Regulatory Property: The New IP

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By Robin Feldman¹

For almost thirty years, a new form of intellectual property has grown up quietly beneath the surface of societal observation. It is a set of government-granted rights that have the quintessential characteristic of intellectual property and other forms of property—that is, the right to exclude others from the territory.

Beginning with a small piece of legislation in the early 1980s, the system now has tentacles stretching out in many directions. It spans more than half a dozen smaller arrangements—established through individual pieces of congressional legislation or regulatory action—and confers hundreds of billions of dollars on those who can fold themselves within its various definitions. Its impact on the US health care system, in particular, is enormous. In 2014 alone, more than 40% of all new drugs approved by the FDA came through just one of these portals, with the companies collecting regulatory property rights along the way.²

Some forms of this regulatory property are quasi-patent. In the same way that patents grant the right to exclude others from making, using, or selling the invention, these types of regulatory property grant the right to exclude others from selling the product. Other forms are

¹ Harry & Lillian Hastings Professor and Director of the Institute for Innovation Law, University of California Hastings College of the Law. I wish to thank Shelley Erin Ackerman for insights into biomedical research.
² See Michael G. Daniel, Timothy M. Pawlik, Amanda N. Fader, Nestor F. Esnaola, & Martin A. Makary, The Orphan Drug Act: Restoring the Mission to Rare Diseases, AMERICAN J. CLINICAL ONCOLOGY 1, at abstract and Figure 1 (2015); http://blogs.fda.gov/fdavoice/index.php/2015/01/cder-approved-many-innovative-drugs-in-2014/
quasi-trade secret. For example, trade secret prevents others from improperly accessing and using a competitor’s information, although one can develop that information on one’s own. Similarly, some forms of this regulatory properly allow a company to exclude others from using its research data for a period of time, although others could develop the same research data on their own. Finally, some forms of this regulatory property are more like pure personal property, in that these benefits can be sold or traded on the open market.

Across the various forms, these pieces of regulatory property have life spans that range from 6 months, to 3, 5, and even 7 years. They can interact with or be added to the patent term length, and they can be added on to each other. In short, the system is extraordinarily complex and largely unnoticed, although some elements occasionally surface.

Creation of this system follows no theoretical design. Sprawling and incremental, it has grown by accretion as various groups have succeeded in making good arguments that they, too, should have a benefit. Accidental property is always a dangerous form for society to create. Property created by accident lacks the thoughtful and considered exploration that provides the only hope of theoretical coherence within the legal system. When accidental property combines with a system that is largely hidden from view, the danger intensifies.

As regulatory property plays an increasingly important role in innovation and in society, it is essential to recognize all of its various tendrils as a single system—a new form of property within the intellectual property domain. Treating regulatory property in its rightful place among the pantheon of intellectual property rights allows appropriate analysis of the interactions among these powerful forces. It isn’t just a matter of labeling these phenomena as forms of property. It is a matter of understanding and making sense out of them as a coherent whole, as
well as making sense of how they interact with other types of rights to exclude, such as patent and trade secret.

To frame the conversation, the title of this article references one of the most influential articles of the last century,\(^3\) *The New Property*, by Charles Reich. Concerned about the rise of the regulatory state, Reich argued that the various permissions and benefits conferred by the government should be understood as forms of property.\(^4\) Reich was worried about protecting those who receive the benefits from being bullied by the government. He called for benefit recipients to have small sovereign islands of their own,\(^5\) that is, protection against the encroaching power of the government that may be exercised in the process of granting or withholding of benefits.\(^6\)

While Reich was worried about protecting those who obtain benefits, the article below is concerned about the rest of society. When government creates this type of quasi-property, along with its surrounding islands of protection, what geologic territory is left for the remainder of its citizens?

Consider the general construct of granting intellectual property rights, such as patents. From the activities that would ordinarily be enjoyed by all, the government removes some and appropriates them to the benefit of the few, in the hopes that the strategy will redound

\(^5\) See Reich, supra note Error! Bookmark not defined., at 774 (noting that “[t]he great error of the public interest state is that it assumes an identity between the public interest and the interest of the majority”).
\(^6\) Reich’s article led to the development of due process rights for those who receive government benefits. See Super, supra note Error! Bookmark not defined., at 1780 (discussing Goldberg v. Kelly, 397 U.S. 254 (1970) which relied on Reich to recognize welfare benefits as property interests protected by the due process clause).
to the advantage of everyone. The same is true for Regulatory IP, and one cannot properly evaluate whether those benefits are accomplishing their intended goals without understanding the system as a whole and understanding its interactions with other forms of IP.

Although one could argue over whether regulatory property should exist, society rarely succeeds in turning back the tide. Thus, the better part of valor would be to make sense of the system that has grown around us, understanding and enhancing its positive aspects while cabining its negative ones. Only if we contemplate regulatory property as a single, unified organism, however, can we wrap our arms around it and make sense out of the whole.

To that end, Section I of the article begins by analyzing the various forms of regulatory property that have emerged according to their similarity to other types of intellectual property—such as patent and trade secret—and to property in general. Section II then examines the emergence of this Regulatory IP, identifying the history of each one and creating the first complete accounting of all of them. This section also demonstrates the relationship between the myriad congressional bills creating these regulatory properties and passage of major legislation that the pharmaceutical industry resisted. In other words, Congress appears to have responded repeatedly to pharmaceutical industry displeasure by passing scattered bills that would grant new forms of Regulatory IP.

If Regulatory IP should be understood as a unified system, one must have some theoretical grounding for its existence. Without a coherent construct, there is no way to intelligently shape its development and test its success. Thus, Section III of the paper sets out a

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general theoretical framework for the type of regulatory property that has emerged. This
section also explores a series of benchmarks to use in establishing Regulatory IP, describing the
logic for these benchmarks, and tests the current forms of Regulatory IP against these
measures. The benchmarks include 1) minimizing overlap with other forms of intellectual
property; 2) ensuring that the system is capable of stimulating results, and that those results
are desirable; and 3) ensuring that there is a metric for measuring outcomes in relationship to
goals. With these and other perspectives, society has an opportunity to think critically and
cohesively about the new intellectual property that has emerged.

The Regulatory IP that has emerged so far falls within the life science industry. That is
understandable. The Food & Drug Administration’s extensive approval and regulatory system
has provided a perfect vehicle for the creation and dissemination of Regulatory IP. The lessons,
however, are widely applicable to other innovative industries. As newcomers in industries such
as transportation (think Uber and Lyft), hospitality (think Airbnb and Villas)\(^8\), and domestic and
construction services (think TaskRabbit) press the boundaries of creativity up against regulatory
networks,\(^9\) government actors may be tempted to create forms of Regulatory IP related to
these innovations, in the hopes of incentivizing innovative entrants as well as placating existing
industry players. Such is the story of the creation of Regulatory IP for the life science industry,
and it is one that easily could be replicated.

\(^8\) Stephanie Rosenbloom, *Giving Airbnb a Run for Its Money*, NEW YORK TIMES (Feb. 15, 2015),
available at http://www.nytimes.com/2015/02/15/travel/giving-airbnb-a-run-for-its-money.html?_r=0
\(^9\) This is not to suggest that regulatory property could only emerge in innovative industries. The
appetite for creating Regulatory IP, however, may be the greatest within fields of intense
innovation in which the desire to protect new ideas clashes against regulatory structures and
established industries.
It is also a story with echoes in the international arena. Various aspects of these rights have tentacles that now reach into the European Union, the North American Free Trade Agreement, and most recently, the Trans-Pacific Partnership. Thus, after 30 years, it is more than time to think comprehensively about this new Intellectual Property rights regime that lies entwined throughout our system.

I. The Nature of the Beast

There is nothing sacred about the current contours of intellectual property as a legal discipline. Although patents and copyrights trace their heritage back to the Constitution, the concept of intellectual property as a unified field developed more recently, emerging in its current incarnation largely in the 1980s. In fact, one can see its emergence through a Google Ngrams graph, a search result that charts the frequency with which a particular term appears in books across a designated time period.¹²

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¹¹ See U.S. Const. art. 1, §8, cl. 8. (authorizing Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

As the graph suggests, the designation of intellectual property as a unified field, did not appear with any frequency until the 1980s. As described in Section II below, Regulatory IP emerged during the same time period, although it has remained strangely absent from the dialogue. Rather, intellectual property is defined as including only copyright, patent, trademark, and trade secret.

Although the term “intellectual property” harkens back to traditional notions of property within the legal system, the characteristics of property and intellectual property diverge considerably. To take a simple example, if I plant corn on an ordinary piece of land, you cannot plant corn there as well, and even my own ability to plant corn will diminish over time as the nutrients in the land are depleted. In contrast, you and I can both sing a song at the same time, and we can sing it over and over again without depleting much more than the patience of our families.\footnote{For less lighthearted discussions of the non-rivalrous nature of intellectual property, including the economic implications of zero marginal cost of production of intellectual property, see, e.g., Kenneth J. Arrow, Economic Welfare and the Allocation of Resources for Invention, in The Rate...}

\footnote{To generate this graph, see https://books.google.com/ngrams/graph?content=intellectual+property&year_start=1950&year_end=2008&corpus=15&smoothing=3&share=&direct_url=t1%3B%2Cintellectual%20property%20%3B%2Cc0. I thank Carl Shapiro’s presentation at the American Economic Association 2016 Annual Meeting for the idea of using Google Ngrams to map the use of various intellectual property terms.}
Despite valiant efforts across time to equate some forms of intellectual property with property such as land, intellectual property defies that categorization.\textsuperscript{15} It is neither tangible nor finite in nature, beyond the duration of the government-granted legal right.\textsuperscript{16} Moreover, the boundaries of intellectual property must be set in the face of rapidly changing knowledge and meaning, as inventions and creations are compared to things that did not exist when protected invention or work was created.\textsuperscript{17} Thus, the process of creating efficient divisions for things of such an unbounded nature will involve quite different considerations from the process of division for efficient division of the more bounded, regardless of the meandering path that the bounded may take.\textsuperscript{18}


\textsuperscript{15} See Robin Feldman, \textit{Rethinking Patent Law}, 9-33 (exploring the ways in which patents are not analogous to land); John F. Duffy, “Rethinking the Prospect Theory of Patents,” 71 \textit{University of Chicago Law Review} 439 (2004) (describing Edmund Kitch’s comparison of patents to mineral claims for land and noting that while Kitch’s theory represents one of the most significant efforts to integrate intellectual property with property rights theory, Kitch’s theory has been criticized as without foundation and divorced from reality); see also Teva Pharmaceuticals USA, Inc. et. al, v. Sandoz, Inc., (2015) (Thomas, J. dissenting) (explaining that the Anglo-American legal tradition has long distinguished between core private rights such as those related to land and other privileges, and that patents fall outside those core private rights); Caleb Nelson, \textit{Adjudication in the Political Branches}, 107 COLUM. L. REV. 559, 567 (2007) (cited in the \textit{Teva} dissent); Robin Feldman, \textit{Federalism, First Amendment & Patents: The Fraud Fallacy}, 17 COLUM. SCI. & TECH. L. REV. 30, 71-72 (2016) (contrasting the respect for real property evidenced in Constitutional language and history with what is reflected in the Constitution’s intellectual property clause).

\textsuperscript{16} Feldman, supra note 15, at 32; see also Reich, supra note 4, at 739 (noting that while wealth and value are created by culture and society, property is a creation of law in that a man who has property has certain legal rights with respect to an item of wealth).

\textsuperscript{17} See id. at 3.

\textsuperscript{18} See id. at 32.
Nevertheless, the various legal rights for intellectual property share significant characteristics with rights related to property, including the right to exclude others. These will become important in comparing intellectual property rights with the emerging Regulatory IP.

As described in Section II below, most forms of Regulatory IP were created by Congress and operate through the Food and Drug Administration (FDA). Although the different forms may combine several types of rights, the rights generally fall into three baskets. The baskets include marketing rights, data rights, and tradeable rights like accelerated approval.

Most of these look like revised forms of other intellectual property rights. They have the feel of having been created by market actors who, after living with certain types of intellectual property and regulatory systems, adjusted existing forms to better fit their needs.

A. Marketing Rights—Quasi-Patents

The first basket consists of Marketing rights, that is, all others are excluded from receiving permission to market the product for a period of time. If a drug company qualifies for marketing rights for 5 years, for example, the FDA cannot grant approval for any other company to market that drug for 5 years.

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20 See Section II, infra.
Marketing rights can be analogized to patent rights.\textsuperscript{21} With patents, one has the right to exclude others from making, using, or selling the patented invention. With marketing rights, others are similarly excluded from selling the product on the market.

Although marketing rights are focused on selling in the market, they are somewhat stronger than ordinary patent rights. First, patent rights are not self-executing. No district attorney, no federal agency will step forward to champion a patent holder’s rights. If a patent holder wishes to exercise its right to exclude someone from selling the product, the patent holder must bring a lawsuit. In contrast, when a company receives marketing rights, the FDA enforces those rights by refusing to grant approval to any other company.\textsuperscript{22}

The second difference relates to a popular misconception about the power of patent rights. For those who are not patent mavens, this is a good moment to hold onto your hats. It would be easy to assume that a patent grants the right to a circle of territory, and all others are excluded from that circle. Such is not the case. The patent does, indeed, grant the right to \textit{exclude others} from a circle of territory, but that does not mean the patent holder controls the entire circle alone. Others have may have exclusion rights to parts of the same circle.

Consider the following example, adapted from discoveries at the University of Rochester.\textsuperscript{23} An inventor obtains a patent on a chemical dye for coloring candy a bright shade

\textsuperscript{21} See note 36, \textit{infra} for authors who have referred to various types of the benefits in regulatory rights as patent like.

\textsuperscript{22} For a discussion of this aspect of FDA marketing exclusivities in the context of Hohfeldian immunities and disabilities, see Yaniv Heled, \textit{Patents v. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?}, 18 MICH. TELECOMM. & TECH. L.J. 419, 431 (2012).

\textsuperscript{23} See Feldman, \textit{supra} note 15, at 24 (describing these circumstances and the patent example and sources in further detail); see also \textit{Same Blue Dye in M&Ms Linked to Reducing Spinal Injury}, www.cnn.com, (July 28, 2009) (describing work in mice at the University of Rochester,
of blue. Under what is known as the one embodiment rule, the patent holder who identifies one use for the chemical can claim rights to all uses of the chemical. A later inventor discovers that the dye is useful for treating spinal cord injuries. The second inventor can receive a patent on the new use of the existing chemical for spinal cord research and treatment. At this point, the first inventor has the right to exclude everyone from using the chemical for anything (including spinal cord research and treatment); the second inventor has the right to exclude everyone from using the chemical for spinal cord research and treatment; and neither can use the chemical for spinal cord research and treatment without the permission of the other. This is the case of overlapping rights, and although most patents do not overlap, it is a limitation of the power of the patent. In short, the patent holder does, indeed, obtain the right to exclude others from a circle of territory. Nevertheless, others may be standing in parts of that circle with their own rights to exclude, effectively shrinking the patent holder’s practical sphere of operations.

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24 See, e.g., Schering Corp. v. Gilbert, 153 F.2d. 428, 432 (2d Cir. 1946); Maurer v. Dickerson, 113 F. 870, 874 (3d Cir. 1902) (finding “that the claim is not restricted to the product made by the described process, but covers the chemical individual, however produced”); Utility Examination Guidelines, 66 Fed. Reg. 1092-02, 1095 (Jan. 5, 2001) (noting that “[a] patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use”); See also Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) (noting that it is not necessary that a patent application test all embodiments of an invention); In re Angstadt, 537 F.2d 498, 503 (C.C.P.A. 1976).

25 35 U.S.C. §101 (“or any new and useful improvement thereof”); see, e.g., Allegheny Drop Forge Co. v. Portec Inc., 541 F.2d 383 (3d Cir. 1976) (“A new use for an old process or product is patentable if the new use or application is itself not ‘obvious’ to one skilled in the art.”).

26 DONALD S. CHISUM, CHISUM ON PATENTS, vol. 5, §16.02 (2010) (“Two patents may be valid when the second is an improvement on the first, in which event, if the second includes the first, neither of the two patentees can lawfully use the invention of the other without the other’s consent.” (quoting Cantrell v. Wallick, 117 U.S. 694 (1886))).
Marketing rights are different, in some circumstances. When a company qualifies for marketing rights under some forms of Regulatory IP, the company gets an affirmative right to market the drug, along with rights that may operate as a blanket exclusion of all other companies for all uses.\footnote{See text accompanying notes 117-118, infra (describing a program created in 2012 for pediatric studies that extends exclusivities, including marketing rights, for all uses and formulations of a drug); text accompanying notes Error! Bookmark not defined.-94, infra (describing ways in which marketing rights for orphan drugs operate to block valuable off-label uses of a drug, in addition to the orphan indication).} Unlike patent rights, therefore, you get to ensure that no others will be standing in the circle with you, and the federal government does the work of enforcing your rights.

B. Data Rights—Quasi Trade Secrets

The second category relates to data rights, in which other companies are prevented from using one’s safety and efficacy data. For example, a company wishing to make a generic version of a drug will be prevented from using the original company’s data for a period of time, although the generic company could conduct its own safety and efficacy trials during that trial.\footnote{See John R. Thomas, The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation, CONGRESSIONAL RESEARCH SERVICE 4 (Jan. 7, 2013) (describing data exclusivity, or the “data package,” submitted by brand-name firms and the ways in which this may be used by generic firms) [hereinafter Congressional Research Service], available at http://www.ipmall.info/hosted_resources/crs/R42890_130107.pdf.}

The right to generate one’s own safety and efficacy data, however, is unlikely to be an attractive pathway.\footnote{See id.} Safety and efficacy trials are lengthy and expensive. Generic companies, trying to enter the market quickly and cheaply, may be loath to follow that path.
Data rights can be analogized to trade secrets. Under trade secret law, a company would be entitled to protect information that would give it a commercial advantage over competitors, as long as that information is not readily ascertainable to others in the field. Competitors who developed the information on their own, however, would be free to use it.

The treatment of independent creation under trade secret law, as well as with data rights, stands in contrast to patent law. No one can use another’s patented invention, even when that invention is created independently.

Data rights are more limited than trade secrets, at least in duration. Trade secret protection essentially lasts as long as the information remains a secret. Data rights, however, are granted only for a limited period of time.

The data rights time period is related to a Congressional choice to require that pharmaceutical companies make their safety and efficacy data available to those who would make lower-cost versions of the drug, once the patent protection ends. The data sharing system is part of a complex legislative scheme designed to get generics to market as quickly as possible and to encourage would-be generic companies to challenge weak patents in court. Thus, the data rights time period ensures a certain length of protection for the original drug maker’s data under all circumstances, even if the generic will eventually succeed in overturning the patent.

From one perspective, one can think of data rights as a pure grant of benefits to pharmaceutical companies—given that data rights have the potential to confer protection to a

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30 Uniform Trade Secrets Act § 1.4.
drug company, even when the company’s patents are invalid or expired. From another perspective, one can think of data rights as a compromise: Trade secret protection would give drug company’s an indefinite length of protection for their data, pure sharing would provide no data protection, and Data rights provide a level of protection somewhere between the two.

C. **Tradeable Rights—Quasi Property**

The third basket of rights that may be granted with Regulatory IP relate to tradeable rights. In most cases, rights that are granted with Regulatory IP are specific to the drug going through the approval process. In some cases, however, a company that engages in the desired behavior receives a right fully stripped from the drug. The company can use that right on another one of its drugs, or it can transfer the right to another company. The ability to freely trade the right makes these benefits analogous to ordinary property rights, which, in general, enjoy the right of transfer.\(^\text{32}\)

Even without an explicit right of transfer, the benefit of any Regulatory IP is a tradeable economic benefit, to some extent. One could always sell the company, transferring the economic value of the right along with it. The benefit might not transfer to another drug, but the overall economic value of the benefit from one drug transfers to the entire operation, as with any corporate asset.

\(^{32}\) *But see*, Robin Feldman, *Whose Body Is It Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law*, 63 STAN. L. REV. 1377, 1382-1383 (2011) (noting that although modern property law scholars think of property as a bundle of rights with four key attributes, including the right of disposition, those rights may be circumscribed, and using medicine as an example in which the right to transfer and even to throw away may be restricted).
There may be more direct ways, moreover, in which Regulatory IP granted to one drug can be transferred to another drug. Consider drug pricing in the context of what are known as pharmacy benefit managers. Pharmacy benefit managers are third-party managers who negotiate pricing between pharmaceutical companies and large purchasers such as hospitals, private health insurance companies (such as Kaiser or Cigna), drugstore chains (such as Walgreen’s or CVS), or government health plans (such as Medicare and Medicaid). A drug company like Merck will work with the pharmacy benefit manager for Kaiser, for example, to negotiate the prices Kaiser will pay on all of Merck’s drugs. As a result, pricing in the pharmaceutical industry is no longer drug specific in many cases.

Such bulk pricing could provide the opportunity for drug companies to use the power of benefits granted in one drug to effect the pricing of other drugs. For example, suppose the company’s drug Life Extender is facing competition from new substitutes.

Now suppose the company has obtained Regulatory IP on another drug SleepAid. This could be marketing rights, for example, that will keep any other company from getting approval to market SleepAid for five years. The company could offer to lower the cost of SleepAid somewhat, without fear of attracting competition for the drug, in exchange for the pharmaceutical benefit manager agreeing to keep Life Extender in the hospital’s standard list of drugs that it stocks. A similar deal could be offered to insurers to get a reduced rate for the well-protected SleepAid in exchange for keeping the more vulnerable Life Extender on the insurer’s formulary either of approved drugs that it will reimburse, reimburse at the lower-deductible rate, or agree to fill without extra layers of approval. Techniques such as these could be particularly effective against younger market entrants who do not have as many goodies in
their bags with which to bargain. In this way, the drug company can transfer the benefit it has received from Regulatory IP on one drug to the benefit of another drug. Thus, while some Regulatory IP is explicitly tradeable, the benefit of any Regulatory IP may be transferrable in more subtle ways.

The transferability of Regulatory IP highlights the importance of contemplating these rights as a whole, as well as understanding the way in which they interact with other forms of Intellectual Property. The Regulatory IP benefits described above can be combined with other forms of IP, such as patents, to extend or enhance the benefits that would be gained under traditional IP alone. In other words, the various forms of Regulatory IP can be added to each other and to patents to extend a company’s ability to ensure protected market space.

The following section will introduce the various forms of Regulatory IP. Each has been created in the hopes of incentivizing certain behaviors that society deems valuable. Implicit or explicit in each is the supposition that ordinary market incentives would be insufficient or that market failures would operate to prevent the desired outcome without the incentive that the Regulatory IP would provide. In some cases, the desired behavior is the creation of lower cost generic or biosimilar drugs. In others, the goal is to challenge weak patents. In others, the desired behavior is investing in certain types of drug testing or drug creation when market incentives might not be sufficiently strong. Society cannot hope to evaluate the effectiveness of

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33 For a discussion of the ways in which other types of bulk pricing schemes can be used to deter market entrants, see Robin Feldman, *Defensive Leveraging in Antitrust*, 87 GEORGETOWN L.J. 2079 (1999).
34 See, e.g., FDA, *supra* note 36, at 3 (explaining that the 6-month exclusivity for first generic filers may run concurrently with patents).
these initiatives or to measure them against externalities, without understanding the system as a whole and examining the ways in which Regulatory IP interacts with other types of rights.

II History and Taxonomy of Regulatory IP

The Regulatory IP described in this article first emerged in the 1980s, with newer forms appearing periodically over the subsequent thirty years. Although the term “Intellectual Property” also emerged during the early 1980s, Regulatory IP has been left out of the broader IP calculus.

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36 When they are grouped together, although often incompletely, they are described as regulatory exclusivities or named by reference to some subtype of right, such as data exclusivity. See, e.g., Congressional Research Service, supra, note 35 (using the term “regulatory exclusivities”); Patents & Exclusivity, Food & Drug Administration Center For Drug Evaluation and Research Small Business and Industry Assistance 1 (May 19, 2015) (describing five forms of “exclusivity”) [hereinafter “FDA”], available at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf; Erica Lietzan, The Myths of Data Exclusivity, 20 LEWIS & CLARK L. REV. 1, 2015 (focusing on “data exclusivity”). Some scholars and commentators have referred in passing to these benefits as patent-like or a form of Intellectual Property. See Lietzan, at 14 (noting that some writers have described data exclusivity as patent-like or a sub-type of intellectual property); see also Daniel J. Hemel & Lisa Larrimore Ouellette, Beyond the Patents-Prizes Debate, 92 TEX. L. REV. 303, 309, 316-325 (2013) (noting that the authors group regulatory exclusivities and patents together as ex post, market set, user pays mechanisms); Congressional Research Service, at 12-13 (describing regulatory exclusivities as a more recent form of intellectual property); Rebecca S. Eisenberg, the Role of the FDA in Innovation Policy, 13 MICH. TELECOMM. & TECH. L. REV. 345, 360 (2007) (describing “FDA administered proprietary rights in regulatory data”); Robert Alan Hess, Excavating Treasure from the Amber of the Prior Art: Why the Public Benefit Doctrine is Ill-Suited to the Pharmaceutical Sciences, 66 FOOD & DRUG. L.J. 105 (2011) (referring to “pseudo-patents”); Jay Thomas, Toward a Theory of Regulatory Exclusivities, in PATENT LAW IN GLOBAL PERSPECTIVE 345, (Ruth L. Okediji & Margo A. Bagley eds. Oxford 2014) (noting that regulatory exclusivities can “fairly be described as the newest form of intellectual property”); Trudo Lemmens & Candice Telfer, Access to Information and the Right
It is challenging, if not downright impossible, to find a clear and comprehensive explanation in any given location of all of the forms of Regulatory IP.\textsuperscript{37} What is even more challenging, however, is to find any inkling of the historic context in which they emerged—and that history is significant. Many of the forms of Regulatory IP were created during periods of time when Congress passed legislation that the pharmaceutical industry vigorously opposed.\textsuperscript{38} In other words, repeatedly over the last 30 years, legislators have approved the creation of some form of Regulatory IP in the same Congress in which the legislators garnered enough votes to pass major laws that the industry resisted.

Other changes have occurred across the 30 years. Congress has amended the various Acts in ways that expanded, or occasionally contracted, the reach of the Regulatory IP that had been created.\textsuperscript{39} Similarly, courts and regulatory authorities have, at times, re-interpreted

\textsuperscript{37} See Congressional Research Service, \textit{supra} note 33, at 4 (noting that regulatory exclusivities are not subject to a standard terminology and that regrettably some commentators use terms such as “statutory exclusivity,” “data protection,” and “marketing exclusivity” synonymously with the term “regulatory exclusivity”); Lietzan, \textit{supra} note 36, at 12-13 (noting confusing uses of various terms). One particularly useful document can be found at the FDA website, which lists five forms of what it calls “exclusivity.” This listing does not include all of the Regulatory IP, omitting the various tradeable rights, and includes various types of Data rights such as rights related to New Chemical Entities within what it describes as “marketing rights granted by the FDA upon approval of the drug”). See FDA, \textit{supra} note 36. Other sources include some, but not all of the various forms. \textit{See e.g.}, Gregory Dolin, \textit{Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials}, 98 \textit{IOWA L. REV.} 1399, 1448-1453 (describing new chemical entity rights but not the similar new clinical studies rights).

\textsuperscript{38} \textit{See text accompanying notes X-Y, infra.}

\textsuperscript{39} For example, although the Orphan Drug Act passed in 1983, it was amended in 1984 (loosened the definition of rare disease), 1985 (extended to patentable as well as unpatentable drugs), 1988 (required applicants to apply for orphan drug status before applying for marketing approval), and 1997 (application user fees exempted). \textit{See The Orphan Drug Act: Implementation and Impact}, Department of Health and Human Services Office of Inspector
aspects of the statute to create a broader reach for Regulatory IP rights holders. Nevertheless, the trend of creation of Regulatory IP in conjunction with swallowing a bitter bill is striking.

To highlight this history, the article will introduce the forms of Regulatory IP grouped together in their historic context. In addition, the section below includes a chart for visualizing all of the forms of Regulatory IP and their relationships.

A. Regulatory IP with the Creation of the Generics Pathway

Regulatory IP was born with the passage of the famous Hatch-Waxman Act, which created the modern pathway for approval of generic drugs. Several forms passed as part of the massive Hatch-Waxman Act itself in 1983. These include marketing rights for the first generic company, data rights for new chemical entities, and various forms of data rights for new clinical studies.

In the same Congress, legislators passed a bill related to marketing rights for what is known as “orphan drugs.” Although the original Orphan Drug Act had been signed into law during the prior Congress, the Act did not stimulate much interest until the changes made

40 David Hoffmeister, Vern Norviel, Prashant Girinath, Chris McAndrew and Charles Andres, Top FDA Developments of 2015 and Predictions for 2016, Law360 (Jan 11, 2016) (noting that the FDA, in response to actions related to Amarin’s drug Vascepa, in 2015 changed its interpretation of New Chemical Entity to include exclusivity for fixed dose combination drugs as long as at least one new active ingredient had not been previously approved by the FDA), available at http://www.law360.com/articles/744364/top-fda-developments-of-2015-and-predictions-for-2016.
during the Hatch-Waxman Congress.\textsuperscript{41} In short, the 1983-1984 Congress set the stage for the system of Regulatory IP, along with its central role in modern drug development.

Together, the Regulatory IP created through the Hatch-Waxman Act and the 1984 Orphan Drug Act Amendments account for a remarkable portion of the medicines approved by the FDA. For example, orphan drugs accounted for 44\% of drugs approved by the FDA in 2015.\textsuperscript{42}

1. Hatch-Waxman

The Hatch-Waxman Act, which the President signed into law in 1984, created the modern pathway for expedited approval of generic drugs.\textsuperscript{43} The law reflects the desire to bring lower-priced drugs to consumers as quickly as possible, balanced against the need to ensure adequate incentives for pharmaceutical research and development. Specifically, the patent system provides a 20-year right to exclude for the invention of new drugs that are sufficiently innovative to receive patent protection. Patent theory holds that during this time, the drug company should be able to recoup its investment in the creation of the drug through the elevated pricing that can occur without direct competitors in the market. When the patent expires, however, other drug makers should be able to enter the market and drive down the price of the drug.

\textsuperscript{41} See David Loughnott, Potential Interactions of the Orphan Drug Act and Pharmacogenomics: A Flood of Orphan Drugs and Abuses?, 2005 AM. J.L. & MED. 365, 375 (explaining reasons why drug companies were reluctant to file orphan drug applications with the FDA until the 1984 amendments to the Act).

\textsuperscript{42} http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm.

\textsuperscript{43} Known colloquially as the Hatch-Waxman Act for the legislators who crafted the law, the formal name is the Drug Price Competition and Patent Term Restoration Act, P.L. 98-417 (Sept. 24, 1984). For a detailed description of the Act, along with other sources discussing Hatch-Waxman, see Robin Feldman & Evan Frondorf, supra note 31.
What works in patent theory does not always work in practice. Those who would compete with the branded drug company faced significant costs and delays, giving the branded drug companies time beyond the expiration of the patent to sail freely in the market. The problem arises through the interaction of the drug approval system with the patent system. Gaining FDA approval is a lengthy and complex process. Given that the patent system grants the right to exclude from making, as well as using and selling the drug, a would-be generic could not go through the steps to prepare for market entry without infringing the patent. Thus, competitors could never be ready to enter the market at the end of the patent term, and the branded company would enjoy continued market freedom.

A more serious problem revolves around the extensive cost of the clinical trials necessary to demonstrate the safety and efficacy of a medication. The original brand-name company could recoup the costs of these trials through higher drug prices during the patent period. Once generic drugs entered the market, however, the price would drop to the marginal cost of production. Thus, generic companies would have no incentive to enter into costly trials, given that there would be no opportunity to recoup those costs, and few generics would be willing to enter the market. Once again, this would leave the price of the drugs elevated beyond the expiration of the patent.

Hatch-Waxman aimed to resolve these problems by providing a pathway so that generic hopefults would be prepared to enter the market immediately at the expiration of the patent. Among other provisions, the Act provided an abbreviated pathway so that companies applying for approval as a generic drug could rely on the safety and efficacy data created by the brand-
name drug company. Under this Abbreviated New Drug Application (ANDA), the generic need only demonstrate that its drug is the same as the brand-name drug.

The architects of Hatch-Waxman were concerned about an additional barrier to getting lower-priced drugs to consumers as quickly as possible. Congressional testimony reflected concern over weak patents that exist throughout the system. Thus, the Hatch-Waxman pathway included an incentive for generic hopefuls to challenge weak patents and to engage in the necessary battles to overturn those patents. Specifically, Hatch-Waxman provides that the first generic to challenge a patent as invalid or not properly applying to the drug will enjoy a 6-month period in which no other generic company can enter the market. Thus, during the 6-months, only the original branded company and the first generic filer can sell in the market. This benefit is available as long as the generic challenger does not lose its patent challenge in court.

a. 6-Month Marketing Right for Generics

Through these pathways, Hatch-Waxman created the first pieces of Regulatory Intellectual Property. The 6-month exclusivity, is a Marketing right that prevents competitors from entering the market during this period of time, much the same way that a patent prevents competitors from making, using, or selling the patented invention for 20 years. Despite its brevity, estimates suggest that the 6-month generic benefit is enormously valuable.

44 This is commonly known as filing a “Paragraph IV certification.”
45 See text accompanying notes, 21-Error! Bookmark not defined. (comparing and contrasting Patents and Marketing rights).
The Hatch-Waxman Act was a masterpiece of legislative compromise. As one can imagine, pharmaceutical companies were not anxious to help generic companies quickly climb the onramp of competition. Thus, the Act offered various balms to soothe the pain of generic competition. The first benefit does not create any new IP and is indicated in the formal name of the Act-- Drug Price Competition and Patent Term Restoration Act. Specifically, the Act provides that a patent’s 20-year term may be extended to compensate for delays at regulatory agencies.

In addition, Hatch-Waxman’s generic pathway created another form of Regulatory IP. Recall that generic hopefuls would now be able to use the safety and efficacy data developed by the brand-name drug company. Hatch-Waxman provided, however, that generic companies could not use this data for periods of time in the following two circumstances:

b. 5-Year (or 4-Year) Data Right for New Chemical Entities

Under Hatch-Waxman, generic hopefuls may not use clinical data from the branded drug company for five years, if the drug is designated as a new chemical entity. A new chemical entity is defined under the Act as “a drug that contains no active moiety that has been approved by the FDA.”

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47 See 21 C.F.R. § 314.108(b)(2).
48 See 21 C.F.R. § 314.108(a); see also Dolin, *supra* note 37, at 1451. For a discussion of court and regulatory interpretations of the statute that provide new chemical entity status for 1) isolated components of a previously approved mixture or 2) a drug that is a combination of previously approved mixtures and at least one new active ingredient, see Hoffmeister et. al., *supra* note 40.
The 5-year Data right is shortened to a 4-year Data right if a generic hopeful files for FDA approval certifying its intent to challenge the patent on the drug as invalid or not properly applied to the drug.\(^{49}\) This Data right ensures a period of time in which the brand-name drug company will be protected from competition, regardless of whether the patent is invalid. Even if the generic succeeds in overturning the patent before the end of the Data rights, the Data rights would still hold.

A generic hopeful could conduct its own clinical trials and submit the data to obtain FDA approval. As described above, however, the generic company would be unable to recoup the cost of the clinical trial with higher prices, making this an unlikely pathway. The existence of the branded drug would be considered prior art under the patent system, eliminating the potential for patent protection. Similarly, the branded drug would constitute an active moiety approved by the FDA, eliminating the potential for even the lesser data protections for a new chemical entity. In short, newcomers rarely will have an incentive to enter the market under the current system, until the Data rights have expired.

One should also note that the 4 or 5-year Data rights for new chemical entities are actually longer in practice. Given that one cannot use the branded company’s data for a period of time, the FDA will not begin considering an application until the rights have expired. FDA approval would then take one to two years beyond that time, at least. Thus, the 5-year Data right, for example, is likely to keep competitors out of the market for 7 years.\(^{50}\)

\(^{49}\) See 21 C.F.R. § 314.108(b)(3); see also FDA, supra note 36, at 3 (describing New Chemical Entity Exclusivity); text accompanying and note 44, supra (describing Paragraph IV certifications).

\(^{50}\) See Congressional Research Service, supra note 28, at 5 (explaining the delay and noting that the real world impact of the new chemical entity exclusivity is seven years).
Ironically, this is the type of delay that Hatch-Waxman tried to eliminate by creating ready-to-market pathways so that generics could enter as soon as the patents expire. Here, competition is still likely to be delayed, even when the Data rights end.

As described above, this type of Regulatory IP looks much like trade secret protection, in that a competitor cannot use a company’s clinical trial data but could develop the information on its own.\(^{51}\) The notion of that regulatory data should be considered secret and proprietary to the company that created it is a relatively new legal concept. The concept emerged in the early 1980s with the creation of data protection for pharmaceuticals and the creation of data protection for pesticides in a different piece of legislation.\(^{52}\) Scholars have differed on the question of whether information necessary to gain approval from a public agency should ever be considered a proprietary secret.\(^{53}\)

c. 3-year Data Right for New Clinical Studies

Hatch-Waxman created an additional set of Data rights aimed at new clinical studies—not to be confused with new chemical entities. These Data rights are available for improvements on existing drugs, for example, new dosages or new indications of an existing

\(^{51}\) See text accompanying notes 28-Error! Bookmark not defined..

\(^{52}\) See Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. Section 136, et. seq; Reichman, supra note 10, at 12 n. 45 (noting that concerns over preserving confidentiality of regulatory data have surfaced only in the last 25 years); see generally TREVOR M. COOK, SPECIAL REPORT: THE PROTECTION OF REGULATORY DATA IN PHARMACEUTICAL & OTHER SECTORS, (Sweet & Maxwell 2000).

\(^{53}\) Compare Reichman, supra note 10, at 9 (arguing that there is a basic conceptual flaw in treating clinical trials as a private rather than a public good) with Erica Leitzan, The Myths of Data Exclusivity 4 (arguing that data exclusivity should be understand not as a government grant but as a period of time when all competitors face the same barriers to entry) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2653770.
chemical entity. They have also been granted for new studies related to switching form prescription to over-the-counter for an existing drug.

Data rights for new clinical studies last for three years. Unlike their sister regime for new chemical entities, the FDA can accept a generic application during the three years and begin considering the approval, but it cannot grant approval until the 3-year period of the Data rights has expired.

As is generally true with various Regulatory IP and other types of Intellectual Property rights, Data rights for new clinical studies can be tacked on to other Data rights. Thus, for example, a company could receive a 5-Year Data rights period for a new chemical entity. Later in the life of the drug, the company could engage in new clinical studies and qualify for an additional 3-year Data right.

d. The Hatch-Waxman Data Rights in General

The remarkable complexity of these provisions is a testament to the legislative compromises embodied in the outcome. That complexity may also have affected the ability of scholars and commentators to visualize these rights as Intellectual Property Rights. A 20-year Patent right is far easier to wrap one’s head around than the complex, 3-year or 5-year (unless it is 4-year) structure of the Data rights in Hatch-Waxman.

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54 See 21 C.F.R. § 314.108 (5)(ii); see also Congressional Research Service, supra note 28, at 6.
56 See id, at 7.
It is certainly true that the Data rights legislation packs an enormous amount of complexity into its provisions. Nevertheless, other forms of Intellectual Property are not the models of elegant simplicity one might imagine. The term of Copyright certainly is not sleek at “life of the author + 70” unless it is a corporate author, in which case the term is “95 years from first publication or 120 years from creation, whichever comes first.” And, as described above, Patents may be extended to reflect regulatory delays. No form of Intellectual Property can claim to be free of internal complexity, even as to term length.

2. Orphan Drugs

Ah, the plight of orphans. Of all the brilliant strategic choices ever made, naming this regulatory scheme “The Orphan Drug Act” surely ranks among the most inspired. After all, who could oppose medical treatment for orphans--particularly not when Congressional testimony includes Hollywood stars re-enacting heart-wrenching dramatizations?

The history of the Act and its legacy are more complex than the name might imply, however. The program was intended to provide incentives for the creation of drugs to treat diseases that affect only small numbers of patients, on the theory that when the customer base is limited, the potential returns are too low to stimulate drug research and development. The program has spread like wildfire, however, to the point at which orphan drugs accounted for 44% of drugs approved by the FDA in 2015. As one scholar has noted, what do we do, “[w]hen everyone is an orphan?”

58 The quoted phrase is the title of an article by Herder. See Matthew Herder, When Everyone Is an Orphan: Against Adopting a U.S.-Styled Orphan Drug Policy in Canada, 20 ACCOUNTABILITY IN RESEARCH 227 (2013).
Timing of the Orphan Drug Act differs slightly from that of the other types of Regulatory IP described above. The 97th Congress passed the original Orphan Drug Act, while the Hatch-Waxman Act did not pass until the 98th Congress. Thus, both Acts were under consideration during the same time, although the passed in separate Congresses.

The timing of the two initiatives matches precisely, however, when one looks at the key amendment to the Orphan Drug Act. The original Orphan Drug Act was not a rousing success, and commentators have suggested that pharmaceutical companies were reluctant to submit applications under the definitions in the Act as passed. 59 In response, the same Congress that passed the Hatch-Waxman Act, also amended the key definition in the Orphan Drug Act, and the orphan drug program took off from there.

There have been other amendments to the Orphan Drug Act across time, however, but these have not had the same impact as the amendment passed at the same time as Hatch-Waxman. 60 For example, Congress approved an amendment to the Act in 1985 to include patentable as well as unpatentable drugs in the program and in 1988 requiring sponsors to apply for orphan designation before applying for drug approval. A graph of designations and approvals of Orphan Drugs from the Department of Health and Human Services, however, shows no significant jump in approvals in the year following either amendment. 61 In short, the key moment in the history of the Orphan Drug Act program took place in the same Congress as

59 See Loughnott, supra note 41, at 375; see also Gary A. Pulsinelli, The Orphan Drug Act: What’s Right With it, 15 SANTA CLARA COMP. & HIGH TECH. L.J. 299, 307 (noting that the response to the 1983 Orphan Drug Act was “underwhelming”).
60 See, Department of Health and Human Services, supra note 39, at 4.
61 See id. at 7.
passage of the Hatch-Waxman Act, and the Act should be understood as part of the benefits granted to the pharmaceutical industry at this time.

i. Logic and Structure of the Orphan Drug Act

As described above, the Orphan Drug Act was intended to stimulate investment in the creation and production of drugs that treat diseases that affect only small numbers of people. Policy makers were concerned that such small populations would not make a revenue base sufficient to recoup the costs, and thus, these disease populations would languish untreated.

The original Orphan Drug Act defined a rare disease as one for which there was no “reasonable expectation that the cost of developing ... will be recovered from sales in the United States.” The 1984 amendment, however, greatly expanded the definition of rare disease so that a drug now qualifies if it meets either of the following two definitions: 1) diseases affecting fewer than 200,000 people in the United States; or 2) diseases that affect more than 200,000 people in the United States but for which there is no reasonable definition that sales would recover the costs. As noted in a government report, the 200,000 threshold was an arbitrary number that was chosen based on the estimated prevalence of narcolepsy and multiple sclerosis.

A drug does not have to be new to qualify for orphan drug status. If existing drugs are approved for an orphan indication, those drugs will receive the benefits of the Act as well. For example, thalidomide, an anti-nausea drug that fell out of favor in the 1960s when it was linked

64 See Department of Health and Human Services, supra note 39, at 4.
to birth defects, receiving an orphan drug designation in 1998 for the treatment of leprosy and in 2006 for the treatment of a form of cancer called multiple myeloma.66

The practice of refreshing old drugs as new orphans has made the national news recently, and not in a flattering manner. For example, patients of a rare neuromuscular disease had been using the drug, Firdapase, which dates back to compounds created in the 1970s and research in the 1980s.67 The drug had never received FDA approval but was provided to patients for free through an FDA program and a generous company.68 In 2015, another company filed an application for approval of a modified version of the drug that does not need refrigeration as an orphan drug.69 The press report suggests that while the drug costs $600 to make a year’s supply for one patient, the company plans to sell it in the range of $100,000 per patient each year.70

The Act provides a variety of benefits for pharmaceutical companies who create medicines to treat rare diseases, including tax breaks, unparalleled assistance through the regulatory process, and various grants.71 The greatest benefit, however, is seven years of

66 Id.
68 Id.
69 Id.
70 Id.
71 See P.L. 97-414, 96 Stat. 2049 (1982); Thomas, supra note 35, at 8. Orphan drug companies are eligible for up to $500,000 a year for up to 4 years; a tax credit of 50% of qualifying clinical trial costs; a waiver of application fees worth more than $2 million, and what I would call “concierge service at the FDA,” that is, assistance from the FDA on what tests and trials the drug company needs to complete to secure marketing approval. See Daniel et. al., supra note 2, at 2; Pulsinelli, supra note 59, at 6. For example, in the drug approval process ordinarily, the FDA maintains a distant, objective, and some would say antagonistic, relationship with the applicant, while during orphan drug approval process, the FDA establishes a more collegial
Marketing rights. These are the quasi-patent rights that prevent the FDA from granting approval to any other company to make the drug, regardless of whether the other company relies on its own clinical trial data. In other words, it is the granddaddy of the rights, both from the perspective of the power of the right and from the perspective of how long it lasts. Seven years is, by far, the longest of any of the forms of Regulatory IP. Thus, it is not surprising that the program has attracted considerable interest from pharmaceutical companies.

Wonderful drugs have been approved through the Orphan Drug Act portal. These have included treatments for a rare genetic disorder called Gaucher’s disease, a truly rare form of the already rare Ebola virus, and many others. Some would say, however, that the program has been too successful. In fact, orphan drugs seem to be dominating the modern medical system. For example, in 2015, more than 40% of all FDA-approved drugs on the market were submitted as orphan drugs, and 44% of the new drugs approved by the FDA in 2014 were for drugs that had an orphan indication. Moreover, of the top ten best-selling drugs in 2015, seven were orphan drugs.

The same is true for biologic drugs as well as the chemical drugs that are more familiar to most of us. In 2001, five of the ten best-selling biologic drugs were originally approved as orphan drugs and three more were approved for orphan indications in addition to

relationship, working with the company to get the trials accomplished and move the drug to market expeditiously. See Loughnott, supra note 41, at 368.
72 See Thomas Maeder, The Orphan Drug Backlash, 288 SCIENTIFIC AMERICAN 5, pp.80, 87 (2003) (quoting Abbey S. Meyers, President of the National Organization for Rare Disorders, as saying “[t]he Orphan Drug Act works fabulously well. . . . We have treatments we never imagined we would”).
73 See Daniel et. al., supra note 2, at 1.
74 See Daniel et. al, supra note 2, at 1.
75 See id.
76 See Daniel et. al, supra note 2, at 1.
their original use. In other words, 80% of the best-selling biologics were related to the Orphan Drug Act in some manner—and that was only in 2001.

It is not surprising that so many of the best-selling biologic drugs have orphan designations. Modern biologics tend to be targeted at specific populations, making the area ripe for universal orphan designation. In fact, some scholars have bemoaned the fact that the Orphan Drug Act is driving medical science overwhelmingly towards cancer therapeutics. Cancer therapeutics focus on precision medicine techniques and small, particularized populations, for which orphan drug designations are a natural fit. As one commentator noted, “all cancers but four are considered to be rare diseases.” Although cancer is certainly an important health concern, one could question whether so much of societal energy should be directed at cancer, and whether Congress intended this result.

The dominance of orphan drugs also can be seen in the value of total sales. For example, one group projects that between 2014 and 2020, orphan drug sales will increase at twice the rate of overall prescription drug sales worldwide, with orphan drug sales reaching $176 billion in 2020. Following those projections, orphan drug sales will constitute almost 20% of worldwide prescription drug sales as a whole by 2020.

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77 See Maeder, supra note 72, at 84.
79 See Wellman-Labadie & Zhou, supra note 78, at 225 (citing Abbey S. Meyers, Director of the National Organization of Rare Diseases).
Finally, the price of orphan drugs is shockingly high. The median cost per patient to use an orphan drug for one year is almost $99,000.\textsuperscript{81} In comparison, for non-orphan drugs, the cost is roughly $5,000.\textsuperscript{82} In addition, the price tag for the most expensive orphan drugs soars well above the median. The poster child is Genzyme’s drug Cerezyme, which is an enzyme replacement therapy for treating the genetic disorder known as Gaucher’s disease. The company reportedly charged between $100,000 and $400,000 a year per patient, depending on whether the patient was a child or an adult, earning close to half a billion dollars a year.\textsuperscript{83}

To some extent, high prices for orphan drugs may be perfectly understandable. If a company must recoup its investment over a small group of customers, the cost per customer is bound to be high. After all, one could argue that an expensive treatment is better than no treatment at all. The problem is that in many cases, those high prices seem to be spread across much larger populations than the Act anticipates. In other words, critics note that companies earn the right to charge mega-prices by claiming to serve small populations, and then use various techniques to charge those mega-prices across broader populations.\textsuperscript{84} One could call these techniques “spillover pricing.”

\textsuperscript{81} Daniel et. al., supra note 2, at 2 (citing Hadjivasilou, supra note 80, at X).
\textsuperscript{82} Id.
\textsuperscript{83} See Maeder, supra note 72, at 85.
\textsuperscript{84} See, e.g., See Daniel et. al., supra note 2; Maeder, supra note 72, at 85; Brian B. Eller, Promoting Innovation in the Pharmaceutical Industry by Expanding the FDA’s Regulatory Powers to Grant Market Exclusivity, text accompanying note 106; Loughnott, supra note 41, at 366; Herder, supra note 58, at 247; Pulsinelli, supra note 59, at 315-316. For similar observations related to orphan drug pricing in other countries, see Panos Kanavos & Elana Nicod, What is Wrong With Orphan Drug Policies: Suggestions for Ways Forward, 15 Value in Health 1182, text accompanying note 19 (2012); A Denis, L Mergaert & C. Fostier, Issues Surrounding Orphan Disease and Orphan Drug Policies in Europe, 8 App. Health Econ. Health Pol. 343 (2010); Eline Picavet, Thomas Morel, David Cassiman & Steven Simoens, Shining a Light in the Black Box of Orphan Drug Pricing, 9 Orphanet J. of Rare Diseases 62 (2014).
Spillover pricing can occur in a variety of ways. The simplest is through off-label use. Off-label use occurs when doctors prescribe a medicine to treat something that is not one of the indications approved by the FDA. It is a common practice in medicine. In fact, the Second Circuit recently ruled that given First Amendment protections for freedom of speech, the FDA cannot prevent a drug company from promoting a drug for off-label uses.

Off-label uses can be a great boon for orphan drug makers. A company can seek approval from the FDA to use their drug for treatment of a small population—small enough to fit within the Orphan Drug Act’s definition of fewer than 200,000 people in the United States. After approval, the company may be able to expand the patient population well beyond the 200,000 through additional uses.

For example, the Lidoderm patch was originally approved for a painful complication of shingles that affects nerve fibers. The company earned more than 80% of its revenue, however, from uses other than the original orphan drug indication.

A similar example can be seen with rituximab, which was originally approved for the treatment of a narrow group of lymphoma patients. Shortly after approval, the drug became widely used off-label for rheumatoid arthritis, which affects 1.3 million people in the United

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\[ ^{85} \text{See Daniel et. al., supra note 2, at 3 (describing Lidoderm’s initial approval for hypersensitivity in postherpetic neuralgia). For an explanation of postherpetic neuralgia, see http://www.mayoclinic.org/diseases-conditions/postherpetic-neuralgia/basics/definition/con-20023743.} \]

\[ ^{86} \text{See Daniel et. al., supra note 2, at 3.} \]
States. As of 2014, the drug ranked as the 12th best-selling medication of all time, having generated $3.7 billion in sales revenue in the United States.

Perhaps the classic case of off-label expansion of an orphan drug can be seen with Epogen. The FDA originally approved Epogen with an orphan designation for the treatment of anemia related to end-stage renal disease. After approval, the drug became widely prescribed for treating a variety of forms of anemia, generating billions of dollars of revenue for the company.

At first glance, one might wonder why in the world this strategy would work. After all, under the Orphan Drug Act, the FDA grants seven years of marketing exclusivity, but only for the particular orphan indication. In other words, if there is no orphan drug exclusivity for those off-label uses, why wouldn’t another company jump in to compete for the off-label use?

In order to get off-label use of one’s drug, however, one has to get onto the market in the first place. A competitor could not get onto the market for the same orphan indication that is blocked by the orphan exclusivity. The competitor could try to get approval for the drug directly for the off-label use, but that would require much time and extensive clinical trials. Those clinical trials, of course, would not have the many advantages of orphan drug clinical trials, including concierge service at the FDA, financial grants, and tax breaks. Thus, in reality,

87 See id; see also Prevalence Statistics, American College of Rheumatology, available at http://www.rheumatology.org/Research/Prevalence_Statistics/.
88 See Daniel et. al., supra note 2, at 1.
90 See id.
91 See FDA, supra note 2, at 2.
one can obtain the benefits of orphan drug status while garnering spillover returns from a much larger off-label population.

In addition to off-label uses, companies can garner spillover returns by applying for separate orphan designations for different uses of the same drug. Once again, this presses against the original purpose of the Orphan Drug Act. For example, the FDA original approved the drug Imatinib with an orphan designation for treating a rare form of leukemia that affects only 9,000 patients.92 The company subsequently received six additional orphan designations for treating other forms of cancer, a syndrome related to an autoimmune disease, and certain bone marrow disorders.93

If a single drug can be used for multiple patient populations, those populations added together should provide enough of a return to tempt the company to make the drug. The return certainly is reduced by the need to engage in separate clinical trials for different uses. Nevertheless, the costs of production and development of a stable, usable compound are spread across a much larger population than what Congress contemplated with its “orphan” designation.

A more extreme form of finding additional designations for a single orphan drug is known as “salami slicing.”94 With salami slicing, a company divides the treatment population into small slices and obtains different orphan designations for each slice. Divisions have been

92 See Daniel et. al., supra note 2, at 3.
93 See Daniel et. al., supra note 2, at 3.
94 See Shannon Gibson & Barbara von Tigerstrom, Orphan Drug Incentives in the Pharmacogenomic Context: Policy Responses to the US and Canada, J.L. & BIOSCIENCES (2015), available at http://jlb.oxfordjournals.org/content/early/2015/05/18/jlb.lsv013.full. Some scholars use the term “salami slicing” to refer not only to additional approved uses but also to off-label uses of the same drug. See id, at text accompany notes 36-38 (describing the off-label uses of Epogen as a form of salami slicing).
based, for example, on whether a particular disease is early stage or end stage, different manifestations of a disease, or different mutations leading to the same genetic disease. The risk is that companies could divide populations into ever-finer slices until, in theory, reaching the absurd point of testing headaches in males who just bumped their head on the car door in the last two weeks.

In 2013, the FDA approved guidelines intended to reduce salami slicing behaviors. The new guidelines are enormously complex, however, and the jury is still out on whether the guidelines will be successful.

The policy implications of behaviors such as off-label uses, additional orphan designations, and salami slicing are unclear. On the one hand, one could argue that society should encourage drug makers to look for all possible uses for the medicines we already have. Society should exploit to the fullest those substances for which we have the greatest experience and knowledge, before we go chasing after new rainbows. On the other hand, a policy that encourages constant repurposing of what researchers already know risks ossifying scientific advancement.

Putting aside the policy implications, however, the economic implications are quite troubling. Congress passed the Orphan Drug Act for the purpose of creating incentives when patient populations were too small for drug companies to serve them. When drug companies aggregate multiple populations, it defeats the purpose of the Act.

95 See Orphan Drug Regulations (Final Rule), 78 Fed. Reg. 35,117, 35,120–1 (June 12, 2013) (clarifying and providing guidance on the circumstances under which a subset of a common disease would qualify for an orphan designation).
96 See Gibson et. al., supra, note 89, at text accompanying notes 47-87 (describing the new guidelines and discussing uncertainty about the impact they will have); Daniel et. al., supra note 2 at 3 (noting that the success of the 2013 wording change remains to be determined).
The saga of the Orphan Drug Act is tantalizingly reminiscent of the Gilbert & Sullivan operetta, Pirates of Penzance. The pirates in the play have declared that they will never harm an orphan, and express frustration that:

“[e]veryone we capture says he’s an orphan. The last three ships we took proved to be manned entirely by orphans, and so, we had to let them go.”

What should society do as more and more companies show up at the FDA, claiming to serve orphans? At least with Gilbert & Sullivan, the characters are unable to make any money from orphans. Here, however, it is the reverse. When so many companies claim they are only serving orphans, the orphans—that is, the patients—may be the ones having their finances ravaged.

The Orphan Drug Act is the last of the pieces of Regulatory IP created at the time of passage of the Hatch-Waxman system for expedited approval of generic drugs. As described above, these forms of Regulatory IP include ones for first generic filers, new chemical entities, new clinical studies, and orphan drugs.

B. Regulatory IP with the America Invents Act

The next major group of Regulatory IP benefits were granted during the Congress that passed the patent reform act known as the America Invents Act. Approved in 2011, the America Invents Act numerous changes to patent law, including creating a series of methods for third parties to challenge the validity of a patent at the Patent and Trademark Office after the patent has been granted. The pharmaceutical industry was deeply opposed to the American Invents
Act, and to patent reform in general. The 112\textsuperscript{th} Congress also approved major legislation to create a pathway for accelerated approval of biologic drugs. Again, the pharmaceutical industry opposed the Biologics Act.

Once again, when Congress passed legislation that the pharmaceutical industry bitterly opposed, the same Congress passed several pieces of legislation that created forms of Regulatory IP. Thus, Congress created Regulatory IP for drugs for infectious diseases, biologics, and clinical trials for pediatric use of drugs. In general, the pattern among this wave Regulatory IP can best be described as “just add more.”

1. Biologics

The 112\textsuperscript{th} Congress embarked on a process reminiscent of the Hatch-Waxman legislation for expedited approval of generic drugs. The Hatch-Waxman pathway covers what is known as chemical drugs. In the decades since introduction of the Hatch-Waxman system have witnessed the development of a new breed of medicines knows as biologics. Biologics differ from ordinary chemical drugs both in terms of structure and in terms of the process of production.\footnote{Bryan A. Liang, \textit{Regulating Follow-On Biologics}, 44 Harvard Law Journal on Legislation 363, 367-372 (2007); Robert N. Sahn, \textit{The Biologics Price Competition and Innovation Act: Innovation Must Come Before Price Competition}, 2009 BOSTON COLLEGE INTELL. PROPL & TECH. FORUM 70201; Wendy H. Schacht & John R. Thomas, \textit{Follow-On Biologics: The Law and Intellectual Property Issues}, CONGRESSIONAL RESEARCH SERVICE 2010 [hereinafter “CONGRESSIONAL RESEARCH SERVICE: BIOLOGICS”]} Consider first ordinary chemical drugs, such as aspirin. These are sometimes called small molecule drugs because their chemical structure is composed of relatively fewer atoms than biologics. A typical chemical drug is made up of dozens of atoms forming one molecule. The structure of a chemical drug is also relatively simple to understand and depict; one can typically
draw the structure with a simple two-dimensional sketch. Finally, chemical drugs are far easier to make than biologics. The proper chemical ingredients are combined in the lab and react together to form a new chemical. Although manufacturing any product is never quite so simple, the process of creating a chemical drug pales in comparison to the process for its cousin, the biologic.

Biologics differ greatly from their country cousins, chemical drugs. Rather than a few dozen atoms forming a single molecule, biologics contain thousands to millions of atoms formed into an intricately integrated set of perhaps thousands of molecules. These numerous molecules are folded into complex shapes that cannot be depicted in a simple two-dimensional drawing. Most important, biologics are so large and complex that scientists do not know how to build them chemically in an efficient manner. Instead, scientists use living cells, carefully nurtured in a laboratory setting to act as a form of living machinery to create the necessary substance. Given that biologic drugs are created through a process involving living cells, that process cannot be controlled with the same precision as mixing chemicals. Just as no two human beings could ever be precisely alike, it is virtually impossible to make a truly identical copy of, for example, a protein made using different production cell lines. Of particular concern are subtle, virtually undetectable variations in structure or stability that may result in a drug that is less effective or downright dangerous. Given the complexities of the drugs, the potential subtle differences, and the potential risks, the process for approval of copies of biologic drugs cannot be as streamlined as the process for approving generic versions of chemical drugs.
The 112th Congress created a pathway for approval of copies of biologic drugs. The legislation was called the Biologics Price Competition and Innovation Act (Biologics Act) and was passed as a last minute addition to massive health care reform law known as the Affordable Care Act. Copies of biologic drugs are called biosimilars or bioequivalents, rather than generics. The pathway for approval is far more rigorous than what is required for generics, and it involves more extensive testing and trials.

As with the Hatch-Waxman Act, the Biologics Act creates several forms of Regulatory IP for biologic drugs, but the Regulatory IP in the Biologics Act lasts longer than the Regulatory IP created in Hatch-Waxman. The following paragraphs describe the two acts in comparison, to highlight the differences.

As described above, the Hatch-Waxman Act created 6-months of Marketing rights for the first generic company and 3-5 years of Data rights for original pharmaceutical makers. In contrast to the Hatch-Waxman’s 6-months of Marketing rights, the Biologics Act contains no marketing rights for the first biosimilar filer, significantly reducing the allure of creating a biosimilar. For those who create bioequivalents, however, the period of Marketing rights last much longer. There is a complicated calculus under the Biologics Act, depending on the state of any litigation, but the shortest period of time is twelve months.

98 See 42 U.S.C. 262.
100 See text accompanying notes x-y, supra.
101 The precise time is the earlier of 1 year after commercial marketing, 18 months after approval if not subject to litigation, 18 months after final court decision or dismissal, or 42 months after approval if litigation is ongoing. The varying times may reflect an attempt to head off the so-called pay-for-delay settlements under Hatch-Waxman. Hatch-Waxman has been plagued by deals in which the branded pharmaceutical company enters into a settlement with the would-be generic in which the generic agrees to stay off the market for a period of time in
The Regulatory IP for the original drug maker is considerably longer and stronger under the Biologics Act. Specifically, the original drug maker receives twelve years of Data rights under the Biologics Act.\textsuperscript{102} For the first four years,\textsuperscript{103} no follow-on companies may apply, even if they use their own data and if patents on the original drug are invalidated. For the remaining eight years, a follow-on company could apply and receive approval, but could not rely on any data from the original drug maker.

The language of the Biologics Act itself is less than a model of clarity, and arguably it could be read to suggest that original biologic drug makers receive twelve years of Marketing rights, rather than twelve years of Data rights. As described above, Marketing rights are the stronger ones because they prevent the FDA from approving follow-on biologics created by any other companies, even those who use their own, original data.\textsuperscript{104} Following letters from members of Congress, however, the FDA has interpreted the twelve years in the Biologics Act to refer to only Data rights.\textsuperscript{105}

In short, the Biologics Act provides a less streamlined pathway for approval of follow on biologic drugs, and the Regulatory IP is generally longer and stronger. Commentators are skeptical of whether the Biologics Act will result in the same type of price reductions that consumers have enjoyed with generic drugs under the Hatch-Waxman regime. In addition to exchange for some form of payment. For a description of this behavior, along with discussion of the judicial, regulatory, and legislative responses, see Robin Feldman & Evan Frondorf, Drug Wars: A New Generation of Generic Pharmaceutical Delay, (forthcoming HARVARD J. OF LEG. 2016).

\textsuperscript{102} See 42 U.S.C. 262(k)(7)(B).
\textsuperscript{103} See 42 U.S.C. 262(k)(7)(A).
\textsuperscript{104} See text accompanying notes x-y, supra.
\textsuperscript{105} For a description of the controversy and excerpts from the Congressional letters, see CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 8-9.
the more complex regulatory pathway, drug companies that make the original biologic drugs have been raising their prices in the years immediately prior to introduction of the follow-on drugs, and the follow-on companies are setting their prices accordingly.\textsuperscript{106} The system is too new, however, and too few follow-on biologics have been approved for scholars to draw generalizable conclusions.

2. Infectious Diseases (QDIP)

In addition to the Biologics Act, the 112\textsuperscript{th} Congress also approved Regulatory IP intended to promote the creation and production of drugs to treat so-called “super bugs” that are resistant to ordinary antibiotics. Thus, the rights are granted for antibacterial or antifungal drugs intended to treat serious or life-threatening infections.\textsuperscript{107}

Regulatory IP for infectious diseases overflows with acronyms. The bill was called the GAIN Act, an abbreviation for “Generating Antibiotic Incentives Now,” and the program is known as QDIP, an abbreviation for “Qualified Infectious Disease Products.”\textsuperscript{108} Perhaps the acronyms were an attempt to mimic the public relations value of the term “orphan” in the wildly successful Orphan Drug Act, although nothing can quite recapture that magic.

The notion of overflowing also is appropriate to the infectious disease legislation because the program follows a pattern of just adding more. Once a drug is designated as a qualified infectious disease product, the various Regulatory IP benefits for the drug are


\textsuperscript{108} See id.; Congressional Research Service, supra note 28, at 10.
extended by five years.\textsuperscript{109} Thus, the four or five-year Data rights a drug may have if it is a new chemical entity are extended five years to reach a new total of nine or ten years. The three-year Data rights a drug may have for performing new clinical trials for improvements on existing drugs (new dosages or new indications) are extended for five years to reach a new total of 8 years. And the seven-year Marketing rights a drug may have if it is an orphan drug are extended five years to reach a new total of twelve years. The legislation also granted various other benefits for qualified infectious disease products, including fast track approval at the FDA, priority review, and the type of concierge assistance with recommendations for clinical and nonclinical trials enjoyed by orphan drugs.\textsuperscript{110}

3. Pediatric Studies

The 112\textsuperscript{th} Congress passed one additional law regarding a form of Regulatory IP related to pediatric drug studies. Regulatory IP for pediatric drug studies was originally created by Congress in 1997 as part of the Food & Drug Act Modernization Act, but it had a sunset provision. The 112\textsuperscript{th} Congress reauthorized the provision, making it permanent.\textsuperscript{111}

With the 1997 start date, the pediatric drug studies IP shows that Regulatory IP has been created outside of these two major waves. The pediatric drug study law is grouped with the 112\textsuperscript{th} Congress for this article, however, given that the law was extended during that wave of Regulatory IP activity.

Pediatric clinical trials are more difficult to perform, with problems including complexity of informed consent, changes that occur as children grow, and the difficulty of obtaining

\textsuperscript{110} See sources cited supra note 109; available at http://www.bioworld.com/content/antibiotics-resistance-rising-can-new-drugs-keep-pace-0.
\textsuperscript{111} See Congressional Research Service, supra note 28, at 10.
accurate descriptions from children.\textsuperscript{112} As a result, few drugs on the market have been tested in children, and doctors lack reliable information on safety and efficacy in this patient population.

Congress responded to these concerns with the creation of a new basket form of Regulatory IP intended to encourage companies to perform pediatric clinical trials. The Regulatory IP is granted when a company completes clinical studies of the effects of a drug on children.\textsuperscript{113}

Regulatory Rights for pediatric studies have an oddly chameleon-like nature. They can take the form of either Marketing rights, Data rights, or both. Specifically, the legislation provides that when a company completes pediatric studies, the company will receive a 6-month extension of its patent rights and or its various forms of exclusivity. Thus, a company’s orphan drug Marketing rights are extended for six months along with its new chemical entity Data rights are extended for six months.\textsuperscript{114} If a company has both patent rights and exclusivities, each one is separately extended for 6 months.\textsuperscript{115} For drugs that have no patent or exclusivity, Congress in 2002 amendments created a system in which the FDA would award contracts to

\begin{itemize}
  \item \textsuperscript{112} SeeCongressional Research Service, supra note 28, at 9.
  \item \textsuperscript{113} The FDA must request that a company perform clinical studies, but companies can ask to receive such a request. See Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act: Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric “Rule,” and Their Interaction, U.S. Food and Drug Administration, available at HTTP://WWW.FDA.GOV/DRUGS/DEVELOPMENTAPPROVALPROCESS/DEVELOPMENTRESOURCES/UCM077915.HTM?SOURCE=GOVDELIVERY\&UTM_MEDIUM=EMAIL\&UTM_SOURCE=GOVDELIVERY.
  \item \textsuperscript{114} See FDA, supra note 2.
  \item \textsuperscript{115} For drugs that have no patent or exclusivity, Congress in 2003 amendments created a system in which the FDA would award contracts to companies willing to engage in pediatric studies. The provision appropriated $200 million to pay for these contracts.
\end{itemize}
companies willing to engage in pediatric studies. The provision appropriated $200 million to pay for these contracts.\footnote{116}

The patent extension for pediatric studies does not operate directly as any alteration to the patent at the Patent & Trademark Office. Rather, it operates as a Marketing right, in which the FDA may not approve another drug with the same active ingredient until 6 months after the original company’s patent expires.

Although 6 months is not a particularly long period of time, the pediatric study rights have aspects that greatly enhance their value. For example, the pediatric rights apply to all formulations and uses of the drug, including those for adults. This expansive application stands in contrast to the rights granted for orphan drugs, which apply only for the particular indication of the drug. Thus, while a new use patent could be limited to a particular use of the drug, if the company carried out pediatric studies, the FDA could not grant approval to new competitor to make the same drug for any use in any population during the extended period.

In addition, the six-month right can be strung together with other rights to enhance the overall value. For example, a company could make a qualified infectious disease product (five years of Data rights) that qualifies as a new chemical entity (five years of Data rights) and do pediatric studies on the drug (six months of extension). Although each program alone looks relatively small, added together, the company would have ten-and-a-half years of Data Exclusivity.\footnote{117}


\footnote{117} See CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 11 (setting out this example).
The most valuable aspect of engaging in pediatric studies is that the right is tradeable, like ordinary assets or personal property. Thus, a company can perform pediatric studies, receive 6-months of additional patent rights or exclusivity, and sell that 6 months to another company making an unrelated drug. Successful drugs bring in hundreds of millions of dollars a year, and so-called Blockbuster drugs bring in more than a billion dollars a year.\textsuperscript{118} Thus, the ability to keep all others out of the market for an additional six months can be extraordinarily valuable.\textsuperscript{119}

The pediatric studies program has, indeed, encouraged numerous companies to conduct clinical studies of safety and efficacy in children. It is unclear, however, whether the breadth of the rights is proportionate to the societal benefits. With most Regulatory IP, a company receives benefits in exchange for success, that is, when a drug is approved or a new chemical or use is identified. In contrast, companies receive the pediatric study rights even when the studies are not successful in demonstrating safety and efficacy in children.\textsuperscript{120} In addition, scholars have raised concerns that the benefits have created a “race to the bottom” because they do not require that the studies have been conducted according to commonly accepted scientific and ethical standards.\textsuperscript{121}

\textsuperscript{118} See Feldman & Frondorf, \textit{Drug Wars}, supra note 31, at text accompanying notes 17-20 (discussing the value of delaying generic entry by 6 months in the context of pay-for-delay settlements); Herder, \textit{supra} note 58, at 242 (defining blockbuster drugs).

\textsuperscript{119} See text accompanying notes x-y, \textit{infra} (explaining tradeable rights that merely accelerate FDA approval by four months, and describing sales of those rights for $125 million and $350 million); see also Cohen, \textit{supra} note 116, at 665-666 (noting that for ten of the first 36 drugs to receive pediatric study rights had sales that exceeded $200 million in six months, with two of them exceeding $800 million and two exceeding $1 billion).

\textsuperscript{120} See \textit{Congressional Research Service}, \textit{supra} note 28, at 10.

\textsuperscript{121} See Cohen, \textit{supra} note 116, at 661.
4. Rare Pediatric Diseases

In the realm of benefits for pediatric diseases, the 112th Congress created an additional form of benefit. As part of the Food and Drug Safety Administration Act of 2012, Congress created a program in which companies that receive approval for drugs to treat certain rare pediatric diseases receive a voucher for priority review of the drug at the FDA. This voucher can be used for priority review of another drug by the same company or sold to another company.

With the voucher, the FDA will review a company’s application for approval of a new drug within 6-months. FDA review typically takes at least ten months or more. Although expediting review by as little as four months may not sound like much, the vouchers are highly valued. Studies estimate that the vouchers are worth hundreds of millions of dollars, and, in fact, AbbVie recently purchased one for $350 million.

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123 Id.

124 The FDA has asserted that the voucher programs do not guarantee review within that period of time, but only that the drug can be entered into the group entitled to expedited review of which the FDA must complete 90% of them in the time specified. See Gaffney & Mezher, supra note 122 (citing FDA guidelines).

Although the program for pediatric priority review vouchers was reauthorized in 2013, a Government Accountability Office (GAO) report on the program in 2015 noted that FDA officials do not support continuation of the program.\textsuperscript{126} The officials expressed concern that the transferable nature of the vouchers interferes with the agency’s ability to set public health priorities in reviewing treat serious conditions or provide significant improvements in safety or efficacy.\textsuperscript{127}

For example, in theory, a company could buy a voucher for a drug that has minimal public benefit in that it represented only minor differences over existing treatments. The drug might have great benefit to the company, however, if it could be combined with other exclusivities and life cycle management techniques to secure market position in a widely used product.\textsuperscript{128} The company could then jump to the front of the line, passing over drugs that show significant benefits for health priorities.

Regardless of the level of invention or health priorities, tradeable vouchers can be used as a competitive tool to beat other pharmaceutical companies to market. For example, the pharmaceutical company Sanofi-Adventis used a pediatric priority review voucher to beat its competitor in a race to first market a new form of cholesterol drug.\textsuperscript{129} Sanofi’s competitor was

\textsuperscript{126} Rare Diseases: Too Early To Gauge Effectiveness of FDA’s Pediatric Voucher Program, GOVERNMENT ACCOUNTABILITY OFFICE (MARCH 2016) (overview) (hereinafter “GAO Report”).

\textsuperscript{127} Id.

\textsuperscript{128} See ROBIN FELDMAN, RETHINKING PATENT LAW (Harvard 2012) (describing product hopping techniques); Feldman & Frondorf (describing product hopping techniques and using weak follow-on patents).

\textsuperscript{129} Use of Rare Pediatric Disease Priority Review Voucher; Approval of a Drug Product, FOOD & DRUG ADMINISTRATION NOTICE (August 24, 2015), available at https://www.federalregister.gov/articles/2015/08/24/2015-20833/use-of-rare-pediatric-
able to reach the market first in Europe, but the priority voucher allowed Sanofi to jump ahead in the US.\textsuperscript{130} Sales of this new class of drugs are expected to reach into billions of dollars a year, and the first company to reach the market in the US enjoys sales and marketing momentum, as well as advantages in the payment and reimbursement system.\textsuperscript{131}

The GAO report concluded that it is too soon to gauge the effectiveness of priority vouchers for rare pediatric diseases.\textsuperscript{132} The program is set to expire in 2016.\textsuperscript{133}

In short, the Regulatory IP created for pediatric studies and rare pediatric diseases follows the pattern of all of the Regulatory IP created by the 112\textsuperscript{th} Congress in 2011-2012. The pattern can be described simply as adding more.

C. Proliferation--Beyond Passage of the Major Generic Regimes

The two sections above chronicled the myriad benefits created at the same time as Congress passed the two major generic regimes. In addition, other forms of Regulatory IP have begun to proliferate. Some of these are simply extensions or adjustments of the existing regimes described above.\textsuperscript{134} In 2014, for example, the FDA expanded its definition of new


Varond, \textit{supra} note 129.\textsuperscript{132} \textit{See GAO Report, supra note 126.}\textsuperscript{133} \textit{Id.} at 2, n. 3.\textsuperscript{134} \textit{See, e.g., text accompanying notes 60-61; CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 9-10 (describing amendments to the pediatric studies legislation); Cohen, supra note 116 (same).} In the same vein, Congress in 2015 passed the Improving Regulatory Transparency for New Medical Therapies Act, which was signed into law later that year. The Act relates to drugs that
chemical entity to include drugs that have a combination of active ingredients, as long as the FDA has not previously granted approval to at least one active ingredient.\textsuperscript{135} Under court pressure in 2015, the FDA further expanded the definition, granting new chemical entity status to isolated components of a drug when the FDA had previously approved the full mixture.\textsuperscript{136}

Entirely new regimes and proposed regimes are popping up, as well.

1. Tropical Diseases

For example, similar to the priority vouchers for pediatric studies, congress approved another set of tradeable vouchers as part of amendments to the FDA Act in 2007.\textsuperscript{137} These vouchers are given for approval of neglected tropical diseases that disproportionately affect poor populations in developing countries.\textsuperscript{138} The legislation lists specific disease, such as malaria, tuberculosis, leishmaniasis and others, and both Congress and the FDA have added more diseases to the list across time.\textsuperscript{139}

Tradeable vouchers, whether for tropical diseases or for pediatric conditions, can garner sky-high prices on the open market. For example, in 2014, Knight therapeutics sold a voucher to

\textsuperscript{135} See Hoffmeister et. al., supra note 40
\textsuperscript{136} See Hoffmeister et. al., supra note 40 (discussing the change in apparent response to the District Court for the District of Columbia’s ruling regarding Amarin’s drug Vascepa).
\textsuperscript{139} Id.
Gilead for $125 million.\textsuperscript{140} Similarly, in 2015, United Therapeutics sold a voucher to AbbVie for $350 million.\textsuperscript{141} These eye-popping numbers offer a glimpse of the value of the Regulatory IP that Congress has been continually creating for the past 30 years. One must ask who is paying the bill in the end, and most likely it is the purchaser. The hundreds of millions of dollars a company spends to jump the approval line are folded into the eventual price of the drug, or into the price of other drugs the company gets to market.

In analyzing the economic effects of vouchers, it is important to note that spending high sums to acquire these vouchers—whether one develops a drug for a favored category or purchases a voucher from another company—is a form of a gamble. The voucher may bring a speedier response, but it does not guarantee the FDA will approve the drug. For example, Novartis used a voucher to accelerate review of its biologic drug for the treatment of gouty arthritis, but the FDA denied approval of the drug.\textsuperscript{142} Any sums that a company spends to try to get various drugs to market are likely to be folded into pharmaceutical prices. If the drug is successful, the cost will be folded into the price of that drug; if the drug is unsuccessful, the cost will be folded into the price of other drugs the company brings to market.\textsuperscript{143} One might ask

\begin{itemize}
    \item \textsuperscript{142} See Gaffney & Mezher, supra note122.
    \item \textsuperscript{143} In explaining drug pricing and the need to recoup costs, pharmaceutical companies and industry groups frequently fold the cost of unsuccessful drug attempts into the cost of drugs
\end{itemize}
whether it makes good policy sense to create a system that encourages companies to drive up drug prices as they gamble on efforts to beat each other to market.

Only a limited number of vouchers have been granted, and the legislation specifically limits the number of some types. These vouchers can be sold and resold an unlimited number of times, however, which amplifies the size of the secondary market for vouchers and the potential economic effects.

The tropical disease voucher program caused a flurry of concern, featuring pharmaceutical bad boy, Martin Shkreli. Shkreli initially enraged lawmakers and commentators as CEO of Turing when the company raised the price of an antimalarial drug used for treatment of infections in HIV patients from $13.50 per pill to $750 per pill. In the case of tropical diseases, Shkreli lead a group of investors who purchased a company with rights to a drug used to treat Chagas disease, which is caused by a parasite and is found most commonly in South and Central America. Although the drug is already in common use in those countries, it has

144 For an easily accessible explanation of the voucher systems along with lists of the vouchers granted through summer of 2015, see Gaffney & Mezher, supra note 122.

145 Originally, rare pediatric drug vouchers could be re-traded, but tropical disease vouchers could only be sold once. A 2014 Congressional amendment to the tropical disease program clarified that the legislation allowed for unlimited transfers; Gaffney & Mezher, supra note 122.


147 See Andrew Pollack, Martin Shkreli’s Latest Plan to Sharply Raise Drug Prices Prompts Outcry, NEW YORK TIMES (Dec. 11, 2015), available at
never been approved for sale in the United States. Shkreli set out his intent to apply for FDA approval of the drug in the United States, garner a tradable voucher, and then sell that voucher. If the move is successful, the company would receive a voucher in exchange for a drug that is already being widely used to treat the particular tropical disease.

The idea of garnering regulatory IP with old medicines is not unique to Martin Shkreli or to the tropical disease voucher program. For example, one of the original forms of Regulatory IP was created for approval of new chemical entities.¹⁴⁸ The legislative language refers to the introduction of entities whose active ingredients have not been approved by the FDA and references the original Food & Drug Act. As a result, drugs whose active ingredients have been used in medication since before that time can be introduced as “new” chemical entities, thereby receiving the benefits.

Other forms of Regulatory IP have emerged either through Congressional legislation or FDA mandate.

2. Unapproved Drugs

In a form of amnesty proposal, the FDA launched an initiative to encourage those who make old drugs--those that have been sold since before implementation of Congress implemented the current FDA drug approval process—to come in from the cold.¹⁴⁹ At least one company working with FDA under the Unapproved Drug Initiative, was able to garner significant

¹⁴⁸ See text accompanying notes 47-50.
¹⁴⁹ See CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 12.
exclusivities and market advantage. Specifically, the maker of an old gout remedy, colchicine, received three years of Data rights for new clinical studies that consisted, in part, of one week of testing 185 patients at a reduced dosage. The reduced dosage had been recommended by one of the major rheumatology societies as well as in a study published by researchers twenty years before.

In addition to benefits for “new” clinical studies, the company also received seven years of Marketing rights as an orphan drug indication for the treatment of a familial Mediterranean fever. As described above, drugs do not need to be new in order to receive benefits for an orphan drug indication, and coming in from the cold allowed the company to benefit from that provision, as well. As a final happy circumstance for the company, the FDA announced its intention to act against other unapproved makers of the product. As the sole remaining provider, the company raised its price from $.09 a pill to $4.85 per pill. Scholars projected that with the price increase, Medicare and Medicaid spending alone would rise from $1 million a year on the drug to $50 million a year.

151 See id.
152 See id.
154 See CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 12.
155 See Kesselheim & Solomon, supra note 150.
The FDA’s Unapproved Drugs initiative does not create its own form of Regulatory IP, but the agency can use the program in ways that are quite helpful for applicants in gaining rights. In short, coming in from the cold can prove quite warm and lovely, indeed.

3. Proposals (Abuse-Deterrent Opioids, Combination Therapies; Dormant Therapies; Diagnostic tests)

As Regulatory IP becomes increasingly popular, numerous new forms are being proposed by legislators. The most recent bill relates to abuse-deterrent opioids and is called the COMBAT Act. Following the “just add more” pattern, the bill would add one year to the 3-year Data rights for new clinical studies for abuse-deterrent opioids. It would also add two months to the Marketing rights for first filing generic drugs that are abuse-deterrent opioids, increasing that benefit from six months to eight months.

Other bills have appeared recently in Congress without passage, although they could be resurrected in the future. These have included the Life-Threatening Diseases Compassion Through Combination Therapy Act of 2012, which would have extended by six months, any Regulatory IP granted to the company for the drug.

Taking a different approach, the MODDERN Cures Act, which stands for the Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act, would shift the emphasis for pharmaceutical companies away from the patent system and toward Regulatory

157 See id.
The bill, which has been reintroduced in various forms since 2011, would provide fifteen years of Marketing rights for certain drugs. Companies could opt into the system, but would have to relinquish patent rights that extend past the fifteen years. Criticisms of the proposal include concerns that a company would only have to relinquish prior patent rights, not patents granted after FDA approval. This would allow for continuation of life-cycle management techniques in which companies file for patents on new uses, methods of manufacture, and variations of a drug in order to extend the time in which the drug is protected by patents.

Finally, one commentator has suggested that legislators in 2016 will consider a bill to grant Regulatory IP for diagnostic tests. In addition to legislative proposals, scholars have advanced numerous proposals to create various forms of Regulatory IP for aspects of the

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160 See CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 13; see also Emily Morris, Patent Exclusivity Versus Regulatory Exclusivity Under the Hatch-Waxman Act, 34-35.
162 See CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 13.
163 See id.
165 See, e.g., FELDMAN, supra 128, at 170-177 (describing ever-greening techniques); C. Scott Hemphill & Bhaven N. Sampat, Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals, 31 J. HEALTH ECON. 327, 336 (2012) (testing evergreening theories through data on generic entry and finding that lower quality later expiring patents disproportionately draw patent challenges).
166 See Hoffmeister, et. al., supra note 40.
pharmaceutical industry. These have included ones for new uses of existing drugs,\footnote{167} product safety testing after FDA approval,\footnote{168} human gene sequences,\footnote{169} ideas described in academic research papers,\footnote{170} as well as doubling the length of all Hatch-Waxman data and marketing rights to achieve ten to fourteen years of protection.\footnote{171}

In short, numerous forms of Regulatory IP have been created over the last 30 years. Moreover, members of Congress and the FDA increasingly reach for Regulatory IP as a solution to various problems.

As society creates this complex web of regulatory benefits, it is important to analyze where the costs fall and whether we have confidence that the programs are sufficiently operating in the service of the intended goals. Approaching these questions, however, requires understanding how all of these various benefits interact with each other as they are linked together like the complex disease processes society hopes to treat.\footnote{172} Only by conceptualizing

\footnote{171} See Benjamin N. Roin, Unpatentable Drugs and the Standards of Patentability, 87 TEX. L. REV. 503, 564-568 (2009).
\footnote{172} In 2012, the FDA established an Exclusivity Board to engage in oversight and recommendations in the interests of clarity and consistency, particularly for individual decisions. See http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm323412.htm. The Board appears to have been established in response to industry concerns about a denial of benefits in a particular case. See http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/11/new-cder-exclusivity-board-focuses-on-clarity-and-consistency-of-exclusivity-decisions.html. Thus, the Board appears
the entire group as a single, interrelated organism can we hope to analyze and evaluate the cost, impact, and effectiveness of the Regulatory IP society continually grants.

Section III: Concepts for a Unified Whole

As outlined in the section above, society has created the system of Regulatory IP by accretion. Rather than having a coherent conceptual plan, Congress has added individual pieces here and there across time, often in conjunction with legislation that was difficult for the pharmaceutical industry to swallow. The result is a tangled beast that is at various points quasi-patent, quasi-trade secret, and quasi-property.

What can be made of the strange nature of Regulatory IP? Does its variable form provide a more efficient method of surgically targeting the evolving problems of incentivizing life science innovation? Or does its variability simply enhance the negative externalities created by the system, whether those externalities are 1) economic loss from the transaction costs of an enormously complex system; 2) loss of oversight by legislators, competition authorities, and the public due to the systems opacity; 3) leakage within the system as its complexity allows market actors to maneuver a way that undermines society’s intended goals?

more likely to be focused on consistency in granting benefits, rather than having a mandate to ask why the exclusivities exist in their current forms.

\[173\] Cf. Morris, supra note 160, at 22 (noting that FDA expertise can tailor exclusivities in a way that can never be achieved in the one-size-fits-all patent system); CONGRESSIONAL RESEARCH SYSTEM, supra note 28, at 15 (noting that international agreements related to patents such as TRIPS require neutrality with respect to the patent system while exclusivities give Congress more flexibility for stimulating particular forms of private activity).
Mismatch between society’s intended goals and the results of the system could occur in multiple forms, and the problems can be far more subtle than simple failure to incentivize new drugs or treatments. In some circumstances, society may be receiving value through the program, but that value may be insufficient for the benefit conferred. For example, a company may receive an exceedingly valuable right in exchange for a minor improvement on existing treatments or the return to a company for an innovative advance may, nonetheless, be far greater than Congress contemplated. Even if the return is appropriate to the cost society is paying, that cost may be beyond our societal capacity. Your family would be far safer if you drove them in a Sherman tank, for example, but the cost may not fit comfortably within the household budget.

In other circumstances, the costs of the new drug may be born, not by the patients who use the drug, but by the patients who use an entirely different drug. In other words, there can be an unintended taxation of people with one type of disease for the benefit of people with another type of disease. For example, when a company treating a rare form of cancer transfers a tradeable right to a company treating Alzheimer’s disease, the Alzheimer’s company is likely to raise its drug price to compensate for buying the voucher. Thus, the Alzheimer’s patients are partly bearing the costs of creating a drug for cancer. In addition, the value of blocking competition for a broad market like Alzheimer’s may be quite great, resulting in a super high price for the tradeable voucher such that the return to the cancer drug company that far exceeds the value added for the cancer patients. In that case, one has unintended taxation of

\[\text{\textsuperscript{174} Cf. Reichman, supra note 10, at 43 (expressing concern that exclusivities granted for new clinical trials merely generate improvements upon existing technical know-how without adding a new inventive step to prior art).}\]
the hypothetical Alzheimer drug patients combined with a benefit for the cancer company that exceeds the value created for society.

In other circumstances, society may have intended to incentive exploration into new drugs, with all of the spillover benefits that may occur for other diseases when new compounds are discovered. Instead, the program incentivized repurposing of existing or extremely old drugs.

Finally, in some circumstances, a program may be too successful. Society could get the innovation it hoped for in a specialized area of health concern. Nevertheless, the cost could be diversion of energy from other health concerns to an extent far greater than anticipated or desired. Society would be unlikely to approve a diversion of all health care research into a single area, for example cancer treatment, yet the various programs may, in concert, have that effect.

In exploring valuation problems with Regulatory IP, the problem is not with the value of each cause. Drugs for anti-biotic resistant bacteria, cancer treatments, and abuse-deterrent opioids are of great value to society. The problem arises when there is a mismatch of the value created with the costs and effectiveness of the various programs. The challenge for analyzing Regulatory IP in this manner, involves obtaining a clear picture of the costs.

All of the questions and potential problems outlined above deserve empirical and theoretical exploration; recognizing the system as an interconnected whole, however, is a prerequisite for those explorations. Most important, without a coherent theoretical framework, one cannot intelligently shape the development of the system and test its success. The remainder of this section provides a general theoretical framework for Regulatory IP and suggests benchmarks to use in establishing and evaluating it. Such benchmarks should include
1) minimizing overlap with other forms of intellectual property; 2) ensuring that the system is capable of stimulating results, and that those results are desirable; and 3) ensuring that there is a metric for measuring outcomes in relationship to goals.

In general, the goal of Regulatory IP can be described as promoting the development of safe and effective life science treatments. Framing the goal in this manner explains, as well as dictates, various aspects of the design. In particular, the goal of safety and efficacy carries with it the need for certain types of value judgments that differ from other forms of Intellectual Property. Compare Regulatory IP with its cousins patent and trade secret. The patent system does not care about how safe a drug is or how effective it is, only that its workings are different from what has come before and that there is some utility. The focus is on new, not on better or safer, and there is little awareness of the type of societal value judgments inherent in safety and efficacy.\(^{175}\)

In fact, the pursuit of safety and efficacy values things that are the antithesis of newness. For example, a safety regime relies on the continued evaluation of patent experiences and adverse events in the life of the drug. Rather than simply pressing for new drugs and new treatments, safety considerations place value on more experience with and information about existing treatments.

Trade secret similarly lacks any focus on safety and efficacy. A trade secret must have value to be protected, but that value is contemplated in reference to conferring an advantage in the marketplace. One might hope that in a rational market, safety and efficacy would win

\(^{175}\) Courts have, on occasion in the distant past, denied patentability on the grounds that the invention was not “useful” for reasons of morality. Modern courts, however, generally have avoided notions of morality in patentability decisions.
out, but that is not necessarily true. If it were, there would be no need for the approval capacity of the FDA. Moreover, trade secret law values numerous categories of secrets unrelated to safety or efficacy, such as customer lists, sales techniques, and marketing strategies. These vie for attention in building the theoretical construct that encompasses trade secret law.

Thus, the goals of Regulatory IP can be understood as both broader and narrower than those for patent and trade secret. The goals are broader in the sense that with Regulatory IP, the focus is on issues generally not contemplated in patent and trade secret laws. The goals are narrower in the sense that the development of safe and effective life science treatments is the sole focus, rather than any other marketplace advantage or any advancements unrelated to life sciences. This laser focus creates the potential for incentives that are far more particularized than Intellectual Property that must suit all types of innovation and serve all types of values.

Other value judgments lie embedded in the goal of safe and effective life science treatments. Medical treatment often involves tradeoffs that differ from other types of innovation. For example, the notion of safety is not an absolute value, and no treatment is 100% safe and effective for all patients in all circumstances. One must always determine what types of risks and side effects are acceptable to treat a particular disease state. This is not the quintessential patent or trade secret analysis.

An incentive structure keyed to safety and efficacy, along with real-time information and cost benefit analyses, must necessarily differ from the more familiar structures of other forms of intellectual property. To accommodate the agility required, such a system would need to be shorter, more flexible, and more targeted than patent and trade secret. And such is the general nature of Regulatory IP.
The greatest danger, however, lies where Regulatory IP overlaps with other intellectual property regimes, and it does so in the realm of innovation. Promoting the development of safe and effective treatments includes, of course, the notion of promoting development. Where the regimes rub shoulders against each other, there is a risk that each one’s goals and limitations will conflict with the other or that both will get lost in the shuffle. This concern is reflected in the Congressional Research Service’s observation that it makes little sense if, in the interests of promoting innovation, society denies patent rights to an invention that is too ordinary, society then grants similar protection in the context of drug testing. Different goals demand different types of incentive structures, not simply one tacked onto another.

Thus, regulatory IP should not be a matter of granting an extra goody here and there. “Patents plus” or “trade secrets plus” is not a good logic for the regime of Regulatory IP. Nor should it be a way to tinker at the margins with something that dissatisfies a particular party or a way of getting a back-door patent. The benefit makes most sense when tethered to the goals of the system and aimed at incentivizing activity for which other intellectual property regimes are fundamentally ill-suited. Thus, frameworks that look like just an extension of another regime without all of the requirements are more likely to be problematic. The goal should be as little overlap as possible.

Areas of overlap tend to create problems for intellectual property regimes, in general. They are a signal of unresolved difficulties, not a joyful combination or an intersection of ideals. One can think of them as analogous to “Rough Road Ahead” traffic signals. Consider patent and copyright protection for software; patent, copyright, and trademark protection for designs; and

176 See CONGRESSIONAL RESEARCH SERVICE, supra note 28, at 13.
the ill-fated Semiconductor Chip Protection Act, heralded with fanfare and then promptly ignored. Each of these marks an area of great and continued turmoil. Regulatory IP will be challenging as well. As difficult as navigating the boundary may be, however, success is critical if there is any hope of meeting the goals of each regime.

In addition to avoiding overlap with other intellectual property regimes, Regulatory IP should be evaluated in terms of whether the programs are capable of stimulating results and, most important, that those results are the ones we desire. Specifically, is society clear about its intended results, is the program stimulating those results, and is the program, nevertheless, creating intolerable externalities such that the program must be adjusted or abandoned? Consider, for example, the Regulatory IP granted for those who engage in pediatric studies. Creating incentives for companies to study the effects of medications in children has brought a wealth of important and sometimes unexpected knowledge about the effectiveness of treatments in that population. Nevertheless, scholars have questioned whether the rush to obtain this benefit has become a race-to-the-bottom in which commonly accepted scientific and ethical protocols are left in the dust.177

Any form of evaluation requires that there is some metric to examine in relationship to the goals. This means that the program itself should be able to articulate its aims in terms of metrics that can be repeatedly tested. It is not enough to articulate a general sense that additional benefits to particular types of actors will be good for particular health issues. Policy makers should identify both the result they intend and how they intend to measure progress.

177 See Cohen, supra note 116, at 661.
toward that result. A system designed to be shorter and more nimble than other areas of intellectual property is particularly appropriate for evaluative metrics.

Most important, no evaluative measures are possible without transparency. Information on a range of issues, from pricing to the percentage of a drug’s sales that are directed towards a desired usage,\(^\text{178}\) will be critical so that legislators and regulators can evaluate the effectiveness of programs on the ground.

The need for evaluation leads back, once again, to the notion that Regulatory IP must be conceptualized as a coherent whole. The appeal of understanding Regulatory IP as a unified system lies beyond the sublime beauty of logical consistency in theoretical constructs. From an instrumental perspective, understanding it as an integrated system is essential for evaluating the effectiveness of each of the programs individually and of the system as a whole. With these perspectives, society has an opportunity to think critically and cohesively about the new intellectual property that has spread its tendrils throughout health care innovation.

\(^\text{178}\) See Daniel, supra note 2, at 4 (suggesting that orphan drug act reforms will require disclosure of percentage of sales that are for orphan conditions as opposed to non-orphan conditions).
### Appendix A: Summary Chart of Regulatory IP Forms

<table>
<thead>
<tr>
<th>Historical Context</th>
<th>Right for...</th>
<th>Type of Right (Marketing, Data, Tradable)</th>
<th>Length of Right</th>
<th>Similar to... (Patent, Trade Secret, Property)</th>
<th>Can add to other regulatory rights</th>
<th>Longer than stated length**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1983 Hatch-Waxman Act &amp; 1984 Orphan Drug Act Amendments</td>
<td>First Generic Filers</td>
<td>Marketing</td>
<td>6 months</td>
<td>Patent</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>New Chemical Entities</td>
<td>Data</td>
<td>5 years or 4 years*</td>
<td>Trade Secret</td>
<td>Yes</td>
<td>Yes (1-2 years)</td>
</tr>
<tr>
<td></td>
<td>New Clinical Studies</td>
<td>Data</td>
<td>3 years</td>
<td>Trade Secret</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Orphan Drugs</td>
<td>Marketing</td>
<td>7 years</td>
<td>Patent</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2011 America Invents Act &amp; Biologics Act</td>
<td>First Biosimilar Filers</td>
<td>None</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>First Interchangeable Filers</td>
<td>Data</td>
<td>&gt;12 months</td>
<td>Trade Secret</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Original Biologic Drug Makers</td>
<td>Marketing***</td>
<td>4 years</td>
<td>Patent</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Original Biologic Drug Makers</td>
<td>Data</td>
<td>12 years</td>
<td>Trade Secret</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>QDIP New Chemical Entities</td>
<td>Data</td>
<td>+5 years (total 9 or 10 years)</td>
<td>Trade Secret</td>
<td>Yes</td>
<td>Yes (1-2 years)</td>
</tr>
<tr>
<td></td>
<td>QDIP New Clinical Studies</td>
<td>Data</td>
<td>+5 years (total 8 years)</td>
<td>Trade Secret</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>QDIP Orphan Drugs</td>
<td>Marketing</td>
<td>+5 years (total 12 years)</td>
<td>Patent</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Pediatric Studies</td>
<td>Marketing, Data</td>
<td>6 months</td>
<td>Patent, Trade Secret, Property</td>
<td>Yes</td>
<td>Depends****</td>
</tr>
<tr>
<td></td>
<td>Rare Pediatric Diseases</td>
<td>Tradable (priority review voucher)</td>
<td>FDA review within 6 months</td>
<td>Property</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>2007 FDA Amendment Acts</td>
<td>Tropical Diseases</td>
<td>Tradable (priority review voucher)</td>
<td>FDA review within 6 months</td>
<td>Property</td>
<td>Yes</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Length is shortened to 4 years if a generic hopeful files for FDA approval certifying its intent to challenge the patent on the drug as invalid or not properly applied to the drug

**FDA is not permitted to begin considering a generic hopeful until the right expires, so time until a generic enters is longer

*** Designated as a marketing right in this chart because no follow-on company may apply

**** Extension is added to prior regulatory right, so depends on nature of prior right