matter how strong and defensible it appears on its face—is subject to a set of legal and equitable defenses to its validity and enforceability.⁷⁶ In patent infringement lawsuits, the complex nature of the patent law means that the patent owner can almost never be categorically certain of successfully asserting its patent infringement claims.

Moreover, the ultimate viability of a patent as an effective IP tool is assessed only at the time a would-be copier surfaces and the originator of the new medicine brings an action to enforce the patent. The facts that may be fatal to the patent's validity may only emerge during discovery after the patent litigation commences. This potential for prolonged uncertainty over the effectiveness of patent protection is not lost on the developer of a new medicine when attempting to calibrate the viability of the investment needed to create the new medicine.

In addition, the grant of a patent is never assured. The standards for securing a patent are intentionally rigorous and inflexible.⁷⁷ Simply because a medicine contains a never-before-

76. See, e.g., 1 DONALD S. CHISUM, CHISUM ON PATENTS § 19.01 (2013).

77. The requirements for effective patent protection do not correlate with any of the requirements for securing regulatory approval to market a new medicine and the failure to meet any of the patentability requirements can either doom the ability to seek a valid patent or, if one has been sought, allow the patent to issue. A new drug must be shown to be "safe and effective" for the clinical uses for which it is approved. Under the current patent statute, Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), the uncorrelated requirements for patentability for a claimed invention in a patent filing can be boiled down to the following:

- *Sufficient differentiation* from the prior art. "Prior art" is defined in a simple and transparent manner as subject matter that, at the time of

approved active ingredient or is to be sold for a never-before-approved use does not guarantee that effective patent protection, once sought, can be secured for the medicine.⁷⁸ A patent that is

an inventor's patent filing, was already available to the public, or available from a previously-filed U.S. patent or published U.S. application for patent, subject to the inventor-friendly and collaboration-friendly "grace period" and "self-collision protection" provisions that have long been part of U.S. patent law.

- *Sufficient disclosure* in the inventor's patent filing to identify the embodiments of the claimed invention and enable them to be put to a specific, practical, and substantial use.
- *Sufficient definiteness* in the inventor's patent claims, to reasonably identify the subject matter being claimed from that not being claimed.
- *Sufficient concreteness* in the subject matter claimed, such that the process or product being claimed is not excessively conceptual or otherwise abstract.

Robert A. Armitage, *The World's First 21st Century Patent Law (Maybe): The Leahy-Smith America Invents Act*, 4 LANDSLIDE, Sept./Oct. 2011, at 1, 1.

78. See Benjamin J. Roin, *Unpatentable Drugs and the Standard of Patentability*, 87 TEX. L. REV. 503 (2009) (discussing implications of just two of the requirements, novelty and nonobviousness).

The role of the patent system in promoting pharmaceutical innovation is widely seen as a tremendous success story. This view overlooks a serious shortcoming in the drug patent system: the standards by which drugs are deemed unpatentable under the novelty and nonobviousness requirements bear little relationship to the social value of those drugs or the need for a patent to motivate their development. If the idea for a drug is not novel or is obvious—perhaps because it was disclosed in an earlier publication or made to look obvious by recent scientific advances—then it cannot be patented. Yet, the mere idea for a drug alone is generally of little value to the public. Without clinical trials proving the drug's safety and efficacy, which is a prerequisite for approval by the Food and Drug Administration (FDA) and acceptance by the medical community, that drug is unlikely to benefit the public. Given the immense investment needed to fund clinical trials on drugs and the ability of generic manufacturers to rely on those tests to secure regulatory approval for their own products, pharmaceutical companies are rarely willing to develop drugs without patent protection. The novelty and nonobviousness requirements make no concession for the development costs of inventions and thus cause patents to be withheld from drugs that are unlikely to reach the public without that protection. This gap in the patent system for drugs has created a pervasive problem in the pharmaceutical industry, causing firms to regularly screen their drugs during the research-and-development process and discard ones with weak patent protection.

never issued, of course, is a patent that can never be enforced against a copier of a new medicine.

There are important medicines that will never enjoy effective patent protection because no patents were ever even sought on the new medicine. Great new medicines, no matter how outstanding their clinical merit, do not automatically qualify for patent protection. However, by far the most perverse aspect of the patent system, arises from the more pervasive inability under the post-URAA patent law to reliably secure long-lived patent protection for the new medicines that are most deserving of—and most in need of—protection from copied versions of those medicines being approved for marketing. Perversely, many of the most significant and important new medicines will typically be saddled with the most short-lived patent protection.

Because the patent law in effect from 1790 to 1995 determined the patent expiration date based upon the issue date of the patent, if a patent on a new medicine did not actually issue until at or after the time at which the new medicine was approved for marketing, the effective patent life for the medicine could be a full seventeen years or even longer.⁷⁹ Using the same formula, a patent issuing less than three years before a new medicine was approved for marketing would have a patent life of more than fourteen years.

Since nothing in the pre-1995 patent law required that the patent owner make undo haste to secure the issuance of a patent, a patent owner could readily achieve fifteen years of patent life—or even longer—even in situations where a new medicine took fifteen years or more to go through the regulatory testing and review process.

Under today's patent law, because the most relevant (and most significant) patents must typically be sought at the earliest point in

The harm to the public from the loss of these drugs is potentially quite significant. Congress can easily avoid this problem by ensuring that the successful completion of the FDA's rigorous clinical-trial process is rewarded with a lengthy exclusivity period enforced by the FDA.

Id. at 503.

79. Teresa Riordan, *Patents*, N.Y. TIMES, June 12, 1995, at 2, available at 1995 WLNR 3836838 (“Under the old system, a patent was valid for 17 years from the date it was issued. Under the new system, a patent is valid 20 years from the date of application. The change, while seemingly subtle, has enormous ramifications for patent attorneys and inventors and the strategies they pursue to maximize patent protection.”). See *infra* note 101, discussing the potential for patent protection lasting more than seventeen years.

the drug development process, an inverse relationship is created between the length of testing required to get to market and the available patent protection once marketing approval is secured. In other words, the longer time period required for the necessary testing to bring a new medicine to market, the shorter the effective patent life that would remain for these most important patents protecting the new medicine. The more difficult—and thus longer—the road to the regulatory approval of a new medicine, the shorter the remaining patent life on the date the new medicine makes its first commercial sale.

A medicine can be more difficult to bring to market for any one of several reasons. Each of these reasons correlates to the potential importance of the medicine to clinical practice. In this case a direct relationship applies—the more difficult the path to gain regulatory approval for a medicine, the greater the potential breakthrough the new therapy typically represents. Sometimes medicine makers seek approval of a new medicine for a disease that has never before been successfully treated with a drug—or seek to treat a disease through a new mechanism of action that has never been successfully employed. In other situations, the use for which the new medicine is being investigated is for a chronic condition rather than an acute episode. Similarly, medicines may be studied for their ability to prevent a disease rather than simply treat the disease once it is diagnosed. In each of these situations, the route to approval of the new medicine will almost certainly prove to be a more prolonged one. The required studies that are needed to establish the merit of the medicine for a chronic, unprecedented, or prophylactic use typically last longer, often much longer, than for medicines where these complications are absent.

Because the only patents that have a realistic potential of providing marketplace exclusivity—patents directed to the medicine's active ingredient and its medicinal uses—must be sought early in the process of the development of a new medicine, the patent term continues to run on these patents throughout the medicine's development process. By the time the medicines that are the most difficult to develop—and are of potentially the greatest importance to patients if successfully developed—finally achieve regulatory approval, the remaining patent life may be highly limited. In some situations, it may be totally exhausted.⁸⁰

80. Discussed *infra* Part III.E are the so-called “patent term restoration”

No one would intentionally design an IP system for the protection of new medicines with a relatively longer IP protection period for experimental medicines that have the shorter and simpler pathway to regulatory approval and relatively shorter IP protection periods for those seeking to develop the most novel, unprecedented, and risky therapies. The very medicines that need—and merit—the greater intellectual property incentive to secure the investments needed to create them are the same medicines that such perverse IP rules would disadvantage, making it less likely that investing to create them would be a sound or a wise investment. Patients, of course, would like access to the best medicines, not medicines that happen to have the best patents. The best medicines, prospectively at least, may well be those for which patent protection might be so transient upon receiving regulatory approval that it cannot serve as a basis to justify the investment needed to create the medicine.

As a result, today, the patent protection of medicines, standing by itself, particularly under the constraint of the URAA's twenty-year, filing-based patent term, is at best flawed. Patent protection under the post-URAA patent law will inevitably operate perversely. To the extent patents serve as the chief form of expected IP protection for new medicines, the patent law would inevitably steer the originators of new medicines in the direction of those with the best prospects for patents, irrespective of whether they would represent the best in new medicines.

C. Data Transparency and Abbreviated Approval Pathways Take a Toll on Trade Secrecy

Trade secret protection can exist with respect to the detailed reports of the studies on a new medicine that are necessary to gain regulatory approval for marketing.⁸¹ Such details are typically not made public by the sponsor of the investigations into the effects of the medicine. However, trade secret protection, the detailed data that defines a new medicine's effects, sits in unavoidable tension with the public interest in a full understanding of the new medicine's properties. The maintenance of trade secret protection, surrounding the data used to demonstrate the merit of a medicine,

provisions of the Hatch-Waxman Act that, on account of their inherent limitations, tend to ameliorate, but not eliminate the perversity of the patent law.

81. See *supra* Part III.A.

is seen by many as contrary to the public interest in full transparency with respect to information used to determine that a new therapy is safe and effective.⁸²

Such information is, at least, potentially of relevance to a patient in deciding what therapy is best. It is of a potentially similar importance to a physician grappling with a difficult prescribing choice for an individual patient. In addition, the greater the secrecy maintained as to the effects of a medicine, the lesser the ability of independent entities to sift through the clinical data and either confirm or dispute the interpretation of the data being advanced by the medicine's originator.⁸³ This same consideration applies as well to the conclusions reached by regulatory authorities in deciding that a medicine can be safely and effectively used.

Thus, proponents of full data transparency, at the expense of trade secrecy, assert that it can produce greater confidence in the appropriateness of a new therapy reaching the market—or it can produce a more sober sense of caution in using a new therapy. Either way, the policy of requiring ever-greater disclosure of the preclinical and clinical trial results leading to the approval to market a new medicine is unlikely to abate.⁸⁴ As ever-greater transparency with respect to a new medicine's effects has been pursued by regulatory authorities, the ability to assert meaningful trade secret protection in the preclinical and clinical investigations that result in the regulatory approval of a new medicine has lessened. Today, at least for some types of new medicines, information on the medicine's effects that is published in

82. See generally EUROPEAN MEDS. AGENCY, EMA/110196/2006, EUROPEAN MEDICINES AGENCY POLICY ON ACCESS TO DOCUMENTS (RELATED TO MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE) 3 (2010), available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf.

83. Erick H. Turner, *How to Access and Process FDA Drug Approval Packages for Use in Research*, BMJ (Oct. 14, 2013), <http://www.bmj.com/content/347/bmj.f5992#xref-ref-1-1>.

Reporting bias leads to an overestimation of drug efficacy and underestimation of drug harms, but its effects can be mitigated by using unpublished data from drug regulatory agencies. Such data can be useful to clinicians interested in going beyond the product labeling and published literature. By comparing drug regulatory data with the published literature, researchers can uncover reporting bias

Id.

84. See Peter Doshi & Tom Jefferson, *The First 2 Years of the European Medicines Agency's Policy on Access to Documents: Secret No Longer*, 173 JAMA INTERNAL MED. 380, 380–82 (2013).

connection with the new medicine's regulatory approval leaves little to the imagination with respect to the properties of a new medicine.

As more detailed information on a medicine becomes public, assertion of trade secret rights based upon clinical trial results is unavailing to the extent the publicly available information is in fact sufficient to reach a justifiable scientific conclusion that any copied version would be equally safe and effective in patients as the original version of the medicine—at least so long as the copied formulation contains the identical⁸⁵ active ingredient and approximates the pattern of absorption and distribution in the patient that is achieved by the original version of the medicine.⁸⁶

All of these considerations pale in comparison to the impact that abbreviated regulatory approval pathways have had on trade secret protection. If a copier need not provide the detailed reports of preclinical and clinical investigations required for the original version of a new medicine to be approved, the fact that such data is maintained as confidential information is of no significance. The secret information affords the originator no residual competitive value or advantage if regulatory authorities are free to consider the

85. Under the Biosimilars Act, a copied or biosimilar version of a biologic product will have active ingredients that are “highly similar,” rather than “identical,” to the active ingredients in the originator's product. “[A] biological product may be demonstrated to be ‘biosimilar’ if data show that, among other things, the product is ‘highly similar’ to an already-approved biological product.” *Drugs*, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm> (last visited Mar. 25, 2014).

86. The extent of the “data package” that becomes publicly available at the time of FDA approval runs from the dozens to hundreds of pages of documentation:

FDA Approval Packages contain the research information on new drugs or biologics submitted to the U.S. Food and Drug Administration (FDA) by drug sponsors that has been analyzed and critiqued by experts at the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). Once a new drug or biologic is approved for marketing, the FDA is required to make the Approval Package available to the public. . . . Approval Packages are typically large, unwieldy documents ranging from 50 to 1500 pages.

FDA Drug Approval Packages, U. IOWA DIVISION DRUG INFO SERVICES, http://www.uiowa.edu/idis/FDA_Approval_Overview.htm (last visited Mar. 2, 2014).

existence of such data when deciding if a copied version of the medicine to which it relates can be approved.

Given that patent protection for new medicines may be perverse and trade secret protection is moving into decline, if not irrelevancy, the future of IP protection for new medicines may increasingly move to the third form of IP protection—providing the originator of a data package containing the preclinical and clinical testing for a new medicine a protection period sufficient to assure that investments needed to create a new medicine have a reasonable prospect of earning back a fair return before a copied version of the new medicine can be approved on the basis of the contents of the originator's data package.

D. Data Package Protection Bars Regulatory Approval of Copies of the Original Version of New Medicines Absent Submitting a Complete Data Package

Data package protection bars the regulatory approval of a new medicine for marketing under an abbreviated regulatory approval pathway except in the situation where the copier has repeated investigations of the type required to gain approval of the original version of the new medicine or, alternatively, has secured a right to reference the originator's investigations. This type of protection has effect, therefore, whenever the copier of the new medicine attempts to take advantage of an abbreviated regulatory approval pathway without repeating—or securing a right of reference to—the studies required for the approval of the original medicines.

A data package protection period can arise from a moratorium placed on the *filing* of an abbreviated regulatory approval application.⁸⁷ Self-evidently, the moratorium period barring the filing of an abbreviated regulatory approval application necessarily affords a minimum time period when an abbreviated regulatory filing cannot be approved. The Hatch-Waxman Act, for the first time in history, provided data package protection independently from the existence of any trade secret protection applicable to

87. The moratorium periods are typically much shorter than the data package protection period. Under the Biosimilars Act, the moratorium period under the biosimilars pathway is four years. 42 U.S.C. § 262(k)(7)(B) (2006). An analogous moratorium period on the filing of an ANDA under the Hatch-Waxman Act is four or five years, depending upon whether a patent challenge has been made. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii) (2012).

originator's clinical and preclinical data.⁸⁸ Even in situations where all the safety and effectiveness information relating to a new medicine had entered the public domain, the Act imposed a five-year moratorium period when an abbreviated regulatory approval application based upon the publicly available information could not be filed.⁸⁹ This provision had the effect of recognizing the originator's data package as an intellectual property right that was entirely separate and independent from trade secret rights.

As a confirmation of the independence of data package protection as a separate form of IP protection from trade secrecy, this new form of IP protection was specifically applied to the so-called "paper new drug application" (paper NDA) provisions of the Hatch-Waxman Act.⁹⁰ A paper NDA can be filed based entirely upon public information concerning a new medicine's safety and effectiveness, but cannot be filed until after the moratorium on paper NDA filings has ended.⁹¹

Aside from its role in assuring that data package protection represented a form of IP protection, paper NDAs have a limited use in securing marketing approval for copied versions of new medicines. By far the predominate role is played by the second of the two abbreviated pathways under the Hatch-Waxman Act, the ANDA provisions.⁹² The ANDA provisions effectively superseded the need for a paper NDA to secure regulatory approval of a generic drug, because the ANDA pathway is available whether or not the originator's data package was wholly public, maintained as a trade secret, or fell somewhere between these two extremes.⁹³

In making the ANDA pathway available, the Hatch-Waxman Act effectively negated the value of the trade secret protection in the safety and efficacy data related to the new medicine, at least once the applicable moratorium period ended. Considering the

88. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, 1590, 1595 (1984) (codified as amended at 21 U.S.C. § 355(b), (j)).

89. *Id.*

90. See 21 U.S.C. § 355(b)(2) ("An application . . . for which the investigations . . . relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted" were permitted to be filed, but only after the expiration of a specified moratorium period.).

91. *See id.*

92. *Id.* § 355(j).

93. *Id.*

paper NDA and ANDA pathways as a whole, the Hatch-Waxman Act assured that the originator of a new medicine was no longer required to maintain trade secrecy to have IP protection against copied versions of the new medicine being approved until after the end of the moratorium period. However, once the moratorium period ended, the originator of a new medicine was not guaranteed that maintaining trade secret protection for the regulatory data would have any economic significance; any postmoratorium trade secret rights that survived could be effectively nullified under the ANDA pathway.

What the Hatch-Waxman ANDA pathway provided was tantamount to a compulsory right to reference the secret content of the safety and effectiveness data package of the originator of a new medicine once the moratorium period ended.⁹⁴ The Hatch-Waxman Act thus set “data package protection” limits on securing the approval of copied versions of new medicines, even if no relevant patents existed—and irrespective of whether the original data package on which the approval of the new medicine was made was entirely public or was maintained as a trade secret.⁹⁵ At the same time, it effectively stripped away trade secret protection in the originator’s preclinical and clinical data package by effectively treating a generic drug application as though it contained the right to reference it, in lieu of repeating the studies needed for the regulatory approval of the original version of the new medicine.⁹⁶

94. Because the application of the Hatch-Waxman Act was not entirely prospective in its application, it raised an unavoidable Takings Clause issue under the Fifth Amendment to the U.S. Constitution. Someone challenging the law could have contended that

any proposal allowing the generic applicant to draw upon data submitted by previous applicants, or to rely on information within the knowledge and experience of the agency that had been generated by previous applicants, would allow the ‘use’ of property for a public purpose without just compensation. Because previously submitted data might, in some forms, constitute trade secrets—a form of intellectual property— . . . any disclosure or use of the information by the agency would constitute a taking for which ‘just compensation’ is required by the Constitution.

John C. Yoo, *Takings Issues in the Approval of Generic Biologics*, 60 FOOD & DRUG L.J. 33, 34–35 (2005). No such challenge was ever made and, after thirty years, has become moot. The issue has been addressed in connection with the Biosimilars Act.

95. See 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

96. *Id.* § 355(b), (j).

Overall, therefore, the Hatch-Waxman Act had the effect of recognizing that this new form of intellectual property right it had created—data package protection—played an independent and essential role in the balance between incentives for innovation and market access for copiers. That is, data package protection was provided even for medicines with no relevant patent protection whatsoever and for which the relevant data on safety and efficacy were in the public domain.

When relevant patents do exist, data package protection under the Hatch-Waxman Act would effectively exist so long as relevant patent protection existed. The Act's "patent linkage" provisions were designed to secure this result.⁹⁷ The Act then provided a further provision that was designed to assure more adequate data package protection, by assuring more adequate patent protection.⁹⁸ This new mechanism was "patent term restoration."

E. Hatch-Waxman "Patent Term Restoration" Ameliorates, but Does Not Eliminate, Patent Perversity

By any measure, the "patent term restoration" provisions constitute another historic element of the Hatch-Waxman Act. Patent term restoration permits the term of a relevant patent for a new medicine to be extended based upon the time consumed in gaining regulatory approval for new medicine.⁹⁹ The regulatory period, codified in the Hatch-Waxman Act's restoration provision, is based upon the period required for clinical testing of the medicine and the time during which the originator's NDA is pending approval by the FDA. The patent term restoration provisions in the Hatch-Waxman Act contain exclusions and exceptions that prevent a full restoration of the marketing time lost to the R&D efforts, resulting in a statute that is remarkably complex.¹⁰⁰

97. See *infra* Part III.F.

98. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, 1598-1603 (1984) (codified as amended at 35 U.S.C. § 156 (2006)).

99. 35 U.S.C. § 156.

100. See *id.* The patent term restoration provisions limit the period of extension to five additional years of patent life. *Id.* § 156(g)(6)(A). The actual period of extension is limited to the "regulatory review period," but only one-half of the time during which a medicine was being investigated clinically can count toward the five-year period. *Id.* § 156(c)(2). The preclinical testing period is entirely disregarded. No matter how many patents might be relevant to a new

In spite of all these complexities, the upshot of the patent term restoration provisions, at least in the context in which they were originally enacted in 1984, was that the originator of a new medicine would have a reasonable expectation in many situations of securing fourteen years of restored patent life and, consequently, the patent-linked “data package protection period” that would result would be a matching fourteen-year period. What made the fourteen-year expectation a reasonable one in most situations was the interplay between the patent term restoration opportunity and the opportunity for delayed patent expiration dates under the seventeen-year patent term.

It was not unknown, for example, for patent term restoration to be unavailable for one or more of the most significant patents on a new medicine, because the remaining patent life for such patents was greater than 14 years at the time of the new medicine’s approval. Indeed, there are examples of patent term restoration being entirely unavailable because no relevant patents on the new medicine providing less than 14 years of post-approval patent life ever existed.¹⁰¹

Under the pre-URAA seventeen-year patent term, the Hatch-Waxman patent term restoration provisions enabled a patent that

medicine, only a single patent can be extended and, if a patent was granted an extension, it cannot be extended a second time. *Id.* § 156(c)(4). Finally, the period of extension cannot exceed fourteen years from the date regulatory approval was secured for the new medicine. *See id.* § 156(c)(3).

101. One example of how the pre-URAA patent law could operate to assure patent protection of greater than 14 years can be found in the relevant patents for the medicine EPOGEN. According to the medicine’s sponsor, Amgen Inc., EPOGEN was first approved for marketing in 1989. Amgen was unable to seek any patent term restoration because no EPOGEN-related patents were ever issued that had a post-approval patent life of less than fourteen years. Amgen’s patents most relevant to EPOGEN were based on a patent filing initially made on December 13, 1983 (United States Application Serial Number 06/561,024). Had Amgen’s patent filings been limited to the URAA’s 20-year term, each of the relevant patents based upon this initial patent filing would have expired before the end of 2003. However, among the patents that ultimately based on the 1983 patent application was U.S. Patent 5,547,933, which was granted on August 20, 1996 and was entitled to a 17-year patent term expiring in 2013. Thus without any patent term restoration benefit under the Hatch-Waxman Act, EPOGEN was able to take advantage of the pre-URAA patent law to achieve a 24-year effective patent life. *See Amgen Inc. Annual Report (Form 10-K) 11 (Feb. 29, 2012), available at <http://www.sec.gov/Archives/edgar/data/318154/000119312512086670/d241420d10k.htm> (last visited on Mar. 26, 2014).*

was issued more than three years prior to the date a new medicine was approved to effectively “top off” the patent term to the fourteen-year mark. As an example, for a patent issuing under the pre-URAA patent law no more than three years before the originator’s NDA was filed, the originator was assured of a fourteen-year patent life—even if the FDA took an atypically long five years to decide to approve the NDA. The date on which the patent was initially sought would make no difference to the calculation.

In contrast, the post-URAA law would frustrate the “topping off” function of the Hatch-Waxman Act’s patent term restoration provisions. If a post-URAA patent was initially sought a decade before the NDA filing, the post-URAA patent law would limit the restored patent term to twelve years instead of fourteen years if the FDA then required a three-year period to approve the NDA once filed—only with a one-year FDA review period could a fourteen-year patent life be achieved. If the patent was initially sought fifteen years before the NDA filing, then only a seven-year restored patent term would remain—*one-half of the restored patent life that would have been achieved under the pre-URAA patent law*—should the FDA take the same three year-period to approve the new medicine.

After the 1994 enactment of the URAA’s twenty-year patent term, the assorted limitations contained in the patent term restoration provisions of the Hatch-Waxman Act were instantly transformed into what might be characterized as serious flaws. Absent the interplay between the issue-based patent term and the patent term restoration opportunity, the fourteen-year limitation on Hatch-Waxman patent term restoration effectively became a ceiling, not a floor on available patent protection for many new medicines. As a result, the Hatch-Waxman patent term restoration provisions as they operate today are at best able to moderate, but not remediate the perversity of patent protection. However, even with patent term restoration, many of the potentially best new medicines face the prospect of being saddled with the dimmest prospects for adequate patent protection.

The URAA changes to the patent term represented, in hindsight at least, a lost opportunity to remedy, rather than reinforce, the perversity that results when the most difficult and risky efforts at creating new medicines are rewarded with shorter and more variable patent lives. In resetting the patent term calculation from a protection based on the patent issue date to

protection based on the original patent filing date, Congress might have concurrently acted to reset the Hatch-Waxman patent term restoration calculation to a fixed period of fourteen years from the original regulatory approval date for the new medicine.

All the complexity of the 1984 Hatch-Waxman Act's patent term restoration provisions could have been eliminated by simply setting the terms of the originator's relevant patents to expire at fourteen years from the date of regulatory approval. Given the "fast track" nature of the adoption of the twenty-year patent term, there was neither the time nor the opportunity for Congress to accomplish this objective.¹⁰²

Nothing, of course, would prevent Congress taking such a remedial action now. The MODDERN Cures Act represents, at least for medicines being studied for unmet medical needs, such a remedial step. The MODDERN Cures Act not only eliminates the possibility for patent perversity but goes a step farther. By setting a fixed and certain fifteen-year IP protection period from the date of the original regulatory approval of a new medicine, all uncertainty and variability in the protection for the original version of a new medicine and market entry for copied versions is ended—both for the originator and the copier.¹⁰³

F. *Hatch-Waxman "Patent Linkage"—A Patent-Dependent Data Package Protection Period Injects Patent Perversity into Data Package Protection*

The Hatch-Waxman Act tied together the concepts of data package protection and patent protection through a then-novel "patent linkage" mechanism. There is a virtual maze of provisions in the Hatch-Waxman Act that implement the patent linkage provisions. Effectively, the linkage provisions place a bar on approval for marketing of either a paper NDA or an ANDA until each of the originator's relevant patents on the new medicine have expired.¹⁰⁴ The only exception that applies is the situation where a

102. For a discussion of the limitations on congressional consideration of the 1994 changes to the patent law due to the "fast track" authority of the President to conclude trade agreements, see Natalie R. Minter, *Fast Track Procedures: Do They Infringe upon Congressional Constitutional Rights?*, 1 SYRACUSE J. LEGIS. & POL'Y 107 (1995).

103. See H.R. 3116, 113th Cong. § 201(i)(4)(B) (2013).

104. 21 U.S.C. § 355(b)(2), (j)(2) (2012).

patent is successfully challenged by the copier.¹⁰⁵ In brief, the “data package protection period” becomes the same as the patent protection period, at least for most patented medicines.

In hindsight at least, the Hatch-Waxman Act could justify its relatively transient data patent moratorium periods that relate to the filing of paper NDAs and ANDAs, because of the linkage provisions that provide the actual marketing approvals for generic copies would await for what might typically be a fourteen-year (or sometimes longer) patent life for the new medicine. In this manner, at least under the 1984 incarnation of the Hatch-Waxman Act, copied versions of new drugs would appear in the marketplace only after the originator of the new medicine had enjoyed a period that, on its face at least, was reasonably sufficient to recover the investment made in creating it.

As noted above, when the URAA changes to the patent laws made the patent term restoration provisions of the Hatch-Waxman Act less effective, it made the patent linkage provisions correspondingly less effective. In effect, the magnification of patent perversity through the new filing-based patent term was imported into the data package protection provisions under the Hatch-Waxman Act. Just as patent protection periods have more uncertain and more variable protection terms, so do the Hatch-Waxman’s data package protection provisions. The Biosimilars Act, among other departures from the Hatch-Waxman Act, dispensed with any patent linkage provisions. It employs a different structure for data package protection, which the proponents of the Act apparently believed would obviate the need for any type of linkage. Expanding the data package protection as it relates to the approval of copied versions of biologic medicines to at least twelve years apparently formed the justification for dispensing with any form of patent linkage.

Again, the MODDERN Cures Act takes the Biosimilars Act one step farther. The data package protection period of fifteen years—and the complete alignment of the period of patent protection to

105. The copier was required to certify, with respect to each relevant, unexpired patent of the originator of the new medicine whether the copier was seeking approval upon the patent expiration date or was prepared to challenge the applicability of the patent to the copied version of the new medicine. These two options are set out in 21 U.S.C. § 355 (j) (2) (A) (vii) (III)–(IV), commonly and respectively referred to as the copier’s “Paragraph III” and “Paragraph IV” certifications.

an identical fifteen-year period—moots the need for any form of patent linkage.

G. *The Hatch-Waxman “Generic Drug Monopoly Period”*

The last of the pioneering IP provisions of the Hatch-Waxman Act was yet another consequence of the decision to link the data package protection period to the patent life in an effort to assure an adequate aggregate protection period before approving copied versions of a new medicine under an abbreviated regulatory approval pathway. This last pioneering feature created a so-called “generic drug monopoly period” in which one or more generic drug manufacturers might preclude all their fellow generic competitors from the market during a 180-day period.¹⁰⁶

Over the past thirty years, the generic drug monopoly period may well have produced more profits for generic drug manufacturers than from sales of generic drugs otherwise. The marketing monopoly’s historic role as a driver of generic drug industry profits was, however, highly attenuated by the Medicare Modernization Act of 2003.¹⁰⁷

Today, all generic drug manufacturers that submit patent challenges on the first day permitted for doing so¹⁰⁸ now share in the “monopoly.” For a typical new medicine, somewhere between five and fifteen generic drug manufacturers may qualify as so-called “first filers.”¹⁰⁹ Having that many competitors sharing a monopoly period is, of course, no monopoly at all. While this aspect of the Hatch-Waxman Act, however flawed, was clearly well intentioned, it has long outlived any usefulness that it might have had. From the

106. Under 21 U.S.C. § 355(j)(5)(B)(iv), the period is referred to as the “180-day exclusivity period.”

107. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (2003) (codified as amended in scattered provisions of 26 and 42 U.S.C.).

108. See 21 U.S.C. § 355(j)(5)(F)(ii) (“[A]n [abbreviated new drug] application may be submitted . . . after the expiration of four years from the date of the approval of the [original version of the new drug] if it contains a certification of patent invalidity or noninfringement described in [Paragraph IV].”).

109. See *id.* § 355(j)(5)(B)(iv)(II)(bb). The statute refers to the “first filers” as “first applicants” and defines a first applicant as “an applicant that, on the first day on which a substantially complete application containing a certification described in [Paragraph IV] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV] certification.” *Id.*

beginning of the Hatch-Waxman era, it has routinely induced patent challenges on the key patents that the originators of new medicines have relied upon to invest in the creation of the new medicine—rather than being confined to its original purpose as a mechanism to challenge questionable, secondary patents.

In other situations, it has provided an unnecessary incentive to challenge patents that would have been challenged with the same vigor and to the same extent even absent any such an incentive. Lastly, it has spawned an unseemly practice of “patent settlements” that, while defended by some antitrust specialists, has been roundly criticized in antitrust policy circles and elsewhere.¹¹⁰

Unsurprisingly, just as the Biosimilars Act avoided patent linkage, it similarly avoided instituting any analog to the generic drug monopoly period. Under the MODDERN Cures Act, such a monopoly period is unnecessary. There will be no relevant patents whose enforceability will extend beyond the date when the data package protection period has ended.

H. MODDERN Cures: One Answer to the Emerging Issues with the Regulatory/IP Interface Under the Hatch-Waxman Act

Whatever its possible shortcomings, the Hatch-Waxman Act has served well the intent of its legislative sponsors to create a vibrant generic drug industry that would exist alongside an equally vibrant industry committed to the discovery and development of new medicines. Today, however, neither the copier industry nor the originator industry looks much like its respective 1984 counterpart. The respective market shares of the innovator industry and the copier industry have essentially reversed—the vast majority of drugs consumed today are copied versions, not the original.

While the Hatch-Waxman Act has left both industries with business models that have thus far proven viable, warning signs exist that suggest the Hatch-Waxman Act may not fulfill its 1984 intent indefinitely into the future. Unlike the 1984 version of the Act, the contemporary version is more deeply infected with patent perversity. This undercuts its ability to provide the consistent promise of the fourteen-year protection period for new medicines that was originally afforded through the combination of a seventeen-year patent term based upon the issue date of the patent

110. See, e.g., *Fed. Trade Comm’n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

and the ability to use the patent term restoration provisions of Hatch-Waxman to “top off” patent term for patents issuing too far in advance of the marketing approval for a new medicine. As noted earlier, by tying data package protection provisions to patent expiration, the Hatch-Waxman Act simply imported patent perversity into its data package protection provisions.¹¹¹

One possibility for improving the Hatch-Waxman Act might be for the Act to morph into a law akin to the Biosimilars Act. Another possibility might be for Congress to consider the missed opportunity from the 1994 patent law changes to simply reset the patent term for the relevant patents of the originator of a new medicine to a fixed period of fourteen, seventeen or even twenty years from the date a new medicine was originally approved—much like the post-1994 patent term runs for twenty years from the date a patent application was originally filed.¹¹²

111. See *supra* Part III.F.

112. An analytical framework has been developed to better understand the economic rationale for measuring IP protection periods from the date of commercialization. Eric Budish et al., Do Fixed Patent Terms Distort Innovation? Evidence from Cancer Trials 1, 14 (Sept. 5, 2013), *available at* <http://economics.mit.edu/files/8651>, advances the proposition that filing-based patent terms have negative, distortive impacts on making R&D investment decisions that could be addressed through a commercialization-based measure for patent term, such as that suggested in the below text:

Since in many industries firms are effectively compelled to file patents at the time of discovery (“invention”) rather than at the time of first sale (“commercialization”), legally fixed patent terms [measured from patent filing dates] generate variable effective patent terms: inventions that commercialize at the time of invention receive a full twenty-year patent term, whereas inventions that take longer to commercialize realize a shorter effective patent term. In the extreme, patents offer no incentive to develop technologies that would take longer than twenty years to commercialize. Thus, under a fixed patent term, research and development (R&D) investments may be distorted away from technologies with long time lags between invention and commercialization. . . .

. . . .

. . . Suppose that the length of the patent term must be fixed, but that the patent clock can start either at invention or commercialization. Given any patent term that runs from the date of invention, there exists a patent term that runs from the date of commercialization that strictly increases social welfare. In particular, the optimal patent term that runs from the date of commercialization

Yet another possibility, of course, would be for Congress to enact the MODDERN Cures Act, with its fixed and certain fifteen-year IP protection period inclusive of both patent protection and data package protection periods. For medicines that meet its qualifications, it would assure that the prospect of transient, questionable, or nonexistent patent protection would no longer imperil the ability to invest in the testing required to bring a promising new experimental medicine to market.

To gain a fuller understanding of why this type of a unified approach to the regulatory/IP interface would merit serious consideration, it is useful to undertake a detailed analysis of the economic and competitive environments in which new medicines have historically been protected from copying—and how those factors have changed in ways that make the MODDERN Cures approach a compelling model.

IV. INVESTMENTS IN MAKING NEW MEDICINES DEPEND UPON IP PROTECTION SUFFICIENT TO JUSTIFY SUSTAINED, HIGH RISK INVESTMENTS CAPABLE OF YIELDING COMMENSURATE RETURNS

The prospect of enjoying adequate IP protection has become a necessary predicate for making the investment needed to create a new medicine. Once a new medicine is approved and reaches the market, it is essential to the ability of the medicine's originator to undertake the follow-on educational and marketing investments that are required to develop a commercial market for those medicines.

For an innovation-focused business model to have any hope of survival, IP protection needs to serve as a bulwark against relatively inexpensive copied versions of new medicines coming to market during the limited period before such IP protection vanishes. The business model for a generic manufacturer permits copied versions of the most valuable and life-changing medicines to be profitably sold into the marketplace at a nominal cost. For consumers, it has made a month's supply of hundreds of miracle medicines less costly than a daily trip to Starbucks.¹¹³

is superior to the optimal patent term running from the date of invention.

113. The average price of Starbucks latte (Venti size) exceeds \$4. *See Starbucks Latte (Venti size) Prices*, HUMUCH?, http://www.humuch.com/prices/Starbucks-Latte-Venti-size/_/819 (last visited Mar. 2, 2014). This compares with the

The economic thesis for creating the new generic drug industry with these characteristics was as simple as it is compelling. The research-based biopharmaceutical industry is the consummate high-risk business, both in its efforts to create new medicines and in subsequent investments to get those innovations understood and used by physicians and their patients. The difficulties of creating even a single successful medicine is the stuff of legend.

There are no high-risk, low-reward businesses that can sustain themselves over the long term. Investors in pharmaceutical and biotechnology companies are not an exception. Where biopharmaceutical companies have failed to sustain an acceptable return¹¹⁴ consistent with the risk the investment in creating new medicines entails, they have disappeared.¹¹⁵ Investors in research-based biopharmaceutical companies expect financial returns on

\$4 generic drug prescription cost. See *\$4 Prescriptions*, *supra* note 17.

114. The difficulties of sustaining a successful return on investment have been well documented.

Over the course of the four years of this analysis, the [study's] cohort of 12 companies has launched 105 products and transferred \$770 billion of projected value into their commercial portfolios to the benefit of patients. Over the same period, the research and development (R&D) engines of these companies have pulled 167 assets into late stage development, with a total risk adjusted value of \$819 billion.

Despite these positive indicators, the projected return on investment in innovation that the cohort's late stage pipeline is expected to deliver has continued to decline across the four years, from 10.5 percent in 2010 to 4.8 per cent in 2013. The cohort result hides wide variations in company performance. Some companies are achieving higher rates of return and others are struggling to safeguard growth.

DELOITTE UK CENTRE FOR HEALTH SOLUTIONS, MEASURING THE RETURN FROM PHARMACEUTICAL INNOVATION 2013: WEATHERING THE STORM? 2 (2013), *available at* <http://www.deloitte.com/assets/Dcom-UnitedKingdom/Local%20Assets/Documents/Industries/Manufacturing/uk-manufacturing-measuring-the-return-from-pharmaceutical-innovation-2013v1.pdf>.

115. A large collection of research-based pharmaceutical companies have disappeared since 1989. The list includes companies that had been in business for over 100 years before being eliminated through a merger. The Upjohn Company, Wyeth, Schering-Plough, Squibb, Syntex, Warner-Lambert, A.H. Robbins, SmithKline, Wellcome, Beecham, American Cyanamid, Sterling Winthrop, Zeneca, Beecham, Hoechst, Marion, Mallinkrodt, Knoll, Schering AG, Alza, McNeil Laboratories, Fisons, Ciba-Geigy, Rhône Poulenc, Synthélabo, DuPont Pharmaceuticals, Roussel, Rorer, Farmitalia Carlo Erba, and Pharmacia are all companies that ceased independent existence during the past twenty-five years.

investments in developing new medicines that are, prospectively at least, commensurate with the development risk as well as the marketing risk. New medicines have, out of necessity, become relatively more costly. They must be priced to pay back the investments needed to create them and to create markets for them. Most new medicines cannot be priced high enough to make the investment in creating them a profitable one.¹¹⁶

Medicines, once approved for marketing, do not make markets for themselves. A new medicine, once available in the marketplace, cannot succeed commercially without changing the practice of medicine. For a new medicine to be used, physicians need to understand the patients who can benefit from a new therapy, understand the limitations on the use of the medicine, learn what side effects to expect, and prescribe the medicine to patients who similarly require information on what to expect (and not to expect) from the new medicine.

The education and marketing investment needed to get a new medicine prescribed by physicians and successfully used by patients is enormous. The ongoing efforts to educate and promote marketed medicines are of the same order of magnitude as the ongoing R&D expenses to create them.¹¹⁷

As noted earlier, the creation risks and marketing risks are compounded by the need for a new medicine just coming into the market to compete against any established medicines in the same therapeutic class, an increasing number of which over time are available in the form of low-cost copies. For a new medicine to break into a market where multiple generic drugs are already available in the marketplace—or would be available by the time the new entrant could gain regulatory approval—requires much more than assuring the new medicine is a safe and effective product.

It requires some basis for projecting that the clinical results from the testing of the medicine, once completed, will produce sufficient advantages over generic copies of all existing medicines

116. See JIM GILBERT ET AL., *supra* note 16.

117. The Congressional Budget Office (CBO) estimated that in 2008 the cost of developing the market from new medicines among major pharmaceutical companies was \$20.5 billion. See CONG. BUDGET OFFICE, ECONOMIC AND ISSUE BRIEF: PROMOTIONAL SPENDING FOR PRESCRIPTION DRUGS 2 (2009), available at http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/105xx/doc10522/12-02-drugpromo_brief.pdf. This compares, according to CBO numbers, with an ongoing annual R&D cost of \$38 billion for the industry. *Id.*

such that patients and their insurers will be willing to pay a 50-fold or 100-fold premium in the pricing for the new medicine. Without the ability to make that projection, the investment to create the new medicine—however promising otherwise—becomes irrational.

Although the generic and the innovative industries both manufacture medicines, the generic drug industry otherwise is everything that the innovative industry is not—and vice versa. The generic industry was designed to exist without the need either to discover new medicines or the need to undertake the massive clinical effort thereafter required to get them approved for marketing. In sum, the “product acquisition” cost for a generic drug manufacturer is negligible.

By way of comparison, the figures set out above indicate the relative difference in product acquisition costs as between the two industries are three or four orders of magnitude different. The development costs to bring a copy of a new drug to market under the generic drug approval pathway under the Hatch-Waxman Act are probably less than a tenth of a penny on the dollar of the comparable cost for a biopharmaceutical company to bring the new medicine to market. On the marketing side, the same ratio applies. For each dollar the originator of a new drug spends to create a market for a new medicine, the copiers can seize the market for the medicine for less than a tenth of a penny on the dollar of marketing spend.

The Hatch-Waxman copied products are marketed as generic drugs. They are literally *generic* products. Most are unbranded. As such they are not promoted in the marketplace—and cannot be promoted in the marketplace. Unlike a typical manufacturer/marketer, a generic drug manufacturer can at most assert in the marketplace that the generic medicine is undifferentiated from the original version of the product being copied. However, the FDA moots even the need for a generic drug manufacturer to note that its products are nondifferentiated. The FDA’s rating system dictates that generic drugs meeting a bioequivalence standard are fully interchangeable with the original version of the new medicine.¹¹⁸

118. See OFFICE OF GENERIC DRUGS, FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, at viii (34th ed. 2014), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf> (commonly referred to as the “Orange Book”).

Under the Drug Price Competition and Patent Term Restoration Act of 1984, manufacturers seeking approval to market a generic drug

In sum, generic drug manufacturers not only do not need to brand their products, they do not need to educate physicians on their use, or otherwise promote them. The FDA regulatory regime provides that generic drugs are approved solely by demonstrating bioequivalence to the new medicine that they have copied. Copied versions of new drugs are government certified as substitutes for the original version of the new medicine.

In the business of prescribing and dispensing medicines to patients, generic drugs are freely substitutable and today are typically freely substituted for the original version of the medicine. Throughout the United States, state law requirements either encourage or mandate that a prescription for a medicine be filled with a generic copy, if available.¹¹⁹ The net effect of these requirements is to transfer to generic drug manufacturers, upon generic drug entry, the bulk of the value created by the originator of the medicine in the medicine's trademarks and associated goodwill.

As a result of the Hatch-Waxman regulatory regime, virtually the only business risk faced by a generic drug manufacturer is the risk of failing to be among the lowest-cost manufacturers of the

product must submit data demonstrating that the drug product is bioequivalent to the pioneer (innovator) drug product. A major premise underlying the 1984 law is that bioequivalent drug products are therapeutically equivalent and, therefore, interchangeable.

Id.

119. Henry Grabowski, *Competition Between Generic and Branded Drugs*, in PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 153, 155–56 (Frank A. Sloan & Chee-Ruey Hsieh eds., 2007).

States generally have one of two types of substitution laws: permissive substitution laws and mandatory substitution laws. Mandatory substitution states require that pharmacists substitute generic drugs for branded drugs where a generic is available and other requirements are fulfilled. Permissive substitution states allow pharmacists to substitute generic drugs for branded drugs. According to the 2003-2004 National Association of Boards of Pharmacy's *Survey of Pharmacy Law* (2004), 11 states and Puerto Rico had mandatory generic substitution laws. In 38 other states plus the District of Columbia and Guam, pharmacists were permitted, but not mandated, to substitute generic drugs for brand name drug products. In either case, payers, physicians, and pharmacists had a strong economic incentive to substitute generic drugs for branded drugs.

Id. (footnote omitted).

copied versions of a new medicine. In effect, the business model of a generic drug manufacturer today means that generic drugs can be profitably sold—and provide a profit for the generic drug manufacturer proportionate to the relatively minimal risks of being in the generic drug business—at little more than the cost to manufacture those copies.¹²⁰

In most industry sectors, it would be difficult to explain how the medicine-creating business could have survived the competitive onslaught of the medicines-copying business that can both free-ride off the R&D of the innovator and then free-ride off the marketing investments. If there is an explanation, that explanation begins—and perhaps ends—with IP protection. The reason that a minority of the research-based, innovative pharmaceutical companies that were in business at the start of the Hatch-Waxman era have survived through today, is that their new medicines were accorded sufficient IP protection to produce a return on the investments needed to create them.

The importance of a secure and predictable IP regime cannot be underestimated when the competition in the marketplace can operate generically with a government certification of equivalence of the products it places into the marketplace. No one can dispute that, in IP-intensive industry sectors with significant R&D costs to create a new product, the emergence of a government-certified “generic copy” industry would have been the death knell for the innovation-based industry absent sufficient IP protection from copying.

120. A possible flaw in the generic drug business model is the loss from the market of generic manufacturers that are not among the lowest-cost producers or, were such manufacturers to make needed investments to remain in the manufacturing business for a generic drug, could not retain the status as a lowest-cost producer. Shortages of generic drugs have become increasingly common in recent years, which may be attributable in part to the type of price competition has served to limit the number of manufacturers that are in, can remain in, or can enter the market for a particular generic medicine. As counterintuitive as it might seem, it might be in the best interests of consumers for the FDA to be given authority to set minimum prices at which shortage-prone generic copies of new medicines might be sold in the marketplace. While the drug shortage topic has been extensively studied by the FDA, their efforts may have missed the IP-related root cause of such shortages and the facile economic solution to address that root cause that a pricing floor might represent. FOOD & DRUG ADMIN., STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES (2013), *available at* <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf> (last visited on Mar. 27, 2014).

Imagine Microsoft staying in business selling Windows 8.1 and its MS Office 2013 if government-certified copied versions of Windows 7 and Office 2010 could be developed today for the market and then sold as government-certified equivalents for quality and functionality for little more than the cost of copying. If, of course, Office 2013 provided revolutionary advantages for users compared to Office 2010, it is possible that users might be willing to pay a ten-fold higher price for the improvements in Office 2013. However, it would take an almost unimaginably improved product for a customer to pay a 100-fold higher price for an innovative, branded product. If Windows 8.1 had been such a revolutionary advance over Windows 7, then this would provide only a small bit of breathing space for the innovator. It would then need a comparably improved product in Windows 9 to gain market share over a generic copy of Windows 8.1. It becomes relatively easy to understand that protection from copying—and protection for a significant time period—lies at the heart of an effective IP regime that is essential for an innovation business to survive the onslaught of competition from government-certified copies.

The risks to the survival of the remainder of the research-based biopharmaceutical industry from the generic drug industry grow more acute over time. Today, as noted earlier, almost every new drug that came to market during the twentieth century now has generic copies in the marketplace. For some important therapeutic categories, multiple new drugs have generic copies competing in the marketplace. With the 2014 commercial reality in mind, what does this suggest about the MODDERN Cures Act paradigm for IP protection vis-à-vis the Hatch-Waxman Act and the Biosimilars Act?

First, with all the risk factors faced by originators in sustaining an innovation model, the risk of insufficient or insecure IP protection can readily be the last straw of risk that breaks the back of the business model. The MODDERN Cures Act was conceived as a means of taking IP risk off the table as a reason why the originator might not proceed to develop a promising experimental medicine.

Second, the MODDERN Cures Act puts a stake in the ground on what the period of IP protection should be to provide the optimal balance between incentives for innovation and the economic value that can arise from access to regulatory pathways for bringing low-cost copies to market. What is the justification for a fifteen-year IP protection period, after which copied versions of

new medicines can be freely approved under abbreviated regulatory approval pathways? As will be discussed below, there are compelling reasons for the fifteen-year IP protection period contained in the Act.

V. THE CASE FOR THE MODDERN CURES ACT: A FIFTEEN-YEAR PATENT PROTECTION AND DATA PACKAGE PROTECTION PERIOD WITH COPIED VERSIONS BEING FREELY MARKETED THEREAFTER

A. *The MODDERN Cures Model Eliminates Any Possible Need for Patent Litigation-Related Provisions in the Regulatory/IP Interface*

Under the Hatch-Waxman Act, patent linkage plays an essential role in the overall IP protection regime. “Patent linkage” means, as noted above, that the data package protection period is ultimately the patent protection period. The only way to determine the applicable patent protection period is to know which of the originator’s relevant patents were valid and infringed. Once patent linkage is elected as the governing principle for determining how long the data package protection period will last, a cascade of related provisions must follow to establish the subsidiary issues of patent validity and patent infringement. This includes setting out provisions that take account of who might sue whom, when, and over what patents.

The MODDERN Cures Act, which uses the patent protection period as the data package protection period, gets to exactly the same end, but arrives from the opposite starting point. Instead of using the vagaries of the patent protection period to define an equally less certain and less predictable data package protection period, the MODDERN Cures Act uses a fixed and certain data package protection period to define an equally fixed and certain patent protection period.¹²¹ While the Hatch-Waxman Act was crafted on the assumption that, given patent term restoration, there would be a floor of fourteen years of patent protection, the MODDERN Cures Act sets out a unified IP protection of fifteen years—the floor and the ceiling are at the same elevation.¹²² The MODDERN Cures framework inherently removes the relevancy for the Hatch-Waxman patent linkage to data protection—if anything,

121. See H.R. 3116, 113th Cong. § 201(e)(2)(C) (2013).

122. *Id.* § 201(i)(4)(B).

it substitutes linking patents to data package protection, rather than vice versa.

The required patent disclaimer provisions under MODDERN Cures assure that there will be no outstanding patent rights of necessary relevance once the fifteen-year protection period ends.¹²³ In the absence of patents that can be infringed after the end of the common IP protection period, there is no reason for a generic drug monopoly period of the type found in the Hatch-Waxman Act. There simply will be no patent litigation related to the approval of copied versions of new medicines—either before the approval or after the approval. As for the patent-related provisions of the Biosimilars Act, there is no basis for a patent dialogue between originator and copier because there will be no relevant patents that can be enforced by the originator against the copier once the data package protection period ends and the copier can secure regulatory approval to market.

The MODDERN Cures Act approach represents the superior public policy. The patent risks and uncertainties in a patent-linked, patent-centric system can equally bedevil both originators and copiers. It follows that both originators and copiers benefit if those risks can be mitigated or, as with the MODDERN Cures Act, even eliminated. Importantly, as outlined earlier, patent perversity disappears. The most challenging and difficult new medicines to develop are no longer punished with disproportionately shorter IP protection periods. The MODDERN Cures Act has provisions that assure that, what otherwise would be pathologically short-lived patents, will be fully restored to the end of the fifteen-year IP protection period. The prospect of inadequate IP protection will no longer be a factor to be weighed against bringing a promising experimental medicine into the clinic.

An interface based entirely upon a common, fixed IP protection period, devoid of patent linkage, can be as simple in actual operation as the Hatch-Waxman patent-centric system is complex. The only significant challenge in creating the new architecture lies in optimizing the length for the protection period itself. It must be a sufficient period for the originator of the new medicine to have the reasonable prospect of earning back the investment required to discover and develop the medicine through FDA approval in the first place, but it must also assure that patients

123. See *id.* § 201(c).

will get the benefits of low-cost, copied versions of those new medicines in as reasonably prompt a timeframe as possible.

B. Setting the Unified IP Protection Period at Fifteen Years is the Optimal Policy Choice

1. Hatch-Waxman's Fourteen-Year Patent Term Restoration Period Translates into a Fifteen-Year IP Protection Period Taking Account of Pediatric Exclusivity and the Generic Drug Monopoly, Making It a Benchmark for Testing the Adequacy for the IP Protection Period for New Medicines Directed to Unmet Medical Needs

In economic terms, the right data package protection period should be relatively straightforward to determine, *if the objective is to assure that the protection period is adequate, on average, for the originator of the new medicine to be able to earn back in profits from sales revenues the investment needed to create the new medicine in the first place.* The Hatch-Waxman Act contained a benchmark for such a period when it authorized patent term restoration for a fourteen-year period from the date the original version of a new medicine was originally approved, whether a new drug subject to the new abbreviated approval pathways in the Act or a biologic medicine for which no like pathway would exist until 2009. The fourteen-year period was adopted in 1984 when—as described earlier—inventors in other technologies might expect a seventeen-year patent life for nonpharmaceutical patented products in any circumstance, where the issuance of the relevant patents coincided with the time at which the patented product entered the marketplace.¹²⁴

Under the post-1994 patent law, Congress concluded that up to a twenty-year patent protection period could be regarded as an appropriate IP protection period for products needing little in the way of engineering or other development work before entering the market. The twenty-year patent life could be achieved given the statutory twenty-year patent term allows for an additional one-year period during which provisional patent filings can be made before the twenty years of patent life commences.¹²⁵ If the provisional patent year was used for the engineering and other development

124. See *supra* Part III.E.

125. See 35 U.S.C. § 154(a)(3) (2006) (providing that a provisional patent filing under 35 U.S.C. § 111(b) “shall not be taken into account in determining the term of a patent”).

work needed to prepare that nonpharmaceutical patented product for the marketplace, the patents on the product would expire twenty years after marketing of the product commenced.

An IP protection period of fourteen, seventeen, or even twenty years would each be consistent with the Hatch-Waxman Act's original intent—and the intent of Congress in setting terms of protection under patents. As noted above, when enacted in 1984, the Hatch-Waxman law effectively created a fourteen-year floor on patent life for many new medicines.¹²⁶ Recent statistics indicate that nearly one in three patents extended since 1984 under the Hatch-Waxman Act were reset to expire at the end of the fourteen-year period from regulatory approval.¹²⁷ Thus, except where patent protection works perversely, the fourteen-year protection period remains the historic benchmark for testing the adequacy of an IP protection period for a new medicine—drug or biologic—coming to market.¹²⁸ In terms of a floor on protection, there would be no reason to reject a fourteen-year protection period.

Also, as intentionally constructed, the MODDERN Cures Act does not permit adding an additional six months of further protection at the end of the fourteen-year patent term restoration

126. See *supra* note 101 (noting the 24-year effective patent life for EPOGEN).

127. See *Patent Term Extensions*, U.S. PAT. & TRADEMARK OFF., <http://www.uspto.gov/patents/resources/terms/156.jsp> (last visited Mar. 2, 2014), for a listing of restored patent terms under 35 U.S.C. § 156, pursuant to the Hatch-Waxman Act. Since 1984, over 600 patents have been extended, the large majority of which are patents claiming new medicines. The five-year or two-year limitation on the length of the permitted period of extension limited approximately 30% of the patents extended. Another approximately 40% of patent extension were ultimately limited by the required deduction from the “regulatory review period” of the testing phase of the product on which the extension was based. The final (approximately) 30% of reported extensions were limited by the fourteen-year cap on the patent expiration from the date of product approval.

128. Moreover, at least in some situations, the patent protection period under the pre-1995 patent law afforded patent protection periods for new medicines of longer than fourteen years based on patents other than the patent selected by the originator for patent term restoration. Finally, in yet other situations no patent term extension was ever sought under the Hatch-Waxman Act because all the relevant patents on the new medicine had longer than fourteen years of remaining patent life at the time the new medicine was approved. As one example, the relevant patents for the medicine Epogen, approved in 1989, all had patent terms extending beyond the fourteen-year Hatch-Waxman limit on patent term restoration. The relevant Epogen patent, U.S. Patent No. 4,703,008 (filed Nov. 30, 1984), entitled “DNA Sequences Encoding Erythropoietin,” issued on October 27, 1987, less than three years from the regulatory approval for Epogen in June 1989.

period based upon “pediatric investigations.”¹²⁹ Under the Hatch-Waxman Act, tacking on an additional six-month pediatric exclusivity period to the end of the fourteen-year protection period suggests an effective floor of fourteen-and-a-half years of IP protection would be appropriate. Additionally, Congress conceived that an additional 180-day generic drug monopoly period might apply in certain situations.¹³⁰ When the additional period applies, the fourteen-and-a-half-year floor on the protection period becomes a fifteen-year period before all generic competitors are permitted to freely enter the market.

While the framework that offered the ability to secure such a fifteen-year protection period under the Hatch-Waxman Act is not dispositive of its appropriateness for the MODERN Cures Act framework, it is relevant in one important respect. It would clearly be perverse if medicines that were relatively simple and more straightforward to develop could readily secure this type of fifteen-year IP protection period under the current Hatch-Waxman Act,¹³¹ but medicines addressing unmet medical needs—with much longer routes to FDA approval—were confined to a shorter IP protection period.

2. *A Fifteen-Year IP Protection Period Is Supported by Economic Analysis Indicating a Fifteen-Year Period Is Typically Essential for a New Medicine to Pay Back the Investment Made to Develop It*

The most significant work analyzing the necessary IP protection period that would allow a new medicine to earn back for the originator the investment needed to create the new medicine was undertaken by Henry Grabowski.¹³² The Grabowski work uses a

129. See Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-114, tit. V, 126 Stat. 993, 1039 (2012) (making permanent the provisions of the Best Pharmaceutical for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002)). Under 21 U.S.C. § 355a(b)(1) (2012), an additional six months of data package protection and effective patent protection is available for submitting information to the FDA.

130. See *supra* Part III.G.

131. For example, because they could be developed so facilely that their patent terms could be restored to the full fourteen-year period, not taking account of the six-month pediatric extension and the 180-day generic drug monopoly period.

132. Henry Grabowski, *Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REVIEWS: DRUG DISCOVERY 479 (2008).

pair of discount rates to calculate possible “breakeven” scenarios for investments made to create new medicines.¹³³ The conclusion from his work is straightforward. An IP protection period that is less than a term of thirteen to sixteen years would not be sufficient.

When the net present values (NPV) of inflow just equals outflows, this is the break-even point at which a firm recovers its R&D investment and earns a risk-adjusted rate of return. The breakeven time is 12.9 years for a discount rate of 11.5%, and 16.2 years for a 12.5% discount rate.¹³⁴

While this work was done on new biologic medicines, its fundamental methodology applies to new medicines of all types—and increasingly so, as the costs and risks of bringing new medicines successfully to market have steadily accelerated. Under the Grabowski analysis, it is clear that the twelve-year data package protection period from the Biologics Act is too short by itself to provide the necessary payback period. Moreover, as suggested by the “patent dialogue” provisions in the Biosimilars Act, Congress anticipated that the effective IP protection period could be significantly longer—the longer period arising from enforcement of patents to yield the appropriate aggregate protection period.

The MODERN Cures Act, in the course of eliminating any patent-based IP protection period after the end of the data package protection period ends, employs a Grabowski-consistent period of fifteen years. This fifteen-year protection period thus can be viewed as neither unwarranted nor excessive given that access to this protection period is limited to experimental medicines being investigated to address unmet medical needs.

3. *The Fifteen-Year IP Protection Period Assures the Fullest and Best Uses of a New Medicine Can Be Investigated and Approved for Use in Patients*

Much of the most important research on every new medicine takes place not before, but *after* the FDA has approved the medicine for use. This is the research into new indications for use, uses to prevent and not just treat a disease, patient populations where the medicine may be especially effective and useful (or carry

133. “The break-even lifetimes for the mean [biologic] product were found to be between 12.9 and 16.2 years at alternative discount rates of 11.5% and 12.5%, respectively.” *Id.* at 487.

134. *Id.* at 486 (text accompanying Figure 6).

particular risks and liabilities), and safety issues that arise and need to be fully understood. For this research to be sustained, and for the fullest and best uses of the medicine to be understood and for physicians to be fully educated on the use of the medicine by the time generic copies arrive on the market, it is critical that incentives exist to continue this type of post-approval research during the decade after the medicine reaches the market.

With a fifteen-year IP protection period, the originator is positioned to continue investments in research during the decade after the medicine first reaches the market. If inexpensive generic copies come to market too soon, the investment needed to create and disseminate the information needed to put the medicine to its fullest uses will never be made.

4. *The National Academies Recommended a Data-Package Protection Period for Protecting All New Medicines That Is Consistent with a Fifteen-Year Protection Period for Medicines to Address Unmet Medical Needs*

In 2007, the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine jointly published a report¹³⁵ in which the deficiencies of the existing data package protection regimes for new medicines were laid out in case-study form. The National Academies concluded that a serious effort was needed to determine how best to balance available patent protection for new medicines with data package protection.¹³⁶ It laid out the case for a more data-focused regime. Pending completion of a study to determine a fully adequate protection period, the National Academies recommended that Congress should move ahead immediately with at least a ten- to eleven-year period of data package protection to provide some parity with the European data package protection regime that currently affords up to an eleven-year¹³⁷ protection from the approval of generic copies of all new medicines.

135. NAT'L RESEARCH COUNCIL, RISING ABOVE THE GATHERING STORM: ENERGIZING AND EMPLOYING AMERICA FOR A BRIGHTER ECONOMIC FUTURE (2007).

136. *Id.* at 190–92.

137. *Id.*

The demands for data on a molecule's safety and efficacy are increasing. The generation of the necessary data requires time and money. It is to patients' benefit for as much time as appropriate to be devoted to the development of the data, but spending the time lessens

The MODDERN Cures Act provision for a fifteen-year fixed and common data package and patent protection period for medicines directed to unmet medical needs is fully consistent with the National Academies' study.¹³⁸

the return on the developer's investment because it encroaches on the patent term. Bringing a new medicine to patients requires a sequence of major breakthroughs, which in the current system must be accomplished well before the life of a patent runs out. Often, the clock does run out, and the innovator must start over with a new molecule simply to get time 'back on the clock.' As a result, there is an ever growing 'graveyard' currently comprising more than 10 million compounds. There is no incentive to exhume these compounds in the absence of substantial data-package exclusivity, because patents will be either unavailable or of such narrow coverage that they would be easy to avoid in developing a related drug.

Id. at 191.

138. One subject not addressed in this article is the issue of additional reforms that might be appropriate once the MODDERN Cures Act is enacted into law. One possible modification to both the Hatch-Waxman Act and the Biosimilars Act, fully consistent with the MODDERN Cure Act principles, would be to provide an alternative to the existing patent term restoration and data package protection provisions of the Hatch-Waxman Act with respect to any medicine for which patent term restoration under the existing law had not been secured. Congress could provide an originator with the option to elect a fixed IP protection period, irrespective of whether the medicine addressed an unmet medical need. Like the MODDERN Cures model, new patent term provisions could extend all relevant patents of the originator of the new medicine so that they would expire at the end of a new fourteen-year IP protection period, thereby superseding the Hatch-Waxman Act's provision that only a single patent would be eligible for such a fourteen-year post-approval patent life. This new IP protection period would include a concurrent fourteen-year data package protection period to accompany the patent term restoration provisions. In addition, as a prerequisite for electing the new IP protection provisions, the originator would be required to proffer a disclaimer of the type set out in the MODDERN Cures Act with respect to any of the relevant patents of the originator that would expire beyond the end of the fourteen-year IP protection period. The current provisions of the Hatch-Waxman Act and the Biosimilars Act would then continue to apply to all new medicines for which no election to operate under the new law was sought. This elective framework, self-evidently, would provide benefits to both the originators of new medicines and the copiers of those medicines and admirably serve the same policy objectives as the MODDERN Cures Act. As such, it might be worth considering on its merits independently of whether the MODDERN Cures Act were to become law.

CONCLUSION

The Hatch-Waxman Act was a bold initiative by its congressional sponsors that today has met or exceeded all of its expectations, at least as they related to the creation of a new generic drug industry able to reliably supply low-cost, high-quality copied versions of new medicines to the marketplace. The generic manufacturers' growing market share of the U.S. prescription drug market suggests that nothing more is needed to further secure the generic industry's role as a major contributor to the health of the American public.

The story for the research-based industry is, however, more mixed. Over the Hatch-Waxman era, its new medicines have revolutionized the treatment of many diseases. It has been able to increase its R&D investments. At the same time, consolidation has reduced the ranks of the innovators dramatically. Its declining share of the prescription medicines business, coupled with the relentlessness of low-cost generic competition from earlier-generation innovations of the research-based industry, makes its future less assured.

For the research-based industry to have a reasonable opportunity to innovate its way to a successful future, it is critical that it be able to focus the talents of its researchers on the best ideas for new medicines. This requires some assurance that, if those ideas are successfully brought through the research process to the market, fair and predictable protection from low-cost generic and other low-cost, follow-on competition will exist—and will continue for a period sufficient to create a reasonable prospect of paying back the investment in the research needed to get those medicines to market.

It should be unacceptable to all the relevant constituencies—patients, providers of healthcare, third-party payors, and public health policymakers—that a highly promising experimental medicine cannot proceed into development because its projected patent life is too short, the patent protection seems too tenuous, or patent protection was simply unavailable. By adopting the MODERN Cures Act's fixed and certain fifteen-year IP protection period for medicines directed to unmet medical needs, patients and their physicians could gain access to the best new choices in therapy—with the best and most complete uses of those medicines fully elaborated through continuing, post-approval research. When low-cost copied versions of those new medicines take over the

market from the original version of the medicine, the market will be a fully developed one in which the best and most complete uses of those medicines will be well understood by physicians.

In the foreword to this issue, Senator Hatch suggests that the success of the Hatch Waxman Act might “inspire[] ideas on how to improve the effects of the Act through additional legislation.”¹³⁹ That, in a nutshell, was the intent of this article, namely that the MODDERN Cures Act holds the promise of being a more modern incarnation of the Hatch-Waxman Act. Congress can achieve a “win-win-win” outcome through the MODDERN Cures Act. Innovators of new medicines would be freed to do what they do best—create the best in new medicines for patients, irrespective of whether those new medicines have the best patents. Copiers would gain easy and predictable access to the new medicine’s market once a fixed IP protection period ends. Above all, patients would secure the benefits from the best of both worlds—new medicines that come from a focus on addressing today’s unmet medical needs and high-quality copies of these new medicines that then become reliably available at the lowest possible cost.

139 Orrin. G. Hatch, *Foreword*, 40 WM. MITCHELL L. REV. 1194, 1199 (2014).