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# Drug Pricing and Intellectual Property: The Legislative Landscape for the 117th Congress

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## Drug Pricing and Intellectual Property: The Legislative Landscape for the 117th Congress

Intellectual property (IP) rights play an important role in the development and pricing of pharmaceuticals, such as prescription drugs and biological products (biologics). To provide incentives for research and development (R&D), IP law grants innovators exclusive rights that may prevent others from making generic or biosimilar versions of a drug or biologic, enabling makers of brand-name pharmaceuticals to charge higher prices in some circumstances. In the pharmaceutical context, such higher-than-competitive prices are intended to allow pharmaceutical manufacturers an opportunity to recoup substantial R&D costs, including clinical trials and other tests necessary to obtain regulatory approval from the Food and Drug Administration (FDA). Although many factors other than IP rights contribute to the cost of prescription drugs and biologics, pharmaceutical products are frequently protected by IP rights, and IP rights are often among the most important factors driving high drug prices.

New pharmaceutical products may benefit from two main forms of IP protection: patents and regulatory exclusivities. Patents are granted by the U.S. Patent and Trademark Office (PTO) to a wide range of inventions that are new, useful, nonobvious, and directed at patent-eligible subject matter. The holder of a valid patent generally has the exclusive right to make, use, sell, or import a patented invention within the United States for a roughly 20-year term. Regulatory exclusivities are granted by FDA for certain categories of pharmaceuticals upon the completion of the regulatory process required before manufacturers can market drugs and biologics in the United States. Generally, regulatory exclusivities prevent FDA from accepting or approving an application for a generic or biosimilar product, or preclude a competitor from relying on safety and efficacy data submitted by the original manufacturer, for a set period. There are many different types of regulatory exclusivities, ranging from six months to 12 years, depending on the type of pharmaceutical product and other factors.

Because of the connection between drug pricing and IP rights, many legislative proposals in the 116th Congress that sought to affect drug pricing focused on reforms to pharmaceutical patents and regulatory exclusivities. For example, a number of bills sought to change the use or enforcement of patent rights in pharmaceuticals, such as by increasing patent transparency; curtailing alleged tactics such as “evergreening,” “product hopping,” “patent thickets,” or “pay-for-delay” settlements; or altering procedures for PTO administrative challenges to pharmaceutical patents. Other bills would have changed the scope or length of various FDA regulatory exclusivities, including those for the new biological products, new chemical entities, or orphan drugs. Still other bills would have allowed the federal government to limit IP rights based on pricing, imposed conditions on IP rights arising from government-supported innovation, or directed the federal government itself to directly manufacture generic drugs and biosimilars. Finally, some bills focused primarily on IP rights in Coronavirus Disease 2019 (COVID-19) countermeasures (such as treatments and vaccines) or combined IP provisions with other drug-pricing or health care provisions not directly related to IP rights.

Dozens of pharmaceutical IP bills were introduced, more than a dozen were reported out of committee, several were passed by the Senate or the House of Representatives, and at least four were enacted into law. Issues relating to drug pricing and IP may continue to be debated in the 117th Congress. To facilitate consideration of these issues, this report summarizes legislative proposals introduced in the 116th Congress that concern drug pricing and relate to patent and regulatory exclusivity rights in drugs and biologics. Among other things, this report classifies bills by legislative status and type, and analyzes and compares bills addressing similar subject matter.

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Intellectual property (IP) rights play an important role in the development and pricing of pharmaceutical products, such as prescription drugs and biological products (biologics).<sup>1</sup> To provide incentives for development, IP law grants creators exclusive rights that may prevent others from making generic or biosimilar versions of a drug or biologic.<sup>2</sup> By limiting competition, IP rights enable makers of brand-name pharmaceuticals (the brand) to charge higher prices in some circumstances.<sup>3</sup> In the pharmaceutical context, IP rights are intended to allow pharmaceutical manufacturers an opportunity to recoup substantial costs in research and development (R&D), including clinical trials and other tests necessary to obtain regulatory approval from the Food and Drug Administration (FDA).<sup>4</sup> Although many factors other than IP rights contribute to the cost of prescription drugs and biologics,<sup>5</sup> IP rights frequently protect pharmaceutical products,<sup>6</sup> and IP rights are often among the most important factors driving high drug prices.<sup>7</sup>

A companion product, CRS Report R46679, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, reviews the essential legal background relating to IP rights in pharmaceuticals, including the basics of patent law, the FDA drug approval process, FDA regulatory exclusivities, and the specialized procedures for pharmaceutical patent disputes. It also discusses various alleged pharmaceutical patenting practices that have attracted legislative attention, such as “product hopping,” “patent thickets,” and “pay-for-delay” settlements. This report presumes knowledge of this legal background and terminology in order to compare and summarize the legislation introduced or enacted in the 116th Congress relating to drug patents and regulatory exclusivities. Accordingly, the report offers only a basic legal overview in the introduction before turning to discussion of the legislative proposals.

New pharmaceutical products generally benefit from two main forms of IP protection: patents and regulatory exclusivities. Patents, which are available to a wide range of technologies, are granted

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<sup>1</sup> See Henry G. Grabowski et al., *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 302, 302 (2015) (“Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals.”).

<sup>2</sup> See, e.g., 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii); 35 U.S.C. § 271; 42 U.S.C. § 262(k)(7).

<sup>3</sup> See *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.”); WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 299–300 (2003).

<sup>4</sup> See Grabowski et al., *supra* note 1, 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 3, at 24, 317.

<sup>5</sup> See generally CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*, by Suzanne M. Kirchoff, Judith A. Johnson, and Susan Thaul, at 3–13.

<sup>6</sup> See, e.g., LANDES & POSNER, *supra* 3, 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 (reviewing data “supporting relatively high dependency of the pharmaceutical industry on patent rights”).

<sup>7</sup> See, e.g., 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, 861 (2016) (“The most important factor that allows manufacturers to set high drug prices for brand-name drugs is market exclusivity, which arises from [IP 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) [hereinafter *Generic Competition and Drug Prices*].

by the U.S. Patent and Trademark Office (PTO) on inventions that are new, useful, nonobvious, and directed at patent-eligible subject matter.<sup>8</sup> The holder of a valid patent generally has the exclusive right to make, use, sell, or import a patented invention within the United States for a term beginning when the patent issues and ending 20 years after the date of the patent application.<sup>9</sup>

Regulatory exclusivities are granted by FDA upon the completion of the regulatory process required before manufacturers can market drugs and biologics in the United States.<sup>10</sup> Generally, regulatory exclusivities prevent FDA from accepting or approving an application for a generic or biosimilar product, or preclude a competitor from relying on safety and efficacy data submitted by the original manufacturer, for a set period.<sup>11</sup> There are many different types of regulatory exclusivities, ranging from six months to 12 years, depending on the type of pharmaceutical product and other factors.<sup>12</sup>

Because of the connection between drug pricing and IP rights, many legislative proposals in the 116th Congress that sought to affect drug pricing focused on reforms to patent and FDA law.<sup>13</sup> This report reviews legislative proposals introduced in the 116th Congress that sought to address drug pricing through changes to patent and regulatory exclusivity rights in drugs and biologics. To better understand and compare the proposed reforms, this report classifies pharmaceutical IP bills into the following five categories:

- 1. Pharmaceutical Patent Reforms.** These bills would have changed the use or enforcement of patent rights in pharmaceuticals, including proposals that sought (i) to increase patent transparency; (ii) to curtail so-called patent “evergreening,” “product hopping,” “patent thickets,” or “pay-for-delay” settlements; or (iii) to change the laws relating to PTO administrative challenges to pharmaceutical patents.
- 2. Regulatory Exclusivity Reforms.** These bills would have changed the scope or length of various FDA regulatory exclusivities, including (i) the 180-day exclusivity for the first-filed generic drug application; (ii) the new biological product exclusivity; (iii) the new chemical entity exclusivity; or (iv) the orphan drug exclusivity.
- 3. Government-Directed Price Regulation or IP Limitations.** These bills would have allowed the federal government to regulate drug prices more directly or to limit IP rights based on pricing. For example, these bills would have (i) permitted compulsory patent licensing; (ii) imposed pricing conditions on government-supported innovation, such as federally funded R&D; or (iii) directed the federal government to manufacture generic drugs and biosimilars to bring down prices.
- 4. COVID-19 Specific Bills.** The provisions in these bills—some of which may fall into other categories as well—were focused on medical countermeasures for Coronavirus Disease 2019 (COVID-19), such as vaccines or treatments.

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<sup>8</sup> See 35 U.S.C. §§ 101–103, 131. Patent applications must also conform to a number of requirements related to the sufficiency of the technical disclosure in the patent. *Id.* § 112.

<sup>9</sup> *Id.* §§ 154(a)(2), 271(a).

<sup>10</sup> See generally CRS In Focus IF11217, *Drug Pricing and the Law: Regulatory Exclusivities*, by Erin H. Ward.

<sup>11</sup> *Id.* at 1.

<sup>12</sup> *Id.* at 1–2.

<sup>13</sup> See *infra* “Drug Pricing and IP Legislation in the 116th Congress.”

**5. Omnibus Drug Pricing Bills with Pharmaceutical IP Provisions.** These bills contained one or more provisions from the categories above, but also contained other drug-pricing or health care provisions not related to IP rights.

This report focuses on legislative proposals that are related to IP rights in pharmaceuticals, specifically patent rights and regulatory exclusivities. Many other legislative proposals in the 116th Congress that were related to drug pricing, but were indirectly or not related to IP, are outside the scope of this report. For example, this report does not address bills introduced in the 116th Congress that would have permitted the government to negotiate drug prices for Medicare Part D;<sup>14</sup> increased transparency in drug pricing;<sup>15</sup> permitted importation of (sometimes cheaper) drugs in certain circumstances;<sup>16</sup> capped out-of-pocket drug costs or required manufacturer rebates in the Medicare program;<sup>17</sup> regulated the actions of pharmaceutical benefit managers;<sup>18</sup> or expanded the Medicare program to cover more Americans.<sup>19</sup> Also outside the scope of this report

<sup>14</sup> See, e.g., Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. tit. I (2019); Medicare Prescription Drug Price Negotiation Act of 2019, H.R. 275, 116th Cong. (2019); Medicare Drug Price Negotiation Act, H.R. 448, 116th Cong. (2019); Medicare Negotiation and Competitive Licensing Act of 2019, H.R. 1046, 116th Cong. (2019); Medicare Prescription Drug Savings and Choice Act of 2019, H.R. 4769, 116th Cong. (2019); Life-Sustaining Prescription Drug Price Relief Act of 2019, H.R. 5039, 116th Cong. (2019); Medicare Drug Price Negotiation Act, S. 99, 116th Cong. (2019); Medicare Negotiation and Competitive Licensing Act of 2019, S. 377, 116th Cong. (2019); Medicare Prescription Drug Savings and Choice Act of 2019, S. 2650, 116th Cong. (2019). Although outside the scope of this report, a few of these bills do contain provisions related to IP rights in pharmaceuticals; for example, one bill would allow the government to license patent rights to generic and biosimilars manufacturers if the government is unable to successfully negotiate an appropriate price. See H.R. 1046 § 2 (proposed 42 U.S.C. § 1395w-111(i)(3)); S. 377 § 2 (proposed 42 U.S.C. § 1395w-111(i)(3)).

<sup>15</sup> See, e.g., Prescription Drug Price Transparency Act, H.R. 1035, 116th Cong. (2019); SPIKE Act, H.R. 2069, 116th Cong. (2019); Drug Price Transparency Act, H.R. 2087, 116th Cong. (2019); Prescription Drug STAR Act, H.R. 2113, 116th Cong. (2019); Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act, H.R. 2115, 116th Cong. (2019); METRIC Act, H.R. 2296, 116th Cong. (2019); Drug Price Transparency for Medicare Patients Act of 2019, H.R. 3327, 116th Cong. (2019); Prescription Drug Price Reporting Act, H.R. 5239, 116th Cong. (2019); Drug Price Transparency for Medicare Patients Act of 2019, H.R. 5281, 116th Cong. (2019); Transparency in Prescription Drug Advertising Act, H.R. 5894, 116th Cong. (2020); SPIKE Act, S. 474, 116th Cong. (2019); Transparent Drug Pricing Act of 2019, S. 977, 116th Cong. (2019); FAIR Drug Pricing Act of 2019, S. 1391, 116th Cong. (2019); Drug-price Transparency in Communications (DTC) Act, S. 1437, 116th Cong. (2019); Prescription Drug Price Reporting Act, S. 1664, 116th Cong. (2019); Strengthening Average Sales Price Reporting Act of 2019, S. 2051, 116th Cong. (2019); Lower Costs, More Cures Act of 2019, S. 3129, 116th Cong. tit. II (2019).

<sup>16</sup> See, e.g., Affordable and Safe Prescription Drug Importation Act, H.R. 447, 116th Cong. (2019); Safe and Affordable Drugs from Canada Act of 2019, H.R. 478, 116th Cong. (2019); Affordable Insulin Act of 2019, H.R. 1478, 116th Cong. (2019); Safe and Affordable Drugs from Canada Act of 2019, S. 61, 116th Cong. (2019); Affordable and Safe Prescription Drug Importation Act, S. 97, 116th Cong. (2019); Short on Competition Act, S. 84, 116th Cong. (2019).

<sup>17</sup> See, e.g., H.R. 3 tit. II–III (2019); Pharmaceutical Rebates for Excessive Pricing Above Inflation Act, H.R. 4619, 116th Cong. (2019); Capping Drug Costs for Seniors Act of 2019, H.R. 4649, 116th Cong. (2019); Freedom from Price Gouging Act, H.R. 4663, 116th Cong. (2019); Lowering Drug Costs for Seniors Act of 2020, H.R. 7877, 116th Cong. (2020); Prescription Drug Pricing Reduction Act of 2019, S. 2543, 116th Cong. (2019); Prescription Drug Pricing Reduction Act of 2020, S. 4199, 116th Cong. (2020).

<sup>18</sup> See, e.g., Prescription Drug Price Transparency Act, H.R. 1035, 116th Cong. (2019); Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act, H.R. 2115, 116th Cong. (2019); Pharmacy Benefit Manager Accountability Study Act of 201, H.R. 3223, 116th Cong. (2019); PBM Transparency in Prescription Drug Costs Act, H.R. 5304, 116th Cong. (2019).

<sup>19</sup> See, e.g., Medicare for All Act of 2019, H.R. 1384, 116th Cong. (2019); Medicare for America Act of 2019, H.R. 2452, 116th Cong. (2019); Medicare for All Act of 2019, S. 1129, 116th Cong. (2019). Although outside the scope of this report, a few of these bills do contain provisions related to IP rights in pharmaceuticals; for example, some would allow the government to license patent rights to generic and biosimilars manufacturers for excessively priced drugs or if the government is unable to successfully negotiate an appropriate drug price. See, e.g., H.R. 1384 § 616; H.R. 2452 §§ 111, 303–304.

are proposals that focused on patent rights generally (but not pharmaceutical patents in particular),<sup>20</sup> or FDA processes generally (but not regulatory exclusivities in particular),<sup>21</sup> including efforts to facilitate market entry for generics and biosimilars by limiting tactics such as denial of drug samples<sup>22</sup> or dilatory citizen petitions.<sup>23</sup> Finally, executive actions taken with the aim of reducing drug prices are not within the scope of this report.<sup>24</sup> Other CRS products cover many of these topics.<sup>25</sup>

## Legislative Progress of Pharmaceutical IP Bills in the 116th Congress

**Table 1** lists the pharmaceutical IP legislation that was enacted into law, passed the House or the Senate, or was reported or ordered to be reported out of a committee.

Some pharmaceutical IP legislative proposals became law as part of other bills, such as P.L. 116-94 (H.R. 1865), Further Consolidated Appropriations Act, 2020,<sup>26</sup> and P.L. 116-260 (H.R. 133), Consolidated Appropriations Act, 2021.<sup>27</sup> Significant differences between the individual bills and the identical or similar provisions that were enacted into law are discussed in the next section.

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<sup>20</sup> See, e.g., Targeting Rogue and Opaque Letters Act of 2019, H.R. 108, 116th Cong. (2019); STRONGER Patents Act of 2019, H.R. 3666, 116th Cong. (2019); IDEA Act, H.R. 4075, 116th Cong. (2019); Inventor Rights Act, H.R. 5478, 116th Cong. (2019); Restoring America's Leadership in Innovation Act of 2020, H.R. 7366, 116th Cong. (2020); IDEA Act, H.R. 7890, 116th Cong. (2020); PACED Act, S. 440, 116th Cong. (2019); STRONGER Patents Act of 2019, S. 2082, 116th Cong. (2019); PALS Act, S. 2178, 116th Cong. (2019); IDEA Act, S. 2281, 116th Cong. (2019); IDEA Act, S. 4394, 116th Cong. (2020).

<sup>21</sup> See, e.g., Lower Insulin Costs Now Act, H.R. 5444, 116th Cong. (2019); MODERN Labeling Act of 2020, H.R. 5668, 116th Cong. (2020); A Bill to Amend the Biologics Price Competition and Innovation Act of 2009 to Make Improvements with Respect to the Transition of Biological Products, H.R. 6155 (2020); ADAPT Act, S. 658, 116th Cong. (2019); Short on Competition Act, S. 844, 116th Cong. (2019); A Bill to Establish a Process for Updating the Labeling of Certain Drugs, S. 1897, 116th Cong. (2019); Affordable Insulin Approvals Now Act, S. 2103, 116th Cong. (2019).

<sup>22</sup> See, e.g., CREATES Act of 2019, H.R. 965, 116th Cong. (2019) (enacted as amended as P.L. 116-94, div. N, tit. I, § 610); FAST Generics Act of 2019, H.R. 985, 116th Cong. (2019); CREATES Act of 2019, S. 340, 116th Cong. (2019) (enacted as amended as P.L. 116-94, div. N, tit. I, § 610).

<sup>23</sup> See, e.g., Stop STALLING Act, H.R. 2374, 116th Cong. (2019); Stop GAMES Act of 2019, H.R. 2387, 116th Cong. (2019); Ensuring Timely Access to Generics Act of 2019, H.R. 2455 (2019); Efficiency and Transparency in Petitions Act, S. 660, 116th Cong. (2019); Ensuring Timely Access to Generics Act of 2019, S. 1169, 116th Cong. (2019); Stop STALLING Act, S. 1224, 116th Cong. (2019).

<sup>24</sup> See, e.g., Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180 (Nov. 27, 2020) (interim final rule); Exec. Order No. 13,948, Lowering Drug Prices by Putting America First, 85 Fed. Reg. 59,649 (Sept. 13, 2020); Exec. Order No. 13,947, Lowering Drug Prices by Putting America First, 85 Fed. Reg. 59,171 (July 24, 2020); Exec. Order No. 13,939, Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, 85 Fed. Reg. 45,759 (July 24, 2020); Exec. Order No. 13,938, Increasing Drug Importation to Lower Prices for American Patients, 85 Fed. Reg. 45,757 (July 24, 2020).

<sup>25</sup> See generally CRS In Focus IF11318, *Negotiation of Drug Prices in Medicare Part D*, by Suzanne M. Kirchhoff; CRS In Focus IF11056, *Prescription Drug Importation*, by Amanda K. Sarata and Agata Bodie; CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis; CRS Report R46525, *Patent Law: A Handbook for Congress*, by Kevin T. Richards; CRS Legal Sidebar LSB10272, *The CREATES Act of 2019 and Lowering Drug Prices: Legal Background and Overview*, by Wen W. Shen; CRS In Focus IF11075, *FDA and Drug Prices: Facilitating Access to Generic Drugs*, by Agata Bodie.

<sup>26</sup> See P.L. 116-94, div. N, tit. I, §§ 606, 133 Stat. 2534, 3127 (2019).

<sup>27</sup> See P.L. 116-260, div. BB, tit. III, subtit. C, §§ 323, 325 (2020).



**Table I. Pharmaceutical IP Bills in the 116th Congress by Legislative Progress**

**Bold** indicates bill enacted in law (as part of a different piece of legislation where noted); *italics* indicate bill passed one house of Congress; underline indicates bill reported or ordered to be reported out of committee. Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor. Asterisk (\*) indicates furthest legislative progress as part of another bill.

Bill No.	Bill Title	Original Cosponsors (OCs)	Category(s)	Legislative Status
H.R. 1503	<b>Orange Book Transparency Act</b>	Rep. Robin Kelly	Pharmaceutical Patenting Reforms (Patent Transparency)	Enacted as P.L. 116-290
H.R. 1520	<b>Purple Book Continuity Act</b> <sup>*28</sup>	Rep. Eshoo	Pharmaceutical Patenting Reforms (Patent Transparency)	Similar to provisions enacted as P.L. 116-260, div. BB, tit. III, subtit. C, § 325
H.R. 2011	<b>Protecting Access to Biosimilars Act of 2019</b> <sup>^*</sup>	Rep. DeGette Rep. Reed Rep. Schrier Rep. Guthrie	Regulatory Exclusivity Reforms (New Biologic Exclusivity)	Similar to provisions enacted as P.L. 116-94, div. N, tit. I, § 606
S. 1140	<b>Protecting Access to Biosimilars Act of 2019</b> <sup>^*</sup>	Sen. Smith Sen. Cassidy	Regulatory Exclusivity Reforms (New Biologic Exclusivity)	Similar to provisions enacted as P.L. 116-94, div. N, tit. I, § 606
S. 1895 § 210	<b>Orphan Drug Clarification</b> <sup>^*</sup>	Sen. Alexander Sen. Murray	Regulatory Exclusivity Reforms (Orphan Drug Exclusivity)	Similar to provisions enacted as P.L. 116-260, div. BB, tit. III, subtit. C, § 323
H.R. 938	<i>BLOCKING Act</i> <sup>^*</sup>	Rep. Schrader Rep. Buddy Carter	Regulatory Exclusivity Reforms (180-day First Generic Exclusivity)	Passed House as Title I, subtitle A of H.R. 987
H.R. 987	<i>Strengthening Health Care and Lowering Prescription Drug Costs Act</i>	Rep. Blunt Rep. Rochester Rep. Castor Rep. McBath Rep. Kildee	Omnibus Drug Pricing Bills	Passed House 5/16/19
H.R. 1499	<i>Protecting Consumer Access to Generic Drugs Act of 2019</i> <sup>*</sup>	Rep. Rush	Pharmaceutical Patenting Reforms ("Pay-for-Delay" Settlements)	Passed House as Title I, subtitle B of H.R. 987
H.R. 4712	<i>Fairness in Orphan Drug Exclusivity Act</i> <sup>^</sup>	Rep. Dean Rep. Veasey Rep. Buddy Carter Rep. McKinley	Regulatory Exclusivity Reforms (Orphan Drug Exclusivity)	Passed House 11/17/20

<sup>28</sup> After passing the House and Senate in non-identical form, the Purple Book Continuity Act (H.R. 1520) was used as a vehicle for the Further Extension of Continuing Appropriations Act, 2021, which was enacted on December 22, 2020, to extend funding for the federal government through December 28, 2020. The substantive provisions of the Purple Book Continuity Act were enacted as part of P.L. 116-260, div. BB, tit. III, subtit. C, § 325.

Bill No.	Bill Title	Original Cosponsors (OCs)	Category(s)	Legislative Status
S. 1636	<u>Ensuring Innovation Act</u> <sup>^</sup>	Sen. Roberts Sen. Smith Sen. Cassidy	Regulatory Exclusivity Reforms (New Chemical Entity Exclusivity)	Passed Senate 12/14/20
H.R. 2375	<u>Preserve Access to Affordable Generics and Biosimilars Act</u> <sup>^</sup>	Rep. Nadler Rep. Collins Rep. Cicilline	Pharmaceutical Patenting Reforms (“Pay-for-Delay” Settlements)	Reported by House Judiciary Comm. 12/24/20 Discharged by House Energy and Commerce 12/24/2020
H.R. 3991	<u>Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019</u> <sup>^</sup>	Rep. Hank Johnson Rep. Roby	Pharmaceutical Patenting Reforms (“Patent Thickets”)	Ordered to be reported by House Judiciary Comm. 11/21/19
H.R. 5133	<u>Affordable Prescriptions for Patients Through Promoting Competition Act of 2019</u> <sup>^</sup>	Rep. Cicilline Rep. Collins Rep. Nadler Rep. Sensenbrenner	Pharmaceutical Patenting Reforms (“Product Hopping”)	Reported by House Judiciary Comm. 12/24/20
S. 1416	<u>Affordable Prescriptions for Patients Act of 2019</u> <sup>^</sup>	Sen. Cornyn Sen. Blumenthal	Pharmaceutical Patenting Reforms (“Product Hopping” and “Patent Thickets”)	Reported by Senate Judiciary Comm. 6/28/19
S. 1895	<u>Lower Health Care Costs Act</u> <sup>^</sup>	Sen. Alexander Sen. Murray	Omnibus Drug Pricing Bills	Reported by Senate Health, Education, Labor, and Pensions Comm. 7/8/19

Source: CRS; congress.gov.

## Pharmaceutical IP Proposals by Category: Comparison and Analysis

### Pharmaceutical Patenting Reforms

Patent rights represent one of the two main forms of IP rights in pharmaceuticals. Strong patent rights are viewed by many as necessary to allow manufacturers to recoup substantial R&D costs and thereby encourage investment in new treatments. Certain pharmaceutical patenting practices have attracted criticism as unduly extending the period of patent exclusivity and contributing to higher prices without sufficient benefits for consumers or innovation.<sup>29</sup> These practices include so-called patent “evergreening,” “product hopping,” “patent thickets,” and “pay-for-delay” settlements.<sup>30</sup> The following sections review legislative proposals that seek to increase patent

<sup>29</sup> See generally CRS Report R46221, *Drug Pricing and Pharmaceutical Patenting Practices*, coordinated by Kevin T. Richards.

<sup>30</sup> *Id.* at 15–32.

transparency, curtail these practices, or change how pharmaceutical patents may be challenged through PTO administrative procedures.

## **Bills Relating to Patent Transparency**

A number of bills in the 116th Congress focused on improving patent transparency as a way to encourage or expedite the market entry of generic drugs or biosimilars, aiming to decrease prices through increased competition. **Table 2** lists information on these bills.

***The Orange Book Transparency Act.*** The Orange Book Transparency Act of 2020 (OBTA), enacted into law as P.L. 116-290, clarified the patent listing requirements for the *Orange Book*.<sup>31</sup> The *Orange Book* lists information on drugs approved by FDA, including approved generic forms, therapeutic equivalence evaluations, and information on patents and regulatory exclusivities.<sup>32</sup> Brand-name drug manufacturers must include any patent that claims the drug or a method of using the drug as part of their new drug application (NDA); the FDA then lists these patents in the *Orange Book*.<sup>33</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>34</sup> The precise set of patents that may be listed in the *Orange Book* is important because generic manufacturers must make a patent certification with respect to *Orange Book*-listed patents, which may affect the timing of FDA approval—particularly the availability of the 30-month stay of FDA approval of a generic under the Hatch-Waxman Act.<sup>35</sup>

The OBTA, among other things, clarified the types of patents that may be listed in the *Orange Book*. Under the OBTA, the *Orange Book* must include only patents that (1) claim methods of using the drug for which approval is sought or had been granted, or (2) claim the drug and are a drug substance (active ingredient) or drug product (formulation) patent.<sup>36</sup> The types of patents that may be listed affect IP rights related to drug pricing because only listed patents may provide a basis for the 30-month stay of FDA approval of a generic.<sup>37</sup>

In addition to this provision, the OBTA requires FDA to list in the *Orange Book* applicable regulatory exclusivity periods for each drug.<sup>38</sup> It also requires NDA holders to notify FDA when any claim of an *Orange Book*-listed patent is invalidated in court or by the PTO, so that FDA can

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<sup>31</sup> Orange Book Transparency Act, H.R. 1503, 116th Cong. (2019) (enacted as P.L. 116-290); *see also* Lower Health Care Costs Act, S. 1895, 116th Cong. § 202 (2019) (provisions similar to H.R. 1503). All citations are to the version of the OBTA as enacted into law.

<sup>32</sup> *See Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN. (Nov. 2020), <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>.

<sup>33</sup> 21 U.S.C. § 355(b)(1), (c)(2).

<sup>34</sup> 21 C.F.R. § 314.53(b)(1).

<sup>35</sup> 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii).

<sup>36</sup> H.R. 1503 § 2(a); *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). In either case, the patent must be one that “for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug.” H.R. 1503 § 2(a).

<sup>37</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>38</sup> H.R. 1503 § 2(c).

“amend or remove” the information about that patent.<sup>39</sup> Finally, OBTA requires FDA to solicit public comment regarding the patent information that should be included or removed from the *Orange Book*, and it requires the Government Accountability Office to submit a report to Congress detailing the types of patents included in the *Orange Book*, including data on listed patents.<sup>40</sup>

***The Purple Book Continuity Act.*** The *Purple Book* is the biologics analogue of the *Orange Book*. It lists licensed biologics, including licensed biosimilar and interchangeable forms of biological products.<sup>41</sup> Prior to the 116th Congress, FDA was not required by statute to produce and publish the *Purple Book*, and patent information was not included.<sup>42</sup>

The Purple Book Continuity Act of 2020 (PBCA) was enacted, as amended, as a provision in the Consolidated Appropriations Act, 2021 entitled “Biological Product Patent Transparency.”<sup>43</sup> The PBCA requires FDA to publish the *Purple Book* in “a searchable, electronic format” and specifies the information (such as date of licensure and licensure status) that must be included in the *Purple Book*.<sup>44</sup> The PBCA further requires biologics license application (BLA) holders to provide to FDA information on patents asserted against a biosimilar company during the Biologics Price Competition and Innovation Act of 2009<sup>45</sup> (BPCIA) patent dispute procedures (the so-called “patent dance”),<sup>46</sup> which FDA would then list in the *Purple Book*.<sup>47</sup> Further, the PBCA requires FDA to revise the *Purple Book* every 30 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>48</sup> The PBCA also requires FDA to list any exclusivity period that applies to each listed biologic “for which the Secretary has determined such biological product to be eligible and that has not concluded.”<sup>49</sup> Also, the brand must notify FDA if any biologic license was revoked or suspended for safety reasons, and FDA must remove that product from the *Purple Book* for the relevant period.<sup>50</sup> Finally, the PBCA directs the Secretary of Health and Human Services (HHS)

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<sup>39</sup> *Id.* § 2(d)(i), (iii).

<sup>40</sup> *Id.* § 2(e)–(f).

<sup>41</sup> See *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, FOOD & DRUG ADMIN. (Aug. 3, 2020), <https://purplebooksearch.fda.gov/>.

<sup>42</sup> See 42 U.S.C. § 262(a); *Background Information: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)*, U.S. FOOD & DRUG ADMIN. (Aug. 3, 2020), <https://www.fda.gov/drugs/biosimilars/background-information-list-licensed-biological-products-reference-product-exclusivity-and> [hereinafter *Purple Book Background Information*]; Andrew Williams, *The Purple Book: The FDA Announces Welcome Enhancements*, WOLF GREENFIELD LIFE SCIS. IP BLOG (Feb. 27, 2020), <https://blog.wolfgreenfield.com/wolf-tracks-life-sciences-blog/the-purple-book-the-fda-announces-welcome-enhancements>.

<sup>43</sup> See P.L. 116-260, div. BB, tit. III, subtit. C, § 325 (2020).

<sup>44</sup> *Id.* § 325(a) (to be codified as 42 U.S.C. § 262(k)(9)(A)(i)).

<sup>45</sup> P.L. 111-148, Title VII, 124 Stat. 199, 804–21 (2010).

<sup>46</sup> See CRS In Focus IF11214, *Drug Pricing and the Law: Pharmaceutical Patent Disputes*, by Kevin J. Hickey. Specifically, the bill would apply 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>47</sup> *Id.* (to be codified as 42 U.S.C. § 262(k)(9)(A)(iii)).

<sup>48</sup> *Id.* (to be codified as 42 U.S.C. § 262(k)(9)(A)(ii)–(iii)).

<sup>49</sup> *Id.* (to be codified as 42 U.S.C. § 262(k)(9)(A)(iv)).

<sup>50</sup> P.L. 116-260, div. BB, tit. III, subtit. C, § 325(a) (proposed 42 U.S.C. § 262(k)(9)(B)).

to conduct a study regarding the type of information that should be included in the *Purple Book*, and transmit the results to Congress.<sup>51</sup>

**The Biologic Patent Transparency Act.** The proposed Biologic Patent Transparency Act (BPTA), similarly to the PBCA, would have required the *Purple Book* to be published as a single searchable list.<sup>52</sup> The BPTA’s patent listing requirement was somewhat broader than the PBCA, however, requiring 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>53</sup> Much like the PBCA, the BPTA would have required FDA to update the *Purple Book* every 30 days.<sup>54</sup> The BPTA would have also barred the brand from bringing an action for infringement of a patent that should have been, but was not, included in the *Purple Book*.<sup>55</sup>

**Table 2. Bills in the 116th Congress Relating to Patent Transparency**

**Bold** indicates bill enacted in law (as part of a different piece of legislation where noted). Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor. Asterisk (\*) indicates furthest legislative progress as part of another bill (see **Table I** for details).

Bill No.	Bill Title	OCs	Summary
H.R. 1503	<b>Orange Book Transparency Act</b>	Rep. Robin Kelly	Clarifies the types of patents that may be listed in the <i>Orange Book</i>
H.R. 1520	<b>Purple Book Continuity Act*</b>	Rep. Eshoo	Required publication of the <i>Purple Book</i> in a searchable format, including regulatory exclusivities and some patent information
H.R. 4850	Biologic Patent Transparency Act <sup>^</sup>	Rep. Spanberger Rep. Reed Rep. Anthony Gonzalez	Would require publication of the <i>Purple Book</i> as a single, searchable list, including patent and regulatory exclusivity information
S. 659	Biologic Patent Transparency Act <sup>^</sup>	Sen. Collins (and 5 OCs)	Would require publication of the <i>Purple Book</i> as a single, searchable list, including patent and regulatory exclusivity information

**Source:** CRS; congress.gov.

## Bills Relating to Patent “Evergreening”

Several bills introduced in the 116th Congress sought to curtail patent “evergreening,” the alleged practice of filing for new patents on secondary features of a pharmaceutical product as earlier-

<sup>51</sup> *Id.* § 325(b).

<sup>52</sup> S. 659, 116th Cong. § 2(a) (2019) (proposed 42 U.S.C. § 262(o)(2)(A), o(3)). An identical version of the BPTA has been introduced in the House of Representatives, *see* H.R. 4850, 116th Cong. (2019). (For simplicity, all citations herein are to the Senate version of the BPTA as introduced on March 5, 2019.) In 2020, FDA updated the *Purple Book* to make it available as a single, searchable online database. *See Purple Book Background Information, supra* note 42.

<sup>53</sup> S. 659 § 2(a) (proposed 42 U.S.C. § 262(o)(3)).

<sup>54</sup> *Id.* (proposed 42 U.S.C. § 262(o)(2)(B)).

<sup>55</sup> *Id.* § 2(c).

filed patents expire, thereby extending patent exclusivity past the original 20-year term.<sup>56</sup> **Table 3** lists information on these bills.

**The TERM Act.** The Terminating the Extension of Rights Misappropriated (TERM) Act of 2019<sup>57</sup> sought to curtail patent evergreening by reducing the impact of later-filed patents. The TERM Act would have established a presumption that, in patent challenges under the Hatch-Waxman Act<sup>58</sup> or BPCIA procedures,<sup>59</sup> the patentee “disclaim[s] the patent term for each of the listed patents after the date on which the term of the first patent expires.”<sup>60</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. The patentee would be able to overcome this presumption by demonstrating that the later-expiring patents on the drug or biologic claim “patentably distinct inventions.”<sup>61</sup> The law of double patenting already requires later-expiring patents to cover patentably distinct inventions to be valid,<sup>62</sup> but under current law, patents are presumed valid in a judicial proceeding unless *the challenger* proves patent invalidity by clear and convincing evidence.<sup>63</sup> The TERM Act would have placed the burden of proving patent validity on *the patentee* for certain later-expiring pharmaceutical patents.

The TERM Act would have further required the PTO to determine if changes to patent examination practice may be necessary. Specifically, the act would have required 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>64</sup> The act would have also required the PTO to submit a report to the House Committee on the Judiciary containing its findings and recommendations.<sup>65</sup>

**The REMEDY Act.** The Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act,<sup>66</sup> like the TERM Act, sought to curb evergreening by reducing the benefit of later-filed patents. Under the REMEDY Act, a generic’s filing of a Paragraph (IV) certification in an abbreviated new drug application (ANDA) would only trigger Hatch-Waxman’s 30-month stay

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<sup>56</sup> See Richards et al., *supra* note 29, at 16–20.

<sup>57</sup> Terminating the Extension of Rights Misappropriated (TERM) Act of 2019, H.R. 3199, 116th Cong. (2019).

<sup>58</sup> P.L. 98-417, 98 Stat. 1585 (1984).

<sup>59</sup> See CRS In Focus IF11214, *Drug Pricing and the Law: Pharmaceutical Patent Disputes*, by Kevin J. Hickey. Specifically, the bill would apply 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>60</sup> H.R. 3199 § 2(a).

<sup>61</sup> *Id.*

<sup>62</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>63</sup> 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95 (2011).

<sup>64</sup> H.R. 3199 § 2(b)(2)(A).

<sup>65</sup> *Id.* § 3.

<sup>66</sup> Reforming Evergreening and Manipulation that Extends Drug Years Act (REMEDY) Act, S. 1209, 116th Cong. (2019). An identical bill was 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 introduced on April 11, 2019.

if the patent claims a “drug substance”—that is, the drug’s active ingredient.<sup>67</sup> The stay would not be available for a patent that claims only a “drug product or method of use for a drug,” unless that patent also claims the drug substance itself.<sup>68</sup> In that case, the bill would have allowed FDA to approve the generic product without waiting for the litigation to determine the validity of the non-drug-substance patents.<sup>69</sup> This approach aimed to allow generic drugs to enter the market more quickly by limiting the grounds under which brands can receive a 30-month stay of FDA approval.<sup>70</sup>

The act would have also required that patents canceled by the PTO be removed from the *Orange Book*.<sup>71</sup> Finally, the bill would have clarified that challenging a patent that is later struck from the *Orange Book* would not affect the first-generic-filer 180-day exclusivity period.<sup>72</sup>

In sum, both the TERM Act and REMEDY Act would have limited the benefits of later-filed drug patents. However, the two bills would have limited those benefits in different ways. The TERM Act would have created a presumption that the patentee disclaimed the term of all listed patents that expired after the earliest-expiring patent. Unless the patentee overcame that presumption, all of those patents would be treated as expired (i.e., they could not be used to exclude the production of generics) after that date, shortening the life of those patents. Thus, the TERM Act would have made it more difficult for the brand to assert those later-filed patents by requiring the brand to establish that the patents are related to distinct inventions, but would allow the brand to assert its full patent portfolio if it could carry that burden. The REMEDY Act, in contrast, would have reduced the types of patents that would trigger a 30-month stay of FDA approval due to litigation, and thus could have allowed for earlier generic approval. Nevertheless, under the REMEDY Act, the brand could have continued to assert any patents relating to the drug for their full term.

**Table 3. Bills in the 116th Congress Relating to Patent “Evergreening”**

Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor.

Bill No.	Bill Title	OCs	Summary
H.R. 3199	TERM Act of 2019 <sup>^</sup>	Rep. Jeffries (and 4 OCs)	Creates presumption that later-expiring patents on pharmaceuticals expire unless proven to claim patentably distinct invention
H.R. 3812	REMEDY Act <sup>^</sup>	Rep. McKinley Rep. Welch	Would limit availability of Hatch-Waxman 30-month stay to certain pharmaceutical patents and require removal of cancelled patents from <i>Orange Book</i>
S. 1209	REMEDY Act <sup>^</sup>	Sen. Cassidy Sen. Durbin	Would limit availability of Hatch-Waxman 30-month stay to certain pharmaceutical patents and require removal of cancelled patents from <i>Orange Book</i>

Source: CRS; congress.gov.

<sup>67</sup> S. 1209 § 2(a)(1).

<sup>68</sup> S. 1209 § 2(a)(1).

<sup>69</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>70</sup> Davis, *supra* note 69.

<sup>71</sup> S. 1209 § 2(b)(1).

<sup>72</sup> *Id.* § 2(b)(2).

## **Bills Relating to “Product Hopping” and “Patent Thickets”**

Several bills introduced in the 116th Congress sought to curtail product hopping or patent thickets. “Product hopping” refers to the alleged practice in which brands, facing the expiration of patents on a particular pharmaceutical, introduce a new, similar product covered by a later-expiring patent and attempt to switch the market to that product.<sup>73</sup> “Patent thickets” refer to the alleged practice of a brand accumulating numerous, overlapping patents on the same product as a way to deter generics from entering the market due to the risk of infringement and the high cost of patent litigation.<sup>74</sup> **Table 4** lists information on these bills.

***The Affordable Prescriptions for Patients Act of 2019.*** The Affordable Prescriptions for Patients Act of 2019 (APPA) would have made product hopping an antitrust violation and set a limit on the number of certain patents that could be asserted in biosimilar litigation.<sup>75</sup>

***Product Hopping Provisions.*** The first portion of the bill would have amended the Federal Trade Commission Act of 1974 (FTCA) to make product hopping a violation of the federal antitrust laws.<sup>76</sup> Antitrust law (which generally aims to protect competition) may provide a natural fit for remedying product hopping because the alleged harm of product hopping is reduced competition for the original product.<sup>77</sup> The Federal Trade Commission (FTC) could prove a prima facie case of product hopping by showing that a manufacturer had engaged in either a “hard switch” or a “soft switch,” explained further below, during the relevant time period. The bill would have addressed “switches” during the time between (1) when the manufacturer first received notice that an applicant submitted an ANDA or biosimilar license application for a particular product; and (2) 180 days after the generic drug or biosimilar product is first marketed.<sup>78</sup>

Current law generally allows manufacturers to take actions that reduce the supply or desirability of an older product, and to replace that older product with a “follow-on product” (i.e., a new version of the drug)—a practice referred to as “product hopping.”<sup>79</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>80</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>81</sup> The APPA covers these situations by subjecting both types of switches

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<sup>73</sup> See Richards et al., *supra* note 29, at 20–24.

<sup>74</sup> See Richards et al., *supra* note 29, at 24–28.

<sup>75</sup> Affordable Prescriptions for Patients Act of 2019, § 2, S. 1416, 116th Cong. (2019). The portion of APPA aimed at preventing patent thickets was 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. (2019). The portion aimed at preventing product hopping was introduced in the House as the Affordable Prescriptions for Patients Through Promoting Competition Act of 2019. H.R. 4398, 116th Cong. (2019). For simplicity, discussion herein summarizes the Senate version as reported to the Senate on June 28, 2019.

<sup>76</sup> S. 1416 § 2.

<sup>77</sup> CRS Report R46679, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, coordinated by Erin H. Ward, at 37–41, 46–49.

<sup>78</sup> *Id.* (proposed FTCA § 27(b)).

<sup>79</sup> Joanna Shepherd, *Deterring Innovation: New York v. Actavis and the Duty to Subsidize Competitors’ Market Entry*, 17 MINN. J. OF L., SCI. & TECH. 663, 668–72 (2016); Ward et al., *supra* note 77, at 46–49.

<sup>80</sup> Ward et al., *supra* note 77, at 46.

<sup>81</sup> See, e.g., Dmitry Karshedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1211 (2019); Steven Adamson, *Pharmaceutical Patent Wars, Reverse-Payment Settlements, and Their Anticompetitive Effects for Consumers*, 30 LOY. CONSUMER L. REV. 241, 258–59 (2018); Justine Amy Park,



to the antitrust laws. The APPA defines a “hard switch” as occurring when a manufacturer requests that FDA withdraw approval for a listed product—possibly preventing a generic from marketing a competing product, because it would then lack a reference product—and then markets a “follow-on product” (i.e., a new version of the drug).<sup>82</sup> Under the APPA, a “hard switch” also occurs when the manufacturer markets a follow-on product after announcing the withdrawal, discontinuation, or intent to withdraw a listed product in a manner that impedes competition, or after destroying inventory of a listed product in a manner that impedes competition.<sup>83</sup> Taken together, the definition would capture circumstances in which a manufacturer removes its product from the market, and markets a new version of that product.

The bill’s definition of a soft switch would have aimed to capture other forms of product hopping that might impede competition but do not specifically fall within the definition of a “hard switch.” Under the proposed language, a soft switch would occur 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>84</sup> Thus, the definition of “soft switch” would serve as something of a catchall, capturing anticompetitive conduct not specifically articulated in the definition of a “hard switch.”

APPA would have allowed a manufacturer to rebut the FTC’s prima facie case of product hopping.<sup>85</sup> First, a manufacturer could justify its conduct by first establishing that it would have taken the same actions even if a generic had already entered the market.<sup>86</sup> For a hard switch, the manufacturer must also establish either that its actions related to safety risks of the original product, or that its actions were due to a supply disruption outside of its control.<sup>87</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>88</sup>

**Patent Thicket Provisions.** The APPA also aimed to reduce the impact of patent thickets for biological products.<sup>89</sup> First, the bill would have broadened the types of patents that could be asserted in pre-marketing litigation to include patents claiming methods or products used to manufacture a biological product.<sup>90</sup> Second, the bill would have limited the number of patents that a brand biologic manufacturer can assert in litigation against a biosimilar manufacturer to at most 20 patents meeting certain conditions.<sup>91</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)

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*Product Hopping: Antitrust Liability and a Per Se Rule*, 35 CARDOZO ARTS & ENT. L.J. 745, 760 n.126 (2017); 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>82</sup> *Id.* (proposed FTCA § 27(b)(1)(A)(i)-(ii)). 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>83</sup> *Id.*

<sup>84</sup> S. 1416 § 2 (proposed FTCA § 27(b)(1)(B)).

<sup>85</sup> *Id.* (proposed FTCA § 27(b)(2)).

<sup>86</sup> *Id.* (proposed FTCA § 27(b)(2)(A)(i)(I)).

<sup>87</sup> *Id.* (proposed FTCA § 27(b)(2)(A)(i)(II)(aa), (bb)).

<sup>88</sup> *Id.* (proposed FTCA § 27(b)(2)(A)(i)(II)(cc)).

<sup>89</sup> *Id.* § 3.

<sup>90</sup> *Id.* § 3(a)(1).

<sup>91</sup> *Id.* § 3(a)(2) (proposed 35 U.S.C. § 271(e)(7)(A)–(B)).

would have been even further limited.<sup>92</sup> The APPA would have nonetheless authorized courts to increase the number of asserted patents in the interest of justice or for good cause.<sup>93</sup>

***Affordable Prescriptions for Patients Through Promoting Competition Act of 2019 (H.R. 5133).*** The Affordable Prescriptions for Patients Through Promoting Competition Act of 2019 (H.R. 5133)<sup>94</sup> would have made product hopping an antitrust violation,<sup>95</sup> and is very similar to the product-hopping portion of the APPA (and H.R. 4398). However, H.R. 5133 adds some provisions that the other bills do not contain.

First, H.R. 5133 adds or changes the scope of certain terms defined in the APPA to clarify that the bill would not address certain practices. Specifically, H.R. 5133’s definition of a “follow-on product” specifically excludes an application that has been granted new chemical exclusivity by FDA,<sup>96</sup> and also excludes an application that has been granted reference product exclusivity.<sup>97</sup> Moreover, H.R. 5133 defines “disadvantage” to include practices that “impede the listed drug or reference product’s ability to compete on the merits with the follow-on product.”<sup>98</sup> This definition excludes “truthful, non-misleading promotional marketing” and also excludes “ceasing promotional marketing for the listed drug or reference product.”<sup>99</sup>

Second, H.R. 5133 uses a time window for determining whether product hopping occurred that is potentially more favorable to the original patent holder. APPA sets the window as between (1) when the manufacturer first received notice that an applicant submitted an ANDA or biosimilar license for a particular product; and (2) 180 days after the generic drug or biosimilar product is first marketed. H.R. 5133 sets the window as between (1) when the manufacturer first received notice that an applicant submitted an ANDA or biosimilar license for a particular product; and (2) *the earlier of* 180 days after the generic drug or biosimilar product is first marketed *and 3 years after the date on which the follow-on product is first marketed.*<sup>100</sup>

H.R. 5133 would have broadened the conduct regarded as a hard switch. Whereas the APPA defines a hard switch as, among other things, *announcing* “withdrawal of, discontinuance of the manufacture of, or intent to withdraw the application with respect to the drug or reference product in a manner that impedes competition from a generic drug or a biosimilar biological product, as established by objective circumstances,” H.R. 5133 adds *actual* withdrawal, discontinuation of

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<sup>92</sup> *Id.*

<sup>93</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>94</sup> Because H.R. 5133 has the same title as H.R. 4398, and deals with similar subject matter, the present discussion will use the bill number for sake of clarity.

<sup>95</sup> Affordable Prescriptions for Patients Through Promoting Competition Act of 2019, H.R. 5199, 116th Cong. (2019).

<sup>96</sup> *Id.* § 2 (proposed FTCA § 27(a)(4)(C)).

<sup>97</sup> *Id.* § 2 (proposed FTCA § 27(a)(4)(D)).

<sup>98</sup> *Id.* § 2 (proposed FTCA § 27(a)(6)).

<sup>99</sup> *Id.* § 2 (proposed FTCA § 27(a)(6)(A)-(B)).

<sup>100</sup> *Id.* § 2 (proposed FTCA § 27(b)(1)).

manufacture, or withdrawal of the application as actions that constitute a hard switch—conduct that arguably would not fall under the definition of a “hard switch” under the APPA.<sup>101</sup>

Finally, while the APPA listed specific remedies that the FTC may pursue for a product hopping violation (such as disgorgement), H.R. 5133 provides that the FTC “shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, duties, and remedies provided for by all applicable terms and provisions of the” FTCA.<sup>102</sup>

**Table 4. Bills in the 116th Congress Relating to “Product Hopping” or “Patent Thickets”**

Underline indicates bill reported or ordered to be reported out of committee. Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor.

Bill No.	Bill Title	OCs	Summary
H.R. 3991	<u>Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019<sup>^</sup></u>	Rep. Hank Johnson Rep. Roby	Would limit the number of patents that biologic manufacturer can assert in litigation against a biosimilar manufacturer
H.R. 5133	<u>Affordable Prescriptions for Patients Through Promoting Competition Act of 2019<sup>^</sup></u>	Rep. Cicilline Rep. Collins Rep. Nadler Rep. Sensenbrenner	Would make “product hopping” an antitrust violation subject to FTC enforcement
S. 1416	<u>Affordable Prescriptions for Patients Act of 2019<sup>^</sup></u>	Sen. Cornyn Sen. Blumenthal	Would make “product hopping” an antitrust violation subject to FTC enforcement, and limit the number of patents that biologic manufacturer can assert in litigation against a biosimilar manufacturer
H.R. 4398	Affordable Prescriptions for Patients Through Promoting Competition Act of 2019	Rep. Cicilline	Would make “product hopping” an antitrust violation subject to FTC enforcement

**Source:** CRS; congress.gov.

### Bills Relating to “Pay-for-Delay” Patent Litigation Settlements

Patent litigation can result when generic drug and biosimilar manufacturers seek to market a drug or biological product before patent rights expire, arguing either that the brand-name company’s patent is invalid or that it does not apply to the generic or biosimilar product. Some brand-name companies have resolved or settled such litigation through agreements with the generic manufacturer wherein the brand-name company pays the generic manufacturer a sum of money, which can be “many millions of dollars,” in return for the generic manufacturer agreeing to wait to enter the market.<sup>103</sup> This practice, referred to as “reverse payment settlements” or “pay-for-delay settlements,” allows the brand-name company to avoid the risk that its patent will be invalidated, potentially delay the market entry of generic competition that could lower drug

<sup>101</sup> *Id.* (proposed FTCA § 27(b)(1)(a)(ii)(I)(aa)).

<sup>102</sup> *Id.* (proposed FTCA § 27(c)).

<sup>103</sup> *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136, 144–45 (2013); *In re Androgel Antitrust Litigation*, No. 1:09-MD-2084-TWT, 2018 WL 298483, at \*3–4 (N.D. Ga. June 14, 2018).

prices, and may effectively extend its exclusive right to market the listed drug.<sup>104</sup> The FTC and private parties have alleged that these pay-for-delay agreements entail the brand-name company paying the generic applicant “many millions of dollars to stay out of its market” and, accordingly, have “significant adverse effects on competition.”<sup>105</sup>

Pay-for-delay agreements may contravene existing antitrust laws if they have anticompetitive effects. Section 1 of the Sherman Act prohibits “contracts . . . in restraint of trade or [interstate] commerce.”<sup>106</sup> The Supreme Court has held that the Sherman Act prohibits only *unreasonable* restraints, recognizing that all contracts operate as a restraint on trade.<sup>107</sup> Section 5 of the FTCA further prohibits “unfair methods of competition”<sup>108</sup>—a category that includes (but is not limited to) conduct that violates the Sherman Act.<sup>109</sup> The Supreme Court has recognized that “reverse payment settlements . . . can sometimes violate the antitrust laws,”<sup>110</sup> and courts have allowed antitrust litigation challenging certain reverse payment settlements to proceed under existing law.<sup>111</sup>

The Supreme Court has observed that pay-for-delay settlements are not inherently anticompetitive and illegal. A valid patent affords the owner the right to exclude infringing products from the market, and settlements (among other things) reduce litigation costs and litigation risk. But “an invalidated patent carries with it no such right,” “[a]nd even a valid patent confers no right to exclude products or processes that do not actually infringe.”<sup>112</sup> Pay-for-delay agreements terminate the litigation, leaving the questions of validity and infringement open.<sup>113</sup> Accordingly, some pay-for-delay settlements may delay the market entry of a generic competitor with a product that would not have infringed a valid patent, while others might allow the generic company to enter the market sooner than it would have despite a valid and infringed patent.

Courts generally apply a totality-of-the-circumstances “rule of reason” analysis to practices that are not per se illegal, such as pay-for-delay settlements.<sup>114</sup> The rule of reason requires the government to demonstrate that a challenged restraint on competition has anticompetitive effects in a properly defined product and geographic market.<sup>115</sup> Only after the government meets this

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<sup>104</sup> See, e.g., *Actavis*, 570 U.S. at 154.

<sup>105</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).

<sup>106</sup> 15 U.S.C. § 1.

<sup>107</sup> See, e.g., *NCAA v. Board of Regents of Univ. of Okla.*, 468 U.S. 85, 98 (1984).

<sup>108</sup> 15 U.S.C. § 45(a).

<sup>109</sup> See *FTC v. Cement Inst.*, 333 U.S. 683, 692 (1948).

<sup>110</sup> *Actavis*, 570 U.S. at 141.

<sup>111</sup> See, e.g., *King Drug Co. of Florence, Inc. v. SmithKlineBeecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 422 (E.D. Pa. 2015); *In re Aggrenox Antitrust Litigation*, 94 F. Supp. 3d 224, 245–46 (D. Conn. 2015).

<sup>112</sup> *Id.* at 147.

<sup>113</sup> *Id.*

<sup>114</sup> *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 387 (1956).

<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); 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 interchangeabl[e]” with the relevant product. See *Brown Shoe Co. v. U.S.*, 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.

burden is the onus on the defendant to provide evidence of a procompetitive justification for the challenged practice.<sup>116</sup> If the defendant can provide this evidence, the burden of proof shifts back to the government 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>117</sup>

A number of bills in the 116th Congress focused on proscribing pay-for-delay settlements or shifting the burden of proof in antitrust litigation over alleged pay-for-delay settlements from the government to the pharmaceutical companies. **Table 5** provides information on these bills.

***Preserve Access to Affordable Generics and Biosimilars Act.*** The Preserve Access to Affordable Generics and Biosimilars Act (PAAGBA) would have established a presumption that it is anticompetitive for brand-name manufacturers to compensate generic or biosimilar product manufacturers for delaying their entry into the market, moving away from a rule-of-reason analysis.<sup>118</sup> The proposed legislation would have amended the FTCA to specifically authorize the FTC<sup>119</sup> to initiate enforcement proceedings against all 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>120</sup> Such agreements would have been presumed to have anticompetitive effects and violate antitrust laws if the brand-name company agrees to provide the generic with “anything of value,” including monetary payments or distribution licenses, in exchange for the generic company agreeing “to limit or forego research, development, manufacturing, marketing, or sales” of the generic product “for any period of time.”<sup>121</sup>

The bill defined the scope of the presumption to focus on agreements that resemble pay-for-delay settlements. For example, the presumption that an agreement is anticompetitive would not have applied to agreements where the only consideration from the brand-name company 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>122</sup> Even where the presumption would have applied, moreover, the parties to the agreement would have had the opportunity to overcome the presumption 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>123</sup>

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

<sup>117</sup> See CRANE, *supra* note 115, at 54; Hovenkamp, *supra* note 115, at 104.

<sup>118</sup> Preserve Access to Affordable Generics and Biosimilars Act, S. 64, 116th Cong. preamble, § 3 (2019) (proposed FTCA § 27(a)(2)(A)). The Preserve Access to Affordable Generics and Biosimilars Act that was introduced in the House of Representatives as H.R. 2375 is substantially similar to S. 64. H.R. 2375 did not include a statement of findings as S. 64 did. H.R. 2375 requires notification of agreements between brand manufacturers and generic manufacturers, in addition to certification requirements provided for in S. 64. Finally, H.R. 2375 requires the FTC to provide a recommendation within a year as to whether brand manufacturers should be allowed to provide releases, waivers, or limitations for claims of damages or other monetary relief as consideration in settlement agreements without violating the provisions of the act.

<sup>119</sup> PAAGBA only addresses actions initiated by the FTC and does not modify the standards that apply to private suits. *See id.*

<sup>120</sup> *Id.* (proposed FTCA § 27(a)(1)).

<sup>121</sup> *Id.* (proposed FTCA § 27(a)(2)(A)).

<sup>122</sup> *Id.* (proposed FTCA § 27(c)).

<sup>123</sup> *Id.* (proposed FTCA § 27(a)(2)(B)). When evaluating a party’s evidence to overcome the presumption, the fact-finder (i.e., jury or, if there is no jury, judge) would have been instructed not to assume that (absent the agreement) the

If the FTC had proved that the agreement was anticompetitive and illegal under these provisions, the proposed legislation would have provided for assessment of a civil penalty against each violating party.<sup>124</sup> The civil penalty must have been “sufficient to deter violations,” based on a variety of factors established in the statute, but the penalty for each party could have been no more than three times the value gained by that party from the agreement.<sup>125</sup> Any penalties assessed would have been in addition to, rather than in lieu of, any penalties imposed by other federal law.<sup>126</sup> The FTC would also have been able to seek injunctions and other equitable relief, including cease-and-desist orders.<sup>127</sup> In addition, an ANDA filer that was party to such an agreement would have forfeited its 180-day exclusivity awarded for challenging a patent using a paragraph (IV) certification.<sup>128</sup>

***Competitive DRUGS Act of 2019.*** The Competitive DRUGS Act of 2019, much like the PAAGBA, would have deemed certain pay-for-delay settlements (specifically, those in which an ANDA filer agreed to limit its activities related to the ANDA product in exchange for receiving something of value from a brand-name manufacturer) to be an unfair method of competition in violation of Section 5 of the FTCA.<sup>129</sup> As with the PAAGBA, the Competitive DRUGS Act of 2019 would have allowed the parties to demonstrate by clear and convincing evidence either that the compensation is “solely for other goods or services” the ANDA filer is to provide or that “the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.”<sup>130</sup> For any such violations, in addition to the remedies provided for under the FTCA, the Competitive DRUGS Act of 2019 would have clawed back certain R&D tax benefits from violators.<sup>131</sup> The Competitive DRUGS Act of 2019 would have also imposed a 50% tax on funds received by parties under the violating agreement and precluded the parties from deducting any payments made pursuant to such an agreement from their taxable income.<sup>132</sup>

***Protecting Consumer Access to Generic Drugs Act of 2019.*** The Protecting Consumer Access to Generic Drugs Act of 2019 was substantively similar to the PAAGBA. However, unlike the PAAGBA and Competitive DRUGS Act of 2019, the Protecting Consumer Access to Generic

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generic would not have entered the market until the patent or exclusivity expired (i.e., that the agreement may have allowed for earlier entry), or that entering the market before the patent or exclusivity period expired would be procompetitive (i.e., that allowing the generic to enter the market sooner makes the agreement procompetitive). *Id.* (proposed FTCA § 27(b)).

<sup>124</sup> *Id.* (proposed FTCA § 27(f)(1)).

<sup>125</sup> *Id.* (proposed FTCA § 27(f)(1)).

<sup>126</sup> *Id.* (proposed FTCA § 27(f)(4)).

<sup>127</sup> *Id.* (proposed FTCA § 27(f)(1) & (2)).

<sup>128</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 generic and biosimilar product applicants and brand-name manufacturers, or among generic/biosimilar applicants for the same drug or biologic, regarding the “manufacture, marketing, or sale” of either the brand-name pharmaceutical product or the generic/biosimilar 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)).

<sup>129</sup> Competitive DRUGS Act of 2019, H.R. 1344, 116th Cong. § 4 (2019) (proposed FTCA § 27(a)(2)(A)).

<sup>130</sup> *Id.* (proposed FTCA § 27(a)(2)(B)).

<sup>131</sup> *Id.* § 2 (proposed Internal Revenue Code of 1986 (IRC) § 41).

<sup>132</sup> *Id.* § 3 (proposed IRC §§ 162(c)(4) & 4501).

Drugs Act of 2019 would not have allowed parties to avoid liability by demonstrating that the agreement’s procompetitive effects outweigh the anticompetitive effects; the exclusion would have been limited to compensation solely for the ANDA providing other goods or services.<sup>133</sup> In addition, the Protecting Consumer Access to Generic Drugs Act of 2019 would have not amended the FTCA directly as the PAAGBA and Competitive DRUGS Act of 2019 do.<sup>134</sup>

**Table 5. Bills in the 116th Congress Relating to “Pay-for-Delay” Patent Settlements**

*Italics indicate bill passed one house of Congress (as part of a different piece of legislation where noted); underline indicates bill reported or ordered to be reported out of committee. Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor. Asterisk (\*) indicates furthest legislative progress as part of another bill (see Table I for details).*

Bill No.	Bill Title	OCs	Summary
H.R. 1499	<i>Protecting Consumer Access to Generic Drugs Act of 2019*</i>	Rep. Rush	Would make certain “pay-for-delay” settlements unlawful and subject to FTC enforcement and civil penalties
H.R. 2375	<u>Preserve Access to Affordable Generics and Biosimilars Act</u> <sup>^</sup>	Rep. Nadler Rep. Collins Rep. Cicilline	Would make certain “pay-for-delay” patent litigation settlements a presumptive antitrust violation subject to FTC enforcement and civil penalties
H.R. 1344	Competitive DRUGS Act of 2019	Rep. Doggett (and 21 OCs)	Would make certain “pay-for-delay” patent litigation settlements a presumptive antitrust violation and impose tax penalties in addition to FTC enforcement
S. 64	Preserve Access to Affordable Generics and Biosimilars Act <sup>^</sup>	Sen. Klobuchar Sen. Grassley	Would make certain “pay-for-delay” patent litigation settlements a presumptive antitrust violation subject to FTC enforcement and civil penalties

Source: CRS; congress.gov.

## Bills Relating to Administrative Patent Challenges

Several bills introduced in the 116th Congress would have affected the strength of drug patents by focusing on patent validity challenges that use PTO administrative proceedings. Those proceedings, including inter partes review (IPR) and post-grant review (PGR), are explained in more detail in other CRS products.<sup>135</sup> PTO procedures generally provide a lower-cost and expedited means of challenging patent validity, as compared to district court litigation.<sup>136</sup> **Table 6** lists information on bills that would have changed these administrative processes as applied to pharmaceutical patents.

***The Hatch-Waxman Integrity Act of 2019.*** The Hatch-Waxman Integrity Act of 2019 (HWIA) would have strengthened the IP rights of brand-name patent holders by reducing a generic or biosimilar manufacturer’s ability to challenge drug patents using IPR and PGR.<sup>137</sup> HWIA would

<sup>133</sup> Protecting Consumer Access to Generic Drugs Act of 2019, H.R. 1499, 116th Cong. § 2(b) (2019).

<sup>134</sup> *Id.* § 2.

<sup>135</sup> See Richards, *supra* note 25, at 24–28.

<sup>136</sup> See H.R. REP. NO. 112-98, at 40 (2011) (legislation creating IPR and PGR “designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs”).

<sup>137</sup> Hatch-Waxman Integrity Act of 2019, H.R. 990, 116th Cong. § 2 (2019). A bill with the same title and proposed

have required a generic or biosimilar manufacturer to certify in its application for FDA approval that neither it nor any other party “in privity with, related to, or cooperating with” it has filed an IPR/PGR or will petition for IPR/PGR.<sup>138</sup> Moreover, HWIA would have required a generic manufacturer to state as part of its ANDA patent certification (for example, that a patent covering a reference product is invalid) that it was not “relying in whole or in part on any” decision in an IPR or PGR.<sup>139</sup> In short, HWIA would have constrained generic and biosimilar manufacturers from using the PTO post-grant processes to attempt to cancel drug patents, thus potentially benefiting brand-name pharmaceutical manufacturers.

Targeting certain practices of hedge fund managers, HWIA also aimed to prevent use of IPR to manipulate stock prices.<sup>140</sup> Specifically, HWIA would have amended the Securities and Exchange Act of 1934 to bar “manipulative or deceptive” use of IPR, that is, filing an IPR petition where the petitioner short sold the patent owner’s publicly traded security “during the 180-day period beginning on the date that is 90 days before the” petition date.<sup>141</sup>

***The Second Look at Drug Patents Act of 2019.*** In contrast to HWIA, the Second Look at Drugs Patents Act of 2019 (SLDPA) would have incentivized administrative challenges to pharmaceutical patents, specifically patents added to the *Orange Book*.<sup>142</sup> Under SLDPA, a brand would have been required to notify the PTO that it was adding patents to the *Orange Book*.<sup>143</sup> The PTO would then publish a notice regarding each patent and request that any eligible person file an IPR challenging the patent.<sup>144</sup> Such patents would be “provisionally” included in the *Orange Book* until either the PTO confirmed the relevant patents’ patentability or until a time period passed without any challenge to the patents (300 days if the patent had issued when FDA approved the relevant drug, or 15 months if the patent issued after approval).<sup>145</sup> If any patent claims are canceled as a result of an IPR, SLDPA would have required 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>146</sup> In sum, SLDPA would have provided greater notice regarding particular patents that generics may want to challenge and would have encouraged such challenges.<sup>147</sup>

HWIA and SLDPA represent different approaches to administrative challenges to pharmaceutical patents. Under HWIA, all issues relating to patent validity during Hatch-Waxman litigation would be determined in the courts, not the PTO. Arguably, this would be faithful to the balance struck when Hatch-Waxman was initially enacted in 1984, but it would forgo some of the potential efficiencies of the administrative processes that have grown in importance since that time. By

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text was also introduced in the Senate. Hatch-Waxman Integrity Act of 2019, S. 344, 116th Cong. (2019). For simplicity, all citations herein are to the House bill as introduced on February, 6, 2019.

<sup>138</sup> *Id.* §§ 2(a)(3), 2(b)(3), 2(c)(1)(C).

<sup>139</sup> *Id.* §§ 2(a)(3), 2(b)(3).

<sup>140</sup> See 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>141</sup> *Id.* § 3.

<sup>142</sup> S. 1617, 116th Cong. § 2(a) (2019).

<sup>143</sup> *Id.* § 2(a)(2)(C).

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> A similar bill with a subset of identical text was also introduced during the 116th Congress. See Second Look at Drug Patents Act of 2020, S. 4253, 116th Cong. (2020). S. 4253 would only require that the brand report patents added to the *Orange Book* to the PTO, and that the PTO publish and invite challenges to those patents. *Id.* § 3. It does not include the “provisional” *Orange Book* inclusion found in the SLDPA of 2019.



contrast, SLDPA would have made it easier to challenge patents that would likely be at issue in Hatch-Waxman litigation by having the PTO publish those patents to a public website and invite IPR/PGR challenges to those patents.

**Table 6. Bills in the 116th Congress Relating to Administrative Patent Challenges**

Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor.

Bill No.	Bill Title	OCs	Summary
H.R. 990	Hatch-Waxman Integrity Act of 2019	Rep. Flores	Would limit administrative challenges for certain pharmaceutical patents
S. 344	Hatch-Waxman Integrity Act of 2019	Sen. Tillis	Would limit administrative challenges for certain pharmaceutical patents
S. 1617	Second Look at Drug Patents Act of 2019 <sup>^</sup>	Sen. Murray Sen. Cornyn	Would require brand-name drug manufacturers to notify the PTO of <i>Orange-Book</i> -listed patents and for PTO to invite administrative challenge to such patents, which would be “provisionally” listed in the <i>Orange Book</i> pending such challenges
S. 4253	Second Look at Drug Patents Act of 2020 <sup>^</sup>	Sen. Murray Sen. Cornyn	Would require brand-name drug manufacturers to notify the PTO of <i>Orange-Book</i> -listed patents and for PTO to invite administrative challenge to such patents

Source: CRS; congress.gov.

## Regulatory Exclusivity Reforms

Regulatory exclusivities are granted to qualifying pharmaceutical products upon being approved or licensed for marketing by FDA. Regulatory exclusivities prevent FDA from accepting or approving an application by a competitor for FDA approval of a generic or biosimilar version of a previously approved pharmaceutical or preclude a competitor from relying on safety and efficacy data submitted by the original manufacturer for a period of time.<sup>148</sup> Depending on the type of pharmaceutical product and other factors, regulatory exclusivities may last anywhere from 6 months to 12 years.<sup>149</sup>

Because regulatory exclusivities prevent certain competing products from entering the market for a period of time, pharmaceutical companies may be able to charge higher prices for those drugs or biologics than they could in a more competitive market.<sup>150</sup> Regulatory exclusivities may accordingly be used to incentivize the development and marketing of certain types of pharmaceutical products, such as innovative products (e.g., a new active ingredient or new indication for an existing drug), first applicant generics, or those that serve a specific need (e.g., treating rare diseases).<sup>151</sup> However, because exclusivities exclude market entry, the benefits gained from encouraging innovation medicine may be weighed against the lower prices that typically result from increased competition.<sup>152</sup>

<sup>148</sup> See John R. Thomas, *The End of “Patent Medicines”? Thoughts on the Rise of Regulatory Exclusivities*, 70 FOOD & DRUG L.J. 39, 44–49 (2015).

<sup>149</sup> *Id.* at 48.

<sup>150</sup> See, e.g., *Generic Competition and Drug Prices*, *supra* note 7.

<sup>151</sup> See 21 U.S.C. §§ 355(c)(3)(E)(ii)-(iv), 355(j)(5)(F)(ii)-(iv), 355(u), 355(j)(5)(B)(iv)-(v), 356h, 360cc.

<sup>152</sup> See, e.g., *Generic Competition and Drug Prices*, *supra* note 7; *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

A number of bills were introduced in the 116th Congress to address which entities are eligible to receive certain types of exclusivities and when those exclusivities may be forfeited. This section addresses bills relating to 180-day first-generic exclusivity, new biological product exclusivity, new chemical entity exclusivity, and orphan drug exclusivity.

### **Bills Relating to the 180-Day First-Generic Exclusivity**

Brand-name drugs containing a new chemical entity may be covered by patents that prevent generic manufacturers from obtaining approval even after the five-year exclusivity for new chemical entities expires. To incentivize generic manufacturers to challenge patents listed in the *Orange Book*, the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides 180 days of exclusivity to the first ANDA applicant that successfully challenges an active patent listed for the reference listed drug (RLD).<sup>153</sup> This exclusivity period precludes FDA from approving another ANDA for the same RLD during the 180-day period. Three bills in the 116th Congress focused on preventing first ANDA applicants from sitting on their rights and delaying the 180-day exclusivity period and, accordingly, their or any other generic entry into the market. **Table 7** provides information on the bills.

**BLOCKING Act.** The Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019 (BLOCKING Act) would have added a new trigger for the 180-day exclusivity period.<sup>154</sup> Under the FD&C Act, the 180-day exclusivity period begins on the date of first commercial marketing of the drug by a first applicant for the RLD.<sup>155</sup> The BLOCKING Act would have amended this provision to begin the 180-day exclusivity period on the earlier of the date of first commercial marketing or the date on which four conditions are met: (1) another ANDA for the same RLD could be made effective but for the first applicant’s exclusivity; (2) at least 30 months have passed since an ANDA for the RLD was submitted to FDA; (3) patent litigation proceedings do not preclude approval of at least one first applicant; and (4) no first applicant’s ANDA has been approved. The effect of this change would have been to make the 180-day exclusivity period begin—and therefore expire—sooner in some cases, giving other generics an opportunity to seek approval to enter the market.<sup>156</sup>

**FAIR Generics Act.** The FAIR Generics Act would have redefined the term “first applicant” for purposes of the 180-day exclusivity period to exclude ANDA filers that entered into “disqualifying agreements.”<sup>157</sup> A disqualifying agreement, as defined by the act, would have been one in which an ANDA applicant agrees to delay seeking approval or beginning commercial marketing until after another ANDA applicant’s 180-day exclusivity period expires.<sup>158</sup> An ANDA applicant that does not file on the first day that any ANDA is filed for the drug would have to meet three other requirements to qualify as a “first applicant”: (1) the ANDA applicant submitted and maintained a paragraph (IV) certification for each listed patent certified by the first ANDA

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more low cost generic drugs, with the value of patent 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>153</sup> 21 U.S.C. § 355(j)(5)(B)(iv), (j)(5)(D)(iii)(II). A successful challenge is one that obtains a court ruling or settlement that a patent is invalid or will not be infringed by the ANDA applicant’s product. The exclusivity period may be shared by multiple applicants if they all file their ANDAs on the same day.

<sup>154</sup> BLOCKING Act of 2019, H.R. 938, 116th Cong. §2 (2019) (amending FD&C Act § 505(j)(5)(B)(iv)).

<sup>155</sup> 21 U.S.C. § 355(j)(5)(B)(iv)(I).

<sup>156</sup> H.R. 938 § 2 (amending FD&C Act § 505(j)(5)(B)(iv)).

<sup>157</sup> FAIR Generics Act, H.R. 1506, 116th Cong. § 2 (2019) (amending FD&C Act § 505(j)(5)(B)).

<sup>158</sup> *Id.* § 3(a) (amending FD&C Act § 505(j)(5)(B)).

filer(s); (2) the brand manufacturer did not pursue patent litigation following the certifications or the litigation resulted in a district court determination that the patents are invalid or not infringed; and (3) if the first ANDA filer(s) began commercially marketing their generic, the ANDA applicant waited to begin commercial marketing for at least 30 days after the first filers began commercial marketing.<sup>159</sup> The act would have also required first applicants to notify FDA of the text or content of any agreement wherein the first applicant agrees to delay seeking approval of its application, commercial marketing, or both.<sup>160</sup> Finally, the bill provided that suit under Hatch-Waxman procedures is the “exclusive remedy” for infringement of *Orange Book*-listed patents, potentially precluding infringement lawsuits if the brand does not sue within the 45-day period following a paragraph (IV) certification.<sup>161</sup>

***Expanding Access to Low-Cost Generics Act of 2019.*** As with the BLOCKING Act, the Expanding Access to Low-Cost Generics Act of 2019 would have changed when ANDAs may be approved for applicants that are not first applicants.<sup>162</sup> Under the Expanding Access to Low-Cost Generics Act of 2019, FDA could have approved a subsequent ANDA immediately, regardless of the 180-day regulatory exclusivity, upon a district court entering a decision that the challenged patents are invalid or not infringed if (1) the infringement proceeding were solely against the subsequent ANDA applicant and (2) the subsequent ANDA applicant did not stay the patent litigation, agree to be bound by the judgment as to another applicant, or request that any other ANDA filer join its petition to challenge the patent before the PTO.<sup>163</sup> FDA could have approved an ANDA that met the requirements of the act regardless of whether a first applicant had been approved or begun commercial marketing.<sup>164</sup>

**Table 7. Bills in the 116th Congress Relating to the 180-Day First-Generic Exclusivity**

*Italics indicate bill passed one house of Congress (as part of a different piece of legislation where noted). Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor. Asterisk (\*) indicates furthest legislative progress as part of another bill (see Table I for details).*

Bill No.	Bill Title	OCs	Summary
H.R. 938	<i>BLOCKING Act</i> <sup>^*</sup>	Rep. Schrader Rep. Buddy Carter	Would start the 180-day exclusivity period prior to first commercial marketing in some circumstances
H.R. 1506	FAIR Generics Act	Rep. Barragán	Would preclude generic applicants who enter into disqualifying agreements to delay seeking approval or commercial marketing from receiving the 180-day exclusivity, and would allow certain generic applicants who file paragraph (IV) certifications but did not file on the first day any ANDA was filed to be considered first generic applicants
S. 3092	Expanding Access to Low Cost Generics Act of 2019 <sup>^</sup>	Sen. Smith Sen. Braun	Would limit the scope of the 180-day exclusivity by allowing certain non-first generic applicants to obtain a court decision of patent invalidity or noninfringement to obtain immediate FDA approval

<sup>159</sup> *Id.* § 2 (amending FD&C Act § 505(j)(5)(B)).

<sup>160</sup> *Id.* § 3(a) (amending FD&C Act § 505(j)).

<sup>161</sup> *Id.* § 3(b).

<sup>162</sup> Expanding Access to Low-Cost Generics Act of 2019, S. 3092, 116th Cong. § 2 (2019) (amending FD&C Act § 505(j)(5)(B)(iv)).

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

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

Source: CRS; congress.gov.

## Bills Relating to the New Biological Product Exclusivity

Some pharmaceutical IP bills focus on biologics, which are medical treatments derived from living organisms, such as a vaccine, blood component, protein, serum, or antibody.<sup>165</sup> As compared to “small molecule” drugs (e.g., inorganic chemical substances), biologics tend to be large, complex organic molecules.<sup>166</sup> Biologics are regulated under different legal provisions than other drugs, and their complexity raises distinct issues.<sup>167</sup> FDA’s regulatory authority, the available regulatory exclusivities, the procedures for FDA licensure, and the pre-marketing patent dispute procedures are all distinct for biologics as compared to small-molecule drugs.

Under the BPCIA, which created an abbreviated approval process for biosimilar and interchangeable products,<sup>168</sup> newly licensed biological products are generally entitled to a 12-year period of regulatory exclusivity.<sup>169</sup> More specifically, FDA may not approve an application to license a biosimilar or interchangeable version of a biologic until 12 years after the date that the product was “first licensed” by FDA.<sup>170</sup> **Table 8** lists information on pharmaceutical IP bills in the 116th Congress that focus specifically on this regulatory exclusivity for new biological products.<sup>171</sup>

**Protecting Access to Biosimilars Act.** The Protecting Access to Biosimilars Act of 2019 (PABA), which was enacted as amended as part of another bill, clarified how the BPCIA’s transition provision interacts with the new biological product exclusivity.<sup>172</sup> Provisions substantively similar to PABA were enacted into law as a provision in the Further Consolidated Appropriations Act, 2020 entitled “Protecting Access to Biological Products.”<sup>173</sup>

For historical reasons, certain biological products (including, notably, insulin) were approved and regulated by FDA as drugs under the FD&C Act, and not as biologics under the Public Health Service Act (PHSA).<sup>174</sup> Under Section 7002(e)(4) of the BPCIA, prior approvals of biological

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<sup>165</sup> 42 U.S.C. § 262(i); U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS, <https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf> (last visited Nov. 11, 2020); see generally CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*, by Agata Bodie.

<sup>166</sup> See Bodie, *supra* note 165, at 1–3.

<sup>167</sup> See generally Bodie, *supra* note 165, at 10–19.

<sup>168</sup> Biologics Price Competition and Innovation Act of 2009, P.L. 111-148, tit. VII, 124 Stat. 119, 804–21 (2010) [hereinafter BPCIA]; see 42 U.S.C. § 262(k).

<sup>169</sup> See 42 U.S.C. § 262(k)(7)(A).

<sup>170</sup> *Id.*

<sup>171</sup> This list discusses bills that would address the new biologic exclusivity generally. Other bills, not included here, would focus solely on insulin, a particularly important biological product. See, e.g., Insulin Access for All Act, H.R. 366, 116th Cong. (2019); Affordable Insulin Act, H.R. 1478, 116th Cong. (2019); Insulin Price Reduction Act, H.R. 4906, 116th Cong. (2019); End Price Gouging for Insulin Act, H.R. 5364, 116th Cong. (2019); Affordable Insulin for All Act, H.R. 5749, 116th Cong. (2020); Matt’s Act, H.R. 7722, 116th Cong. (2020); Biosimilar Insulin Access Act, H.R. 8190, 116th Cong. (2020); Insulin Price Reduction Act, S. 2199, 116th Cong. (2019); End Price Gouging for Insulin Act, S. 2817, 116th Cong. (2019).

<sup>172</sup> Protection Access to Biosimilars Act of 2019, H.R. 2011, 116th Cong. (2019). A nearly identical bill was introduced in the Senate, see S. 1140, 116th Cong. (2019). For simplicity, all citations are to the House version as introduced on April 1, 2019.

<sup>173</sup> See P.L. 116-94, div. N, tit. I, § 606, 133 Stat. 2534, 3127 (2019).

<sup>174</sup> See U.S. FOOD & DRUG ADMIN., INTERPRETATION OF THE “DEEMED TO BE A LICENSE” PROVISION OF THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 1999: GUIDANCE FOR INDUSTRY 1–2, 14 (Dec. 2018), <https://www.fda.gov/media/119590/download> [hereinafter FDA “DEEMED TO BE A LICENSE” GUIDANCE].

products made under the FD&C Act shall be “deemed to be a license” of a biologic under the PHS Act on March 23, 2020.<sup>175</sup> In guidance released in late 2018, FDA interpreted the BPCIA transition provision to mean that, although a biological product formerly approved under the FD&C Act will be “deemed” to have a biologics license on March 23, 2020, such a product will *not* be eligible for the 12-year new biological product exclusivity.<sup>176</sup>

PABA, as amended and enacted, codified this FDA guidance by establishing that an approved application “deemed to be a license” under the BPCIA transition provision shall not be treated as a “first licensure” of a biological product for purposes of the BPCIA’s regulatory exclusivities.<sup>177</sup> The statute further clarifies that the “anti-evergreening” provisions of BPCIA apply to “deemed” licenses.<sup>178</sup>

***The PRICED Act and the Emergency Access to Insulin Act.*** The Price Relief, Innovation, and Competition for Essential Drugs Act (PRICED Act) would have shortened the length of the new biological product exclusivity from 12 years to 5 years for biologics licensed after the enactment of the act.<sup>179</sup> (The BPCIA’s 12-year exclusivity for new biological products is several years longer than comparable regulatory exclusivities in some other nations.<sup>180</sup>)

The Emergency Access to Insulin Act of 2019, in addition to a number of provisions designed to decrease cost and increase access to insulin (including for uninsured and underinsured individuals), included provisions that would have shortened the new biological product exclusivity from 12 years to 7 years.<sup>181</sup>

**Table 8. Bills in the 116th Congress Relating to the New Biological Product Exclusivity**

**Bold** indicates bill enacted in law (as part of a different piece of legislation where noted). Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor. Asterisk (\*) indicates furthest legislative progress as part of another bill (see **Table I** for details).

Bill No.	Bill Title	OCs	Summary
H.R. 2011	<b>Protecting Access to Biosimilars Act of 2019<sup>^*</sup></b>	Rep. DeGette Rep. Reed Rep. Schrier Rep. Guthrie	Clarifies that no additional regulatory exclusivity is available for biological products previously regulated as drugs
S. 1140	<b>Protecting Access to Biosimilars Act of 2019<sup>^*</sup></b>	Sen. Smith Sen. Cassidy	Clarifies that no additional regulatory exclusivity is available for biological products previously regulated as drugs

<sup>175</sup> BPCIA § 7000(e)(4), 124 Stat. at 817; *see* 42 U.S.C. § 262 note.

<sup>176</sup> *See* FDA “DEEMED TO BE A LICENSE” GUIDANCE, *supra* note 174, at 9–10.

<sup>177</sup> *See id.*; Protecting Access to Biosimilars Act of 2019, H.R. 2011, 116th Cong. § 2 (2019) (proposed 42 U.S.C. § 262(k)(7)(D)).

<sup>178</sup> P.L. 116-94 § 606; H.R. 2011, § 2.

<sup>179</sup> PRICED Act, H.R. 3379, 116th Cong. § 2 (2019).

<sup>180</sup> CRS In Focus IF11314, *USMCA: Intellectual Property Rights (IPR)*, by Shayerah Ilias Akhtar and Ian F. Fergusson (noting five-year and eight-year new biologic exclusivities in Mexico and Canada, respectively). Europe generally has eight years of data exclusivity followed by two years of marketing exclusivity for both biologics and small-molecule drugs. *See* Commission Regulation 726/2004, art. 14(11), 2004 O.J. (L 136) 10.

<sup>181</sup> Emergency Access to Insulin Act of 2019, S. 2004, 116th Cong. § 5 (2019). An identical bill was introduced in the House, *see* H.R. 4010, 116th Cong. (2019).

Bill No.	Bill Title	OCs	Summary
H.R. 3379	PRICED Act <sup>^</sup>	Rep. Schakowsky (and 16 OCs)	Would shorten regulatory exclusivity for new biologics from 12 to 5 years
H.R. 4010	Emergency Access to Insulin Act of 2019	Rep. Craig Rep. Phillips	Inter alia, would shorten new biologic regulatory exclusivity from 12 to 7 years
S. 2004	Emergency Access to Insulin Act of 2019 <sup>^</sup>	Sen. Smith Sen. Cramer	Inter alia, would shorten new biologic regulatory exclusivity from 12 to 7 years

Source: CRS; congress.gov.

## Bills Relating to the New Chemical Entity Exclusivity

Whether the “active ingredient” of a particular drug product is “novel” is an important consideration for many provisions of the FD&C Act. In particular, FDA must assess the novelty of the active ingredient in a new drug to determine whether the new drug qualifies for the five-year “new chemical entity” (NCE) exclusivity.<sup>182</sup> FDA generally cannot accept new drug applications or ANDAs that refer to a drug with NCE exclusivity (i.e., rely on its clinical data and FDA’s approval of the drug) for five years.<sup>183</sup> Companies that receive approval for drugs with new active ingredients generally enjoy a competitive advantage in the market while the exclusivity is in effect, because that exclusivity prevents generic drugs from entering the market.<sup>184</sup> Given how expensive it can be to bring a new drug to market,<sup>185</sup> when Congress passed the Hatch-Waxman Amendments in 1984 to allow an abbreviated pathway for approval of generic drugs, it also created NCE exclusivity to reward innovators of new pharmaceutical products with an opportunity to recoup their investment.<sup>186</sup>

It can be technically complicated to determine whether the “active ingredient(s)” of a drug is the same as that in a previously approved drug.<sup>187</sup> For instance, compounds in a final drug product may convert to other compounds through chemical reactions inside the body before arriving at the site of the therapeutic effect, and related but distinct drug molecules may be clinically indistinguishable or convert into the same pharmacologically or physiologically active component inside the body.<sup>188</sup> This phenomenon raises the question of which molecule—the one existing before or after ingestion—should be the relevant molecule for purposes of determining active ingredient.

<sup>182</sup> 21 U.S.C. §§ 355(j)(5)(F)(ii) & 355(c)(3)(E)(ii).

<sup>183</sup> *Id.* ANDAs that challenge non-expired listed patents may be submitted after four years. *Id.*

<sup>184</sup> *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN. (Nov. 28, 2017), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (finding association between generic competition and lower drug prices).

<sup>185</sup> See generally Joseph A. Di Masi, Henry G. Grabowski, & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016).

<sup>186</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,’ H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647–48, with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement, see H.R. Rep. No. 98-857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2714.”); 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>187</sup> See, e.g., 21 U.S.C. § 355(c)(3)(E).

<sup>188</sup> See, e.g., *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 762–63, 766 (D.C. Cir. 2010); *Abbott Laboratories v. Young*, 920 F.2d 984, 986 (D.C. Cir. 1990).

Alternatively, two drug molecules with the same core compound may have different compounds appended to them by either covalent (i.e., shared electrons) or noncovalent (i.e., no shared electrons) bonds.<sup>189</sup> For example, replacing a hydrogen atom in an acid molecule with “a metal or its equivalent” forms a salt, whereas replacing the hydrogen atom with “an organic radical” forms an ester.<sup>190</sup> These derivatives may or may not vary from each other in clinically significant ways,<sup>191</sup> raising the question of *which* derivative(s), if any, should be considered as the same active ingredient as the core or base molecule.

Congress has considered ways to affect drug pricing and IP by addressing how an “active ingredient” is determined. Generally, a more expansive interpretation of the phrase “active ingredient” (i.e., one that considers more types of derivatives to be the same active ingredient) increases the number of drugs that are considered to be previously approved. This, in turn, reduces the number of drugs eligible for NCE regulatory exclusivity and allows for earlier introduction of generic versions of those drugs.

Historically, for purposes of the exclusivity provisions, FDA has interpreted the statutory term “active ingredient” to mean “active moiety,” as defined by FDA regulations.<sup>192</sup> The FDA generally defines active moiety as the core molecule or ion of a drug that is “responsible for the physiological or pharmacological action of a drug substance.”<sup>193</sup> FDA’s interpretation has generated disputes between FDA and pharmaceutical companies, as FDA’s approach tends to exclude some drugs from being afforded five-year NCE exclusivity under the FD&C Act.<sup>194</sup> In 2015, a federal district court rejected FDA’s interpretation as inconsistent with the statutory language, though it did not explicitly invalidate FDA’s regulations.<sup>195</sup>

***The Ensuring Innovation Act.*** The Ensuring Innovation Act would have generally (1) codified FDA’s interpretation that eligibility for NCE exclusivity should be based on the drug’s active moiety and (2) incorporated FDA’s definition of active moiety by reference.<sup>196</sup> Specifically, the proposed legislation would have done so by replacing the entire phrase “active ingredient (including any ester or salt of the active ingredient)” with “active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))” wherever it is found, except for a few provisions that expired in 1984.<sup>197</sup> This change would have affected several FD&C Act provisions, including the NCE exclusivity provision, three-year exclusivity for other changes, and provisions providing priority review

<sup>189</sup> *Actavis Elizabeth LLC*, 625 F.3d at 765–66.

<sup>190</sup> *Amarin Pharm. Ireland Ltd. v. FDA*, 106 F. Supp. 3d 196, 199 n.1 (D.D.C. 2015).

<sup>191</sup> *Actavis Elizabeth LLC*, 625 F.3d at 765–66.

<sup>192</sup> See 21 C.F.R. § 314.3; 59 Fed. Reg. 50,338, 50,357–58, 50,368–69 (Oct. 3 1994).

<sup>193</sup> 21 C.F.R. § 314.3(b).

<sup>194</sup> See generally, *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760 (D.C. Cir. 2010); *Abbott Labs. v. Young*, 920 F.2d 984 (D.C. Cir. 1990); *Otsuka Pharm. Co. v. Burwell*, 302 F. Supp. 3d 375 (D.D.C. 2016); *Ferring Pharm., Inc. v. Burwell*, 169 F. Supp. 3d 199 (D.D.C. 2016).

<sup>195</sup> *Amarin Pharm. Ireland Ltd. v. FDA*, 106 F. Supp. 3d 196, 217–19 (D.D.C. 2015).

<sup>196</sup> Ensuring Innovation Act, S. 1636, 116th Cong. (2019). The same provisions are found in the Protecting Access to Safe and Effective Medicines Act of 2019 that was introduced in the House of Representatives. H.R. 4955, 116th Cong. (2019). For simplicity, citations herein are to the Senate version of S. 1636 as passed by the Senate on December 14, 2020.

<sup>197</sup> See S. 1636; see also H.R. 4955; Lower Health Care Costs Act, S. 1895, 116th Cong. § 208 (2019). Specifically, the bills would amend 21 U.S.C. § 355(c)(3)(E)(ii) & (iii); 21 U.S.C. § 355(j)(5)(F)(ii) & (iii); 21 U.S.C. § 355(l)(2)(A)(i); 21 U.S.C. § 355(s); 21 U.S.C. § 355(u)(1); 21 U.S.C. § 360b(c)(2)(F)(i), (ii), and (v); 21 U.S.C. § 360n(a)(4)(C); 21 U.S.C. § 360ff(a)(4)(A)(ii); and 21 U.S.C. § 360bbb-4a(a)(4)(D). Note that it is unclear whether FDA currently uses its definition of active moiety in 21 C.F.R. § 314.3 when administering all of these provisions.

vouchers for tropical disease treatments, rare pediatric disease treatments, and countermeasures for agents that threaten national security.<sup>198</sup> The proposed legislation would have both adopted FDA’s current approach, by incorporating FDA’s current definition, and allowed FDA to modify its approach going forward as its understanding changed, by including any successor regulations.<sup>199</sup> In effect, the proposed legislation would have left the decision as to which molecules should be deemed effectively the same and therefore not innovative enough to merit NCE exclusivity to FDA’s judgment.

**Table 9. Bills in the 116th Congress Relating to the New Chemical Entity Exclusivity**

*Italics indicate bill passed one house of Congress. Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor.*

Bill No.	Bill Title	OCs	Summary
S. 1636	<i>Ensuring Innovation Act</i> <sup>^</sup>	Sen. Roberts Sen. Smith Sen. Cassidy	Would codify FDA’s regulatory definition of active ingredient for, inter alia, purposes of the new chemical entity regulatory exclusivity
H.R. 4955	Protecting Access to Safe and Effective Medicines Act of 2019 <sup>^</sup>	Rep. Engel Rep. Guthrie Rep. Schrader Rep. Hudson	Would codify FDA’s regulatory definition of active ingredient for, inter alia, purposes of the new chemical entity regulatory exclusivity

Source: CRS; congress.gov.

## Bills Relating to the Orphan Drug Exclusivity

Congress passed the Orphan Drug Act in 1983 to encourage the development of “orphan drugs” (i.e., drugs and biologics to treat rare diseases and conditions).<sup>200</sup> Because these drugs often treat small patient populations and there may be fewer financial incentives for pharmaceutical manufacturers to develop them, the law provides a seven-year marketing exclusivity for companies that obtain approval for these drugs.<sup>201</sup> During the seven-year period, FDA cannot approve an NDA or BLA for the same product to treat the same disease or condition, even if the second applicant generates its own safety and efficacy data.<sup>202</sup>

To receive the orphan drug exclusivity, (1) the drug must be intended to treat a “rare disease or condition,”<sup>203</sup> and (2) FDA must not have previously approved the same drug “for the same use or indication.”<sup>204</sup> To meet the first condition, a sponsor may request, before submitting an NDA or BLA, that FDA designate its drug as a drug for a rare disease or condition. To be designated as an orphan drug, FDA must determine that—when the designation is requested—the disease or

<sup>198</sup> S. 1636 § 1.

<sup>199</sup> S. 1636 § 1.

<sup>200</sup> P.L. 97-414, § 1, 96 Stat. 2049 (1983).

<sup>201</sup> 21 U.S.C. § 360cc(a).

<sup>202</sup> *Id.* § 360cc. This exclusivity is subject to two exceptions: (1) if the exclusivity holder “cannot ensure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated,” and (2) if the NDA or BLA holder consents to the approval of another application for the same drug. *Id.* § 360cc(b).

<sup>203</sup> 21 U.S.C. §§ 360bb, 360cc.

<sup>204</sup> *Id.* § 360cc; 21 C.F.R. § 316.3(b)(12). However, an NDA or BLA filer may receive exclusivity for an already-approved drug designated for the same rare disease or condition if it can demonstrate clinical superiority. 21 U.S.C. § 360cc(c).



condition the drug will treat “(A) affects less than 200,000 persons in the United States or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.”<sup>205</sup> Drugs so designated are entitled to the seven-year exclusivity if they also meet the second condition (i.e., that FDA has not previously approved the same drug for the same use).

***Fairness in Orphan Drug Exclusivity Act.*** The Fairness in Orphan Drug Exclusivity Act would have amended the orphan drug exclusivity provision, Section 527 of the FD&C Act. In order to qualify for orphan drug exclusivity under the bill, the sponsor would have had to demonstrate, at the time of FDA’s approval or licensure of the drug or biologic, that the sponsor had “no reasonable expectation” of recovering the cost of developing and making the drug or biologic available in the United States within the first 12 years of marketing the drug.<sup>206</sup> This requirement would have applied equally to drugs or biologics that were approved or licensed before the act was enacted and after, except that sponsors of drugs or biologics approved or licensed before the date of enactment would have had 60 days from enactment to make the required showing to FDA.<sup>207</sup> This bill could have had the effect of reducing the availability of orphan drug exclusivity for certain orphan drug sponsors, because existing law requires such a showing only for products that are intended to treat diseases that affect *more* than 200,000 people in the United States.<sup>208</sup> The act would also have placed a new limit (12 years) on the period over which the sponsors must show they cannot recoup their costs.<sup>209</sup>

***Orphan Drug Clarification.*** In the FDA Reauthorization Act of 2017, Congress imposed a clinical superiority standard for manufacturers seeking orphan drug exclusivity for a drug that is the same as an already-approved drug used to treat the same disease or condition.<sup>210</sup> Specifically, to receive the orphan drug exclusivity after the same drug has been approved to treat the same rare disease or condition, the sponsor must demonstrate that the drug has “significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.”<sup>211</sup> This provision was intended to prevent later sponsors from receiving the benefit of orphan drug exclusivity—excluding further competitors from the market for seven years—for drug products already known to treat the disease or condition that offered no further clinical benefit.

A provision labeled Orphan Drug Clarification (ODC), which was included in several omnibus drug pricing bills but not introduced as stand-alone legislation,<sup>212</sup> was enacted by the 116<sup>th</sup> Congress as part of the Consolidated Appropriations Act, 2021.<sup>213</sup> ODC clarifies the temporal scope of the clinical superiority requirement, providing that it applies to all drugs approved after

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

<sup>206</sup> Fairness in Orphan Drug Exclusivity Act, H.R. 4712, 116th Cong. § 2 (2019) (proposed FD&C Act § 527(f)). A Senate bill of the same name, S. 3271, 116th Cong. 2019), contains very similar provisions to H.R. 4712. For simplicity, citations herein are to the House version as passed on November 17, 2020.

<sup>207</sup> H.R. 4712 § 2 (proposed FD&C Act § 527(f)).

<sup>208</sup> *Id.*; 21 U.S.C. § 360bb(a)(2).

<sup>209</sup> H.R. 4712 § 2 (proposed FD&C Act § 527(f)); 21 U.S.C. § 360bb(a)(2).

<sup>210</sup> See P.L. 115-52, § 607, 131 Stat. 1005, 1049–50 (2017) (codified at 21 U.S.C. § 360cc(c)–(e)).

<sup>211</sup> See 21 U.S.C. § 360cc(c)(2).

<sup>212</sup> See Lower Costs, More Cures Act of 2019, H.R. 19, 116th Cong. § 392 (2019); Lower Health Care Costs Act, S. 1895, 116th Cong. § 210 (2019).

<sup>213</sup> See P.L. 116-260, div. BB, tit. III, subtit. C, § 323 (2020).

the FDA Reauthorization Act of 2017, regardless of when the drug received an orphan drug designation.

**Table 10. Bills in the 116th Congress Relating to the Orphan Drug Exclusivity**

**Bold** indicates bill enacted in law (as part of a different piece of legislation where noted); *italics* indicate bill passed one house of Congress. Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor. Asterisk (\*) indicates furthest legislative progress as part of another bill (see **Table I** for details).

Bill No.	Bill Title	OCs	Summary
S. 1895 § 210	<b>Orphan Drug Clarification<sup>^*</sup></b>	Sen. Alexander Sen. Murray	Clarifies that the clinical superiority standard applies to all drugs approved after the FDA Reauthorization Act of 2017
H.R. 4712	<i>Fairness in Orphan Drug Exclusivity Act<sup>^</sup></i>	Rep. Dean Rep. Veasey Rep. Carter Rep. McKinley	Would limit orphan drug exclusivity to drugs with no reasonable expectation of recouping development costs with U.S. sales, regardless of patient population
S. 3271	Fairness in Orphan Drug Exclusivity Act <sup>^</sup>	Sen. Cassidy Sen. Baldwin Sen. Shaheen	Would limit orphan drug exclusivity to drugs with no reasonable expectation of recouping development costs with U.S. sales, regardless of patient population

**Source:** CRS; congress.gov.

## Government-Directed Price Regulation or IP Limitations

Another category of IP-related drug pricing bills would involve more direct government involvement in drug pricing. Depending on the particular proposal, these requirements may be focused on a particular class of drugs (e.g., COVID-19 treatments, or drugs developed with federal funding) or apply more broadly to any drug or biologic. This section groups these proposals into three categories: bills that sought to (1) limit IP rights based on pricing; (2) impose pricing and other conditions for government-supported innovation; or (3) direct the federal government to manufacture generic drugs and biosimilars.

### Limiting IP Rights Based on Drug Pricing

In light of the importance of patents and regulatory exclusivities in the pharmaceutical industry, limiting IP rights based on drug costs is a potential means of leverage over drug prices. **Table 11** lists information on bills that would have authorized compulsory patent licensing or otherwise restricted IP rights based on pricing behavior.

**The FLAT Prices Act.** The FLAT Prices Act<sup>214</sup> aimed to discourage pharmaceutical product manufacturers from significantly increasing the prices of their products. To this end, the bill would have shortened the relevant periods of regulatory exclusivity for a pharmaceutical product if the manufacturer increases the price by more than certain percentages within specified time periods.<sup>215</sup> Specifically, the regulatory exclusivity period would have been shortened by 180 days

<sup>214</sup> Identical bills have been introduced in the House of Representatives, *see* H.R. 1188, 116th Cong. (2019), and the Senate, *see* S. 366, 116th Cong. (2019). For simplicity, all citations herein are to the Senate version as introduced on February 6, 2019.

<sup>215</sup> FLAT Prices Act, S. 366, 116th Cong. § 2 (2019). The relevant regulatory exclusivities that would be subject to reduction for a drug under the bill include (1) the five-year new chemical entity exclusivity, (2) the three-year clinical

if the price<sup>216</sup> increased by more than 10% over a one-year period, 18% over a two-year period, or 25% over a three-year period.<sup>217</sup> For every price increase that is 5% over these thresholds, the exclusivity period would have been further shortened by an additional 30 days.<sup>218</sup>

The FLAT Prices Act would have also required manufacturers to report significant price increases to the Secretary of HHS.<sup>219</sup> The bill would have authorized the Secretary to waive or decrease an exclusivity-period reduction if the Secretary determines that “the price increase is necessary to enable production of the drug, does not unduly restrict patient access to the drug, and does not negatively impact public health.”<sup>220</sup>

***The Prescription Drug Price Relief Act.*** The Prescription Drug Price Relief Act of 2019 (PDPRA) would have created a process by which the Secretary of HHS would review the pricing of all brand-name drugs and biologics to determine whether their prices are “excessive.”<sup>221</sup>

The bill would have required NDA and BLA holders to submit an annual report to HHS including information about the pricing of brand-name drugs, including costs, revenues, R&D expenditures, and the average price of the drug in the United States and reference countries.<sup>222</sup> Using this information, the Secretary would, on at least an annual basis, determine whether the price of any brand-name drug or biologic is excessive.<sup>223</sup> The bill would have established two different criteria under which the Secretary would determine that a brand-name drug price is excessive. First, the Secretary would be required to determine that a drug has an excessive price if the “average [U.S.] manufacturing price” exceeds “the median price charged for such drug in the 5 reference countries.”<sup>224</sup> Second, the Secretary would determine that a drug has an excessive price if “the price of the drug is higher than reasonable,” taking into account a number of factors.<sup>225</sup>

If the Secretary determines that a drug price is excessive, he would have the authority to “waive or void” any government-granted exclusivities, including FDA regulatory exclusivities, and issue “open, non-exclusive compulsory” licenses allowing any person to make, use, sell, or import the

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trial exclusivity, and (3) the 180-day first generic exclusivity. *Id.* § 2(e). The relevant regulatory exclusivities for a biological product include (1) the 12-year market exclusivity for a new biological product and (2) the first interchangeable biological product exclusivity. *Id.*

<sup>216</sup> Under the bill, the relevant price increase is the increase in the drug or biological product’s wholesale acquisition cost, *id.* § 2(b), which is “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . as reported in wholesale price guides or other publications of drug or biological pricing data.” 42 U.S.C. § 1395w-3a(c)(6)(B).

<sup>217</sup> S. 366 § 2(a)(1), (b).

<sup>218</sup> *Id.* § 2(a)(2).

<sup>219</sup> *Id.* § 2(c)(1). If a manufacturer fails to timely submit the report, the exclusivity period for the relevant drug or biological product would be shortened by an additional 30 days for each day that the report is late. *Id.* § 2(c)(2).

<sup>220</sup> *Id.* § 2(d).

<sup>221</sup> See Prescription Drug Price Relief Act of 2019, H.R. 465, 116th Cong. § 2 (2019). An identical bill has been introduced in Senate, see S. 102, 116th Cong. (2019). For simplicity, all citations herein are to the House version as introduced on January 25, 2019.

<sup>222</sup> H.R. 465 § 6(a). “Brand name drugs” are prescription drugs and biologics approved or licensed by FDA under a nonabbreviated regulatory pathway (i.e., not generic drugs or biosimilars) and that are “claimed in a patent or the use of which is claimed in a patent.” *Id.* § 8(3).

<sup>223</sup> *Id.* § 2(a).

<sup>224</sup> *Id.* § 2(b)(1)(A). If information about the price of the drug is not available for all the reference countries, the Secretary still must make a determination so long as pricing information is available for at least three of the reference countries. *Id.* § 2(b)(1)(C).

<sup>225</sup> *Id.* § 2(b)(2). In addition, members of the public would be able to petition the Secretary to make an excessive price determination with respect to a particular drug under some circumstances. *Id.* § 2(c).

excessively priced drug, despite applicable patents.<sup>226</sup> The compulsory patent license, which the bill calls a “excessive drug price license,” would permit the Secretary to authorize third parties to make and use the excessively priced drug despite patents that claim a brand-name drug or the use of a brand-name drug.<sup>227</sup> It would also allow third parties to “rely upon regulatory test data for such drug.”<sup>228</sup> However, any entity that accepts this compulsory license would be required to pay a “reasonable royalty” to the applicable patent holder and any NDA holder whose regulatory exclusivity was voided under the bill’s provisions.<sup>229</sup>

**The Prescription Drug Affordability and Access Act.** Like PDPRA, the Prescription Drug Affordability and Access Act (PDAAA) would have created a system for the government to determine whether the prices of prescription drugs in the United States are “appropriate.”<sup>230</sup> The bill would have established a Bureau of Prescription Drug Affordability and Access within HHS to review the wholesale acquisition cost of approved drugs and biologics.<sup>231</sup> Based on information submitted by pharmaceutical manufacturers and upon consideration of a number of factors, the Bureau would determine whether the cost of the drug is appropriate.<sup>232</sup> If the Bureau found that a drug price is not appropriate, the manufacturer would be directed to lower the price to an appropriate level and remit the “excess revenue” to the Bureau, which would establish a process to distribute that revenue to patients.<sup>233</sup> Should a drug manufacturer not reduce prices to an appropriate level, the Secretary of HHS would have been required to authorize the use of patents and regulatory exclusivities by other entities, who would be permitted to manufacture the drug and provide “reasonable compensation” to the original manufacturer.<sup>234</sup>

**Table 11. Bills in the 116th Congress Limiting IP Rights Based on Drug Pricing**

Bill No.	Bill Title	OCs	Summary
H.R. 465	Prescription Drug Price Relief Act of 2019	Rep. Khanna (and 14 OCs)	Would authorize compulsory licensing for “excessively priced” drugs
H.R. 1188	FLAT Prices Act	Rep. Golden (and 5 OCs)	Would reduce regulatory-exclusivity lengths if drug prices are sharply increased
S. 102	Prescription Drug Price Relief Act of 2019	Sen. Sanders (and 5 OCs)	Would authorize compulsory licensing for “excessively priced” drugs

<sup>226</sup> *Id.* § 3(a)(1)–(2).

<sup>227</sup> *Id.* § 8(7).

<sup>228</sup> *Id.*

<sup>229</sup> *Id.* § 4(a)(1). The royalty rate would either be based on an average rate for pharmaceuticals estimated by the Internal Revenue Service or set by the Secretary based on a number of factors. *Id.* § 4(a)(2)(A)–(B). Any party accepting a compulsory license for an excessively priced drug would still need to apply for FDA approval (or licensure) in order to market a generic (or biosimilar) version. Accordingly, the bill would require FDA to expedite review of such applications and “act within 8 months.” *Id.* § 3(b). During the period between the Secretary’s excessive price determination and generic or biosimilar product approval, the bill would prohibit the brand-name drug manufacturer from increasing the price of the drug or biologic. *Id.* § 3(c).

<sup>230</sup> Prescription Drug Affordability and Access Act, S. 3166, 116th Cong. § 3 (2020).

<sup>231</sup> *Id.* §§ 2, 3(a)(1), (d).

<sup>232</sup> *Id.* § 3(a)(2)–(3), (e), (f). For “applicable drugs” with limited generic or biosimilar competition, the bill would establish an “interim appropriate price” based on the median price in a number of foreign countries. *Id.* § 3(e)(2), (h)(7).

<sup>233</sup> *Id.* § 3(f), (h)(2).

<sup>234</sup> *Id.* § 3(g)(1).

Bill No.	Bill Title	OCs	Summary
S. 366	FLAT Prices Act	Sen. Durbin (and 4 OCs)	Would reduce regulatory-exclusivity lengths if drug prices are sharply increased
S. 3166	Prescription Drug Affordability and Access Act	Sen. Booker Sen. Sanders Sen. Harris	Would establish independent government agency to review whether drug prices are appropriate and permit compulsory licensing for inappropriately priced drugs

Source: CRS; congress.gov.

## Government-Supported Innovation Reforms

Several pharmaceutical IP bills in the 116th Congress focused on drugs and biologics that are developed with federal support, such as federal funding for biomedical R&D. **Table 12** lists information on these bills.

***Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2019.*** The Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2019 (APTPDA) would have imposed “reasonable pricing” conditions on certain patents on drugs, biologics, and health care technologies.<sup>235</sup> Specifically, under APTPDA, federal agencies and nonprofits engaged in federally funded health care R&D would not be able to license or assign patent rights in drug, biologic, and health care inventions developed with federal funds, unless the licensee or assignee commits to a “reasonable pricing agreement” with HHS.<sup>236</sup> In particular, the reasonable pricing agreement must not result in “discriminatory pricing” wherein the federal government is charged more than certain foreign countries.<sup>237</sup>

***We PAID Act.*** The We Protect American Investment in Drugs Act (We PAID Act) would have imposed reasonable pricing conditions on prescription drugs that are developed with federal funding or that rely on federally owned inventions.<sup>238</sup> The bill’s provisions would have reached applicable drugs covered by a “qualifying patent”—that is, a patent owned by the federal government or within the scope of the Bayh-Dole Act’s<sup>239</sup> disclosure requirements for federally funded inventions.<sup>240</sup> For such drugs, the We PAID Act would have established a nongovernmental nonprofit corporation, the Drug Affordability and Access Committee, tasked with determining a reasonable price.<sup>241</sup> The Committee would rely on a study by the National Academy of Medicine, input from the public, and information submitted by drug manufacturers in setting reasonable prices.<sup>242</sup>

<sup>235</sup> Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2019, H.R. 4640, 116th Cong. § 2 (2019).

<sup>236</sup> *Id.* § 2(a).

<sup>237</sup> *Id.* § 2(b). The Secretary of HHS may waive the reasonable pricing agreement upon a determination that the public interest is served by a waiver if he follows specified procedures. *Id.* § 2(a), (c).

<sup>238</sup> We PAID Act, S. 2387, 116th Cong. § 6 (2019).

<sup>239</sup> P.L. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. chs. 18, 30).

<sup>240</sup> S. 2357, § 3(1), (5). As the bill’s definitions reach any patent for which government support was required to be disclosed under the Bayh-Dole Act, *see* 35 U.S.C. § 202(c)(6), the We PAID Act’s scope would seemingly align with the “subject inventions” of the Bayh-Dole Act: those conceived or reduced to practice by a federal contractor during the course of a funding agreement with the federal government, such as a grant from the National Institutes of Health. *See* 35 U.S.C. § 201(b), (e). For a general overview of the Bayh-Dole Act, *see* generally Vanessa Bell, *The State Giveth and the State Taketh Away: Patent Rights Under the Bayh-Dole Act*, 24 S. CAL. INTERDISC. L.J. 491, 496–527 (2015).

<sup>241</sup> S. 2387 §§ 5(a)–(b).

<sup>242</sup> *Id.* §§ 4, 5(f)(2), 6(a).

Manufacturers of applicable drugs made with federal funding or patents would have been required, as a condition of licensing a federally owned patent or taking title to a patent on a federally funded invention, not to exceed the reasonable price set by the Committee and to limit annual price increases based on inflation.<sup>243</sup> Penalties for exceeding these price limits include the loss of regulatory exclusivities and prohibitions on future federal patent licenses.<sup>244</sup> Finally, the We PAID Act would have created new penalties for failing to disclose federal support on patent applications as required by the Bayh-Dole Act.<sup>245</sup>

**MMAPPP Act.** The Make Medications Affordable by Preventing Pandemic Price-gouging (MMAPPP) Act, which focused on pricing for COVID-19 treatments developed with support from the federal government, is discussed in more detail below in the “COVID-19-Specific Bills” section.

**Table 12. Bills in the 116th Congress Relating to Government-Supported Innovation**

Caret (^) indicates bill has at least one original cosponsor of a different party than the sponsor.

Bill No.	Bill Title	OCs	Summary
H.R. 4640	Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2019	Rep. DeFazio	Would require “reasonable pricing” as condition in licensing drug patents owned by a federal agency or nonprofit developed with federal funding
H.R. 7296	MMAPPP Act of 2020 <sup>^</sup>	Rep. Schakowsky (and 6 OCs)	Would require open, nonexclusive licensing, and reasonable pricing for federally supported COVID-19 treatments and prohibit excessive pricing of COVID-19 countermeasures
S. 2387	We PAID Act <sup>^</sup>	Sen. Van Hollen Sen. Rick Scott	For applicable drugs developed with federal funding or patents, would impose reasonable pricing requirements and penalties for failing to disclose government support
S. 4439	MMAPPP Act of 2020	Sen. Smith (and 4 OCs)	Would require open, nonexclusive licensing, and reasonable pricing for federally supported COVID-19 treatments and prohibit excessive pricing of COVID-19 countermeasures

Source: CRS; congress.gov.

## Government Production of Pharmaceuticals

The proposals discussed above have largely addressed the incentives of private companies to manufacture generics and biosimilars. Another means of creating greater competition in the pharmaceutical market—and, potentially, lower prices—would be for the government itself to manufacture and sell drugs and biologics. **Table 13** lists information on bills that would have directed the federal government to produce pharmaceuticals.

<sup>243</sup> *Id.* § 6(a)(1), (3)–(4).

<sup>244</sup> *Id.* § 6(b).

<sup>245</sup> *Id.* § 7; 35 U.S.C. § 202(c)(6).

***The Affordable Drug Manufacturing Act.*** The Affordable Drug Manufacturing Act of 2019 (ADMA) would have directed the government to manufacture certain pharmaceuticals.<sup>246</sup> In particular, ADMA aimed to facilitate competition in the pharmaceutical market by establishing an Office of Drug Manufacturing within HHS that would oversee the production of “applicable drugs.”<sup>247</sup>

“Applicable drugs” within ADMA’s scope would have included drugs and biologics that FDA has approved or licensed, and which further satisfy one of two conditions.<sup>248</sup> Under the first condition, the relevant regulatory exclusivities and patents must have expired, and, in addition, the drug must either (a) not be currently marketed in the United States or (b) be marketed by fewer than three manufacturers (in addition to other criteria, such as a recent price increase).<sup>249</sup> Under the second condition, the United States must have a license to use any relevant patents, including pursuant to exercises of march-in rights under the Bayh-Dole Act or patent “eminent domain” authority under 28 U.S.C. § 1498.<sup>250</sup> (In this way, ADMA differs from many of the proposals discussed above in that it, in itself, would not have altered existing pharmaceutical IP rights, but would have introduced the government as a competitor in markets where the government does not need or can obtain the necessary IP rights.) Insulin, certain antibiotics, and naloxone are listed specifically as meeting this applicable drug definition; ADMA would have directed public manufacturing of these drugs within one year of its enactment.<sup>251</sup>

ADMA would have directed the Office of Drug Manufacturing, with respect to applicable drugs, to (1) prepare and submit applications for FDA approval, (2) acquire the relevant manufacturing rights, (3) manufacture the drugs or contract with other entities to do so, and (4) sell the drugs at a fair price, taking into account specified factors in setting that price.<sup>252</sup> The bill would have set certain criteria for selecting drugs to produce and required a gradual increase in the number of drugs manufactured by the Office over time.<sup>253</sup> The Office would have been required to report to the President and Congress annually on specified topics, including a description of the status of applicable drugs for which manufacturing has been authorized.<sup>254</sup>

***The COVID-19 Emergency Manufacturing Act.*** The COVID-19 Emergency Manufacturing Act of 2020 (CEMA), is similar to ADMA but would have focused on COVID-19 medical countermeasures. CEMA is discussed in more detail below in the “COVID-19-Specific Bills” section.

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<sup>246</sup> Affordable Drug Manufacturing Act of 2019, H.R. 5501, 116th Cong. § 2 (2019). A related bill, the Affordable Drug Manufacturing Act of 2020, was introduced in the Senate. S. 3162, 116th Cong. (2020). For simplicity, all citations are to the House bill as introduced on December 20, 2019.

<sup>247</sup> H.R. 5501 § 2 (proposed new PHSA § 310B(a)).

<sup>248</sup> *Id.* (proposed new PHSA § 310B(g)(1)–(2)).

<sup>249</sup> *Id.* (proposed PHSA § 310B(g)(1)).

<sup>250</sup> *Id.* (proposed PHSA § 310B(g)(2)).

<sup>251</sup> *Id.* (proposed PHSA § 310B(d)–(f)).

<sup>252</sup> *Id.* § 2 (proposed PHSA § 310B(a)(4)(A)). In addition, the Office would also manufacture or contract with other entities to manufacture active pharmaceutical ingredients (APIs) under specified conditions, including if an API is not readily available from existing suppliers, and set the API’s prices based on specified factors. *Id.* (proposed PHSA § 310B(a)(4)(A)(vi) and § 310B(a)(4)(D)).

<sup>253</sup> *Id.* (proposed PHSA § 310B(a)(6)–(7)).

<sup>254</sup> *Id.* (proposed PHSA § 310B(a)(5)).

**Table 13. Bills in the 116th Congress Relating to Government Pharmaceutical Production**

Bill No.	Bill Title	OCs	Summary
H.R. 5501	Affordable Drug Manufacturing Act of 2019	Rep. Schakowsky	Would create government office to manufacture generic drugs and biosimilars
H.R. 7113	COVID-19 Emergency Manufacturing Act of 2020	Rep. Schakowsky	Would create government office to manufacture COVID-19 medical countermeasures
S. 3162	Affordable Drug Manufacturing Act of 2020	Sen. Warren	Would create government office to manufacture generic drugs and biosimilars
S. 3847	COVID-19 Emergency Manufacturing Act of 2020	Sen. Warren	Would create government office to manufacture COVID-19 medical countermeasures

Source: CRS; congress.gov.

## COVID-19-Specific Bills

Several pharmaceutical IP bills in the 116th Congress focused more narrowly on COVID-19 medical countermeasures (such as vaccines and treatments), as opposed all drugs and biologics. **Table 14** lists information on these COVID-19-specific bills.

***The Make Medications Affordable by Preventing Pandemic Price-gouging Act of 2020.*** The Make Medications Affordable by Preventing Price-gouging Act of 2020 (MMAPPP Act) would have addressed COVID-19-related inventions, particularly those owned by the federal government or developed with federal support.<sup>255</sup> First, the MMAPPP Act would have required that patent licenses granted by the federal government for federally owned COVID-19-related inventions be open and non-exclusive.<sup>256</sup> Second, for drugs intended for use against COVID-19 that are developed with federal funding or support, the MMAPPP Act would have required a guarantee of “fair and reasonable” pricing by the federal contractor or licensee,<sup>257</sup> and would have further required such federal contractors to grant open and nonexclusive patent licenses with respect to COVID-19-related inventions developed with federal support.<sup>258</sup> Third, for any drug intended for use against COVID-19 (whether or not federally supported), the MMAPPP Act would have imposed reporting requirements related to the price of the drug, development expenditures, and federal benefits received.<sup>259</sup> Finally, during the duration of a public health emergency (not limited to COVID-19), the MMAPPP Act would have authorized compulsory licensing for excessively priced drugs and biologics used against the disease that is the subject of the emergency.<sup>260</sup>

***The Facilitating Innovation to Fight Coronavirus Act.*** The Facilitating Innovation to Fight Coronavirus Act (FIFCA) would have, among other things, changed the term of certain patents

<sup>255</sup> MMAPPP Act of 2020, H.R. 7296, 116th Cong. (2020). A similar bill has been introduced in the Senate. See MMAPPP Act of 2020, S. 4439, 116th Cong. (2020). For simplicity, all citations are to the House bill as introduced on June 22, 2020.

<sup>256</sup> H.R. 7296 § 2(a), (d)(1), (d)(5).

<sup>257</sup> *Id.* §§ 2(d)(2), 3(a).

<sup>258</sup> *Id.* § 2(b).

<sup>259</sup> *Id.* § 4.

<sup>260</sup> *Id.* § 5. The MMAPPP Act’s compulsory licensing provisions bears some similarity to those of the PDPPRA. See discussion *supra* in “Limiting IP Rights Based on Drug Pricing.”



used in the treatment of COVID-19.<sup>261</sup> Under the bill, the term for patents issued that claim a new or existing pharmaceutical, medical device, or other inventions used or intended for use to treat COVID-19 would not have begun until the national emergency declared by the President with respect to COVID-19 terminates.<sup>262</sup> However, an additional 10 years would have been added to the term of these COVID-19-treatment patents.<sup>263</sup> The overall effect of FIFCA would have been to delay the start of the effective term for certain patents on COVID-19 treatments—potentially allowing more companies to produce treatments needed during the COVID-19 national emergency—but to compensate those patentees by extending the term of these patents by 10 years.

***The COVID-19 Emergency Manufacturing Act.*** The COVID-19 Emergency Manufacturing Act of 2020 (CEMA) would have created a government office within HHS to manufacture COVID-19 medical countermeasures—including treatments, vaccines, diagnostic tests, and PPE—and provided those products at no cost to state and local public health authorities and domestic health care providers.<sup>264</sup> Among other things, CEMA would have authorized the government to manufacture “applicable COVID-19 products,” with the aim of ensuring an adequate supply of, and increased access to, COVID-19 medical countermeasures.<sup>265</sup>

Specifically, CEMA would have created the Emergency Office of Manufacturing for Public Health (the Emergency Office) within HHS, which would obtain the rights to manufacture applicable COVID-19 products and manufacture applicable COVID-19 products.<sup>266</sup> Such products would have included not only COVID-19 vaccines and treatments, but also personal protective equipment (PPE), diagnostic tests, and other drugs, biologics, and medical devices used to diagnose, prevent, mitigate, treat, or cure COVID-19.<sup>267</sup> CEMA would have identified PPE, materials for COVID-19 diagnostic tests, and certain COVID-19 treatments for immediate public manufacturing by the Emergency Office.<sup>268</sup> The Emergency Office would provide applicable COVID-19 products at no cost to state, local, and tribal health programs, and other domestic health care providers, and at cost to other commercial and international entities.<sup>269</sup> CEMA would have granted the Secretary of HHS authority to issue compulsory licenses to

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<sup>261</sup> Facilitating Innovation to Fight Coronavirus Act, S. 3630, 116th Cong. § 3 (2020). The bill would also immunize health care providers from legal liability for certain actions, such as using or modifying a medical device for an unapproved use, during the duration of the COVID-19 national emergency declared by the President. *Id.* § 2.

<sup>262</sup> *Id.* § 3(a), (c).

<sup>263</sup> *Id.* § 3(b).

<sup>264</sup> COVID-19 Emergency Manufacturing Act of 2020, S. 3847, 116th Cong. (2020). A similar bill was introduced in the House, *see* COVID-19 Emergency Manufacturing Act of 2020, H.R. 7113, 116th Cong. (2020). For simplicity, all citations are to the Senate version as introduced on June 1, 2020.

<sup>265</sup> *See* S. 3847 § 2 (proposed PHSA § 310B(a)(2), (f)(2)). CEMA also contains provisions for the government to manufacture and sell, at a fair price, applicable drugs that are included on FDA’s drug shortage list or are vulnerable to shortage, with the aim of addressing shortages in the strategic national stockpile. *Id.* § 2 (proposed PHSA § 310B(a)(2)(B), (c)(2)).

<sup>266</sup> *Id.* § 2 (proposed PHSA § 310B(a)(4)).

<sup>267</sup> *Id.* § 2 (proposed new PHSA § 310B(b)(1), (b)(3), (f)(2)). CEMA’s definition of “applicable COVID-19 product” largely traces the definition of “qualified pandemic or epidemic product” under the Public Readiness and Emergency Preparedness (PREP) Act, plus a specific inclusion for PPE. *Compare id.* § 2 (proposed PHSA § 310B(f)(2)(A) with 42 U.S.C. § 247d-6d(i)(7); *see generally* CRS Legal Sidebar LSB10443, *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures*, by Kevin J. Hickey.

<sup>268</sup> S. 3847 § 2 (proposed PHSA § 310B(b)(3)).

<sup>269</sup> *Id.* § 2 (proposed PHSA § 310B(a)(4)(A)(vi)–(vii), (c)(1)).

authorize the use of patented inventions and other IP rights to manufacture and sell applicable COVID-19 products, provided that “reasonable remuneration” is paid to the rights holders.<sup>270</sup>

**Table 14. COVID-19-Specific Pharmaceutical IP Bills in the 116th Congress**

Caret (^) indicates bill has at least one original cosponsor of a different party than the sponsor.

Bill No.	Bill Title	OCs	Summary
H.R. 7113	COVID-19 Emergency Manufacturing Act of 2020	Rep. Schakowsky	Would create government office to manufacture COVID-19 medical countermeasures
H.R. 7296	MMAPPP Act of 2020 <sup>^</sup>	Rep. Schakowsky (and 6 OCs)	Would require open, nonexclusive licensing, and reasonable pricing for federally supported COVID-19 treatments and prohibit excessive pricing of COVID-19 countermeasures
S. 3630	Facilitating Innovation to Fight Coronavirus Act	Sen. Sasse	Inter alia, would delay the start of, but subsequently extend, patent terms for COVID-19 treatments
S. 3847	COVID-19 Emergency Manufacturing Act of 2020	Sen. Warren	Would create government office to manufacture COVID-19 medical countermeasures
S. 4439	MMAPPP Act of 2020	Sen. Smith (and 4 OCs)	Would require open, nonexclusive licensing, and reasonable pricing for federally supported COVID-19 treatments and prohibit excessive pricing of COVID-19 countermeasures

Source: CRS; congress.gov.

## Omnibus Drug Pricing Bills with Pharmaceutical IP Provisions

A number of bills introduced in the 116th Congress combined pharmaceutical IP proposals with other provisions. Many of these bills also contained provisions focused on health care costs but not related to IP, such as Medicare or Medicaid reforms, limits on surprise medical billing, or transparency provisions. **Table 15** lists information on these bills, noting the provisions that related to drug patents and regulatory exclusivities. The provisions in these omnibus bills may or may not be identical to the stand-alone bills summarized in the preceding sections, but the provisions are typically similar (as noted in the table).

**Table 15. Omnibus Drug Pricing Bills with Pharmaceutical IP Provisions in the 116th Congress**

*Italics* indicate bill passed one house of Congress; underline indicates bill reported or ordered to be reported out of committee. Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor.

Bill No.	Bill Title	OCs	Summary
H.R. 987	<i>Strengthening Health Care and Lowering Prescription Drug Costs Act</i>	Rep. Blunt Rep. Rochester Rep. Castor Rep. McBath Rep. Kildee	Inter alia, contains provisions similar to (1) BLOCKING Act; and (2) Protecting Consumer Access to Generic Drugs.

<sup>270</sup> *Id.* § 2 (proposed PHSA § 310B(a)(4)(C)).

<b>Bill No.</b>	<b>Bill Title</b>	<b>OCs</b>	<b>Summary</b>
S. 1895	<u>Lower Health Care Costs Act<sup>A</sup></u>	Sen. Alexander Sen. Murray	Inter alia, contains provisions similar to (1) Biologic Patent Transparency Act; (2) Orange Book Patent Transparency Act; (3) Protecting Access to Biosimilars Act of 2019; (4) BLOCKING Act; (5) Ensuring Innovation Act; and (6) Orphan Drug Clarification.
H.R. 19	Lower Costs, More Cures Act of 2019	Rep. Walden (and 111 OCs)	Inter alia, contains provisions similar to (1) Protecting Consumer Access to Generic Drugs Act; (2) Orange Book Transparency Act; (3) Purple Book Continuity Act; (4) Protecting Access to Biosimilars Act of 2019; (5) BLOCKING Act; (6) Ensuring Innovation Act; and (7) Orphan Drug Clarification.
H.R. 1332	Fair Care Act of 2019	Rep. Westerman	Inter alia, contains provisions similar to the PRICED Act and would reduce terms for serial orphan-drug regulatory exclusivities.
H.R. 2700	Lowering Prescription Drug Costs and Extending Community Health Centers and Other Public Health Priorities Act	Rep. Burgess (and 29 OCs)	Inter alia, contains provisions similar to (1) BLOCKING Act; and (2) Protecting Consumer Access to Generic Drugs Act.
H.R. 3947	Competition Prescription Act of 20189	Rep. Meadows	Inter alia, includes provisions similar to the Biologic Patent Transparency Act.
H.R. 8527	Fair Care Act of 2020	Rep. Westerman Rep. Burchett Rep. Smucker Rep. Riggleman	Inter alia, includes provisions similar to (1) Biologic Patent Transparency Act; (2) Orange Book Transparency Act; (3) PRICED Act; (4) Protecting Access to Biosimilars Act of 2019; and (5) Ensuring Innovation Act.
S. 1801	Affordable Medications Act	Sen. Smith (and 14 OCs)	Inter alia, contains provisions similar to (1) Preserve Access to Affordable Generics and Biosimilars Act; and (2) FAIR Generics Act. Also limits certain regulatory exclusivities, including reducing the new biologic exclusivity from 12 to 7 years.
S. 3384	Lowering Prescription Drug Prices for America's Seniors and Families Act of 2020	Sen. McSally	Inter alia, contains provisions similar to the Preserve Access to Affordable Generics and Biosimilars Act.
S. 4796	Fair Care Act of 2020	Sen. Braun	Inter alia, includes provisions similar to (1) Biologic Patent Transparency Act; (2) Orange Book Transparency Act; (3) PRICED Act; (4) Protecting Access to Biosimilars Act of 2019; and (5) Ensuring Innovation Act.

**Source:** CRS; congress.gov.

## Appendix A. Drug Pricing and IP Legislation in the 116th Congress

**Table A-1** surveys the legislative activity of the 116th Congress relating to drug pricing and pharmaceutical IP, listing all the bills and laws discussed in this report by bill number, including information on legislative status and category.

**Table A-1. Drug Pricing and IP Legislation in the 116th Congress**

**Bold** indicates bill **enacted in law** (as part of a different piece of legislation where noted); *italics* indicate bill *passed one house of Congress*; underline indicates bill reported or ordered to be reported out of committee. Caret (^) indicates bill had at least one original cosponsor of a different party than the sponsor. Asterisk (\*) indicates furthest legislative progress as part of another bill (see **Table I** for details).

Bill No.	Bill Title	OCs	Category
H.R. 19	Lower Costs, More Cures Act of 2019	Rep. Walden (and 111 OCs)	Omnibus Drug Pricing Bills
H.R. 465	Prescription Drug Price Relief Act of 2019	Rep. Khanna (and 14 OCs)	Limiting IP Rights Based on Drug Pricing
H.R. 938	<i>BLOCKING Act</i> <sup>*</sup>	Rep. Schrader Rep. Buddy Carter	Regulatory Exclusivity Reforms (180-day First-Generic Exclusivity)
H.R. 987	<i>Strengthening Health Care and Lowering Prescription Drug Costs Act</i>	Rep. Blunt Rochester Rep. Castor Rep. McBath Rep. Kildee	Omnibus Drug Pricing Bills
H.R. 990	Hatch-Waxman Integrity Act	Rep. Flores	Pharmaceutical Patenting Reforms (Administrative Patent Challenges)
H.R. 1188	FLAT Prices Act	Rep. Golden (and 5 OCs)	Limiting IP Rights Based on Drug Pricing
H.R. 1332	Fair Care Act of 2019	Rep. Westerman	Omnibus Drug Pricing Bills
H.R. 1344	Competitive DRUGS Act of 2019	Rep. Doggett (and 21 OCs)	Pharmaceutical Patenting Reforms (“Pay-for-Delay” Settlements)
H.R. 1499	<i>Protecting Consumer Access to Generic Drugs Act of 2019</i> <sup>*</sup>	Rep. Rush	Pharmaceutical Patenting Reforms (“Pay-for-Delay” Settlements)
H.R. 1503	<b>Orange Book Transparency Act</b>	Rep. Robin Kelly	Pharmaceutical Patenting Reforms (Patent Transparency)
H.R. 1506	FAIR Generics Act	Rep. Barragán	Regulatory Exclusivity Reforms (180-day First-Generic Exclusivity)
H.R. 1520	<b>Purple Book Continuity Act</b> <sup>*</sup>	Rep. Eshoo	Pharmaceutical Patenting Reforms (Patent Transparency)
H.R. 2011	<b>Protecting Access to Biosimilars Act of 2019</b> <sup>^*</sup>	Rep. DeGette Rep. Reed Rep. Schrier Rep. Guthrie	Regulatory Exclusivity Reforms (New Biologic Exclusivity)
H.R. 2375	<u>Preserve Access to Affordable Generics and Biosimilars Act</u> <sup>^</sup>	Rep. Nadler Rep. Collins Rep. Cicilline	Pharmaceutical Patenting Reforms (“Pay-for-Delay” Settlements)

<b>Bill No.</b>	<b>Bill Title</b>	<b>OCs</b>	<b>Category</b>
H.R. 2700	Lowering Prescription Drug Costs and Extending Community Health Centers and Other Public Health Priorities Act	Rep. Burgess (and 29 OCs)	Omnibus Drug Pricing Bills
H.R. 3199	TERM Act of 2019 <sup>^</sup>	Rep. Jeffries (and 4 OCs)	Pharmaceutical Patenting Reforms (Patent “Evergreening”)
H.R. 3379	PRICED Act <sup>^</sup>	Rep. Schakowsky (and 16 OCs)	Regulatory Exclusivity Reforms (New Biologic Exclusivity)
H.R. 3812	REMEDY Act <sup>^</sup>	Rep. McKinley Rep. Welch	Pharmaceutical Patenting Reforms (Patent “Evergreening”)
H.R. 3947	Competition Prescription Act of 20189	Rep. Meadows	Omnibus Drug Pricing Bills
H.R. 3991	<u>Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019<sup>^</sup></u>	Rep. Hank Johnson Rep. Roby	Pharmaceutical Patenting Reforms (Patent “Thickets”)
H.R. 4010	Emergency Access to Insulin Act of 2019	Rep. Craig Rep. Phillips	Regulatory Exclusivity Reforms (New Biologic Exclusivity)
H.R. 4398	Affordable Prescriptions for Patients Through Promoting Competition Act of 2019	Rep. Cicilline	Pharmaceutical Patenting Reforms (“Product Hopping”)
H.R. 4640	Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2019	Rep. DeFazio	Government-Supported Innovation Reforms
H.R. 4712	<i>Fairness in Orphan Drug Exclusivity Act<sup>^</sup></i>	Rep. Dean Rep. Veasey Rep. Buddy Carter Rep. McKinley	Regulatory Exclusivity Reforms (Orphan Drug Exclusivity)
H.R. 4850	Biologic Patent Transparency Act <sup>^</sup>	Rep. Spanberger Rep. Reed Rep. Anthony Gonzalez	Pharmaceutical Patenting Reforms (Patent Transparency)
H.R. 4955	Protecting Access to Safe and Effective Medicines Act of 2019 <sup>^</sup>	Rep. Engel Rep. Guthrie Rep. Schrader Rep. Hudson	Regulatory Exclusivity Reforms (New Chemical Entity Exclusivity)
H.R. 5133	<u>Affordable Prescriptions for Patients Through Promoting Competition Act of 2019<sup>^</sup></u>	Rep. Cicilline Rep. Collins Rep. Nadler Rep. Sensenbrenner	Pharmaceutical Patenting Reforms (“Product Hopping”)
H.R. 5501	Affordable Drug Manufacturing Act of 2019	Rep. Schakowsky	Government Production of Generics and Biosimilars
H.R. 7113	COVID-19 Emergency Manufacturing Act of 2020	Rep. Schakowsky	Government Production of Generics and Biosimilars; COVID-19-Specific Bills
H.R. 7296	MMAPPP Act of 2020 <sup>^</sup>	Rep. Schakowsky (and 6 OCs)	Government-Supported Innovation Reforms; COVID-19-Specific Bills
H.R. 8527	Fair Care Act of 2020	Rep. Westerman Rep. Burchett Rep. Smucker Rep. Riggleman	Omnibus Drug Pricing Bills

<b>Bill No.</b>	<b>Bill Title</b>	<b>OCs</b>	<b>Category</b>
S. 64	Preserve Access to Affordable Generics and Biosimilars Act <sup>^</sup>	Sen. Klobuchar Sen. Grassley	Pharmaceutical Patenting Reforms (“Pay-for-Delay” Settlements)
S. 102	Prescription Drug Price Relief Act of 2019	Sen. Sanders (and 5 OCs)	Limiting IP Rights Based on Drug Pricing
S. 344	Hatch-Waxman Integrity Act of 2019	Sen. Tillis	Pharmaceutical Patenting Reforms (Administrative Patent Challenges)
S. 366	FLAT Prices Act	Sen. Durbin (and 4 OCs)	Limiting IP Rights Based on Drug Pricing
S. 659	Biologic Patent Transparency Act <sup>^</sup>	Sen. Collins (and 5 OCs)	Pharmaceutical Patenting Reforms (Patent Transparency)
S. 1140	<b>Protecting Access to Biosimilars Act of 2019<sup>^*</sup></b>	Sen. Smith Sen. Cassidy	Regulatory Exclusivity Reforms (New Biologic Exclusivity)
S. 1209	REMEDY Act <sup>^</sup>	Sen. Cassidy Sen. Durbin	Pharmaceutical Patenting Reforms (Patent “Evergreening”)
S. 1416	<u>Affordable Prescriptions for Patients Act of 2019<sup>^</sup></u>	Sen. Cornyn Sen. Blumenthal	Pharmaceutical Patenting Reforms (“Patent Thickets” and “Product Hopping”)
S. 1617	Second Look at Drug Patents Act of 2019 <sup>^</sup>	Sen. Murray Sen. Cornyn	Pharmaceutical Patenting Reforms (Administrative Patent Challenges)
S. 1636	<i>Ensuring Innovation Act<sup>^</sup></i>	Sen. Roberts Sen. Smith Sen. Cassidy	Regulatory Exclusivity Reforms (New Chemical Entity Exclusivity)
S. 1801	Affordable Medications Act	Sen. Smith (and 14 OCs)	Omnibus Drug Pricing Bills
S. 1895	<u>Lower Health Care Costs Act<sup>^</sup></u>	Sen. Alexander Sen. Murray	Omnibus Drug Pricing Bills
S. 2004	Emergency Access to Insulin Act of 2019 <sup>^</sup>	Sen. Smith Sen. Cramer	Regulatory Exclusivity Reforms (New Biologic Exclusivity)
S. 2387	We PAID Act <sup>^</sup>	Sen. Van Hollen Sen. Rick Scott	Government-Supported Innovation Reform
S. 3092	Expanding Access to Low Cost Generics Act of 2019 <sup>^</sup>	Sen. Smith Sen. Braun	Regulatory Exclusivity Reforms (180-day First-Generic Exclusivity)
S. 3162	Affordable Drug Manufacturing Act of 2020	Sen. Warren	Government Production of Generic and Biosimilars
S. 3166	Prescription Drug Affordability and Access Act	Sen. Booker Sen. Sanders Sen. Harris	Limiting IP Rights Based on Drug Pricing
S. 3271	Fairness in Orphan Drug Exclusivity Act <sup>^</sup>	Sen. Cassidy Sen. Baldwin Sen. Shaheen	Regulatory Exclusivity Reforms (Orphan Drug Exclusivity)
S. 3384	Lowering Prescription Drug Prices for America’s Seniors and Families Act of 2020	Sen. McSally	Omnibus Drug Pricing Bills
S. 3630	Facilitating Innovation to Fight Coronavirus Act	Sen. Sasse	COVID-19-Specific Bills
S. 3847	COVID-19 Emergency Manufacturing Act of 2020	Sen. Warren	Government Production of Generic and Biosimilars; COVID-19-Specific Bills

<b>Bill No.</b>	<b>Bill Title</b>	<b>OCs</b>	<b>Category</b>
S. 4253	Second Look at Drug Patents Act of 2020 <sup>^</sup>	Sen. Murray Sen. Cornyn	Pharmaceutical Patenting Reforms (Administrative Patent Challenges)
S. 4439	MMAPPP Act of 2020	Sen. Smith (and 4 OCs)	Government-Supported Innovation Reforms; COVID-19-Specific Bills
S. 4796	Fair Care Act of 2020	Sen. Braun	Omnibus Drug Pricing Bills

**Source:** CRS; congress.gov.

## Appendix B. Glossary of Acronyms

<b>General Acronyms</b>	
<b>ANDA</b>	Abbreviated new drug application
<b>BLA</b>	Biologics license application
<b>BPCIA</b>	Biologics Price Competition and Innovation Act of 2009
<b>FDA</b>	U.S. Food and Drug Administration
<b>FD&amp;C Act</b>	Federal Food, Drug, and Cosmetic Act
<b>FTC</b>	Federal Trade Commission
<b>FTCA</b>	Federal Trade Commission Act of 1974
<b>HHS</b>	U.S. Department of Health and Human Services
<b>IP</b>	Intellectual property
<b>IPR</b>	Inter partes review
<b>NCE</b>	New chemical entity
<b>NDA</b>	New drug application
<b>PPE</b>	Personal protective equipment
<b>PGR</b>	Post-grant review
<b>PHSA</b>	Public Health Service Act
<b>PTO</b>	U.S. Patent and Trademark Office
<b>OCs</b>	Original cosponsors
<b>RLD</b>	Reference listed drug
<b>R&amp;D</b>	Research and development
<b>Acronyms for Legislation in the 116th Congress</b>	
<b>ADMA</b>	Affordable Drug Manufacturing Act of 2019
<b>APPA</b>	Affordable Prescriptions for Patients Act of 2019
<b>APTPDA</b>	Affordable Pricing for Taxpayer-Funded Prescription Drugs Act
<b>BLOCKING Act</b>	Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019
<b>CEMA</b>	COVID-19 Emergency Manufacturing Act of 2020
<b>FIFCA</b>	Facilitating Innovation to Fight Coronavirus Act
<b>HWIA</b>	Hatch-Waxman Integrity Act of 2019
<b>MMAPPP Act</b>	Make Medications Affordable by Preventing Price-gouging Act of 2020
<b>OBTA</b>	Orange Book Transparency Act of 2020
<b>ODC</b>	Orphan Drug Clarification
<b>PAAGBA</b>	Preserve Access to Affordable Generics and Biosimilars Act
<b>PABA</b>	Protecting Access to Biosimilars Act of 2019
<b>PBCA</b>	Purple Book Continuity Act of 2020
<b>PBTA</b>	Biologic Patent Transparency Act
<b>PDAAA</b>	Prescription Drug Affordability and Access Act



<b>PDPRA</b>	Prescription Drug Price Relief Act of 2019
<b>PRICED Act</b>	Price Relief, Innovation, and Competition for Essential Drugs Act
<b>REMEDY Act</b>	Reforming Evergreening and Manipulation that Extends Drug Years
<b>SLDPA</b>	Second Look at Drugs Patents Act of 2019
<b>TERM Act</b>	Terminating the Extension of Rights Misappropriated Act
<b>We PAID Act</b>	We Protect American Investment in Drugs Act

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