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# Drug Pricing and Pharmaceutical Patenting Practices

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## Drug Pricing and Pharmaceutical Patenting Practices

Intellectual property (IP) rights in pharmaceuticals are typically justified as necessary to allow manufacturers to recoup their substantial investments in research, development, and regulatory approval. IP law provides exclusive rights in a particular invention or product for a certain time period, potentially enabling the rights holder (e.g., a brand-name drug manufacturer) to charge higher-than-competitive prices. If rights holders are able to charge such prices, they have an incentive to lengthen the period of exclusive rights as much as possible. Indeed, some commentators allege that pharmaceutical manufacturers have engaged in patenting practices that unduly extend the period of exclusivity. These critics argue that these patenting practices are used to keep drug prices high, without any benefit for consumers or innovation. Criticisms center on four such practices:

- **“Evergreening”**: So-called patent “evergreening” is the practice of filing for new patents on secondary features of a particular product as earlier patents expire, thereby extending patent exclusivity past the original twenty-year term. Later-filed patents may delay or prevent entry by competitors, thereby allowing the brand-name drug manufacturer (the brand) to continue charging high prices.
- **“Product Hopping”**: Generic drug manufacturers allege that as patents on a particular product expire, brand manufacturers may attempt to introduce and switch the market to a new, similar product covered by a later-expiring patent—a process known as “product hopping” or “product switching.” This practice takes two forms: a “hard switch,” where the older product is removed from the market, and a “soft switch,” where the older product is kept on the market with the new product. In either case, the brand will focus its marketing on the new product in order to limit the market for any generic versions of the old product.
- **“Patent Thickets”**: Generic and biosimilar companies also allege that the brands create “patent thickets” by filing numerous patents on the same product. These thickets allegedly prevent generics from entering the market due to the risk of infringement and the high cost of patent litigation.
- **“Pay-for-Delay” Settlements**: Litigation often results when a generic or biosimilar manufacturer attempts to enter the market with a less expensive version of a branded pharmaceutical. Core issues usually include whether the brand’s patents are valid, and whether the generic or biosimilar product infringes those patents. Rather than litigate these issues to judgment, however, the parties will often settle. Such settlements may involve the brand paying the generic or biosimilar to stay out of the market—referred to as “reverse payment” or “pay-for-delay” settlements. These settlements are allegedly anticompetitive because they allow the brand to continue to charge high prices without risking invalidation of its patent, thus unjustifiably benefiting the settling companies at the expense of the consumer.

Drug manufacturers respond that their patenting practices protect new, innovative inventions, as Congress intended when it created the patent system. In their view, the terms for these practices are unfairly pejorative, or, at most, describe outlier behavior by a few companies. Defenders of these patenting practices reject their characterization as anticompetitive and emphasize that strong patent rights are needed to encourage innovation and life-saving research and development efforts.

In recent years, some commentators and Members of Congress have proposed patent reforms that seek to limit or curtail these patenting practices, which some perceive as contributing to high prices for pharmaceutical products. Such proposals aim, for example, to reduce the impact of later-filed patents (e.g., TERM Act of 2019, H.R. 3199, and REMEDY Act, S. 1209/H.R. 3812); to encourage challenges to pharmaceutical patents (e.g., Second Look at Drugs Patents Act of 2019, S. 1617); to make product hopping an antitrust violation in certain circumstances (e.g., Affordable Prescriptions for Patients Act of 2019, S. 1416); to facilitate generic market entry (e.g., Orange Book Transparency Act of 2019, H.R. 1503); to increase transparency as to the patents that cover biological products (e.g., Purple Book Continuity Act of 2019, H.R. 1520, and Biologic Patent Transparency Act, S. 659); and to reform pay-for-delay settlements (e.g., Preserve Access to Affordable Generics and Biosimilars Act, S. 64/H.R. 2375).

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One of the basic rationales underlying the grant of patent rights is that such rights provide an incentive for inventors to innovate.<sup>1</sup> Part of the bargain, however, is that those rights will expire after a defined time period. This principle appears in the U.S. Constitution, which empowers Congress “[t]o 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.”<sup>2</sup> Congress has also enacted this principle into law: a patent on a new invention will generally expire twenty years after the corresponding patent application was filed.<sup>3</sup>

Intellectual property (IP) rights, including patent rights, are generally considered to play an essential role in encouraging the research and development (R&D) necessary to create new pharmaceutical products.<sup>4</sup> Because these periods of exclusivity can allow the patent holder, such as a drug manufacturer, to charge higher-than-competitive prices,<sup>5</sup> the patent holder has an incentive to prolong the period of exclusivity, such as by filing for additional patents to cover a product.<sup>6</sup> In the pharmaceutical context, critics argue that some brand-name drug and biological product manufacturers (the brands) use patenting strategies to “game[] the patent system” to maximize profits and forestall competition from generic drug or biosimilar manufacturers (the generics).<sup>7</sup> Others reject this charge, contending that these practices are a legitimate use of the patent system and are necessary to incentivize the billions of dollars in R&D that lead to new, life-saving drugs.<sup>8</sup>

This report discusses four pharmaceutical patenting practices commentators have criticized:

- **“Evergreening”:** Commentators allege that some pharmaceutical companies obtain new patents to cover a product as older patents expire to extend the period of exclusivity without significant benefits for consumers.<sup>9</sup>

<sup>1</sup> See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) (“The patent laws promote [the progress of the useful arts] by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development.”).

<sup>2</sup> U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

<sup>3</sup> 35 U.S.C. § 154(a)(2).

<sup>4</sup> Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFF. 302, 302 (2015) (“Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals.”).

<sup>5</sup> See WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 299-300 (2003); *FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013) (“[Patent rights] may permit the patent owner to charge a higher-than-competitive price for the patented product.”). In this report, we use the term “period of exclusivity” to refer to the period during which a particular product is covered by a patent or regulatory exclusivity right.

<sup>6</sup> See *infra* “Pharmaceutical Patenting Practices.”

<sup>7</sup> Press Release, Office of Sen. Dick Durbin, Durbin, Cassidy Introduce REMEDY Act To Lower Drug Prices By Curbing Patent Manipulation, Promoting Generic Competition (Apr. 11, 2019), <https://www.durbin.senate.gov/newsroom/press-releases/durbin-cassidy-introduce-remedy-act-to-lower-drug-prices-by-curbing-patent-manipulation-promoting-generic-competition> (“Americans are facing skyrocketing prescription drug costs in part because brand-name pharma manufacturers have gamed the patent system to extend their monopolies and avoid competition from lower-cost generic drugs.”) (quoting Sen. Durbin); Press Release, Office of Sen. John Cornyn, Cornyn, Blumenthal Introduce Bill to Prevent Drug Companies from Abusing Patent System (May 9, 2019), <https://www.cornyn.senate.gov/content/news/cornyn-blumenthal-introduce-bill-prevent-drug-companies-abusing-patent-system> (“Drug companies have taken advantage of the patent system to maintain their monopoly on certain drugs and prevent generics from coming to market.”) (quoting Sen. Cornyn).

<sup>8</sup> See, e.g., *infra* notes 157-179 and accompanying text.

<sup>9</sup> Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 354 (2007); Julian W. Marrs, *Forever Green? An Examination of Pharmaceutical Patent Extensions*, 18 OR. REV. INT’L L. 81, 83-89 (2016); Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63

- **“Product Hopping”**: Commentators also contend that as patents on a product expire, pharmaceutical companies will attempt to switch the market to a slightly different product covered by a later-expiring patent, “hopping” from one product to the next.<sup>10</sup>
- **“Patent Thickets”**: Commentators further argue that pharmaceutical companies have allegedly surrounded their products with many overlapping patents on a single product.<sup>11</sup> Critics allege that these patent “thickets” may deter potential competitors even if the patents are weak or invalid, due to the time, expense, and uncertainty of challenging a significant number of patents.<sup>12</sup>
- **“Pay-for-Delay” Settlements**: Brand and generic pharmaceutical companies will often settle litigation that results when a generic seeks to enter the market to compete with the patented branded product.<sup>13</sup> Certain settlement agreements involve the transfer of value from the brand to the generic in return for the generic delaying its market entry.<sup>14</sup> Such “pay-for-delay” or “reverse payment” settlements are characterized as anticompetitive because they may delay the entry of cheaper generic drugs into the market, thereby allowing the brand to maintain its exclusivity period on a patent that otherwise may have been invalidated, to the benefit of the settling companies but at the expense of consumers.<sup>15</sup>

These practices take place against a backdrop of a broader public policy debate over drug pricing. The Department of Health and Human Services (HHS) has found that national spending on pharmaceutical products has risen in recent years and predicted that these expenditures will continue to rise faster than overall healthcare spending.<sup>16</sup> Commentators acknowledge that factors

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FOOD & DRUG L.J. 275, 276 (2008). Although the literature is not entirely consistent regarding the definition of “evergreening,” sometimes equating it with other patenting practices, *see, e.g.*, Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 171 (2016) (equating evergreening with “product hopping”), this report uses the term to refer to using later-filed patents to extend the length of a product’s effective protection.

<sup>10</sup> *See, e.g.*, Carrier & Shadowen, *supra* note 9, at 171-72.

<sup>11</sup> Cynthia Koons, *This Shield of Patents Protects the World’s Best-Selling Drug*, BLOOMBERG BUSINESSWEEK (Sept. 7, 2017), <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug> (using “patent thicket” to refer to large patent portfolio amassed on one product by single biologics manufacturer); *see also* America’s Overspend: *How the Pharmaceutical Patent Problem is Fueling High Drug Prices*, I-MAK 4 (Oct. 2017), [https://www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL\\_-2017-10-24.pdf](https://www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf) [hereinafter *America’s Overspend*] (using “thicket of patents” to refer to large patent portfolio claiming aspects of a single drug); Robin Feldman, *“One-and-Done” for New Drugs Could Cut Patent Thickets and Boost Generic Competition*, STAT (Feb. 11, 2019), <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (“[D]rug companies build massive patent walls around their products, extending the protection over and over again.”).

<sup>12</sup> *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America’s Patients*, BIOSIMILARS COUNCIL 8 (June 2019), <https://www.biosimilarscouncil.org/wp-content/uploads/2019/06/Biosimilars-Council-White-Paper-Failure-to-Launch-June-2019.pdf> [hereinafter *Failure to Launch*] (estimating that it would cost \$3 million per patent to challenge the patent thicket surrounding Humira).

<sup>13</sup> Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1014 (2010) (stating that the 180-day exclusivity period “has resulted in numerous settlements between brand firms and first-filing generic companies”).

<sup>14</sup> Erik Hovenkamp, *Antitrust Law and Settlement Design*, 32 HARV. J.L. & TECH. 417, 434 (2019) (“[T]he brand-name firm agrees to give a ‘reverse payment’ (conventionally a cash lump sum) to the generic firm. In exchange, the latter agrees to terminate its challenge and delay its entry into the market for some number of years, often until soon before the patent expires.” (footnote omitted)).

<sup>15</sup> *See id.*

<sup>16</sup> CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*, by Suzanne M.

other than IP rights contribute to the price consumers pay for prescription drugs and biological products (biologics), including consumer demand, manufacturing costs, R&D costs, the terms and structure of private health insurance, and the involvement of government insurance programs such as Medicaid.<sup>17</sup> Nevertheless, pharmaceutical products are often protected by IP rights.<sup>18</sup> Some studies have shown that IP rights are among the most important factors driving high drug prices.<sup>19</sup>

As these pharmaceutical patenting practices may affect drug prices, they have attracted congressional interest. Several legislative proposals seek to curtail these patenting practices by reducing their effectiveness or outlawing them entirely.<sup>20</sup> Proponents see such legislation as a potential way to lower pharmaceutical prices.<sup>21</sup>

This report explains these allegedly anticompetitive patenting practices and reviews a number of proposals to reform them. First, this report provides a brief legal background, including the basics of Food and Drug Administration (FDA) law, patent law, antitrust law, and the interaction between patent rights and FDA approval of pharmaceutical products. This report next overviews the patenting practices that some pharmaceutical companies have allegedly used to extend their effective periods of patent protection. Finally, this report details a number of proposals aimed at reforming or limiting such practices.

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Kirchhoff, Judith A. Johnson, and Susan Thaul, at 3-6.

<sup>17</sup> See generally DEP'T OF HEALTH & HUMAN SERVS., OBSERVATIONS ON TRENDS IN PRESCRIPTION DRUG SPENDING 1 (Mar. 8, 2016), <https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf>; see also Kirchhoff et al., *supra* note 16, at 3-13; Joseph Antos & James C. Capretta, *Prescription Drug Pricing: An Overview of the Legal, Regulatory and Market Environment*, AM. ENTER. INST. 4-12 (2018), <https://www.aei.org/wp-content/uploads/2018/07/Prescription-Drug-Pricing.pdf>; Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA: J. AM. MED. ASS'N 858, 860-63 (2016).

<sup>18</sup> See, e.g., LANDES & POSNER, *supra* note 5, at 313 (citing data that new drug manufacturers are unusually “avid in seeking patent protection”); Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 252 (2012) (“[P]harmaceuticals are also widely recognized as one of the industries most dependent on patent protection to recoup its enormous research, development, regulatory, and post-marketing costs.”); Adi Gillat, *Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry*, 58 FOOD & DRUG L.J. 711, 722 (2003) (reviewing data “supporting relatively high dependency of the pharmaceutical industry on patent rights”).

<sup>19</sup> See, e.g., Kesselheim et al., *supra* note 17, at 861 (“The most important factor that allows manufacturers to set high drug prices for brand-name drugs is market exclusivity, which arises from 2 forms of legal protection against competition [i.e., regulatory exclusivities and patent rights.]”); *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN. (Nov. 28, 2017), <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm> (finding association between generic competition and lower drug prices); see also *America's Overspend*, *supra* note 11, at 1 (arguing that patenting strategies caused \$55 billion in excess costs for the American health care system with respect to just three drugs).

<sup>20</sup> See *infra* “Selected Proposals for Addressing Pharmaceutical Patenting Practices.”

<sup>21</sup> See, e.g., Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 499, 556-61 (2016) (urging “comprehensive overhaul” of pharmaceutical patent laws to curtail strategies allegedly used by pharmaceutical companies to avoid competition and maintain monopoly pricing); Kesselheim et al., *supra* note 17, at 864 (proposing limits on secondary patents and increased policing of pay-for-delay patent settlements as possible means to curtail high drug prices).

## Legal Background

### FDA Regulation of Pharmaceutical Products

FDA must approve new drugs and biologics prior to their marketing in interstate commerce.<sup>22</sup> The FDA regulatory processes for drugs and biologics are similar, broadly speaking, but also distinct in certain aspects.

### New and Generic Drug Approval

FDA approves new drugs through the new drug application (NDA) process. To obtain approval, the manufacturer must submit an NDA that demonstrates, among other things, that the drug is safe and effective for its intended use.<sup>23</sup> The manufacturer must provide to FDA clinical data establishing the new drug's safety and effectiveness.<sup>24</sup> The studies necessary to establish safety and efficacy are often expensive and lengthy; in 2015 to 2016, the median cost of a single clinical trial was \$19 million, and in one instance was \$347 million.<sup>25</sup> The average cost to develop a new drug has been generally estimated to be between \$1 billion to \$3 billion,<sup>26</sup> and the average time for FDA approval is over twelve years.<sup>27</sup>

To encourage competition and lower drug prices through generic drug entry, the Hatch-Waxman Act of 1984 (Hatch-Waxman) created a streamlined approval process for generic drugs.<sup>28</sup> Rather than file an NDA, Hatch-Waxman allows generics to file an abbreviated new drug application (ANDA) that relies on FDA's prior approval of another drug with the same active ingredient (the "reference listed drug" or RLD) to establish that the generic drug is safe and effective.<sup>29</sup> The

<sup>22</sup> See generally Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FOOD & DRUG ADMIN. (1981), <https://www.fda.gov/downloads/aboutfda/history/forghistory/evolvingpowers/ucm593437.pdf>; 21 U.S.C. § 355(a); 42 U.S.C. § 262(a)(1).

<sup>23</sup> 21 U.S.C. § 355(d).

<sup>24</sup> FOOD & DRUG ADMIN., DEVELOPMENT & APPROVAL PROCESS (DRUGS), <https://www.fda.gov/drugs/development-approval-process-drugs> (last visited Sept. 8, 2019).

<sup>25</sup> Thomas J. Moore et al., *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, 178 JAMA INTERNAL MEDICINE 1451, 1451, 1454 (2018) (study of 138 clinical trials finding a median estimated cost of \$19 million per trial, with \$346.8 million as the highest estimated cost in the sample; the middle half of trials ranged in cost from \$12 million to \$33 million).

<sup>26</sup> See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. OF HEALTH ECON. 20, (2016) (studying estimating \$2.6 billion in 2013 dollars as the average total R&D costs for new drug development). Other studies have reached different estimates for average drug development costs, ranging from \$161 million to \$1.8 billion in 2009 dollars. See, e.g., Aaron E. Carroll, *\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES (Nov. 18, 2014), <https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html> ("In 2010, a systematic review of studies that looked at the cost of drug development was published in Health Policy. The review found 13 articles, with estimates ranging from \$161 million to \$1.8 billion (in 2009 dollars)."); see generally Kirchhoff et al., *supra* note 16, at 23-24 (reviewing different estimates and noting that "estimates for new drug development range from \$1.2 billion to \$2.6 billion and are highly sensitive to such factors as assumptions about development time; cost of capital; and [other factors].").

<sup>27</sup> Daniel Gervais, *The Patent Option*, 20 N.C. J.L. & TECH. 357, 395 (2019).

<sup>28</sup> Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, § 101, 98 Stat. 1585 (1984) (the Hatch-Waxman Act).

<sup>29</sup> 21 C.F.R. §§ 314.92, 314.94.

generic may thus forgo conducting lengthy and expensive clinical trials by instead demonstrating that the generic drug is pharmaceutically equivalent and bioequivalent to the RLD.<sup>30</sup>

## Biological Products and Biosimilar Licensure

Like drugs, biologics are products intended for use in the prevention and treatment of human disease.<sup>31</sup> Biologics are distinct from drugs, however, in that they are derived from biological material, such as a virus or blood component.<sup>32</sup> Biological products “are generally large, complex molecules” that “may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell.”<sup>33</sup>

A biologic may only be marketed in the United States after its manufacturer submits and FDA approves a biologics license application (BLA).<sup>34</sup> To approve a BLA, FDA must determine that the biologic is “safe, pure, and potent,” and that the production and distribution process “meets standards designed to assure that the biological product continues to be safe, pure, and potent.”<sup>35</sup>

Like Hatch-Waxman, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) sets out an abbreviated approval process to encourage early market entry of biologics that are sufficiently similar to an already approved biological product (the “reference product”).<sup>36</sup> A biological product is sufficiently similar to an approved biologic if it is “biosimilar” to (or interchangeable with) the reference product.<sup>37</sup> To show biosimilarity, the manufacturer must submit, among other things, data demonstrating that its product is “highly similar to the reference product notwithstanding minor differences in clinically inactive components” with no “clinically meaningful differences” between the two products “in terms of the safety, purity, and potency of the product.”<sup>38</sup>

To balance the interest in competition—which the abbreviated approval pathways aim to encourage—with the countervailing interest in encouraging innovation, federal law also establishes periods of regulatory exclusivity that limit FDA’s ability to approve generic drugs and biosimilars under certain circumstances.<sup>39</sup> These exclusivities generally aim to encourage new

<sup>30</sup> 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. §§ 314.94, 320.21. Drugs are pharmaceutically equivalent if they have the same active ingredient(s), strength, dosage form, and route of administration. 21 C.F.R. § 314.3. Other elements that do not affect safety or effectiveness, such as the drug’s inactive ingredients, may be different. *Id.* Bioequivalence means the drugs work the same way inside the body; that is, there is no significant difference in the rate at which and the extent to which the drug’s active ingredient reaches the place in the body where the drug is active, when administered at the same dose and under similar conditions. *Id.* § 320.1(e).

<sup>31</sup> See generally CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*, by Agata Dabrowska.

<sup>32</sup> 42 U.S.C. § 262(i); 21 C.F.R. § 600.3.

<sup>33</sup> U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS, <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM581282.pdf> (last visited Sept. 8, 2019).

<sup>34</sup> 42 U.S.C. § 262(a)(1); 21 C.F.R. § 601.2(a).

<sup>35</sup> 42 U.S.C. § 262(a)(2)(C); 21 C.F.R. § 600.3(p), (r)-(s).

<sup>36</sup> Pub. L. No. 111-148, Title VII, 124 Stat. 199, 804-21 (2010); 42 U.S.C. § 262(k).

<sup>37</sup> 42 U.S.C. § 262(k).

<sup>38</sup> *Id.* § 262(i)(2). To be “interchangeable,” the biologic must be biosimilar to a reference product, “expected to produce the same clinical result as the reference product in any given patient,” and, “for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.” *Id.* § 262(k)(4)(A)-(B).

<sup>39</sup> See, e.g., *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (“Congress attempted to balance the goal of ‘mak[ing] available more low cost generic drugs,’ with the value of patent



drug or biologic applicants to undertake the expense of generating clinical data and other information needed to support an NDA or BLA.<sup>40</sup> Other exclusivities are designed to encourage generic or biosimilar (follow-on product) manufacturers to submit abbreviated applications as soon as permissible.<sup>41</sup>

## Patent Law

Patents, which are available for a wide variety of technologies beyond pharmaceuticals,<sup>42</sup> grant the patent holder the right to exclude others from making, using, selling, or importing a patented invention within the United States for a defined term of years.<sup>43</sup> A person who makes, uses, sells, or imports a patented invention without permission from the patent holder during this period infringes the patent and is potentially liable for monetary damages and subject to other legal remedies.<sup>44</sup>

Patents are generally justified on the basis that temporary exclusive rights are necessary to provide incentives for inventors to create new and useful technological innovations.<sup>45</sup> This rationale maintains that absent legal protections, competitors could freely copy inventions once marketed, denying the original creators the ability to recoup their investments in time and effort, and reducing the incentive to create in the first place.<sup>46</sup> Patent incentives are said to be particularly necessary for products like pharmaceuticals, which are costly to develop, but easily copied once marketed.<sup>47</sup>

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monopolies in incentivizing beneficial pharmaceutical advancement[.]” (citations omitted); Yaniv Heled, *Patents v. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. & TECH. L. REV. 419, 427-30, 434-36 (2012).

<sup>40</sup> Heled, *supra* note 39, at 427-30, 440.

<sup>41</sup> 21 U.S.C. § 355(j)(5)(B)(iii), (iv); 42 U.S.C. § 262(k)(6); *see also* Actavis v. FTC, 570 U.S. 136, 143-44 (2013); Heled, *supra* note 39, at 428-29.

<sup>42</sup> In general, a patent may be granted on any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101. However, “laws of nature, natural phenomena, and abstract ideas are not patentable.” *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)); *see generally* CRS Report R45918, *Patent-Eligible Subject Matter Reform in the 116th Congress*, by Kevin J. Hickey.

<sup>43</sup> 35 U.S.C. § 271(a).

<sup>44</sup> *Id.* §§ 271, 281, 284.

<sup>45</sup> *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) (“The patent laws promote [the progress of the useful arts] by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development.”); *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (describing intellectual property rights as premised on an “economic philosophy” that the “encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors”).

<sup>46</sup> *See Kewanee Oil*, 416 U.S. at 480.

<sup>47</sup> *See Grabowski et al.*, *supra* note 4, at 302 (“[T]he process of developing a new drug and bringing it to market is long, costly, and risky, and the costs of imitation are low. After a new drug has been approved and is being marketed, its patents protect it from competition from chemically identical entrants (or entrants infringing on other patents) for a period of time.”); LANDES & POSNER, *supra* note 5, at 24 (“If the fixed costs of intellectual property—the costs incurred before a single sale is made—are very high and . . . the costs of duplication are slight, then in the absence of intellectual property rights either the intellectual property will not be created or the government will have to finance it . . . .”); *id.* at 317 (“In the case of new drugs . . . the fixed costs of research and development are very high, in part because of stringent regulatory requirements, but the marginal costs [of imitators] are very low.”).

Because patents grant a temporary and limited “monopoly”<sup>48</sup> to the patent holder, they may lead to increased prices for goods or services that the patent covers.<sup>49</sup> The existence of a patent on a particular manufacturing process, for example, generally means that only the patent holder (and persons licensed by the patent holder) can use that patented process until the patent expires.<sup>50</sup> In some circumstances, this legal exclusivity may allow the patent holder (or her licensees) to charge higher-than-competitive prices for goods made with the patented process, as a monopolist would, because the patent effectively shields the patentee from competition.<sup>51</sup>

Patents are obtained by formally filing a patent application with the U.S. Patent and Trademark Office (PTO), initiating a process called patent prosecution.<sup>52</sup> A PTO patent examiner will evaluate the patent application to ensure it meets all the applicable legal requirements to merit the grant of a patent.<sup>53</sup> In addition to requirements regarding the technical disclosure of the invention,<sup>54</sup> the claimed invention must be (1) new, (2) useful, (3) nonobvious, and (4) directed to patentable subject matter.<sup>55</sup>

If the PTO issues (i.e., grants) a patent, its term typically expires twenty years from the patent application’s filing date.<sup>56</sup> This twenty-year term may be extended in certain circumstances. For example, the patent term may be adjusted to account for excessive delays in patent examination at the PTO.<sup>57</sup> In the pharmaceutical context, patents claiming a drug product or medical device (or a method of using or manufacturing the same) may be extended for up to five years to account for delays in obtaining regulatory approval from FDA, if certain statutory conditions are met.<sup>58</sup>

Patent rights are generally independent and distinct from the regulatory exclusivities administered by FDA. Patent rights granted by the PTO are based primarily on the technological novelty of the claimed invention, while regulatory exclusivities granted by FDA result from the completion of FDA’s regulatory process for particular pharmaceutical products meeting certain criteria.<sup>59</sup>

<sup>48</sup> See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730 (2002) (characterizing patents as a “temporary monopoly”); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 147 (1989) (characterizing patents as a “limited monopoly”). It should be noted that the use of the term “monopoly” is somewhat imprecise because the exclusive rights IP law provides do not necessarily confer monopolistic market power in the economic sense. For example, there may be noninfringing substitutes for a patented good in the relevant market. See LANDES & POSNER, *supra* note 5, at 22 (“Intellectual property protection creates a monopoly, in the literal sense in which a person has a monopoly in the house he owns but [only] occasionally in a meaningful economic sense as well because there may be no good substitutes for a particular intellectual work.”).

<sup>49</sup> See LANDES & POSNER, *supra* note 5, at 299-300; *FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013) (“[Patent rights] may permit the patent owner to charge a higher-than-competitive price for the patented product.”).

<sup>50</sup> 35 U.S.C. §§ 154(b), 271(a).

<sup>51</sup> *Actavis*, 570 U.S. at 147.

<sup>52</sup> See *General Information Concerning Patents*, U.S. PATENT & TRADEMARK OFFICE (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents>.

<sup>53</sup> 35 U.S.C. § 131.

<sup>54</sup> See *id.* § 112.

<sup>55</sup> See *id.* §§ 101-03. For a fuller discussion of these requirements, see CRS Report R45666, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress*, coordinated by Kevin J. Hickey, at 6-9.

<sup>56</sup> 35 U.S.C. § 154(a)(2).

<sup>57</sup> *Id.* § 154(b)(1).

<sup>58</sup> *Id.* § 156; *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670-71 (1990); *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1320-21 (Fed. Cir. 2007); Stephanie Plamondon Bair, *Adjustments, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense?*, 41 CAP. U. L. REV. 445, 460 (2013).

<sup>59</sup> See CRS In Focus IF11217, *Drug Pricing and the Law: Regulatory Exclusivities*, by Erin H. Ward.

Patents are not self-enforcing. That is, to obtain relief from infringement, the patent holder generally must sue the alleged infringer in court.<sup>60</sup> If such a lawsuit succeeds, the patent holder may obtain monetary damages<sup>61</sup> and, in certain cases, an injunction, which is a court order that prohibits the defendant from infringing the patent in the future.<sup>62</sup> Patents thus provide a *negative* right to prevent another person from practicing (i.e., making, using, selling, or importing) the claimed invention. Patents do not themselves, however, provide the patent holder any *affirmative* right to practice the invention.<sup>63</sup> In the pharmaceutical context, this principle means that even if a drug or biologic manufacturer has a patent on a particular product (or inventions related to making or using that product), it still cannot market that product without FDA approval.

## Types of Pharmaceutical Patents

If a person is the first to synthesize a particular chemical believed to be useful for the treatment of human disease, she may file for a patent on that chemical itself, and—presuming that the application meets all requirements for patentability—the PTO will grant the patent.<sup>64</sup> Patents on a pharmaceutical product’s active ingredient (sometimes called “primary patents”<sup>65</sup>) may be of particular value to the manufacturer because these patents are usually difficult to “invent around” (i.e., develop a competing product that does not infringe the patent).<sup>66</sup> However, primary patents are hardly the only patents that cover pharmaceuticals, and are not necessarily the most important to manufacturers as a practical matter.<sup>67</sup> Indeed, for biologics, if the active ingredient is naturally occurring, it may not be legally possible to patent an unaltered form of the biologic itself because it constitutes patent-ineligible subject matter.<sup>68</sup>

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<sup>60</sup> 35 U.S.C. § 281.

<sup>61</sup> *Id.* § 284.

<sup>62</sup> *Id.* § 283. Courts commonly grant injunctions to remedy patent infringement as justified by traditional equitable principles, but such injunctions are not automatically issued solely because the patent holder succeeds in proving infringement. *See eBay, Inc. v. MercExchange LLC*, 547 U.S. 388, 394 (2006).

<sup>63</sup> *Leatherman Tool Grp. v. Cooper Indus.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997) (“[T]he federal patent laws do not create any affirmative right to make, use, or sell anything.”).

<sup>64</sup> *See* 35 U.S.C. §§ 101 (allowing patents on “any new and useful . . . composition of matter”), 102-03, 112.

<sup>65</sup> *See, e.g.,* Marrs, *supra* note 9, at 82 (distinguishing between “primary patents, which protect an active ingredient directly” and “secondary patents” that “protect a range of chemicals related to an active ingredient, methods of use, alternate formulations, or dosages”). Patents on a device to administer a drug or biologic are sometimes called “tertiary patents” to distinguish these patents from other types of secondary patents. *See* Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug-Device Combination Products in the United States*, 36 NATURE BIOTECH. 142, 144 (2018).

<sup>66</sup> *See* Margaret K. Kyle, *Competition Law, Intellectual Property, and the Pharmaceutical Sector*, 81 ANTITRUST L.J. 1, 2 (2016) (“[A]t least one type of pharmaceutical patent, the product patent on the molecule itself, is particularly hard to invent around.”).

<sup>67</sup> *See id.* at 6 (“[T]he primary patent on the molecule is rarely the only one associated with a drug. Typically, the innovator (or others) files additional patent applications [that] may cover methods of manufacturing the chemical or biological substance, purified forms, new salts or esters, new uses of the substance, new combinations, new delivery routes, etc.”).

<sup>68</sup> *See generally* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580, 589-96 (2013) (discussing the “natural phenomena” category of patent-ineligible subject matter and holding that a “naturally occurring DNA segment is a product of nature and not patent eligible”); Priti Deka Phukan, *Patenting Proteins After Myriad*, 23 FED. CIR. B.J. 619, 621 (2014) (analyzing “whether synthetically produced biological compounds,” such as therapeutic proteins and hormones, are patentable “when the synthetic compound is indistinguishable from the naturally occurring compound”).

Pharmaceutical patents may cover many different features of a drug or biologic beyond a claim on the active ingredient itself.<sup>69</sup> Such “secondary patents” may claim, among other things

1. formulations of the drug or biologic (e.g., an administrable form or dosage);
2. methods of using the pharmaceutical (e.g., an indication or use for treating a particular disease);
3. methods of manufacturing the pharmaceutical product or manufacturing technologies used to make the pharmaceutical;
4. methods of administering the pharmaceutical or technologies used to administer the pharmaceutical; or
5. other chemicals related to the active ingredient, such as crystalline forms, polymorphs, intermediaries, salts, and metabolites.<sup>70</sup>

Like other inventions, for an inventor to receive a patent on any of these innovations, it must be new, useful, nonobvious, and sufficiently described in the patent application.<sup>71</sup>

In addition, if a person invents an *improvement* on any of these technologies—for example, a new formulation of the drug, a new use, a different manufacturing process, etc.—then the inventor can file for a patent on that improvement, which receives its own patent term.<sup>72</sup> Although the term “improvement patent” is traditionally used, it is a somewhat misleading phrase, as the new version need not be “better” to be patentable.<sup>73</sup> Rather, the improvement must simply be new and *nonobvious*—that is, “more than the predictable use of prior art<sup>74</sup> elements according to their established functions.”<sup>75</sup> Any person wishing to practice the improved form of the invention will need permission from both the holder of the patent on the original technology *and* the holder of the improvement patent (who need not be the same entity), if neither patent has yet expired.<sup>76</sup> If

<sup>69</sup> Studies have found that active ingredient patents are a minority of pharmaceutical patents. See Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONE 1, 4-6 (2012) (surveying patents listed in FDA’s *Orange Book* for new chemical entities and finding that secondary patents, such as formulations and methods of use, were more common than active ingredient patents); Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, 31 HEALTH AFF. 2286, 2289 (2012) (finding only about 1% of the 108 patents covering particular HIV drugs claimed the active ingredient, with around 39% claiming formulations and related chemicals, 32% claiming manufacturing processes, 15% claiming methods of treatment, and 13% claiming other aspects).

<sup>70</sup> See JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 46-64 (3d ed. 2015) (describing these and other categories of pharmaceutical patent claims).

<sup>71</sup> See 35 U.S.C. §§ 101-03, 112.

<sup>72</sup> *Id.* § 101 (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . .” (emphasis added)).

<sup>73</sup> Carrier & Shadowen, *supra* note 9, at 181 (“The granting of a patent by the [PTO] certainly does not guarantee, or even suggest, that the reformulated product is superior in any way to existing products. The PTO requires only that the product be ‘novel[.]’ and ‘nonobvious,’ not that it be an improvement [over existing technology].”); Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955, 960 (Fed. Cir. 1986) (“Finding that an invention is an ‘improvement’ is not a prerequisite to patentability. It is possible for an invention to be less effective than existing devices but nevertheless meet the statutory criteria for patentability.”).

<sup>74</sup> Prior art is any material that has been “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention,” or was described in a patent application that was later published and filed before the effective filing date of the claimed invention, 35 U.S.C. §§ 102(a), with certain exceptions, *see id.* § 102(b).

<sup>75</sup> KSR Int’l Co. v. Teleflex, Inc., 550 U.S. 398, 417 (2007).

<sup>76</sup> See Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 80-82 (1994) (analyzing “blocking patents” situation in which holder of improvement patent and

the original patent has expired but the improvement patent has not, patent law does not impede any person from making and using the original, unimproved version.<sup>77</sup>

## Patent Dispute Procedures for Generic Drugs and Biosimilars

Federal law contains specialized procedures for certain pharmaceutical patent disputes, with the general goal of encouraging early resolution of disputes relating to generic and biosimilar market entry.<sup>78</sup> The act of applying with FDA for approval of a generic drug or biosimilar triggers these procedures. Under certain circumstances, patent law treats the filing of such FDA applications as an “artificial” act of patent infringement,<sup>79</sup> allowing for the resolution of patent disputes before the generic or biosimilar product is marketed to the public. These procedures can affect whether and when a generic drug or biosimilar can be marketed and, as a result, determine when a brand-name product becomes subject to direct competition. The procedures differ depending on whether the pharmaceutical is regulated as a drug or as a biologic.<sup>80</sup>

The Hatch-Waxman Act governs the approval process for small-molecule drugs.<sup>81</sup> Under Hatch-Waxman, a drug manufacturer must list in its NDA any patent claiming the drug that is the subject of the application or a method of using that drug.<sup>82</sup> FDA includes these patents in its list of approved products known as the *Orange Book*.<sup>83</sup> When a generic manufacturer files an ANDA, it must provide a certification for each patent listed in the *Orange Book* with respect to the referenced drug.<sup>84</sup> In particular, with some exceptions,<sup>85</sup> the generic applicant must provide one of four certifications under the following paragraphs: (I) there is no patent information listed; (II) the patent has expired; (III) the date the patent will expire; or (IV) the patent is invalid and/or not infringed by the generic applicant.<sup>86</sup>

Paragraph (I) and (II) certifications do not affect FDA’s ability to approve the ANDA.<sup>87</sup> If the generic applicant makes a Paragraph (III) certification, however, FDA may not approve the ANDA until the patent at issue has expired.<sup>88</sup> A Paragraph (IV) certification triggers Hatch-

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holder of the original patent need each other’s permission before either can practice the improved invention).

<sup>77</sup> *Id.* at 91; see also Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 991, 1010 (1997).

<sup>78</sup> See generally Hickey et al., *supra* note 55, at 27-35.

<sup>79</sup> See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); 35 U.S.C. § 271(e)(2)-(6). The “artificial” act of infringement (filing an application with FDA) is distinguished from traditional direct patent infringement—making, using, selling, or importing the patented invention. See 35 U.S.C. § 271(a).

<sup>80</sup> For a summary comparison, see CRS In Focus IF11214, *Drug Pricing and the Law: Pharmaceutical Patent Disputes*, by Kevin J. Hickey.

<sup>81</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>82</sup> 21 U.S.C. § 355(b)(1). Other types of pharmaceutical patents, such as manufacturing process patents or patents claiming intermediaries or metabolites, are not submitted with the NDA or listed in the *Orange Book*. See 21 C.F.R. § 314.53(b).

<sup>83</sup> U.S. FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2019), <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/ucm071436.pdf> [hereinafter *Orange Book*].

<sup>84</sup> 21 U.S.C. § 355(j)(2)(A)(vii).

<sup>85</sup> With respect to patents that claim a method of using a drug, the generic applicant may file a “section viii” statement when seeking approval only for a use that is not claimed in the listed patent. *Id.* § 355(j)(2)(A)(viii).

<sup>86</sup> *Id.* § 355(j)(2)(A)(vii)(I)-(IV).

<sup>87</sup> *Id.* § 355(j)(5)(B)(i).

<sup>88</sup> *Id.* § 355(j)(5)(B)(ii).

Waxman’s specialized patent dispute procedures, often resulting in litigation.<sup>89</sup> First, the generic applicant must give notice of the ANDA and the Paragraph (IV) certification to the patentee and NDA holder.<sup>90</sup> The patent holder then has forty-five days to sue the generic applicant.<sup>91</sup> If she does file suit, FDA generally cannot approve the ANDA for thirty months while the parties litigate the patent dispute—a period often referred to as the “thirty-month stay.”<sup>92</sup> As an incentive for a generic to enter the market, Hatch-Waxman also provides 180 days of marketing exclusivity to the first generic to make a Paragraph (IV) certification.<sup>93</sup>

A different patent dispute resolution scheme, governed by the BPCIA, applies to biologics and biosimilars.<sup>94</sup> Under the BPCIA, regulatory approval of biologics is not directly contingent on resolution of patent disputes. Moreover, in contrast to the Hatch-Waxman approach, patent information need not be listed as part of the original BLA.<sup>95</sup> As a result, no patent information is currently listed in the *Purple Book*, FDA’s list of approved biological products (i.e., the biologics analogue of the *Orange Book*).<sup>96</sup> Accordingly, patent disputes involving biosimilars may be resolved through the BPCIA’s “patent dance,” “a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement.”<sup>97</sup> The first step in the patent dance process is triggered when, not later than twenty days after FDA accepts a biosimilar application, the applicant provides the application to the reference product sponsor, along with information on how the biosimilar is manufactured.<sup>98</sup> “These disclosures enable the [reference product] sponsor to evaluate the biosimilar for possible infringement of patents it holds on the reference product (i.e., the corresponding biologic).”<sup>99</sup> The biosimilar applicant and reference product sponsor then engage in a series of information exchanges regarding the patents that each party believes are relevant, as well as the parties’ positions as to the validity and infringement of the patents.<sup>100</sup> Depending on the extent of their participation in this information exchange, each party may have the opportunity to litigate the patents at the conclusion of the patent dance, or later on, when the

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<sup>89</sup> *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012).

<sup>90</sup> 21 U.S.C. § 355(j)(2)(B)(i)-(iv).

<sup>91</sup> *Id.* § 355(j)(5)(B)(iii).

<sup>92</sup> *See id.*; *Caraco Pharm.*, 566 U.S. at 407-08.

<sup>93</sup> 21 U.S.C. § 355(j)(5)(b)(iv); *Carrier*, *supra* note 13, at 1014.

<sup>94</sup> Pub. L. No. 111-148, Title VII, 124 Stat. 199, 804-21 (2010).

<sup>95</sup> *See* 42 U.S.C. § 262(a); Daniel M. Scolnick, *FDA’s ‘Purple Book’ for Biologics: Patents Not Included* (Sept. 9, 2014), <https://www.pepperlaw.com/publications/fdas-purple-book-for-biologics-patents-not-included-2014-09-15/>.

<sup>96</sup> *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, U.S. FOOD & DRUG ADMIN. (Mar. 20, 2019), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm> [hereinafter the *Purple Book*]. Unlike the *Orange Book*, no statute requires FDA to publish the *Purple Book*, but it has chosen to do so voluntarily. *See Background Information: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)*, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2015), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411424.htm>.

<sup>97</sup> *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017); 42 U.S.C. § 262(l).

<sup>98</sup> 42 U.S.C. § 262(l)(2).

<sup>99</sup> *Sandoz*, 137 S. Ct. at 1670-71.

<sup>100</sup> *Id.* at 1671-72.

biosimilar is marketed.<sup>101</sup> Injunctive relief to compel the biosimilar applicant to engage in the patent dance is unavailable under federal law.<sup>102</sup>

## Antitrust Law

Some of the patenting practices described below have been challenged under the federal antitrust laws; thus, background on this area is helpful in understanding those challenges. The Supreme Court has stated that the “primary purpose of the antitrust laws” is to protect and promote competition “from which lower prices can later result.”<sup>103</sup> To this end, antitrust law generally aims to “prohibit . . . anticompetitive conduct and mergers that enable firms to exercise market power.”<sup>104</sup> The Sherman Antitrust Act of 1890 (the Sherman Act) “contains two main substantive provisions that prohibit agreements in restraint of trade and monopolization, respectively.”<sup>105</sup> Certain pharmaceutical patenting practices have been challenged under each of these two sections.<sup>106</sup>

### Section 1 of the Sherman Act

Section 1 of the Sherman Act bars “[e]very contract, combination . . . , or conspiracy, in restraint of trade or commerce.”<sup>107</sup> Although that language appears to sweep broadly, the Supreme Court has interpreted Section 1 to only bar *unreasonable* restraints on trade.<sup>108</sup> In evaluating the reasonableness of contractual restraints on trade under Section 1, courts have found that “some agreements and practices are invalid per se, while others are illegal only as applied to particular situations.”<sup>109</sup> Unless the agreement falls within a per se illegal category, courts generally apply a “rule-of-reason” analysis to determine whether a restraint on trade is reasonable.

*Per Se Illegal.* Certain agreements are considered per se illegal “without regard to a consideration of their reasonableness”<sup>110</sup> “because the probability that these practices are anticompetitive is so high.”<sup>111</sup> Only restraints that “have manifestly anticompetitive effects” and lack “any redeeming virtue” are held to be per se illegal.<sup>112</sup> Examples of per se illegal restraints include agreements for horizontal price fixing, market allocations, and output limitations.<sup>113</sup> To prevail on a claim of a

<sup>101</sup> *Id.* at 1672.

<sup>102</sup> *Id.* at 1675. Rather, the exclusive remedy for the biosimilar applicant’s failure to commence the patent dance is provided by 42 U.S.C. § 262(l)(9)(C), which provides that, in that situation, “the reference product sponsor, but not the [biosimilar] applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.” *Sandoz*, 137 S. Ct. at 1675.

<sup>103</sup> *Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 895 (2007) (“[T]he antitrust laws are designed primarily to protect interbrand competition, from which lower prices can later result.”); *State Oil Co. v. Khan*, 522 U.S. 3, 15 (1997) (“Our analysis is also guided by our general view that the primary purpose of the antitrust laws is to protect interbrand competition.”).

<sup>104</sup> CRS In Focus IF11234, *Antitrust Law: An Introduction*, by Jay B. Sykes.

<sup>105</sup> *Id.*

<sup>106</sup> 15 U.S.C. §§ 1-2.

<sup>107</sup> *Id.* § 1.

<sup>108</sup> *See, e.g.*, *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 98 (1984).

<sup>109</sup> *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 387 (1956).

<sup>110</sup> *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 607 (1972).

<sup>111</sup> *NCAA*, 468 U.S. at 99, 103-04.

<sup>112</sup> *Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 886 (internal citations omitted).

<sup>113</sup> *See, e.g.*, *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 218 (1940); *NCAA*, 468 U.S. at 99, 103-04; *Stop*

per se illegal agreement, the plaintiff need only demonstrate that the agreement in question falls in one of the per se categories; in other words, “liability attaches without need for proof of power, intent or impact.”<sup>114</sup>

*The Rule-of-Reason Analysis.* Challenged restraints that are not in the per se illegal category are generally analyzed under the rule-of-reason approach. While the Supreme Court has not developed a canonical framework to guide this totality-of-the-circumstances reasonableness inquiry, most courts take a similar approach in resolving rule-of-reason cases.<sup>115</sup> Under this burden-shifting approach, a Section 1 plaintiff has the initial burden of demonstrating that a challenged restraint has anticompetitive effects in a “properly defined product” and geographic market—that is, that the restraint causes higher prices, reduced output, or diminished quality in the relevant market.<sup>116</sup> If the plaintiff succeeds in making this showing, the burden then shifts to the defendant to rebut the plaintiff’s evidence with a procompetitive justification for the challenged practice.<sup>117</sup> For example, if a Section 1 plaintiff alleges that the challenged restraint produces higher prices, the defendant might attempt to contest that allegation or show that any price increases are offset by improvements in its products or services. If the defendant cannot produce such a justification, the plaintiff may prevail. However, if the defendant adequately demonstrates a procompetitive justification, the burden then shifts back to the plaintiff to show either (1) that the restraint’s anticompetitive effects outweigh its procompetitive effects or (2) that the restraint’s procompetitive effects could be achieved in a manner that is less restrictive of competition.<sup>118</sup>

*Quick Look Analysis.* In certain instances, courts may use “something of a sliding scale in appraising reasonableness,” applying a more abbreviated rule-of-reason analysis to an agreement, referred to as a “quick look.”<sup>119</sup> In identifying this intermediate standard of review, the Supreme Court explained that, because “[t]here is always something of a sliding scale in appraising reasonableness,” the “quality of proof required” to establish a Section 1 violation “should vary with the circumstances.”<sup>120</sup> As a result, the Court has concluded that in certain cases—specifically, those in which “no elaborate industry analysis is required to demonstrate the anticompetitive character” of a challenged agreement—plaintiffs can establish a prima facie case that an agreement is anticompetitive without presenting the sort of market power evidence traditionally required at the first step of the rule-of-reason analysis.<sup>121</sup>

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& Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I., 373 F.3d 57, 61 (1st Cir. 2004).

<sup>114</sup> *Stop & Shop Supermarket Co.*, 373 F.3d at 61; see also *Leegin Creative Leather Prods.*, 551 U.S. at 886; *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692-93 (1978).

<sup>115</sup> See DANIEL CRANE, ANTITRUST 53-6 (2014); see also Herbert Hovenkamp, *The Rule of Reason*, 70 FLA. L. REV. 81, 103 (2018) (collecting cases).

<sup>116</sup> See CRANE, *supra* note 115, at 53-4; HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 103 (5th ed. 2015). The Supreme Court has explained that a properly defined market includes the product at issue and its substitutes—that is, other products that are “reasonably interchangeable[e]” with the relevant product. See *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). Stated differently, whether two products compete in the same market depends on the extent to which an increase in the price of one product in a given geographic region would cause consumers to purchase the other product instead. HOVENKAMP, *supra*, at 111-17.

<sup>117</sup> See CRANE, *supra* note 115, at 54; Hovenkamp, *supra* note 116, at 103.

<sup>118</sup> See CRANE, *supra* note 115, at 54; Hovenkamp, *supra* note 116, at 104.

<sup>119</sup> *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999).

<sup>120</sup> *Id.* at 780 (internal quotation marks and citation omitted).

<sup>121</sup> *Id.* at 770.



While there is no universally accepted “quick look” framework, several courts of appeals have endorsed a modified burden-shifting approach in “quick look” cases.<sup>122</sup> Under this approach, if a Section 1 plaintiff can establish that a challenged restraint is obviously likely to harm consumers, the restraint is deemed “inherently suspect,” and therefore presumptively anticompetitive.<sup>123</sup> A defendant can rebut this presumption by presenting “plausible reasons” why the challenged practice “may not be expected to have adverse consequences in the context of the particular market in question,” or why the practice is “likely to have beneficial effects for consumers.”<sup>124</sup> If the defendant fails to offer such reasons, the plaintiff prevails. However, if the defendant offers such an explanation, the plaintiff must address the justification by either explaining “why it can confidently conclude, without adducing evidence, that the restraint very likely harmed consumers” or providing “sufficient evidence to show that anticompetitive effects are in fact likely.”<sup>125</sup> If the plaintiff succeeds in making either showing, “the evidentiary burden shifts to the defendant to show the restraint in fact does not harm consumers or has ‘procompetitive virtues’ that outweigh its burden upon consumers.”<sup>126</sup> However, if the plaintiff fails to rebut the defendant’s initial justification, its challenge is assessed under a full rule-of-reason framework.

## Section 2 of the Sherman Act

Section 2 of the Sherman Act makes it unlawful to monopolize, attempt to monopolize, or conspire to monopolize “any part of the trade or commerce among the several States, or with foreign nations.”<sup>127</sup> Despite the facially broad language of Section 2, the Supreme Court has clarified that monopolization is only illegal if “it is accompanied by an element of anticompetitive conduct.”<sup>128</sup> It is *not* illegal to possess monopoly power that is the result of, for example, “a superior product, business acumen, or historic accident.”<sup>129</sup> Thus, establishing a Section 2 violation requires proving that the defendant “possessed monopoly power in the relevant market” and acquired or maintained that power using anticompetitive conduct.<sup>130</sup> Courts generally analyze whether conduct is anticompetitive (i.e., step two of the analysis) using a rule-of-reason approach.<sup>131</sup>

## Enforcement

Federal antitrust laws are primarily enforced through three mechanisms: (1) enforcement actions brought by the U.S. Department of Justice’s Antitrust Division, (2) enforcement actions brought by the Federal Trade Commission (FTC), or (3) lawsuits brought by a private party or by a state attorney general on behalf of a private party.<sup>132</sup> In particular, Section 5 of the FTC Act gives the

<sup>122</sup> See *N.C. St. Bd. Dental Exs. v. FTC*, 717 F.3d 359, 374, 374 n.11 (4th Cir. 2013); *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 361 (5th Cir. 2008); *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 35 (D.C. Cir. 2005).

<sup>123</sup> *Polygram Holding*, 416 F.3d at 35-36.

<sup>124</sup> *Id.* at 36 (internal quotation marks and citation omitted).

<sup>125</sup> *Id.* (internal quotation marks and citation omitted).

<sup>126</sup> *Id.*

<sup>127</sup> 15 U.S.C. § 2.

<sup>128</sup> *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

<sup>129</sup> *Id.* (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)).

<sup>130</sup> *Schneiderman v. Actavis PLC*, 787 F.3d 638, 651 (2d Cir. 2015).

<sup>131</sup> *Id.* at 652.

<sup>132</sup> *Antitrust Enforcement and the Consumer*, U.S. DEP’T OF JUSTICE, <https://www.justice.gov/atr/file/800691/download> (last visited January 22, 2019); *The Enforcers*, U.S. FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/competition->

FTC authority to combat “[u]nfair methods of competition” generally, which includes violations of the Sherman Act.<sup>133</sup>

FTC enforcement typically begins with a confidential investigation into the relevant conduct.<sup>134</sup> A company may resolve the investigation by entering into a consent order agreeing to stop or to address the potentially anticompetitive practices.<sup>135</sup> If the FTC and the company do not reach a consent order, the FTC may begin an administrative proceeding or may seek relief in the federal courts.<sup>136</sup> The administrative proceeding is similar to a court proceeding, but is overseen by an administrative law judge (ALJ).<sup>137</sup> If the ALJ finds that there has been a violation, the FTC may issue a cease-and-desist order. The ALJ’s decision is appealable to the full FTC, then to a U.S. Court of Appeals and, finally, to the Supreme Court.<sup>138</sup>

## Pharmaceutical Patenting Practices

Patent holders generally seek to use their rights to the fullest extent permitted by law, regardless of their patent’s technological field.<sup>139</sup> From the patent holders’ perspective, the practices described below are appropriate uses of the legal rights granted by their patents, which were obtained only after a rigorous examination process that demonstrated compliance with the patentability requirements.<sup>140</sup> Critics, however, view these practices as harmful strategies that exploit the patent system in ways that Congress did not intend.<sup>141</sup>

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guidance/guide-antitrust-laws/enforcers (last visited January 22, 2019) [hereinafter *The Enforcers*].

<sup>133</sup> 15 U.S.C. § 45; *FTC v. Cement Inst.*, 333 U.S. 683, 690 (1948) (holding that the FTC may pursue violations of the Sherman Act as unfair methods of competition); *FTC v. Motion Picture Advert. Serv. Co.*, 344 U.S. 392, 394 (1953) (“The ‘Unfair methods of competition’, which are condemned by § 5(a) of the [FTC] Act, are not confined to those that were illegal at common law or that were condemned by the Sherman Act.”).

<sup>134</sup> *The Enforcers*, *supra* note 132.

<sup>135</sup> *Id.* (“If the FTC believes that a person or company has violated the law or that a proposed merger may violate the law, the agency may attempt to obtain voluntary compliance by entering into a consent order with the company. A company that signs a consent order need not admit that it violated the law, but it must agree to stop the disputed practices outlined in an accompanying complaint or take certain steps to resolve the anticompetitive aspects of its proposed merger.”).

<sup>136</sup> *Id.* (“If a consent agreement cannot be reached, the FTC may issue an administrative complaint and/or seek injunctive relief in the federal courts.”).

<sup>137</sup> *Id.* (“The FTC’s administrative complaints initiate a formal proceeding that is much like a federal court trial but before an administrative law judge: evidence is submitted, testimony is heard, and witnesses are examined and cross-examined.”).

<sup>138</sup> *Id.* (“If a law violation is found, a cease and desist order may be issued. An initial decision by an administrative law judge may be appealed to the Commission. Final decisions issued by the Commission may be appealed to a U.S. Court of Appeals and, ultimately, to the U.S. Supreme Court.”).

<sup>139</sup> Peter Thomas Luce, *Hiding Behind Borders in a Borderless World: Extraterritoriality Doctrine and the Inadequacy of U.S. Software Patent Protections in a Networked Economy*, 10 TUL. J. TECH. & INTELL. PROP. 259, 280 n.118 (2007) (“If the patent is legitimate, the patent holder would be a patent fool if he did not protect his rights to the fullest extent of the law.”).

<sup>140</sup> GlaxoSmithKline, *GSK Public Policy Positions: Evergreening*, May 2019, <https://www.gsk.com/media/2949/evergreening-policy.pdf> [hereinafter *GlaxoSmithKline Positions*] (“GSK rejects the accusation that improvement patents are not justified within patent law. Patents for improvements to existing products, in the field of pharmaceutical and other technologies, are only available if they meet the requirements of patentability (i.e. that they are new, useful and involve an inventive step) as assessed by trained patent examiners.”).

<sup>141</sup> *See, e.g.*, Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 3 (2018).

## “Evergreening”

### Definition

Evergreening, also known as patent “layering” or “life-cycle management,” is a practice by which drug innovators allegedly seek “to prolong their effective periods of patent protection [through] strategies that add new patents to their quivers as old ones expire.”<sup>142</sup> As discussed above, because different aspects of pharmaceutical products (and improvements thereon) are patentable,<sup>143</sup> dozens of different patents can protect a single pharmaceutical product. The average number of patents per drug has been steadily rising since Hatch-Waxman was enacted in 1984.<sup>144</sup> On average, there are 2.7 patents listed for each product listed in the *Orange Book*.<sup>145</sup> Particularly profitable products, however, are usually protected by many more patents. One recent study of the top twelve drugs by gross U.S. revenue found that pharmaceutical manufacturers obtained an average of seventy-one patents on each of these drugs.<sup>146</sup> For example, this study found that Celgene, the maker of the top-selling plasma cell myeloma drug Revlimid, filed 106 U.S. patent applications covering that product, resulting in ninety-six issued patents.<sup>147</sup> The study also found that the price of Revlimid increased by 79% since 2012.<sup>148</sup>

### Debate

Because later-filed patents often claim aspects of the drug other than its active ingredient, these patents are sometimes called “secondary” patents.<sup>149</sup> Critics of evergreening maintain that, by obtaining secondary patents on improvements or ancillary aspects of a pharmaceutical product, manufacturers effectively extend patent protection beyond the term set by Congress. In doing so, according to these critics, secondary patents unfairly shield a pharmaceutical product from generic or biosimilar competition, thereby resulting in higher drug prices.<sup>150</sup> In the view of evergreening critics, moreover, many of these secondary patents are of questionable validity.<sup>151</sup>

<sup>142</sup> Eisenberg, *supra* note 9, at 354; *see also* Marrs, *supra* note 9, at 83-89; Furrow, *supra* note 9, at 276.

<sup>143</sup> *See supra* “Types of Pharmaceutical Patents.”

<sup>144</sup> C. Scott Hemphill & Bhaven V. Sampat, *When Do Generics Challenge Drug Patents*, 8 J. EMPIRICAL L. STUD. 613, 619-20 (2011).

<sup>145</sup> *Id.* Other commentators have found a similar average. *See, e.g.*, Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. & TECH. L. REV. 299, 314 (2010) (finding, on average, 2.97 patents listed per drug in FDA’s *Orange Book*).

<sup>146</sup> *See Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK 6-8 (Aug. 2018), <https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf> [hereinafter *Overpatented*].

<sup>147</sup> *Id.* at 7.

<sup>148</sup> *Id.*

<sup>149</sup> *See supra* “Types of Pharmaceutical Patents.”

<sup>150</sup> *See, e.g.*, Marrs, *supra* note 9, at 83-86; Feldman & Frondorf, *supra* note 21, at 555 (“Pharmaceutical company behavior [such as evergreening] that extends the period in which the company can hold off competition runs contrary to the patent bargain [leading to] losses to society in the form of higher prices.”); Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCI. 590, 590 (2018) (criticizing drug companies for “recycling and repurposing old [medicines]” to stifle competition).

<sup>151</sup> *See, e.g.*, Aaron S. Kesselheim, *Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines*, 34 AM. J.L. & MED. 125, 136 (2008) (“Loose interpretation of patent laws has permitted patent evergreening, where overly broad or otherwise inappropriate patents have been granted on peripheral aspects of pharmaceutical products . . . .”); Eisenberg, *supra* note 9, at 354 (noting that although “innovating firms have succeeded in getting [secondary] patents issued by the PTO,” “[t]he industry’s track record in

While secondary patents tend to be challenged more frequently and more successfully than patents covering a pharmaceutical's active ingredient,<sup>152</sup> the combination of secondary patents and a strong primary patent creates a barrier to generic entry because a generic manufacturer may delay or simply decline entry when faced with the prospect of defeating both patents.<sup>153</sup>

According to *Bloomberg Law*, in 2017 the cost of litigating a Hatch-Waxman lawsuit was \$1.8 million in cases involving over \$25 million in risk.<sup>154</sup> Commentators have suggested that these costs can be compounded when there are several patents at issue, even if those patents are comparably weaker.<sup>155</sup> Thus, even when a product is protected by comparably weak patents, critics of evergreening argue that the costs of invalidating those patents strengthen the branded products' position in the market and can lengthen its effective period of exclusivity.<sup>156</sup>

Defenders of evergreening respond that the term is "inherently pejorative" because it creates the impression that pharmaceutical companies are exploiting the patent system.<sup>157</sup> Defenders contend that there is nothing inherently suspect about secondary patents, which must meet the same requirements for patentability and pass through the same examination procedures as any other patent.<sup>158</sup> Indeed, those requirements bar a secondary patent on an obvious variation of the primary patent or on another product or invention already available to the public.<sup>159</sup> "[I]t is often the case," defenders contend, "that the value of a follow-on patent is comparable to, or even might exceed, that of a primary patent."<sup>160</sup> One example arguably supporting this view is the drug Evista (raloxifene). Evista was "initially studied as a potential treatment for breast cancer" but, in 1997, FDA approved the drug for the prevention of osteoporosis.<sup>161</sup> At that time, there were only a few years left on Evista's initial patent, which was filed in 1983.<sup>162</sup> If the brand could not patent the new use (i.e., for prevention of osteoporosis), one commentator has argued that insufficient

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actually winning these infringement claims . . . has been considerably worse").

<sup>152</sup> C. Scott Hemphill & Bhaven V. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 21 J. HEALTH ECON. 327 (2012) (finding that secondary patents relating to ancillary aspects of a drug are more frequently challenged by generics).

<sup>153</sup> Hemphill & Sampat, *supra* note 144, at 621 ("These patents, though weak, nevertheless have the effect of making the patent portfolio stronger. If they overlap in duration with a strong composition of matter patent, they provide an additional barrier to generic entry prior to expiration of the strong patent, since the generic must defeat the weak patent in addition to the strong one.").

<sup>154</sup> Malathi Nayak, *Cost of Patent Infringement Litigation Falling Sharply*, BLOOMBERG LAW (Aug. 11, 2017), <https://biglawbusiness.com/cost-of-patent-infringement-litigation-falling-sharply>.

<sup>155</sup> See Hemphill & Sampat, *supra* note 144, at 621.

<sup>156</sup> *Id.*; 35 U.S.C. § 103.

<sup>157</sup> *GlaxoSmithKline Positions*, *supra* note 140, at 1 ("Evergreening' is an inherently pejorative term. It is used by some to convey the false impression that research-based pharmaceutical companies abuse the patent system by obtaining patents on what are characterised as 'minor' improvements to existing medicines in order to prevent competition by delaying the legitimate market entry of generic products.").

<sup>158</sup> *Id.* ("Patents for improvements to existing products, in the field of pharmaceutical and other technologies, are only available if they meet the requirements of patentability (i.e. that they are new, useful and involve an inventive step) as assessed by trained patent examiners.").

<sup>159</sup> *Id.*

<sup>160</sup> Christopher M. Holman et al., *Patentability Standards for Follow-On Pharmaceutical Innovation*, 37 BIOTECH. L. REP. 131, 134 (2018).

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

incentives would have existed to make the investment in R&D necessary to bring the drug to market.<sup>163</sup>

Defenders also argue that the ability to receive a patent on a later-developed formulation provides a significant incentive to address problems with the original formulation. For example, the original formulation of Lumigan, which is used to treat glaucoma, resulted, at times, in sufficiently severe red eye that patients would discontinue its use.<sup>164</sup> Researchers subsequently developed an improved formulation with significantly decreased risk of this side effect.<sup>165</sup> Defenders of secondary patents contend that without the possibility of patent protection, there would have been little incentive to perform this sort of research due to the significant costs involved.<sup>166</sup>

Secondary patents are also defended on the grounds of being necessary to recoup development costs. A recent study found that even though the patent term is generally twenty years, delays in PTO and FDA approval can decrease the nominal *Orange Book* patent term to 15.9 years, and generic competition can result in an effective market exclusivity of only 12.2 years.<sup>167</sup> This effective market exclusivity is less than the sixteen years that one commentator suggests is necessary to recoup the brand's fixed costs for research, development, and clinical testing.<sup>168</sup>

Moreover, as secondary patents tend to be improvements to primary patents, brands argue that they are necessarily narrower than those primary patents.<sup>169</sup> Thus, brands argue that when the primary patent expires, any other company—including a generic—may enter the market and produce the invention covered by that primary patent, assuming that the generic can design around any unexpired secondary patents.<sup>170</sup> Doctors and patients can then decide whether the benefit conferred by a product covered by a secondary patent is worth the increased cost over the generic version of the product formerly covered by the primary patent.<sup>171</sup>

Finally, defenders also note that recent congressional action has decreased the cost of challenging patents, decreasing the impact of these later-filed “evergreening” patents. In 2011, Congress enacted the America Invents Act (AIA), which created a number of proceedings for reviewing a patent's validity after it is granted.<sup>172</sup> One such proceeding is inter partes review (IPR), a PTO procedure that was implemented to “improv[e] patent quality and provide a more efficient system for challenging patents that should not have issued; and reducing unwarranted litigation costs.”<sup>173</sup> Generally, any person who is not a patent's owner may file a petition for IPR beginning nine

<sup>163</sup> *Id.*

<sup>164</sup> *Id.* at 135.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

<sup>167</sup> Hemphill & Sampat, *supra* note 152. “Nominal patent term” is “the time between brand approval and expiration of the last expiring patent.” *Id.*

<sup>168</sup> Morris, *supra* note 18, at 267-68.

<sup>169</sup> *GlaxoSmithKline Positions*, *supra* note 140, at 2 (“Patents cannot give exclusive rights for things that are already known or obvious. Therefore, patents for modifications of existing products, sometimes referred to as ‘secondary patents’, are necessarily narrower in scope than what has gone before.”).

<sup>170</sup> *Id.* (“It follows that, following expiry of an earlier patent, a secondary patent cannot preclude a generic competitor from selling products defined in that earlier patent and which are not covered by the secondary patent.”).

<sup>171</sup> *Id.* (“It is the medical community and paying authorities that will decide whether a price premium for the [later-patented] product is worth paying.”).

<sup>172</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6; 125 Stat. 284, 299-305 (2011).

<sup>173</sup> H.R. REP. No. 112-98, at 39-40 (2011).

months after the patent issues.<sup>174</sup> The PTO then decides whether to initiate review of the patent.<sup>175</sup> If review is initiated, then the patent challenger must prove that the patent is invalid by a preponderance of the evidence<sup>176</sup>—a lower requirement than the clear-and-convincing-evidence standard used when challenging the patent in court.<sup>177</sup> The statute requires that the PTO’s final decision be issued not more than one year after the decision to institute review.<sup>178</sup> The median cost for litigating an IPR to that final decision is \$324,000.<sup>179</sup> Thus, IPR provides a relatively fast and relatively inexpensive method to challenge issued patents, particularly when compared to litigating in the courts.

## Current Law

No statute currently specifically forbids evergreening. Instead, substantive patent law, particularly the law of obviousness, provides limits on whether the PTO may grant later-filed patents. Specifically, a patent may not be granted if “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious” before the patent application was filed.<sup>180</sup> The Supreme Court has not articulated a specific test for whether an invention would have been obvious, instead preferring a flexible approach that takes the facts and circumstances of the state of the art into account.<sup>181</sup> The Court has identified, however, some situations in which an invention likely would have been obvious.<sup>182</sup> For example, if the invention involves “the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement,” the invention likely would have been obvious.<sup>183</sup> At bottom, if the invention is “a predictable variation” of what came before, then the law of obviousness “likely bars its patentability.”<sup>184</sup>

Other doctrines also affect the viability of later-filed patents. Because the patent statute limits a person to “a patent” for a new invention,<sup>185</sup> a single patentee may not obtain a later patent that covers the exact same invention as an earlier patent.<sup>186</sup> This doctrine is referred to as “statutory double patenting” because it derives from the patent statute and prevents patenting of the same invention twice by the same inventor.<sup>187</sup> The courts have extended double patenting to bar an inventor from patenting obvious variations of his earlier patents as well.<sup>188</sup> This second form of

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<sup>174</sup> 35 U.S.C. § 311. A similar proceeding, postgrant review (PGR), allows for challenges in the initial nine months after the patent grant. 35 U.S.C. §§ 321–29.

<sup>175</sup> *Id.* § 314(a).

<sup>176</sup> *Id.* § 316(e).

<sup>177</sup> *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011).

<sup>178</sup> 35 U.S.C. § 316(e)(11).

<sup>179</sup> Stephen Yelderman, *Prior Art in Inter Partes Review*, 104 IOWA L. REV. 2705, 2706 (2019).

<sup>180</sup> 35 U.S.C. § 103.

<sup>181</sup> *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

<sup>182</sup> *Id.* at 417–22.

<sup>183</sup> *Id.* at 417.

<sup>184</sup> *Id.*

<sup>185</sup> 35 U.S.C. § 101 (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”) (emphasis added).

<sup>186</sup> *Sun Pharm. Indus., Ltd. v. Eli Lilly and Co.*, 611 F.3d 1381, 1384–85 (Fed. Cir. 2010).

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

double patenting, referred to as “obviousness-type double patenting,” prohibits a later patent that is not “patentability distinct” from an earlier commonly owned patent.<sup>189</sup> In other words, the doctrine bars a patent owner from receiving a patent on an obvious variation of one of its earlier-filed patents.<sup>190</sup> A patentee may overcome the obviousness-type double patenting issue, however, by using a “terminal disclaimer”—that is, by disclaiming any portion of the later patent’s term after the expiration of the earlier patent.<sup>191</sup>

## “Product Hopping”

### Definition

Critics of current pharmaceutical patent practices have observed that patent evergreening can be used in conjunction with a practice they call “product hopping.”<sup>192</sup> Product hopping is the process by which a brand, as the patents on an older branded drug are expiring, uses its current dominant market position to switch doctors, pharmacists, and consumers to a newer version of the same (or similar) drug with later-expiring patents. In other words, the brand forces a “hop” from one product to another.<sup>193</sup> The new version of the product may be, for example, an extended release form or new dosage (e.g., moving from twice-a-day to once-a-day), a different route of administration (e.g., moving from capsules to tablets, or tablets to film strips), or a chemical change (e.g., moving to a different enantiomer).<sup>194</sup> The switch to the new version may be accompanied by a marketing campaign or discounts and rebates to encourage doctors, insurers, and patients to switch to the new version; in some cases, production of the older version may even be discontinued.<sup>195</sup>

Product hopping tends to take one of two forms: a “hard switch,” where the brand removes the original product from the market, and a “soft switch,” where the brand leaves the original product on the market.<sup>196</sup> The case of *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*<sup>197</sup> provides an example of a hard switch. That case involved Abbott’s changes to its drug TriCor, which was used to treat cholesterol and triglycerides.<sup>198</sup> Abbott allegedly lowered the strength of the drug,

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

<sup>191</sup> See, e.g., *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1210 (Fed. Cir. 2014); *STC.UNM v. Intel Corp.*, 754 F.3d 940, 942 (Fed. Cir. 2014).

<sup>192</sup> This term was coined by Professor Herbert Hovenkamp in the early 2000s. See Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 658 (2007) (citing HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 12.5 (2002)).

<sup>193</sup> See generally Feldman & Frondorf, *supra* note 21, at 527-30; Carrier & Shadowen, *supra* note 9, at 171-73; Tobin Klusty, *A Legal Text for the Pharmaceutical Company Practice of “Product Hopping”*, 17 AM. MED. ASS’N J. ETHICS 760, 760 (2015).

<sup>194</sup> See Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 25 (2009) (categorizing pharmaceutical reformulations); Feldman & Frondorf, *supra* note 21, at 529-32 (reviewing examples of product hopping); Carrier & Shadowen, *supra* note 9, at 172 (same).

<sup>195</sup> Shadowen et al., *supra* note 194, at 3 (“In addition to physically altering the product, manufacturers often also: (1) switch promotional efforts from the original product to the reformulated product; (2) introduce the redesigned product before generic entry; or (3) withdraw the original product from the market”); accord Feldman & Frondorf, *supra* note 21, at 527-29.

<sup>196</sup> Carrier & Shadowen, *supra* note 9, at 192.

<sup>197</sup> 432 F. Supp. 2d 408 (D. Del. 2006).

<sup>198</sup> *Id.* at 415.

switched it from a capsule to a tablet, stopped selling capsules, bought back supplies of capsules from pharmacies, and marked capsules as “obsolete” in the national drug database.<sup>199</sup> Once generics developed equivalents for the reformulation, Abbott allegedly again lowered the strength of the drug, stopped selling the original tablets, and again changed the code for the old tablets to “obsolete.”<sup>200</sup>

A soft switch allegedly occurred in *Schneiderman v. Actavis PLC*.<sup>201</sup> There, Actavis produced Namenda IR (IR), a twice-daily drug designed to treat Alzheimer’s disease.<sup>202</sup> As the patents on IR neared expiration and generics prepared to enter the market, Actavis introduced a once-daily version of the drug, Namenda XR (XR), and allegedly attempted to induce doctors and patients to switch from IR to XR.<sup>203</sup> Although the generic versions would have been substitutable for IR, the differences in dosing (10 mg in IR and 28 mg in XR) meant that the generic versions would not be substitutable for the new XR product.<sup>204</sup> Initially, both IR and XR were on the market together.<sup>205</sup> During that time, Actavis allegedly stopped marketing IR and “spent substantial sums of money promoting XR to doctors, caregivers, patients, and pharmacists.”<sup>206</sup> Actavis also sold XR at a discount, making it much less expensive than IR, and issued rebates to ensure that patients did not have to pay higher copayments for XR than IR.<sup>207</sup> When it appeared that the soft switch would only convert 30% of IR users to XR, Actavis allegedly implemented a hard switch by announcing that it would discontinue IR and attempting to stop Medicare health plans from covering IR.<sup>208</sup>

## Debate

Critics of product hopping deride it as an anticompetitive practice that inhibits the entry of generic and biosimilar competitors, allowing the brand to maintain its dominant market position (and higher prices) without substantial benefits for consumers.<sup>209</sup> In particular, critics contend that

<sup>199</sup> *Id.* at 415-17. As explained in more detail *infra*, making these types of changes may render any current generic version of a branded drug no longer therapeutically equivalent to the branded version, thus generally preventing a pharmacist from substituting the generic version for the branded version. *See id.*

<sup>200</sup> *Id.* A Delaware district court determined that these allegations were sufficient to support an antitrust claim. *Id.* at 419-33.

<sup>201</sup> 787 F.3d 638 (2d Cir. 2015). Since this case, Actavis has changed its name to Allergan. Andrew Berg, *Actavis Moves to Adopt New “Allergan” Corporate Name*, R&D, May 20, 2016, <https://www.rdmag.com/news/2016/05/actavis-moves-adopt-new-allergan-corporate-name>.

<sup>202</sup> *Schneiderman*, 787 F.3d at 642.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.* at 647.

<sup>205</sup> *Id.* at 648.

<sup>206</sup> *Id.* (footnote omitted).

<sup>207</sup> *Id.*

<sup>208</sup> *Id.* The district court determined that Actavis’s conduct was anticompetitive and issued a preliminary injunction ordering Actavis to make IR available on the same terms and conditions as before. *Id.* at 662. The Second Circuit affirmed the district court’s determination and the preliminary injunction, although the court determined that it was only the *hard* switch that crossed the line into illegal behavior. *Id.* at 654. The Court reasoned that as long as both IR and XR were on the market with generic drugs on the horizon, doctors and patients could evaluate whether the benefits of switching to once-daily XR outweighed the increased costs as compared to the generic form of IR. *Id.* at 655.

<sup>209</sup> *See, e.g.,* Carrier & Shadowen, *supra* note 9, at 168 (“The concern with [product hopping] is that some of these switches can significantly decrease consumer welfare, impairing competition from generic drugs to an extent that greatly exceeds any gains from the ‘improved’ branded product.”); Justine Amy Park, *Product Hopping: Antitrust Liability and a Per Se Rule*, 35 CARDOZO ARTS & ENT. L.J. 745, 773 (2017) (“The use of product hopping to circumvent the entry of generic competitors is a gross violation of [antitrust law] and encourages brand name



by shifting product demand from the previous product to a new product, the market for a generic form of the previous version dissipates by the time the generic can enter the market.<sup>210</sup>

All fifty states have enacted drug product selection (DPS) laws, which aim to lower consumer prices by allowing, and sometimes even requiring, pharmacists to fill a prescription written for a brand-name drug with a generic version of that drug.<sup>211</sup> Typically, however, pharmacists may only substitute a generic drug for a branded drug if the generic version is “AB-rated” by FDA.<sup>212</sup> To receive an AB rating, the generic must be therapeutically equivalent to the branded drug, which means it must have the same active ingredient, form, dosage, strength, and safety and efficacy profile.<sup>213</sup> The generic must also be bioequivalent—in other words, the rate and extent of absorption of the generic cannot significantly differ from that of the brand drug.<sup>214</sup> Thus, if the brand’s new version of a drug, for example, changes the form of the drug (e.g., capsule to tablet) or the dosage of the active ingredient (e.g., 10 mg to 12 mg) from the older version, the generic product may not receive the AB rating required to be substitutable by pharmacists.<sup>215</sup> Even if the generic is eventually able to obtain an AB rating to allow substitution, that process may take years to achieve.<sup>216</sup> Thus, the “hop” to a new product can prevent automatic substitution with a generic product, thereby giving the brand an additional period during which it is substantially unaffected by generic competition.

Defenders of product hopping respond that manufacturers have legitimate reasons to create new patented products and encourage doctors to prescribe the new product instead of an old product for which there is generic competition.<sup>217</sup> One commentator has argued that patent law encourages brands to create new drugs or switch to new versions of drugs because they receive an exclusive period during which they may charge higher prices.<sup>218</sup> That period is critical, it is argued, to recoup the estimated \$2.6 billion average cost of bringing a new drug to market—compared to the \$1 million to \$2 million to bring a new generic product to market.<sup>219</sup> Once a branded drug’s patents expire, however, the brand will lose 80% to 90% of its sales to generic

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manufacturers to thinly disguise their products as innovative while maintaining patent monopolies on products.”); Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472 (2008) (“[P]roduct hopping amounts to little more than a thinly disguised scheme to manipulate the pharmaceutical industry’s regulatory system and frustrate generic competition.”).

<sup>210</sup> Vikram Iyengar, *Should Pharmaceutical Product Hopping Be Subject to Antitrust Scrutiny?*, 97 J. PAT. & TRADEMARK OFF. SOC’Y 663, 669-70 (2015) (“If the brand firm withdraws its existing product from pharmacy shelves and convinces doctors to write prescriptions for its new product, the market for the generic collapses.”); Shadowen et al., *supra* note 194, at 7-18 (describing how the regulatory and economic context creates “price disconnect” that prevents generics from effectively competing on price following a product reformulation).

<sup>211</sup> Carrier & Shadowen, *supra* note 9, at 175. Questions have been raised as to whether DPS laws are still important, considering the increased power of drug plans and pharmacy benefit managers. See, e.g., Joanna Shepherd, *Deterring Innovation: New York v. Actavis and the Duty to Subsidize Competitors’ Market Entry*, 17 MINN. J. OF L., SCI. & TECH. 663, 688-92 (2016) (arguing that pharmacy benefit managers and insurers have adopted methods for providing patients with less-expensive alternatives to branded pharmaceuticals).

<sup>212</sup> Carrier & Shadowen, *supra* note 9, at 175.

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

<sup>215</sup> *Id.* at 176.

<sup>216</sup> *Id.*

<sup>217</sup> Shepherd, *supra* note 211, at 668; see also Tyler J. Klein, *Antitrust Enforcement Against Pharmaceutical Product Hopping: Protecting Consumers or Reaching Too Far?*, 10 ST. LOUIS U. J. HEALTH L. & POL’Y 213 (2016).

<sup>218</sup> Shepherd, *supra* note 211, at 668.

<sup>219</sup> *Id.*

drugs.<sup>220</sup> Thus, according to one commentator, brands have little incentive to keep marketing a product that is subject to generic competition; doing so would arguably transfer approximately 80% of the sales to their generic competitors. That is, even if the brand succeeds in convincing a doctor to prescribe the old product, DPS laws would allow a pharmacist to substitute a generic product instead.<sup>221</sup> Given these economic realities, defenders argue that the brand would be effectively paying to market its competitors' products.<sup>222</sup> Accordingly, it is argued that product hopping aims at maximizing profits for the brand (which can be used for additional R&D) and preventing free-riding by generics, not at preventing competition.<sup>223</sup>

Commentators also respond that generic manufacturers could reduce the impact of product hopping by marketing their own products.<sup>224</sup> In that view, generic manufacturers *choose* to rely on DPS laws for sales.<sup>225</sup> Instead, one commentator argues, the generic companies could promote their own products in the same way that brand manufacturers do.<sup>226</sup> In any event, patients and doctors can arguably choose to use the generic version of the old product if the brand's new product is not worth the cost.<sup>227</sup>

## Current Law

There is no existing statute specifically prohibiting product hopping. Those practices, however, have been challenged under the antitrust laws as anticompetitive attempts to maintain a monopoly in violation of Section 2 of the Sherman Act.<sup>228</sup> *Schneiderman* provides one example. In that case, the U.S. Court of Appeals for the Second Circuit (Second Circuit) held that the soft switch, described above, was not sufficiently anticompetitive to violate Section 2.<sup>229</sup> Specifically, the court determined that as long as Actavis continued to sell both XR and IR, with generic IR drugs on the market, "patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives."<sup>230</sup> The Second Circuit further held that once Actavis implemented a hard switch by withdrawing IR, it "crosse[d] the line from persuasion to coercion" and therefore violated Section 2.<sup>231</sup> The court next determined that Actavis's purported procompetitive justifications for the hard switch were pretextual because the hard switch was an attempt to impede generic competition<sup>232</sup> and, in any event, the procompetitive benefits were

<sup>220</sup> *Id.* at 668-69 (further noting that "eighty percent of marketed brand drugs never earn enough sales" to recoup development costs).

<sup>221</sup> *Id.* at 670.

<sup>222</sup> *See id.* at 670-71.

<sup>223</sup> *Id.* at 694.

<sup>224</sup> *See, e.g.,* Erika Lietzan, *A Solution in Search of a Problem at the Biologics Frontier*, 2018 U. ILL. L. REV. ONLINE 19, 27 (2018).

<sup>225</sup> *Id.*

<sup>226</sup> *Id.* ("[G]eneric companies choose to rely on automatic substitution but could in fact market their products.").

<sup>227</sup> *Id.* ("[R]ational payers and physicians will select the generic first-generation product if the innovative second-generation product is not meaningfully better.").

<sup>228</sup> *See, e.g.,* *Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

<sup>229</sup> *Id.* at 655 ("As long as Defendants sought to persuade patients and their doctors to switch from Namenda IR to Namenda XR while both were on the market (the soft switch) and with generic IR drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.").

<sup>230</sup> *Id.*

<sup>231</sup> *Id.* ("Defendants' hard switch crosses the line from persuasion to coercion and is anticompetitive.").

<sup>232</sup> *Id.* at 658 ("All of Defendants' procompetitive justifications for withdrawing IR are pretextual. The record is replete with evidence showing that Defendants were, in the words of Defendants' own CEO, 'trying to . . . put up barriers or

outweighed by anticompetitive harms.<sup>233</sup> Accordingly, the court affirmed the district court’s grant of an injunction requiring Actavis to make IR “available on the same terms and conditions” as before the hard switch.<sup>234</sup>

## “Patent Thickets”

### Definition

Critics have argued that pharmaceutical manufacturers develop “patent thickets” to protect their products. This term is used in two slightly different ways, both relating to products covered by a high number of patents. First, a patent thicket may describe the situation in which *multiple parties* have overlapping patent rights on one product, such that a “potential manufacturer must negotiate licenses with each patent owner in order to bring a product to market without infringing.”<sup>235</sup> Patent thickets, in this sense, raise concerns about inefficient exploitation of a technology because the multiplicity of patent owners increases transaction costs and creates coordination challenges.<sup>236</sup> Second, the term may be used in a different sense to describe an incumbent manufacturer’s practice of amassing a *large number of patents* relating to a single product, with the intent of intimidating competitors from entering the market, or to make it too costly and risky to do so.<sup>237</sup>

### Debate

Commentators have observed that it is generally not unusual for a single product to be protected by multiple patents.<sup>238</sup> For example, it has been estimated that a single smartphone may be protected by as many as 250,000 patents.<sup>239</sup> Even the individual technologies in the phone may be covered by many patents. For example, Bluetooth 3.0 incorporates “contributions of more than

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obstacles’ to generic competition.”).

<sup>233</sup> *Id.* (“Because we have determined that Defendants’ procompetitive justifications are pretextual, we need not weigh them against the anticompetitive harms. But in any event, New York has shown that whatever procompetitive benefits exist are outweighed by the anticompetitive harms.”).

<sup>234</sup> *Id.* at 662 (“Defendants argue that the injunction provision requiring them to make Namenda IR tablets available on the same terms and conditions applicable since July 21, 2013 is vague because the terms and conditions have shifted over the past 17 months. We disagree. The injunction plainly prohibits Defendants from charging more for Namenda IR than it did during the specified timeframe and from restricting access to IR. If Defendants need additional clarification, they can seek it in the district court.”).

<sup>235</sup> Stu Woolman et al., *Evidence of Patent Thickets in Complex Biopharmaceutical Technologies*, 53 IDEA: INTELL. PROP. L. REV. 1, 2 (2013); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, 1 INNOVATION POL’Y & ECON. 119, 119 (2001).

<sup>236</sup> See Gavin D. George, *What Is Hiding in the Bushes? eBay’s Effect on Holdout Behavior in Patent Thickets*, 13 MICH. TELECOMM. & TECH. L. REV. 557, 558-60 (2007) (summarizing the economic literature); see generally Shapiro, *supra* note 235; Michael A. Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

<sup>237</sup> Koons, *supra* note 11 (using “patent thicket” to refer to large patent portfolio amassed on one product by single biologics manufacturer); see also *America’s Overspend*, *supra* note 11, at 4 (using term “thicket of patents” to refer to large patent portfolio claiming aspects of a single drug); Feldman, *supra* note 11 (“[D]rug companies build massive patent walls around their products, extending the protection over and over again.”).

<sup>238</sup> Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1590-91 (2003) (stating that a one-to-one correspondence between patents and products “is the exception rather than the rule”).

<sup>239</sup> Steve Lohr, *Apple-Samsung Patent Battle Shifts to Trial*, N.Y. TIMES, (July 29, 2012), <https://www.nytimes.com/2012/07/30/technology/apple-samsung-trial-highlights-patent-wars.html>. Notably, not all of the patents covering aspects of a smartphone are owned by the same entity. *Id.*

30,000 patent holders,” and more than 800 patent holders contributed to the micro SD removable memory storage card.<sup>240</sup> Unlike pharmaceuticals, however, the patents on products like semiconductors or smartphones are typically not all owned by the same entity, and thus are examples of the first type of patent thicket (i.e., one in which multiple parties have overlapping patent rights on one product). Commentators contend that patent thickets on such technologies generally do not confer the same market power as a patent portfolio on a new pharmaceutical owned by a single drug manufacturer.<sup>241</sup>

In the pharmaceutical context, concerns about patent thickets have mainly been raised with regard to the second type of patent thicket and, in particular, with regard to biologics. This may be, at least in part, because those pharmaceuticals are derived from living cells or other biological material.<sup>242</sup> Naturally occurring source material is generally not eligible for patenting under Section 101 of the Patent Act,<sup>243</sup> but methods for transforming that source material into a biological product generally are patentable.<sup>244</sup> Manufacturing a pharmaceutical using living cells is often complicated, offering more opportunities for patenting relative to chemically synthesizing small-molecule drugs.<sup>245</sup> As changes are implemented to either the biologic product or its manufacturing process throughout the original patent term, those changes can be claimed as inventions and used to extend the effective patent protection.<sup>246</sup> For example, a company producing a biologic could attempt to patent the use of a different medium for cell growth or an adjustment to the dosing.<sup>247</sup>

The patent portfolio that covers Humira, pharmaceutical manufacturer AbbVie’s flagship biologic, has been characterized as an example of the second type of patent thicket.<sup>248</sup> Critics contend that this patent portfolio has helped keep Humira competitors off the market for an extended time period.<sup>249</sup> One study found that AbbVie filed 247 patent applications on various aspects of Humira, resulting in 132 issued patents.<sup>250</sup> The Biosimilars Council alleges that AbbVie filed seventy-five patents relating to Humira in the three years before biosimilar

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<sup>240</sup> Evan Engstrom, *So How Many Patents Are In A Smartphone?*, ENGINE (Jan. 19, 2017) <https://www.engine.is/news/category/so-how-many-patents-are-in-a-smartphone>.

<sup>241</sup> Burk & Lemley, *supra* note 238, at 1591. *See also* Dmitry Karshedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1158 (2019).

<sup>242</sup> Koons, *supra* note 11 (“[B]iologic medicines such as Humira . . . are typically made in living cells rather than chemically manufactured. That process often involves more steps and a higher level of complexity, which opens the door to more potential steps to patent.”).

<sup>243</sup> *See, e.g., Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590-94 (2013).

<sup>244</sup> *See, e.g., Amgen, Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1156 (Fed. Cir. 2019) (describing patent on purifying step of manufacturing a biologic).

<sup>245</sup> *See* Koons, *supra* note 11.

<sup>246</sup> *Id.* (“[C]ompanies can claim any changes to their drugs over the years—say, using a slightly different medium in which to grow cells or adjusting the dosing—warrant new legal protections that can keep generic competitors at bay.”).

<sup>247</sup> *Id.*

<sup>248</sup> *See* AbbVie Inc. v. Boehringer Ingelheim Int’l GmbH, No. 17-CV-01065-MSG-RL, 2019 WL 917990, at \*4 (D. Del. Feb. 25, 2019) (summarizing allegation that AbbVie created a “thicket of dubious and overlapping patents to delay biosimilar competition”).

<sup>249</sup> *See Overpatented*, *supra* note 146, at 7.

<sup>250</sup> *Id.*

competition was set to begin, extending nominal patent protection through 2034.<sup>251</sup> The council alleges that it will cost “roughly \$3 million per patent” to challenge the Humira patents.<sup>252</sup>

In August 2017, just before biosimilar manufacturer Boehringer received FDA approval to launch its Humira biosimilar in the United States, AbbVie filed a lawsuit alleging that the biosimilar would infringe 1,600 claims across 74 of AbbVie’s patents.<sup>253</sup> Boehringer settled the lawsuit earlier this year, citing “the inherent unpredictability of litigation, [and] the substantial costs of what would have been a long and complicated legal process and ongoing distraction to our business.”<sup>254</sup> AbbVie has similarly settled litigation with the other potential manufacturers of Humira biosimilars.<sup>255</sup> Although the primary patent on Humira expired in 2016, no biosimilars will enter the U.S. market until January 31, 2023, at the earliest.<sup>256</sup> The alleged patent thicket surrounding Humira has been the subject of litigation on other bases, including under the antitrust laws. In March 2019, a welfare fund filed an antitrust suit against AbbVie alleging that its patent thicket approach unreasonably restrained competition in violation of Sections 1 and 2 of the Sherman Act,<sup>257</sup> and seeking billions of dollars in damages when AbbVie doubled the cost of Humira.<sup>258</sup> Also in March, the mayor and city council of Baltimore, MD, brought a class action lawsuit alleging that, absent AbbVie’s conduct, biosimilars of Humira could have been available in the United States as early as 2016.<sup>259</sup> Other similar lawsuits have been filed, although none is aimed at invalidating AbbVie’s patents.<sup>260</sup> The lawsuits currently remain pending.

Critics have voiced concerns that other drug manufacturers may attempt to amass similar patent portfolios on their biologics as those covering Humira, thereby postponing biosimilar competition from entering the market.<sup>261</sup> Johnson & Johnson, for example, protects its Remicade product with more than one hundred patents.<sup>262</sup> Biogen/Genentech similarly protects its cancer treatment

<sup>251</sup> *Failure to Launch*, *supra* note 12, at 8.

<sup>252</sup> *Id.*

<sup>253</sup> Complaint at 1, *AbbVie v. Boehringer Ingelheim Int’l GmbH*, No. 1:17-cv-01065-MSG-RL (D. Del. Aug. 2, 2017) (stating that Humira “has resulted in more than 100 issued United States patents . . . 74 of which AbbVie has identified as infringed”); Nicole D. Prysby, *Patent News: AbbVie Facing First-of-Its-Kind ‘Patent Thicket’ Antitrust Suit*, IP LAW DAILY (Mar. 19, 2019), <https://lrus.wolterskluwer.com/news/antitrust-law-daily/abbvie-facing-first-of-its-kind-patent-thicket-antitrust-suit/75518/>.

<sup>254</sup> Andrew Dunn, *With Boehringer Settlement, AbbVie Completes Humira Sweep*, BIOPHARMADIVE (May 14, 2019), <https://www.biopharmadive.com/news/abbvie-boehringer-ingelheim-settle-humira-patent-biosimilar/554729/>.

<sup>255</sup> *Id.*

<sup>256</sup> *Id.* In Europe, by contrast, Humira biosimilars entered markets in October 2018, and within four months had captured 15% of the European market. Ned Pagliarulo, *Humira Biosimilars Launch in Europe, Testing AbbVie*, BIOPHARMADIVE (Oct. 19, 2018) <https://www.biopharmadive.com/news/abbvie-humira-biosimilars-launch-europe/539938/>; Dunn, *supra* note 254 (“Humira biosimilars captured 15% of the European market in February, the fourth month since launching.”). It is estimated that biosimilars could claim up to 50% of the Humira market in Europe within the first year. *Id.* (“[B]iosimilars growing to take 50% of the Humira market in Europe within a year remains a possibility.”).

<sup>257</sup> Prysby, *supra* note 253. The complaint also presents “state law claims for conspiracy and combination in restraint of trade, monopolization, state consumer protection law violation, and unjust enrichment.” *Id.*

<sup>258</sup> *Id.*

<sup>259</sup> Kelly Davio, *Baltimore, Maryland, Sues Both AbbVie and Amgen over Humira*, THE CENTER FOR BIOSIMILARS (Apr. 2, 2019), <https://www.centerforbiosimilars.com/news/baltimore-maryland-sues-both-abbvie-and-amgen-over-humira>.

<sup>260</sup> Zachary Brennan, *Six Lawsuits Target AbbVie’s Humira and its Patent Thicket*, REG. AFF. PROFS. SOC’Y, Apr. 2, 2019, <https://www.raps.org/news-and-articles/news-articles/2019/4/six-lawsuits-target-abbvies-humira-and-its-patent>.

<sup>261</sup> Koons, *supra* note 11.

<sup>262</sup> *Id.*

Rituxin with what some could characterize as a patent thicket.<sup>263</sup> Rituxin was the subject of 204 patent applications and ninety-four issued patents, potentially resulting in forty-seven years blocking competition.<sup>264</sup> Indeed, the success of the patent thickening strategy has led to speculation that other companies will follow suit.<sup>265</sup>

Defenders of this patenting practice raise similar arguments as those in support of evergreening: that the patents on these products represent innovation that the patent laws were designed to incentivize, and that each patent has passed through the rigorous examination process and been determined to be novel and nonobvious.<sup>266</sup> For example, AbbVie has stated that Humira “represents true innovation in the field of biologics,”<sup>267</sup> warranting protection through various patents. Other experts note that “[t]here’s nothing unusual about the multilayered way AbbVie has sought to patent and protect Humira,” and that patent thickets simply “tak[e] advantage of existing law.”<sup>268</sup> Accordingly, companies with patents relating to numerous aspects of their products likely view each patent as protecting significant patentable innovations of the sort that the patent system is designed to incentivize.<sup>269</sup>

Indeed, experts note that creating a biologic like Humira “isn’t easy work.”<sup>270</sup> Scientists must genetically engineer a cell line to secrete large amounts of the biologic, purify the results, and modify dosages for different diseases, among other “incremental tweaks.”<sup>271</sup> Each of those steps in the process brings challenges that may require innovative solutions, and those solutions may be the subject of patents.<sup>272</sup> As AbbVie’s CEO noted, the Humira “patent portfolio evolved as [AbbVie] discovered and learned new things about Humira.”<sup>273</sup> Thus, defenders view this practice as a legitimate method of protecting the different aspects of their innovations.

## Current Law

No statute specifically forbids patent thickets. As with evergreening, substantive patent law (including the nonobviousness requirement and prohibition on double patenting) provides some of the primary restrictions on patent thickets. In other words, the ability to receive secondary patents is limited by the rule that new patents cannot be an obvious variation on the prior art or on the patentee’s own prior patents.<sup>274</sup> On the other hand, obviousness-type double patenting restrictions may have less impact on patent thickets than on evergreening due to the availability of terminal disclaimers. As explained *supra*, a patentee may overcome obviousness-type double

<sup>263</sup> See *Overpatented*, *supra* note 146, at 7.

<sup>264</sup> *Id.*

<sup>265</sup> Koons, *supra* note 11 (“After seeing [AbbVie’s strategy for protecting Humira] laid out in a company presentation, Ronny Gal, a research analyst for Sanford C. Bernstein & Co., said at a conference of makers of biosimilars (generic-like drugs, in biologic drug parlance) last fall: ‘I’m pretty sure every CEO in biopharma sent that to their head of IP [intellectual property] and said, ‘Can we do that?’””).

<sup>266</sup> See *supra* “Evergreening”

<sup>267</sup> *Id.*

<sup>268</sup> Sy Mukherjee, *Protect at All Costs: How the Maker of the World’s Bestselling Drug Keeps Prices Sky-High*, FORTUNE (July 18, 2019), <https://fortune.com/longform/abbvie-humira-drug-costs-innovation/>.

<sup>269</sup> See Koons, *supra* note 11.

<sup>270</sup> Mukherjee, *supra* note 268.

<sup>271</sup> *Id.*

<sup>272</sup> See *id.*

<sup>273</sup> *Id.*

<sup>274</sup> See *supra* “Evergreening”

patenting issues by disclaiming any portion of the later patent's term after the expiration of the earlier patent.<sup>275</sup> Because the alleged goal of evergreening is to extend the exclusivity period for as long as possible, there is little incentive to file a terminal disclaimer. By contrast, the purported goal of a patent thicket is to accumulate a large number of patents protecting a single product, a goal that would be unaffected by terminal disclaimers. Thus, restrictions on obviousness-type double patenting have a lesser impact on preventing patent thickets, as compared to preventing evergreening.

## “Pay-for-Delay” Settlements

### Definition

As described above, patent litigation can result when generic drug and biosimilar manufacturers seek to market a drug or biologic before patent rights on the branded version expire by challenging the validity of the brand-name companies' patents and/or their applicability to the follow-on product.<sup>276</sup> Some brand-name companies resolve or settle such litigation through settlement agreements with the generic manufacturer whereby the brand-name company pays the generic manufacturer a sum of money (or other compensation) in return for the generic manufacturer agreeing to delay market entry.<sup>277</sup> This practice, referred to as “reverse payment settlements” or “pay-for-delay settlements,” allows the brand-name company to (1) avoid the risk that its patents will be invalidated, (2) delay the market entry of generic competition, and (3) effectively extend its exclusive right to market the listed drug.<sup>278</sup> Because these agreements terminate the litigation, the questions of patent validity and infringement remain open.<sup>279</sup>

Pay-for-delay settlements are not limited to cash payments from the brand to the generic. The U.S. Court of Appeals for the Third Circuit (Third Circuit) recently addressed such a settlement involving Wyeth, Inc.'s branded depression treatment drug, Effexor XR.<sup>280</sup> In that case, the plaintiffs alleged that Wyeth and generic manufacturer Teva Pharmaceutical Industries Ltd. (Teva) reached an anticompetitive pay-for-delay settlement.<sup>281</sup> This agreement is an example of the varied facts that result in such settlements.

Teva filed an ANDA for a generic version of Effexor XR, and Wyeth sued for patent infringement.<sup>282</sup> According to the plaintiffs (a class of direct purchasers of Effexor XR), an unfavorable preliminary ruling caused Wyeth to fear that it would lose the litigation, allowing

<sup>275</sup> See, e.g., *Gilead Sci., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1210 (Fed. Cir. 2014); *STC.UNM v. Intel Corp.*, 754 F.3d 940, 942 (Fed. Cir. 2014).

<sup>276</sup> See *supra* “Patent Dispute Procedures for Generic Drugs and Biosimilars.”

<sup>277</sup> See, e.g., *FTC v. Actavis, Inc.*, 570 U.S. 136, 144-45 (2013); *In re Androgel Antitrust Litig.*, No. 1:09-MD-2084-TWT, 2018 WL 298483, at \*3-4 (N.D. Ga. June 14, 2018).

<sup>278</sup> See, e.g., *Actavis*, 570 U.S. at 154.

<sup>279</sup> *Id.*

<sup>280</sup> *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017).

<sup>281</sup> *Id.*

<sup>282</sup> *Id.* at 247 (“On December 10, 2002, Teva obtained ANDA first-filer status for a generic version of Effexor XR. Teva’s ANDA included paragraph IV certifications, asserting that Teva’s sale, marketing, or use of generic Effexor would not infringe Wyeth’s patents or that those patents were invalid or unenforceable. . . . Within the 45-day period prescribed by the Hatch-Waxman Act, Wyeth brought suit against Teva for patent infringement in the District of New Jersey.”).

generic manufacturers to enter the Effexor XR market.<sup>283</sup> Accordingly, Wyeth and Teva entered into a settlement in which

- the parties agreed to vacate the unfavorable preliminary ruling;<sup>284</sup>
- Teva agreed not to enter the market with its Effexor XR generic until approximately five years after the agreement (nearly seven years before Wyeth’s patents expired);<sup>285</sup>
- Wyeth agreed not to market a competing “authorized generic” during Teva’s 180-day exclusivity period;<sup>286</sup>
- Wyeth agreed to permit Teva to sell a generic version of another product, Effexor IR, before the original patent on Effexor expired and without a Wyeth-authorized generic;<sup>287</sup> and
- Teva agreed to pay royalties to Wyeth on its sales of both generic versions of Effexor.<sup>288</sup>

Pursuant to a consent decree, Wyeth and Teva submitted the agreement to the FTC.<sup>289</sup> The FTC did not object to the agreement.<sup>290</sup> Notably, unlike *Actavis*, in this case Wyeth did not pay money directly to Teva. Instead, Wyeth’s agreement not to market an authorized generic during Teva’s 180-day exclusivity period would cause Teva to reap increased sales during that period. In other words, although Wyeth did not *directly* pay Teva to stay off of the market, the agreement ensured that Teva would receive compensation in other ways.

## Debate

The FTC and others have alleged that pay-for-delay settlements “have significant adverse effects on competition” in violation of antitrust laws, including Section 1 of the Sherman Act and Section 5 of the FTC Act.<sup>291</sup> When evaluating agreements for potential antitrust violations, the court focuses its inquiry on “form[ing] a judgment about the competitive significance of the [settlement] . . . ‘based either (1) on the nature or character of the contracts, or (2) on surrounding circumstances giving rise to the inference or presumption that they were intended to restrain trade

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<sup>283</sup> *Id.*

<sup>284</sup> *Id.*

<sup>285</sup> *Id.*

<sup>286</sup> *Id.* (“Wyeth further agreed that it would not market an authorized-generic Effexor XR during Teva’s 180-day exclusivity period. . . . Effexor plaintiffs allege that Wyeth’s promise to stay out of the generic Effexor XR market was worth more than \$500 million, observing that Teva would gain all the sales of generic Effexor XR during Teva’s generic exclusivity period.”).

<sup>287</sup> *Id.*

<sup>288</sup> *Id.* (“With regard to its generic Effexor XR sales, Teva would pay Wyeth royalties beginning at 15% during its 180-day exclusivity period. If Wyeth chose not to introduce an authorized generic after 180 days and no other generic entered the market, Teva was required to pay Wyeth 50% royalties for the next 180 days and 65% royalties thereafter for up to 80 months. As to Teva’s sales of generic Effexor IR, Teva agreed to pay Wyeth 28% royalties during the first year and 20% during the second year.”).

<sup>289</sup> *Id.* Pursuant to a 2002 consent decree, the FTC “possessed the right to weigh in on and raise objections to Wyeth’s settlements.” *Id.*

<sup>290</sup> *Id.* While “[t]he FTC offered no objection” to the settlement agreement, it “reserved its right to take later action.” *Id.*

<sup>291</sup> *Id.* at 147-48; *see also* King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 398 (3d Cir. 2015).



and enhance prices.”<sup>292</sup> The Supreme Court has recognized that “reverse payment settlements . . . can sometimes violate the antitrust laws,”<sup>293</sup> and courts have allowed antitrust litigation challenging certain reverse payment settlements to proceed under existing law.<sup>294</sup>

Defenders of such agreements contend there are significant benefits from pay-for-delay settlements. For example, AbbVie has settled suits with each of the companies that sought to introduce biosimilars to Humira.<sup>295</sup> Even while accusing AbbVie of “patent abuses” relating to Humira, the Biosimilars Council has touted using settlements between brands and biosimilars to resolve patent thickets.<sup>296</sup> The council contends that the Humira settlements are “pro-consumer” because, although biosimilar market entry will be delayed until seven years after the primary patent on Humira has expired, entry will still occur before several of the secondary patents covering Humira will expire.<sup>297</sup> As the Supreme Court has recognized, pay-for-delay settlements may provide significant procompetitive benefits, and whether a particular settlement is procompetitive or anticompetitive will depend on a number of factors that vary from case to case.<sup>298</sup>

## Current Law

In *Actavis v. FTC*, the Supreme Court held that the rule of reason is the appropriate level of analysis in challenges to pay-for-delay agreements.<sup>299</sup> Although the Court recognized the potential for such agreements to have anticompetitive effects, it acknowledged that “offsetting or redeeming virtues are sometimes present.”<sup>300</sup> Such justifications might include “traditional settlement considerations, such as avoided litigation costs or fair value for services.”<sup>301</sup> Accordingly, the FTC (or other plaintiffs) has to prove fully the anticompetitive effects of a particular agreement before the burden shifts to the defendant.<sup>302</sup>

The Third Circuit case involving Wyeth provides an example of the current analysis. Although the FTC did not object to the agreement, purchasers of Effexor XR filed a class action lawsuit against

<sup>292</sup> *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 103 (1984) (quoting *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 690 (1978)).

<sup>293</sup> *FTC v. Actavis, Inc.*, 570 U.S. 136, 141 (2013).

<sup>294</sup> *See, e.g., Smithkline Beecham Corp.*, 791 F.3d at 403; *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 422 (E.D. Pa. 2015); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245-46 (D. Conn. 2015).

<sup>295</sup> *Dunn*, *supra* note 254.

<sup>296</sup> *Failure to Launch*, *supra* note 12, at 8 (“[A] critical element of biosimilar entry is the ability for two parties to reach a settlement agreement providing for competition earlier than the expiration of the last patent, rather than bear the time and expense of litigating through these thickets in court.”).

<sup>297</sup> *Id.* (stating that fewer agreements of the kind at issue in *Actavis* “paved the way for pro-consumer patent settlement agreements and earlier entry while avoiding expensive and burdensome litigation costs”). *Cf. Actavis*, 570 U.S. at 136 (“We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer’s benefit. But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related \$500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.”).

<sup>298</sup> *Actavis*, 570 U.S. at 158-60.

<sup>299</sup> *Id.* at 159.

<sup>300</sup> *Id.* at 156.

<sup>301</sup> *Id.*; *see also id.* at 159.

<sup>302</sup> *Id.* at 159; *see also United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) (“The plaintiff bears an initial burden under the rule of reason of showing that the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets.”).

Wyeth and Teva alleging, *inter alia*, that the settlement agreement was an unlawful restraint of trade under Section 1 of the Sherman Act.<sup>303</sup> The Third Circuit concluded that the plaintiffs had plausibly alleged an anticompetitive pay-for-delay settlement.<sup>304</sup> The court determined that Wyeth's agreement not to manufacture a competing generic product during Teva's 180-day exclusivity period was an adequate allegation of a sufficiently large payment because it ensured that Teva would be the only generic product on the market, and thus Teva would receive all generic Effexor XR sales during that period.<sup>305</sup> Moreover, the court concluded that the payment could not be justified as a simple effort to avoid the costs of litigation.<sup>306</sup> Accordingly, the court determined that the plaintiffs had adequately alleged that the agreement between Wyeth and Teva was the kind of pay-for-delay agreement forbade by the Supreme Court in *Actavis*.<sup>307</sup>

## Combinations of Practices

Although this report has described the various patenting practices in isolation, they can be used concurrently. For example, product hopping can be combined with pay-for-delay settlements to delay generic entry while the brand switches the market to a new product. A manufacturer considering product hopping will often be more successful in preventing competition from the generic if it can convert the market to the new product before the generic enters the market.<sup>308</sup> In one case, the brand estimated that it would sell ten times more tablets if it could switch doctors to the new product before the generic entered the market.<sup>309</sup>

One example of a drug manufacturer allegedly combining product hopping and pay-for-delay settlements to prevent competition for its product involves Cephalon, maker of the branded sleep disorder medication Provigil.<sup>310</sup> Between its secondary patent and a period of regulatory exclusivity, protection of Provigil expired in April 2015.<sup>311</sup> Due to the narrowness of the secondary patent, however, the generic companies planned to enter the market with noninfringing products in 2006.<sup>312</sup> Cephalon estimated that, once the generic versions entered the market, there

<sup>303</sup> *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 248 (3d Cir. 2017).

<sup>304</sup> *Id.* at 258-62.

<sup>305</sup> *Id.* at 260 (“The no-[authorized-generic (AG)] agreement used by Wyeth to induce Teva to stay out of the Effexor XR market was alleged to have been worth more than \$500 million. *Effexor* plaintiffs note that the Effexor XR market is a multi-billion dollar market annually, and, with the no-AG agreement, ‘Teva would (a) garner all of the sales of generic Effexor XR during Teva’s generic exclusivity period. . . and (b) charge higher prices than it would have been able to charge if it was competing with Wyeth’s authorized generic.’”).

<sup>306</sup> *Id.* at 261 (“[T]he no-AG agreement ‘cannot be excused as a litigation cost avoidance effort by Wyeth.’ *Effexor* plaintiffs’ complaint states that Wyeth’s litigation costs with Teva would have totaled only between \$5 million to \$10 million, and those costs ‘would have been the tiniest of a fraction the size of the payment likely over \$500 million effectuated by Wyeth to Teva.’”) (citations omitted).

<sup>307</sup> *Id.* at 262 (stating that the plaintiffs’ complaints “contain sufficient factual detail about the settlement agreement between Teva and Wyeth to plausibly suggest that Wyeth paid Teva to stay out of the market by way of its no-AG agreement [and] that is the very anticompetitive harm that the Supreme Court identified in *Actavis*”).

<sup>308</sup> *Carrier & Shadowen*, *supra* note 9, at 176-77 (“Put simply, the brand firm will be much more successful in forestalling generic competition if it can switch the market to the reformulated drug *before* a generic of the original product enters the market.”) (emphasis in original).

<sup>309</sup> *Id.* at 177 (“In the *TriCor* case, . . . the brand firm predicted that it would sell more than ten times as many tablets if it was able to switch doctors to the reformulated product before the generic version of the original product entered the market.”).

<sup>310</sup> *Carrier*, *supra* note 13, at 1022-27.

<sup>311</sup> *Id.* at 1022.

<sup>312</sup> *Id.* at 1022-23 (“The four first-filing generic firms planned for a launch in June 2006, at the latest.”).

would be a 75% to 90% price reduction in Provigil, reducing revenues by more than \$400 million in the first year alone.<sup>313</sup> In 2006, Cephalon attempted to move the market to a new product, Nuvigil, which was patent-protected until 2023.<sup>314</sup> But because FDA had not yet approved Nuvigil in late 2005, Cephalon settled its patent lawsuits with the generics, paying them more than \$200 million to delay market entry until 2012.<sup>315</sup>

Although Cephalon argued its settlement would allow generic versions of Provigil to enter the market three years before the expiration of the Provigil secondary patent in 2015, following the settlement, Cephalon increased the price of Provigil and stopped marketing it.<sup>316</sup> At the same time, Cephalon promoted Nuvigil both through its sales force and by discounting its price.<sup>317</sup> Because of the pay-for-delay settlement, Cephalon had three years to switch the market to Nuvigil before generic entry in 2012, rather than have Provigil compete with the generics in 2006. Thus, Cephalon combined product hopping with pay-for-delay settlements to prolong its period of exclusivity.

## Selected Proposals for Addressing Pharmaceutical Patenting Practices

Pharmaceutical patenting practices have attracted significant interest from both commentators and Congress. This section of the report reviews several proposals, from both legislation and the academic literature, that seek to reduce or eliminate these patenting practices. This review is not intended to be comprehensive, nor does it evaluate the merits of these proposals. Instead, the proposals are reviewed as representative examples of the various types of legal changes under consideration.

As discussed above, patenting practices are only one factor that may contribute to consumer prices in the highly complex pharmaceutical market. Thus, the discussed proposals relating to patenting practices are one potential method to reduce drug prices. Numerous legislative proposals intended to reduce drug prices exist,<sup>318</sup> but because these proposals relate only indirectly to pharmaceutical patenting practices, they are outside the scope of this report.

### Limiting Evergreening

Proposals targeting evergreening primarily aim to make it harder for companies to receive later-filed or secondary patents, reduce the impact of later-filed patents, or incentivize challenges to patents.

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<sup>313</sup> *Id.* at 1023 (“A Cephalon vice president projected a 75%-90% price reduction that would lower revenues by more than \$400 million (nearly 75% of the drug’s annual sales) within one year.”).

<sup>314</sup> *Id.* at 1023-25.

<sup>315</sup> *Id.* at 1024 (“Cephalon paid more than \$200 million to the four generic firms to agree to forgo entry until April 2012.”).

<sup>316</sup> *Id.* at 1025 (“The easiest way to make Provigil less desirable was to increase its price. . . . Another means to reduce Provigil’s attractiveness was to stop promoting it.”).

<sup>317</sup> *Id.* at 1026.

<sup>318</sup> *See, e.g.,* Hickey et al., *supra* note 55, at 35-51.

## Increasing Examination Resources

Several commentators have proposed that increasing patent examination resources could reduce the number of arguably weaker later-filed patents.<sup>319</sup> These commentators contend that patent examiners “often do not have enough time or resources to investigate whether a patent application is truly inventive.”<sup>320</sup> In these commentators’ view, allocating more resources to the PTO would potentially prevent low-quality patents from issuing in the first place, thus preventing the need for accused infringers to spend time and resources defending against infringement or attempting to invalidate such patents.<sup>321</sup> Although one commentator notes that “most patents are not economically significant,” he also recognizes that the PTO “is not well positioned to identify which patents are important and which are worthless.”<sup>322</sup>

## Enhancing Patentability Standards

Some proposals aim to reduce evergreening by making it more difficult for later-filed applications to meet the requirements for patentability. For example, one commentator has suggested raising the substantive patentability requirements for later-filed or secondary patents.<sup>323</sup> Specifically, the commentator suggests amending the patent statute to require that an application for a patent on a secondary invention “demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.”<sup>324</sup> The proposal defines “increased efficacy” as “a proven improvement in the mechanism of action, as disclosed in the patent claims,” and “mechanism of action” as “the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims.”<sup>325</sup> In the commentator’s view, this would reduce evergreening by requiring that the secondary patent actually improve the manner in which the pharmaceutical product operates, and thus incentivize pharmaceutical companies to create new drugs, “rather than creating minor changes that prolong the time they can profit off monopolies at the expense of patients.”<sup>326</sup> At least one other country has adopted a similar standard: Under Indian law a patent may not issue on “a new form of a known substance which does not result in enhancement of the known efficacy of that substance.”<sup>327</sup>

<sup>319</sup> Michael Xun Liu, *Balancing the Competing Functions of Patent Post-Grant Proceedings*, 25 J. INTELL. PROP. L. 157, 165 (2018) (“Given the cost of error, one could argue that it would make sense to devote more resources to examining patent applications in the first instance, instead of revisiting patents that have already issued.”); *see also* Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 986 (2019) (finding that “results from our prior research suggest that examiners are facing binding time constraints and that these time constraints are inducing examiners to grant invalid patents”); *id.* at 1021 (“[T]he current level of resources the Patent Office extends to review patent applications is insufficient.”).

<sup>320</sup> Liu, *supra* note 319, at 165-66.

<sup>321</sup> *Id.* at 166 (“[D]evoting more resources to the initial examination may lead to substantial improvements in overall patent quality. Moreover, there are clear benefits to avoiding errors during examination in the first place instead of going back to invalidate patents after they have already been granted.”).

<sup>322</sup> *See id.* at 166-67 (“[P]ost-grant proceedings are a means of outsourcing to private parties the task of identifying which patents should receive additional scrutiny.”).

<sup>323</sup> Ashley Newsome, Note, *Side Effects of Evergreening May Include Decreased Competition & Increased Prices in the Pharmaceutical Industry*, 45 AIPLA Q.J. 791, 811-12 (2017).

<sup>324</sup> *Id.* (proposing new 35 U.S.C. § 106).

<sup>325</sup> *Id.* at 812-13.

<sup>326</sup> *See id.*

<sup>327</sup> *See, e.g.,* Dorothy Du, *Novartis AG v. Union of India: “Evergreening,” TRIPS, and “Enhanced Efficacy” Under*

## Reducing the Impact of Later-Filed Patents

The Terminating the Extension of Rights Misappropriated (TERM) Act of 2019<sup>328</sup> is one example of a legislative proposal to curtail patent evergreening by reducing the impact of later-filed patents. If enacted, it would establish a presumption that, in patent challenges under Hatch-Waxman or BPCIA procedures,<sup>329</sup> the patentee “disclaimed the patent term for each of the listed patents after the date on which the term of the first patent expires.”<sup>330</sup> In effect, this presumption would mean that later-expiring patents listed in the *Orange Book* (or provided during the BPCIA’s “patent dance”) would, as a default, be treated as expiring on the date when the earliest-expiring patent on the drug or biologic expires. However, the patentee would be able to overcome this presumption by affirmatively demonstrating with a preponderance of the evidence that the later-expiring patents on the drug or biologic claim “patentably distinct inventions.”<sup>331</sup> Because the law of double patenting already requires later-expiring patents to cover patentably distinct inventions to be valid,<sup>332</sup> the TERM Act’s legal effect would be to place the burden of proving patent validity on the patentee for certain later-expiring pharmaceutical patents. Under current law, patents are presumed valid in a judicial proceeding unless *the challenger* proves patent invalidity by clear and convincing evidence.<sup>333</sup>

The TERM Act would also require the PTO to determine if changes to patent examination practice may be necessary. Specifically, the Act would require the PTO to review the agency’s patent examination procedures to determine whether the PTO is using the best practices to avoid the issuance of duplicative patents relating to the same drug or biologic.<sup>334</sup> The bill would also require the PTO to determine the need for new practices or procedures to (1) improve examination of patents relating to the same drug or biological product and (2) reduce the issuance of patents that “improperly extend the term of exclusivity.”<sup>335</sup> Finally, the Act would require the PTO to submit a report to the House Committee on the Judiciary containing its findings and recommendations.<sup>336</sup>

The Reforming Evergreening and Manipulation that Extends Drug Years Act (REMEDY) Act,<sup>337</sup> like the TERM Act, seeks to curb evergreening by reducing the benefit of later-filed patents.

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Section 3(D), 21 J. INTELL. PROP. L. 223, 228 (2014).

<sup>328</sup> Terminating the Extension of Rights Misappropriated (TERM) Act of 2019, H.R. 3199, 116th Cong. (2019).

<sup>329</sup> See *supra* “Patent Dispute Procedures for Generic Drugs and Biosimilars.” Specifically, the bill applies to proceedings “challenging the validity of patents under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) with respect to a drug, under section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)) with respect to a biological product, or a Federal district court proceeding involving patents that are the subject of an action under section 271(e)(2).” H.R. 3199 § 2(a).

<sup>330</sup> H.R. 3199 § 2(a).

<sup>331</sup> *Id.*

<sup>332</sup> See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001) (“The judicially-created doctrine of obviousness-type double patenting . . . prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.”).

<sup>333</sup> 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011).

<sup>334</sup> H.R. 3199 § 2(b)(2)(A).

<sup>335</sup> *Id.* § 2(b)(2)(B). The TERM Act does not define what it means to “improperly extend the term of exclusivity.”

<sup>336</sup> *Id.* § 3.

<sup>337</sup> Reforming Evergreening and Manipulation that Extends Drug Years Act (REMEDY) Act, S. 1209, 116th Cong. (2019). An identical bill has been introduced in the House. See Reforming Evergreening and Manipulation that Extends Drug Years Act (REMEDY) Act, H.R. 3812, 116th Cong. (2019). For simplicity, all citations herein are to the Senate version as of January 17, 2020.

Under the REMEDY Act, a generic’s filing of a Paragraph (IV) certification in an ANDA would only trigger Hatch-Waxman’s thirty-month stay if the patent claims a “drug substance”—that is, the drug’s active ingredient.<sup>338</sup> The stay would not be available for a patent that claims only a “drug product or method of use for a drug,” unless the patent also claims the drug substance itself.<sup>339</sup> In that case, the bill would allow FDA to approve the generic product immediately, without waiting for the litigation to determine the validity of the nondrug substance patents.<sup>340</sup> This approach is aimed at allowing the generic to enter the market more quickly by limiting the grounds under which a brand can receive a thirty-month stay of FDA approval.<sup>341</sup> The Act would also require that patents canceled by the PTO be removed from the *Orange Book*.<sup>342</sup> The bill would also clarify that challenging a patent that is later struck from the *Orange Book* would not affect the first-generic-filer 180-day exclusivity period.<sup>343</sup>

## Encouraging Patent Challenges

Other anti-evergreening proposals aim to incentivize challenges to pharmaceutical patents after those patents issue. For example, the Second Look at Drugs Patents Act of 2019 (SLDPA) would encourage administrative challenges to patents added to the *Orange Book*.<sup>344</sup> Under the SLDPA, unlike current law, a brand would be *required* to notify the PTO that it was adding patents to the *Orange Book*.<sup>345</sup> After receiving that notification, the PTO would need to publish a notice regarding each patent and request that any eligible person file an IPR challenging that patent.<sup>346</sup> Such patents would be “provisionally” included in the *Orange Book* until either the PTO confirmed the relevant patents’ patentability or until certain time has passed without any challenge to the patents (300 days if the patent had issued when FDA approved the relevant drug, or fifteen months if the patent issued after approval).<sup>347</sup> If any patent claims are canceled as a result of an IPR, the bill would require the brand to submit a request that the patent be removed from the *Orange Book* (if all claims are canceled) or that the canceled claims be removed from the *Orange Book*.<sup>348</sup> Taken together, the SLDPA would provide notice regarding particular patents that generics may want to challenge and would encourage such challenges.<sup>349</sup>

<sup>338</sup> S. 1209 § 2(a)(1). FDA regulations define a “drug substance” as the active ingredient in a drug. 21 C.F.R. § 314.3(b).

<sup>339</sup> S. 1209 § 2(a)(1). FDA regulations define a “drug product” as “a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.” 21 C.F.R. § 314.3(b).

<sup>340</sup> See *id.*; Ryan Davis, *Breaking Down 3 New Senate Bills Targeting Drug Prices*, LAW360 (Apr. 18, 2019), <https://www.law360.com/articles/1150045/breaking-down-3-new-senate-bills-targeting-drug-prices>.

<sup>341</sup> Davis, *supra* note 340.

<sup>342</sup> S. 1209 § 2(b)(1).

<sup>343</sup> *Id.* § 2(b)(2).

<sup>344</sup> S. 1617, 116th Cong. § 2(a) (2019).

<sup>345</sup> *Id.* § 2(a)(2)(C).

<sup>346</sup> *Id.*

<sup>347</sup> *Id.*

<sup>348</sup> *Id.*

<sup>349</sup> Other bills, however, look to *reduce* IPR challenges to drug patents. For instance, the Hatch-Waxman Integrity Act of 2019 (HWIA) would reduce a generic or biosimilar’s ability to challenge drug patents in an IPR. H.R. 990, 116th Cong. (2019), § 2. Specifically, it would require a generic or biosimilar to certify in its application for FDA approval that neither it nor any other party it is “in privity with, related to, or cooperating with” has filed an IPR/PGR or will petition for IPR/PGR. *Id.* §§ 2(a)(3), 2(b)(3), 2(c)(1)(C). The HWIA, then, would constrain generic companies from using the PTO post-grant processes to attack drug patents.

As another method of encouraging patent challenges, one commentator has proposed that Congress require the PTO to implement an “Invalidity Challenge Reimbursement Program” (ICR program) that would require the PTO to reimburse “petition fees, reasonable attorney fees, and related expenses incurred by accused infringers who have prevailed in a post-issuance proceeding” at the PTO “by invalidating at least one patent claim.”<sup>350</sup> The proposal envisions that such a program could be paid for by the PTO charging an “ICR fee” on each patent in force.<sup>351</sup> As their costs would be reimbursed if they are successful, the commentator contends that this system would provide greater incentives to encourage an accused infringer to challenge a weak patent.<sup>352</sup> Moreover, the commentator notes that the PTO is currently generally unaffected when it issues a low-quality patent.<sup>353</sup> In the commentator’s view, requiring the PTO to reimburse successful challenges to patents may create an incentive for the PTO to examine applications more carefully before issuing patents.<sup>354</sup>

## Addressing Product Hopping and Patent Thickets

Some bills aim to curtail certain pharmaceutical patenting practices directly. One such proposal is the Affordable Prescriptions for Patients Act of 2019 (APPA), which would make product hopping an antitrust violation and would set a limit on the number of certain patents that could be asserted in biologics litigation.<sup>355</sup>

The first portion of the bill addresses product hopping. It would amend the FTC Act to define when product hopping constitutes a violation of the federal antitrust laws.<sup>356</sup> The bill would allow the FTC to prove a prima facie case of product hopping by showing that a manufacturer had engaged in either a “hard switch” or a “soft switch” during a certain period. Specifically, the manufacturer would have to engage in a switch between when the manufacturer first received

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Targeting certain practices of hedge fund managers, the bill would also make it a manipulative or deceptive device under the securities laws to petition for IPR and, within ninety days of filing the petition, to engage in a short sale of any publicly traded security of the challenged patent’s owner. *Id.* § 3. See also J. Gregory Sidak & Jeremy O. Skog, *Attack of the Shorting Bass: Does the Inter Partes Review Process Enable Petitioners to Earn Abnormal Returns?*, 63 UCLA L. REV. DISC. 120, 122-25 (2015).

<sup>350</sup> Jeremy W. Bock, *Expanding the Patent Office’s Regulatory Footprint: A Proposal for Reimbursing Invalidity Challenges*, 96 DENV. L. REV. 441, 462-63 (2019).

<sup>351</sup> *Id.*

<sup>352</sup> *Id.* at 463 (“As devised, the ICR program may encourage some accused infringers who otherwise would have paid a nuisance fee (to avoid or settle litigation) to instead challenge weak patents.”).

<sup>353</sup> *Id.* at 461 (“Presently, the cost of handling problematic patent assertions—and by extension, policing patent quality—is borne primarily by accused infringers, while the PTO generally takes a hands-off approach after issuance and remains largely insulated from the consequences of granting low quality patents.”).

<sup>354</sup> *Id.* at 468-69 (“The requirement to compensate successful invalidations at the PTAB could also provide the necessary impetus for the PTO to come up with better ways to filter weak applications prior to issuance, in order to better manage the risk of payouts.”).

<sup>355</sup> Affordable Prescriptions for Patients Act of 2019, § 2, S. 1416, 116th Cong. (2019). The portion of APPA aimed at preventing patent thickets has been introduced in the House of Representatives as the Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019. H.R. 3991, 116th Cong. The portion aimed at preventing product hopping has been introduced in the House as the Affordable Prescriptions for Patients Through Promoting Competition Act of 2019. H.R. 4398, 116th Cong. For simplicity, all citations herein are to the Senate version as of January 17, 2020.

<sup>356</sup> S. 1416 § 2.

notice that an applicant submitted an ANDA or biosimilar license for a particular product and 180 days after the generic drug or biosimilar product is first marketed.<sup>357</sup>

The APPA defines a “hard switch” in two ways.<sup>358</sup> The first definition would prevent a manufacturer from requesting that FDA withdraw approval for a listed product and then marketing a “follow-on product” (i.e., a new version of the drug).<sup>359</sup> Accordingly, the bill would alter current law, under which a brand manufacturer can freely ask FDA to withdraw approval for one of its products, possibly preventing a generic from marketing a competing product due to the lack of a reference product.<sup>360</sup> The APPA’s second definition of a hard switch would prevent a manufacturer from marketing or selling a follow-on product after withdrawing, intending to withdraw, discontinuing the manufacture of, or destroying a product to impede competition from a generic.<sup>361</sup> The bill would therefore change current law, which generally allows manufacturers to take those actions to reduce the supply or desirability of an older product.<sup>362</sup> Commentators have argued that such practices encourage patients to use the new follow-on product, reducing demand for the original product and the opportunity for competition from any potential generic for the original product.<sup>363</sup>

The bill’s definition of a soft switch aims to capture other forms of product hopping that impede competition. Under the proposed language, a soft switch occurs when a manufacturer markets or sells a follow-on product and takes actions to impede competition for a generic product or a biosimilar version of the manufacturer’s product.<sup>364</sup>

The bill would also allow the manufacturer to rebut a prima facie case of product hopping.<sup>365</sup> First, a manufacturer would be able to justify its conduct by first establishing that it would have taken the same actions even if a generic had already entered the market.<sup>366</sup> For a hard switch, the manufacturer must also establish either (1) the actions that it took related to safety risks to patients of the original product;<sup>367</sup> or (2) if it withdrew, intended to withdraw, discontinued the manufacture of, or destroyed a product, that there was a supply disruption that was outside the control of the manufacturer.<sup>368</sup> For a soft switch, the manufacturer must establish that it had “legitimate pro-competitive reasons, apart from the financial effects of reduced competition, to take the action.”<sup>369</sup>

<sup>357</sup> *Id.* (proposed FTCA § 27(b)).

<sup>358</sup> *Id.* (proposed FTCA § 27(b)(1)(A)).

<sup>359</sup> *Id.* (proposed FTCA § 27(b)(1)(A)(i)). The bill defines the term “follow-on product” as an approved drug or biologic that changes, modifies, or reformulates “the same manufacturer’s previously approved drug or biological product that treats the same medical condition.” *Id.* (proposed FTCA § 27(a)(4)).

<sup>360</sup> Karshedt, *supra* note 241, at 1211; Lars Noah, *Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents*, 19 MARQ. INTELL. PROP. L. REV. 161, 172-79 (2015).

<sup>361</sup> S. 1416 § 2 (proposed FTCA § 27(b)(1)(A)(ii)).

<sup>362</sup> Shepherd, *supra* note 211, at 668-72.

<sup>363</sup> See, e.g., Karshedt, *supra* note 241, at 1211; Noah, *supra* note 360, at 172-79; Steven Adamson, *Pharmaceutical Patent Wars, Reverse-Payment Settlements, and Their Anticompetitive Effects for Consumers*, 30 LOY. CONSUMER L. REV. 241, 258-59 (2018); Park, *supra* note 209, at 760 n.126.

<sup>364</sup> *Id.* (proposed FTCA § 27(b)(1)(B)).

<sup>365</sup> *Id.* (proposed FTCA § 27(b)(2)).

<sup>366</sup> *Id.* (proposed FTCA § 27(b)(2)(A)(i)(I)).

<sup>367</sup> *Id.* (proposed FTCA § 27(b)(2)(A)(i)(II)(aa)).

<sup>368</sup> *Id.* (proposed FTCA § 27(b)(2)(A)(i)(II)(bb)).

<sup>369</sup> *Id.* (proposed FTCA § 27(b)(2)(A)(i)(II)(cc)).



The APPA would also make two changes aimed at reducing the impact of patent thickets for biological products.<sup>370</sup> First, the bill would broaden the types of patents that a brand biologic manufacturer could assert in premarketing litigation by extending the list of “artificial” acts of infringement under 35 U.S.C. § 271(e) to include patents claiming methods or products used to manufacture a biological product.<sup>371</sup> Second, the APPA would limit the number of certain patents that the brand could assert in litigation.<sup>372</sup> Specifically, the brand would be limited to asserting at most twenty patents that (1) claim the biologic or method or product used in the manufacture of a biologic, (2) were listed during the patent dance, and (3) were filed more than four years after approval of the reference product or include a claim to a manufacturing process not used by the brand.<sup>373</sup> Certain later-issued patents (i.e., those that issued after the brand provided its initial list to the biosimilar manufacturer during the patent dance) would be even further limited.<sup>374</sup> The APPA would nonetheless authorize a court to increase how many patents the brand can assert if done so promptly and if such an increase is in the interest of justice or for good cause.<sup>375</sup>

### Limiting the Availability of Hatch-Waxman’s Thirty-Month Stay

A number of bills, such as the Orange Book Transparency Act of 2019 (OBTA),<sup>376</sup> would change the patent listing requirements for the *Orange Book*.<sup>377</sup> Under current law, the brand must include any patent that claims the drug or a method of using the drug.<sup>378</sup> FDA regulations specify that “drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents” must be listed in the *Orange Book*, whereas “[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates” shall not be submitted to FDA.<sup>379</sup>

The OBTA would clarify the types of patents that may be listed in the *Orange Book*, only allowing listing of patents that (1) claim methods of using a drug or (2) claim the drug and are a drug substance (active ingredient) or drug product (formulation) patent.<sup>380</sup> Limiting the types of patents that may be listed would limit the availability of the thirty-month stay of FDA approval of

<sup>370</sup> *Id.* § 3.

<sup>371</sup> *Id.* § 3(a)(1).

<sup>372</sup> *Id.* § 3(a)(2) (proposed 35 U.S.C. § 271(e)(7)(A)-(B)).

<sup>373</sup> *Id.*

<sup>374</sup> *Id.*

<sup>375</sup> *Id.* (proposed 35 U.S.C. § 271(e)(7)(C)). Good cause “shall” be established if the biosimilar company did not supply information that would allow the brand to determine whether the application product is infringing on the patent. *Id.* (proposed 35 U.S.C. § 271(e)(7)(C)(ii)(II)(aa)). Good cause “may be established” if (1) there is a material change to the biosimilar or a process regarding the biosimilar, (2) the PTO failed to issue or delayed issuing a patent, or (3) the brand shows other good cause. *Id.* (proposed 35 U.S.C. § 271(e)(7)(C)(ii)(II)(bb)). The limit only applies if the biosimilar company completes the patent dance, and does not apply to any patent that claims a method for using a biological product in “therapy, diagnosis, or prophylaxis, such as an indication or method of treatment or other condition of use.” *Id.* (proposed 35 U.S.C. § 271(e)(7)(E)).

<sup>376</sup> H.R. 1503, 116th Cong. (2019).

<sup>377</sup> *See, e.g.*, Orange Book Transparency Act, H.R. 1503, 116th Cong. (2019); *see also* Lower Health Care Costs Act, S. 1895, 116th Cong. § 202 (2019) (provisions similar to H.R. 1503). OBTA passed the House of Representatives on May 8, 2019; all citations are to the version of the bill as passed and referred to the Senate.

<sup>378</sup> 21 U.S.C. § 355(b)(1).

<sup>379</sup> 21 C.F.R. § 314.53(b)(1).

<sup>380</sup> H.R. 1503, § 2(a), (d); *see also* 21 C.F.R. § 314.3(b) (defining, *inter alia*, “drug product” as “a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients” and defining “drug substance” as the drug’s active ingredient).

a generic because the stay is available only if the brand sues on one of the patents for which the generic made a Paragraph (IV) certification.<sup>381</sup> Moreover, the OBTA would require FDA to list in the *Orange Book* each applicable regulatory exclusivity period for each drug.<sup>382</sup> Finally, the bill would require the Government Accountability Office to submit a report to Congress detailing the types of patents included in the *Orange Book*, to include data on certain drug patents.<sup>383</sup>

## Increasing Biologic Patent Transparency

Other bills would focus on increasing transparency to combat patent thickets and facilitate generic or biosimilar entry. The Purple Book Continuity Act of 2019 (PBCA) would require a BLA holder to provide to FDA, and FDA to publish in the *Purple Book*, any patents the brand provides to the biosimilar company during the patent dance.<sup>384</sup> Further, the bill would require FDA to revise the *Purple Book* every thirty days to include (1) any new biologics that FDA licensed during that period and (2) information on patents that BLA holders provided to FDA during that period.<sup>385</sup> The PBCA would also require FDA to list any exclusivity period that applies to each listed biologic,<sup>386</sup> information that is not always currently included in the *Purple Book*.<sup>387</sup> Moreover, the brand must notify FDA if any biologic license was withdrawn or suspended for safety reasons, and FDA would, in turn, have to remove that product from the *Purple Book* for the relevant period.<sup>388</sup> By including the patents associated with a particular biologic, supporters of this approach argue that biosimilar manufacturers will be better able to evaluate the relevant patents before market entry.<sup>389</sup> PBCA further directs the Secretary of HHS to conduct a study regarding the type of information that should be included in the *Purple Book*, and transmit the results to Congress.<sup>390</sup>

The Biologic Patent Transparency Act (BPTA) similarly would require patent information to be listed in the *Purple Book*, and would require the *Purple Book* more generally to be published in “a single, easily searchable, list.”<sup>391</sup> However, the BPTA’s listing requirement is somewhat broader than the PBCA, including any patent that the brand “believes a claim of patent infringement could reasonably be asserted by the holder” (and not just patents provided during the patent dance) to be listed in the *Purple Book*.<sup>392</sup> Much like the PBCA, the BPTA would also require FDA to update

<sup>381</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>382</sup> H.R. 1503, § 2(c).

<sup>383</sup> *Id.* § 3.

<sup>384</sup> H.R. 1520, 116th Cong. § 2 (2019) (proposed 42 U.S.C. § 262(k)(9)(A)(iii)).

<sup>385</sup> *Id.* (proposed 42 U.S.C. § 262(k)(9)(A)(ii)-(iii)).

<sup>386</sup> *Id.* (proposed 42 U.S.C. § 262(k)(9)(A)(i)(III)).

<sup>387</sup> See *Background Information: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)*, U.S. FOOD & DRUG ADMIN. (Mar. 5, 2015), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411424.htm>.

<sup>388</sup> H.R. 1520 § 2 (proposed 42 U.S.C. § 262(k)(9)(B)).

<sup>389</sup> Zachary Brennan, *Biologic Patent Thickets: New Bill Aims to Publicize Info*, REG. AFF. PROFS. SOC’Y (Mar. 6, 2019), <https://www.raps.org/news-and-articles/news-articles/2019/3/biologic-patent-thickets-new-bill-aims-to-publicize>.

<sup>390</sup> H.R. § 1520 § 3.

<sup>391</sup> S. 659, 116th Cong. § 2(a) (2019) (proposed 42 U.S.C. § 262(o)(2)(A)). A version of the BPTA has been introduced in the House of Representatives, see H.R. 4850, 116th Cong. (2019), and similar provisions are included in the Lower Health Care Costs Act, see S. 1895, 116th Cong. § 201 (2019). For simplicity, all citations herein are to the Senate version of the BPTA as of January 17, 2020.

<sup>392</sup> S. 659 § 2(a) (proposed 42 U.S.C. § 262(o)(3)).

the *Purple Book* every thirty days.<sup>393</sup> The bill would further bar the brand from bringing an action for infringement of a patent that should have been, but was not, included in the *Purple Book*.<sup>394</sup>

## Reforming Pay-for-Delay Settlements

The Preserve Access to Affordable Generics and Biosimilars Act (PAAGBA) seeks to limit the ability of brands to pay generic or biosimilar manufacturers to delay their market entry.<sup>395</sup> To this end, PAAGBA creates a presumption of illegality for certain patent settlement agreements, moving away from a rule-of-reason analysis.<sup>396</sup> The proposed legislation would amend the FTC Act to specifically authorize the FTC<sup>397</sup> to initiate enforcement proceedings against parties to “any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product or biological product.”<sup>398</sup> Such agreements would be presumed to have anticompetitive effects if the brand agrees to provide the generic with “anything of value,” including monetary payments or distribution licenses, in exchange for the generic agreeing “to limit or forego research, development, manufacturing, marketing, or sales” of the generic product “for any period of time.”<sup>399</sup> The presumption would not attach, however, to agreements where the only compensation given to the generic is the right to market the product before relevant patents or exclusivities expire, reasonable litigation expenses, or a covenant not to sue for infringement.<sup>400</sup>

PAAGBA would not make agreements that fit its definitions per se illegal. The parties to the agreement could overcome the presumption of anticompetitive effect with “clear and convincing evidence” that (1) the agreement provides compensation “solely for other goods or services” from the generic company or (2) the agreement’s “procompetitive benefits . . . outweigh the anticompetitive effects.”<sup>401</sup> In evaluating this evidence, the fact finder cannot presume that entry would only have occurred after the expiration of the patent or statutory exclusivity.<sup>402</sup> It also cannot presume that allowing entry into the market before the patent or statutory exclusivity period expires is necessarily procompetitive.<sup>403</sup>

If the FTC proves that parties to an agreement violated these provisions, PAAGBA would provide for assessment of a civil monetary penalty against each violating party.<sup>404</sup> The civil penalty must be “sufficient to deter violations,” but no more than three times the value that the respective

<sup>393</sup> *Id.* (proposed 42 U.S.C. § 262(o)(2)(B)).

<sup>394</sup> *Id.* § 2(c).

<sup>395</sup> S. 64, 116th Cong. preamble (2019). The Competitive DRUGS Act of 2019, H.R. 1344, 116th Cong., and the Protecting Consumer Access to Generic Drugs Act of 2019, H.R. 1499, 116th Cong., include similar provisions to S. 64. In the 115th Congress, several comparable bills were introduced. *See, e.g.*, Expanding Access to Low Cost Generic Drugs Act, S. 2476, 115th Cong. (2018); Competitive DRUGS Act of 2017, H.R. 4117, 115th Cong. (2017).

<sup>396</sup> S. 64 preamble, § 3 (proposed FTCA § 27(a)(2)(A)).

<sup>397</sup> PAAGBA only addresses actions initiated by the FTC and does not modify the standards that apply to private suits. *See id.*

<sup>398</sup> *Id.* (proposed FTCA § 27(a)(1)).

<sup>399</sup> *Id.* (proposed FTCA § 27(a)(2)(A)).

<sup>400</sup> *Id.* (proposed FTCA § 27(c)).

<sup>401</sup> *Id.* (proposed FTCA § 27(a)(2)(B)).

<sup>402</sup> *Id.* (proposed FTCA § 27(b)).

<sup>403</sup> *Id.*

<sup>404</sup> *Id.* (proposed FTCA § 27(f)(1)).

violating party gained from the agreement.<sup>405</sup> If the brand did not gain demonstrable value from the agreement, the value the generic received would be used to calculate the penalty.<sup>406</sup> In calculating the penalty for a particular party, an FTC ALJ would consider “the nature, circumstances, extent, and gravity of violation”; the agreement’s impact on commerce; and the culpability, history of violations, ability to pay, ability to continue doing business, and profits or compensation gained by all parties.<sup>407</sup> Any penalties assessed would be in addition to, rather than in lieu of, any penalties imposed by other federal law.<sup>408</sup> The FTC would also be able to seek injunctions and other equitable relief, including cease-and-desist orders.<sup>409</sup> In addition, an ANDA filer that was party to such an agreement would forfeit its 180-day exclusivity awarded for challenging a patent using a Paragraph (IV) certification.<sup>410</sup>

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<sup>405</sup> *Id.*

<sup>406</sup> *Id.*

<sup>407</sup> *Id.* (proposed FTCA § 27(f)(3)).

<sup>408</sup> *Id.* (proposed FTCA § 27(f)(4)).

<sup>409</sup> *Id.* (proposed FTCA § 27(f)(1) & (2)).

<sup>410</sup> *Id.* § 5 (amending FD&C Act § 505(j)(5)(D)(i)(V)). Other provisions of PAAGBA would amend Section 1112 of the Medicare Prescription Drug Improvement and Modernization Act of 2003. S. 64 § 4 (proposed Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. § 355 note) § 1112(d)). This section currently requires parties to submit to the FTC and Department of Justice any agreements between follow-on product applicants and brand-name manufacturers, or among follow-on product applicants for the same drug or biologic, regarding the “manufacture, marketing, or sale” of either the brand-name pharmaceutical product or the follow-on product, or the 180-day exclusivity period. 21 U.S.C. § 355 note. PAAGBA would amend this section to require the CEO or “company official responsible for negotiating any agreement” to file a certification affirming that the materials filed were the complete agreements between the parties, including any ancillary agreements or written descriptions of oral agreements. S. 64 § 4 (proposed Medicare Prescription drug, Improvement, and Modernization Act of 2003 (21 U.S.C. § 355 note) § 1112(d)).

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