Free markets. Real solutions.

R STREET POLICY STUDY NO. 220
February 2021

BIOLOGICS PATENT LITIGATION: REFORMS FOR LOWERING DRUG PRICES

By Charles Duan

CONTENTS

INTRODUCTION

According to poll data, eight in ten Americans have characterized the cost of prescription drugs as "unreasonable."[1] As a result, millions of citizens are becoming sicker or even dying because they cannot afford necessary medications.[2] The issue is so pervasive that voters for both parties report that the "rising price of prescription drugs was an important factor," in their voting decisions.[3] Lawmakers on both sides of the aisle have committed to tackling the problem, but finding the right solution has proven to be difficult.

In the 116th Congress, legislators introduced over a hundred bills to address prescription drug prices.[4] Recently, Sen. John Cornyn (R-Texas) introduced one such bill to tackle the drug pricing problem: the Affordable Prescriptions for Patients Act of 2019 (APPA).[5] The bill received a fair amount of attention and was quickly reported favorably out of the Senate Judiciary Committee, but stalled due to unrelated external events.[6] The APPA takes a unique approach to addressing high drug prices: It targets costly patent litigation practices that raise entry barriers for competitor generic manufacturers, thereby preserving patent-holding pharmaceutical firms' monopoly power to raise prices.[7] In particular, the APPA—as amended in committee—places limits on litigation over biologics, a particular class of medical treatments that have become especially costly and hotly litigated in recent years.[8]

Yet despite the potential for legislation like the APPA to advance, there has been little scholarly attention to the bill's approach of using litigation limits to increase competition and lower drug prices.[9] Some commentary has focused on

1. Ashley Kirzinger et al., "KFF Health Tracking Poll—February 2019: Prescription Drugs," *Kaiser Family Foundation*, March 1, 2019. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs.

2. Ibid; "High Drug Prices and Patient Costs: Millions of Lives and Billions of Dollars Lost," Council for Informed Drug Spending Analysis, Nov. 18, 2020, p. 13. https://www.cidsa.org/publications/xcenda-summary; "2017 *Generic Drug Access and Savings in the U.S.,*" Association for Accessible Medicines, 2017. https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report.

3. Coalition Against Patent Abuse and Morning Consult, "*Reforming the Patent System,*" November 2020, p. 1. https://www.capanow.org/wp-content/uploads/2020/11/CAPA_Memo_MC.pdf.

4. For a general overview of selected bills, see, e.g., Kevin J. Hickey et al., *Report No. R45666, Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress,* Congressional Research Service, (5th ed. 2019), pp. 35–51. https://www.crsreports.congress.gov/product/pdf/R/R45666.

5. S. 1416, Affordable Prescriptions for Patients Act of 2019 (APPA), 116th Congress.

6. Sarah Owermohle, "'Patent thicket' bill caught in price reform tug-of-war," *Politico*, Oct. 25, 2019, https://www.politico.com/newsletters/prescription-pulse/2019/10/25/patent-thicket-bill-caught-in-price-reform-tug-of-war-781485.

7. S. 1416, sec. 2, sec. 3.

8. Ibid., sec. 3.

9. Stephen Barlas, "Bipartisan Drug-Patent Bills Ready for Senate Vote," *Pharmacy and Therapeutics* 44:9 (September 2019), p. 516. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6705482/pdf/ptj4409516.pdf.

earlier versions of the bill, which employed a substantially different legislative approach involving the Federal Trade Commission, and some industry members have commented on the bill as amended in committee.[10] The Congressional Budget Office estimated that the bill in total would save the government over $500 million over ten years, but there appear to be no analyses of what impact the bill would have in view of present litigation patterns.[11]

This paper aims to assess what impact the APPA would have on patent litigation over biologics, as a first step to assessing the bill's impact on drug prices. It does so by looking at data on past patent litigation to estimate what effect the APPA's changes would have on the biologics litigation landscape.

Briefly, the analysis reveals that, as a general matter, the approach of imposing limits on biologics patent litigation would likely be beneficial in terms of increasing competition and lowering drug prices. Industry members and experts widely believe that patent litigation has stymied the development of competition in the U.S. biologics market.[12] Similarly, manufacturers of Food and Drug Administration (FDA)-approved biosimilars "have already delayed market entry to avoid patent litigation."[13] This study confirms that biologics patent litigation is becoming increasingly complex and voluminous, so imposing limits could cut down on the most cost-prohibitive litigation.

At the same time, nearly all biologics litigation would be unaffected by the particular numerical limitations that the APPA provides, which is both a positive and a negative. On the one hand, it suggests that the bill would not affect the vast majority of biologics patent litigation, thereby lessening concerns that the bill would be disruptive to innovation in the biologics industry. On the other hand, the effect of the bill as written is likely to be so minimal that it will probably have almost no effect on competition or drug prices. More stringent litigation limits may increase the effectiveness of the legislation while still avoiding widescale industry disruption.

This paper begins by reviewing the nature of biologics, the rules of biologics patent litigation and the governing regulatory framework. It then reviews the APPA and its litigation-limiting provisions in detail, and briefly discusses the history and progress of that legislation. It discusses the methodology used for collecting information on litigated cases and patents of relevance, and then presents findings based on that population of cases and simulations of the APPA's litigation limits on that population. Based on those findings, the paper identifies improvements and areas of further reform that could strengthen the bill.

BACKGROUND

Biologics, Biosimilars and the BPCIA

As a class of medical treatments, biologics are rapidly growing in importance. Like other pharmaceuticals, biologics are chemical compounds that are administered to treat particular medical indications. Unlike "small-molecule" drugs, the active ingredients in biologics are large, complex molecules derived from or manufactured using living organisms, such as vaccines grown in poultry eggs or proteins produced by genetically modified bacteria. Biologics are far from new in the practice of medicine—insulin was first isolated a century ago—but modern advances in biotechnology have enabled the rapid development of new biologic treatments for conditions such as rheumatoid arthritis, cancer and autoimmune diseases.[14]

With drug prices rapidly increasing in the United States, Congress sought to introduce competition in the biologics market when it passed the Biologics Price Competition and Innovation Act (BPCIA) in 2009 as part of the Obama-era Affordable Care Act.[15] The BPCIA was designed to "balance[e] innovation and consumer interests" by creating a simplified regulatory pathway for approval of "generic" biologics, called "biosimilars."[16] The entering competitor files an "abbreviated Biologics License Application" (aBLA) which ties the biosimilar to a reference biologic.[17] To be approved,

10. S. 1416, Affordable Prescriptions for Patients Act of 2019 (APPA), 116th Congress; Christopher M. Holman, "Congress Should Decline Ill-Advised Legislative Proposals Aimed at Evergreening of Pharmaceutical Patent Protection," *University of the Pacific Law Review* 51:3 (2020), pp. 509–13; Erika Lietzan, "The 'Evergreening' Metaphor in Intellectual Property Scholarship," *Akron Law Review* 53:4 (2019), p. 808 n.14. https://ideaexchange.uakron.edu/akronlawreview/vol53/iss4/2; Simone Rose and Tracea Rice, "The Biosimilar Action Plan: An Effective Mechanism for Balancing Biologic Innovation and Competition in the United States?", *University of the Pacific Law Review* 51:3 (2020), p. 565 n.166; Barlas, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6705482/pdf/ptj4409516.pdf; Nicholas Florko, "After a Pharma Lobbying Blitz, Congress Softens Legislation on Drug Patents," *STAT*, June 21, 2019. https://www.statnews.com/2019/06/21/pharma-win-congress-patents; Denise Bell, "Senate Judiciary Committee Approves Modified Drug Patent Measure," *BioUtah*, July 5, 2019. https://bioutah.org/senate-judiciary-committee-approves-modified-drug-patent-measure.

11. "*Cost Estimate: S. 1416, Affordable Prescriptions for Patients Act of 2019,*" Congressional Budget Office, July 19, 2019. https://www.cbo.gov/system/files/2019-07/s1416.pdf.

12. See, e.g., Louise C. Druehdal et al., "A Qualitative Study of Biosimilar Manufacturer and Regulator Perceptions on Intellectual Property and Abbreviated Approval Pathways," *Nature Biotechnology* 38:11 (2020), p. 1255. https://www.nature.com/articles/s41587-020-0717-7.

13. Andrew W. Mulcahy et al., "*Biosimilar Cost Savings in the United States,*" *Rand Health Quarterly 7:4* (2017), p. 13. https://www.rand.org/pubs/perspectives/PE264.html.

14. Agata Dabrowska, *Report No. R44620, Biologics and Biosimilars: Background and Key Issues,* Congressional Research Service, June 6, 2019, pp. 1–3. https://fas.org/sgp/crs/misc/R44620.pdf; Thomas Morrow, "Defining the Difference: What Makes Biologics Unique," *Biotechnology Healthcare*, September 2004, pp. 24–26. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/pdf/bh0104024.pdf.

15. Biologics Price Competition and Innovation Act of 2009 (BPCIA) sec. 7001(b), 124 Stat. p. 804, in Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. vii, subtit. A, 124 Stat. 119, p. 804 (2010) (codified at Public Health Service Act (PHSA) § 351, 42 U.S.C. § 262).

16. BPCIA sec. 7001(b), 124 Stat. p. 804; PHSA § 351(k) (providing regulatory approval pathway for biosimilars).

17. Ibid. § 351(k)(3).

the Food and Drug Administration (FDA) must find that the biosimilar applicant's product is "highly similar to the reference product" with "no clinically meaningful differences" in "safety, purity, and potency."[18]

Regulatory approval is not enough to enable biosimilar competition, though, because the maker of the reference biologic may hold patents that can prevent the biosimilar from entering the market. Such patents grant a temporary monopoly over the reference biologic, in order to stimulate investment in research and development.[19] Nevertheless, many patents on biologics would not prevent biosimilar market entry, either because the patent is defectively invalid or because the patent was required to be drawn so specifically to the reference product that the biosimilar falls outside the patent's ambit. Ultimately, the validity and scope of patents can only be determined in an adjudicatory process.[20] As a result, the reference product sponsor and the biosimilar applicant frequently fall into vigorous patent law disputes that, like most patent litigation, can cost millions in attorney fees and can keep the competitive biosimilar off the market for years.[21]

In an effort to streamline this complex patent litigation, the BPCIA lays out an intricate negotiation procedure—affectionately called the "patent dance"—between the reference product patent holder and the biosimilar applicant.[22] Within this procedure, after filing its aBLA with the FDA, the biosimilar applicant transmits a copy of the application and other manufacturing data to the reference product sponsor, who in turn provides a list of patents that the sponsor believes the biosimilar may infringe, known as a "3A" list.[23] (The sponsor must update the list if new patents issue thereafter.[24])

Based on the production of the 3A list, the biosimilar applicant and the reference product sponsor exchange their legal analyses of the patents identified and negotiate a subset of the 3A list for early litigation.[25] Specifically, there are two pathways for negotiating this early litigation subset. First, the parties could reach agreement within 15 days of exchanging legal positions on which patents should be litigated; the resulting list of patents is called the "4A" list.[26] Second, the parties may unilaterally declare lists of patents to be litigated, based on a procedure specified in the law; the resulting list here is called the "5B" list.[27]

The BPCIA creates three new pathways to patent litigation that occur within the aforementioned negotiation process:[28]

- Phase 1 litigation: Within 30 days of negotiating a 4A or 5B list of patents, the reference product sponsor "shall bring an action for patent infringement with respect to each such patent."[29]
- Phase 2 litigation: The BPCIA requires the biosimilar applicant to give the reference product sponsor at least 180 days of advance notice before any commercial marketing of the biosimilar.[30] Upon receipt of that notice, either party may initiate litigation over any remaining 3A-listed patents.[31]
- "Failure phase" litigation: If the biosimilar applicant chooses not to engage in the statutory process, the reference product sponsor can immediately bring suit over any of the 3A patents or, if the biosimilar applicant never provided the application and manufacturing data in the first place, over any relevant patent.[32] As the Supreme Court recognized in Sandoz Inc. v. Amgen Inc., the biosimilar applicant has no obligation to participate in the patent dance, at least under federal law; however, the possibility of this form of litigation is the penalty for opting out.[33]

The BPCIA thus attempts to balance interests of the patent-holding reference product sponsor and the biosimilar applicant in an effort to prevent an uncontrolled level of litigation over biologics patents.[34] The biosimilar applicant enjoys near-unilateral control over the number of patents to litigate in the first BPCIA phase, and unilaterally chooses the timing of the second phase of litigation.[35] But the biosimilar applicant maintains this control only by providing

18. Ibid. § 351(i)(2)(A)–(B); Dabrowska, pp. 8–10. https://fas.org/sgp/crs/misc/R44620.pdf.

19. For a basic overview of patents, see Peter S. Menell et al., Federal Judicial Center, *Patent Case Management Judicial Guide* (2016), ch. 14. https://www.fjc.gov/sites/default/files/2017/PCMJG3d_2016_final.pdf .

20. Mark A. Lemley and Carl Shapiro, "Probabilistic Patents," *Journal of Economic Perspectives* 19:2 (2005), p. 80. https://pubs.aeaweb.org/doi/pdfplus/10.1257/0895330054048650.

21. See, e.g., American Intellectual Property Law Association, *Report of the Economic Survey* (2019), pp. 50–52.

22. Hickey et al., pp. 32–34. https://crsreports.congress.gov/product/pdf/R/R45666.

23. PHSA § 351(*l*)(2), (*l*)(3)(A).

24. Ibid. § 351(*l*)(7).

25. Ibid. § 351(*l*)(3)(B)–(C).

26. Ibid. § 351(*l*)(4)(A).

27. Ibid. § 351(*l*)(5)(B).

28. 35 U.S.C. § 271(a)–(c).

29. PHSA § 351(*l*)(6)(A); ibid. § 351(*l*)(6)(B); see also *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, p. 1671 (2017).

30. PHSA § 351(*l*)(8)(A).

31. Ibid. § 351(*l*)(8)(B), (*l*)(9)(A).

32. PHSA § 351(9)(B)–(C).

33. *Sandoz*, 137 S. Ct. p. 1675.

34. Joanna M. Shepherd, "Biologic Drugs, Biosimilars, and Barriers to Entry," Health Matrix 25 (2014), p. 139. https://scholarlycommons.law.case.edu/healthmatrix/vol25/iss1/8.

35. Ibid. § 351(*l*)(5)(A), (*l*)(8)(A).

extensive information disclosures on product information, manufacturing, and legal positions, information that many would consider confidential and highly sensitive.[36] Whether these elements of the legislative arrangement have struck a proper balance, however, has remained an open question, giving rise to calls for reform.[37]

Recent Concerns and Proposed Legislation

Despite these efforts in the BPCIA to streamline and limit biologics patent litigation, recent experience suggests that such litigation—and the BPCIA patent dance itself—may be increasing in complexity, size and cost. For example, some biologics developers have started applying for dozens or hundreds of patents—described as a "thicket" or an "estate" of patents—in an effort to protect their products.[38] Some commentators have contended that the phenomenon of patent thicketing is not new. [39] However, the trend in biologics differs on sheer scale. Historically, patent thickets involved numbers in the tens, not a hundred or more as seen with biologics.[40] Should these trends continue, they may ultimately deter the development of new cost-saving biosimilars and undermine the BPCIA's intent of lowering drug prices for Americans through robust competition.

Thickets of patents pose at least two problems for entry of biosimilars: cost and time barriers. Each patent, being a separate legal instrument, must be analyzed and disputed separately. A legal opinion on a patent can run over $100,000, so when a biologic patent holder asserts 50 or 100 patents, the attorney costs even before litigation could be in the millions.[41]

In terms of time, many of these patents are directed not to the active ingredient in the biologic, but rather to particular uses, indications, combinations or formulations of the compound.[42] These "secondary" patents are commonly found in the thickets of patents surrounding contemporary drugs.[43] Because they are applied for later in time than the initial active-ingredient patent, secondary patents generally expire later, effectively "extending" patent protection on the biologic beyond the patent term that Congress provides by statute.[44] For example, by one estimate, patents on the biologic Humira may insulate it from competition for 39 years, two decades past the 20-year statutory patent term.[45] Furthermore, many secondary patents are likely invalid. Multiple studies find that secondary patents frequently fail the statutory tests for inventiveness when scrutinized.[46] And two scholars have suggested that many secondary biologics patents are logically contradictory in view of the earlier-filed active ingredient patent.[47]

To the extent that invalid or questionable secondary patents on biologics persist for years or decades beyond the expected lifetime of patent protection, they improperly block biosimilar entry and impose undue monopoly pricing on American consumers. That consequence is multiplied many times over for large patent thickets, as the sheer cost of analyzing and litigating those patents can prevent even the least valid patents from being fully adjudicated. Nevertheless, holders of these biologics patent thickets do not appear to be reluctant to take advantage of these barriers to biosimilar entry: AbbVie, holder of patents on Humira, regularly threatens biosimilar competitors with multiple "wave[s] of litigation" over scores of patents.[48]

In May 2019, Sen. Cornyn introduced the Affordable Prescriptions for Patients Act (APPA) to address the increasing complexity of biologics patent litigation under the BPCIA.

36. Ibid. § 351(*l*)(1).

37. See, e.g., Ude Lu, "Biologics Price Competition and Innovation Act: Striking a Delicate Balance Between Innovation and Accessibility," Minnesota Journal of Law, Science and Technology 15:1 (2014), p. 614. https://conservancy.umn.edu/bitstream/handle/11299/162661/lu_mn_journal_of_law_science_and_technology_issue_15-1.pdf; Jon Tanaka, "'Shall' We Dance? Interpreting the BPCIA's Patent Provisions," Berkeley Technology Law Journal 31 (2016), pp. 662-67. https://btlj.org/data/articles2016/vol31/31_ar/0659_0686_Tanaka_WEB.pdf.

38. "*Overpatented, Overpriced: Special Edition,"* Initiative for Medicines, Access and Knowledge, October 2020. https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf; Peter Loftus and Denise Roland, "By Adding Patents, Drugmaker Keeps Cheaper Humira Copies Out of U.S.," The *Wall Street Journal*, Oct. 16, 2018, https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603; Andrew Pollack, "Makers of Humira and Embrel Using Patents to Delay Generic Versions," The *New York Times*, Jan. 16, 2017, p. B1. https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html.

39. Christopher Beauchamp, "The First Patent Litigation Explosion," Yale Law Journal 125 (2016), pp. 865-66. https://www.yalelawjournal.org/pdf/n.848.Beauchamp.944_dywbcn97.pdf; Adam Mossoff, "The Rise and Fall of the First American Patent Thicket: The Sewing Machine Wars of the 1850s," Arizona Law Review 53 (2011), p. 165.

40. See, e.g., Ryan Lampe and Petra Moser, "Do Patent Pools Encourage Innovation? Evidence from the Nineteenth-Century Sewing Machine Industry," *Journal of Economic History* 70:4 (2010), p. 902; Ralph Cassady, Jr., "Monopoly in Motion Picture Production and Distribution: 1908–1915," *Southern California Law Review* 32:4 (1959), p. 330.

41. Matthew D. Powers and Steven C. Carlson, "The Evolution and Impact of the Doctrine of Willful Patent Infringement," *Syracuse Law Review* 51:1 (2001), p. 102.

42. Kevin T. Richards et al., *Report No. R46221, Drug Pricing and Pharmaceutical Patenting Practices,* Congressional Research Service, Feb. 11, 2020, pp. 16–19. https://www.everycrsreport.com/reports/R46221.html.

43. Robin Feldman, "May Your Drug Price Be Evergreen," *Journal of Law and the Biosciences* 5:3 (2018), p. 630, table 6. https://academic.oup.com/jlb/article/5/3/590/5232981.

44. Competition Directorate-General, European Commission, *Pharmaceutical Sector Inquiry: Final Report* (July 8, 2009), para. 526, p. 196. https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

45. "*Overpatented, Overpriced*," p. 2. https://www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf; 35 U.S.C. § 154(a)(2).

46. See, e.g., C. Scott Hemphill and Bhaven Sampat, "Drug Patents at the Supreme Court," *Science* 339:6126 (2013), p. 1398. http://awa2014.concurrences.com/IMG/pdf/drug_patents_at_the_supreme_court_science.pdf; Competition Directorate-General, European Commission, P. 501, p. 191. https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

47. W. Nicholson Price II and Arti K. Rai, "How Logically Impossible Patent Block Biosimilars," *Nature Biotechnology* 37:8 (2019), p. 862. https://www.nature.com/articles/s41587-019-0196-x.

48. See, e.g., Complaint at p. 3, *AbbVie Inc. v. Boehringer Ingelheim Int'l GMBH*, No. 1:17-cv-1065 (D. Del. Aug. 02, 2017). https://images.law.com/contrib/content/uploads/documents/394/2433/AbbVie-Boehringer-complaint.pdf.

The bill, as reported out of the Senate Judiciary Committee, limits the number of patents that may be litigated in a patent infringement lawsuit between a reference product sponsor and a biosimilar applicant.[49] It is unclear whether the bill limits only patent litigation under the BPCIA or all patent litigation between the reference product sponsor and the biosimilar applicant. Courts may relax the limits upon appropriate showings of cause,[50] and the limits only apply if the biosimilar applicant completes every step of the patent dance.[51] According to Sen. Cornyn, the purpose of the bill is to "resolve patent issues faster and focus on those patents that really matter the most."[52]

The particular numerical limits provided in the bill are based on the nature of each patent at issue. Specifically, the bill proposes three major categories of litigated biologics patents:

- Excluded patents: Those that were filed with the U.S. Patent and Trademark Office (USPTO) within four years of the reference biologic product being approved. The APPA imposes no limit on how many of these patents may be asserted, so long as any methods of manufacturing the biologic covered by the patents are actually used by the reference product sponsor.[53] Also excluded are patents dealing with uses of the biologic, such as new indications or methods of treatment.[54]
- Late-issued patents: Those that the USPTO granted after the reference product sponsor transmitted its 3A list to the biosimilar applicant. The bill permits up to 10 such patents to be litigated.
- Other limited patents: Litigated biologics patents that do not fall into the above two categories. The bill limits lawsuits to up to 20 patents total, between this and the previous category.

Limiting the number of patents in litigation is not a new approach: District court judges have been calling on patent litigants to winnow their cases down to a small subset for years, with approval from the Federal Circuit appellate court that reviews patent cases.[55] For example, in *In re Katz Interactive Call Processing Patent Litigation* a district court ordered a patent litigant to limit his case from 1,975 asserted patent claims down to 64, unless he could offer good reason to exceed that limit.[56] The Federal Circuit approved the procedure.[57] Because the district court permitted the patent holder to show cause for a larger set of patent assertions (which he "made no effort" to do), the Federal Circuit found no improper deprivation of rights in the district court's narrowing of the case.[58]

Subsequently, the Federal Circuit Advisory Council, a body of patent experts that offers nonbinding advice to the Federal Circuit, developed a "Model Order Limiting Excess Claims and Prior Art."[59] The introductory text to the model order criticizes the "problematically excessive" number of patent claims asserted, which "inflate litigation costs" and "unduly burden the judiciary."[60] The model order recommends limiting patent cases to "no more than ten claims from each patent and not more than a total of 32 claims" during the discovery phase of litigation, with further limits as the case progresses.[61] Although the Council has since removed the model order from its website, courts and commentators continue to cite the model order as guidance for appropriate limits on patent litigation.[62] And the Eastern District of Texas, one of the nation's most active patent courts, has adopted a modified form of the model order.[63]

The APPA and its House companion have attracted a substantial number of bipartisan cosponsors, which suggests a degree of consensus to its approach.[64] Patient groups and others advocating for lower drug prices also supported the

49. S. 1416, Affordable Prescriptions for Patients Act of 2019 (APPA), 116th Congress sec. 3(a)(2), § 271(e)(7)(A) (as reported from committee, June 28, 2019).

50. S. 1416, sec. 3(a)(2), § 271(e)(7)(C).

51. Ibid., sec. 3(a)(2), § 271(e)(7)(E)(i).

52. Bruce M. Wexler et al., "Senate Judiciary Committee Passes Bill Limiting the Number of Patents for BPCIA Litigation," *Paul Hastings Insights*, July 3, 2019. https://www.paulhastings.com/publications-items/details/?id=e09c606d-2334-6428-811c-ff00004cbded.

53. S. 1416, sec. 3(a)(2), § 271(e)(7)(B)(ii).

54. Ibid., sec. 3(a)(2), § 271(e)(7)(E)(ii).

55. Menell et al., § 2.1.3.1. https://www.fjc.gov/sites/default/files/2017/PCMJG3d_2016_final.pdf.

56. *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, p. 1309 (Fed. Cir. 2011).

57. Ibid., pp. 1311–13.

58. Ibid., p. 1312.

59. Federal Circuit Advisory Council, *Model Order Limiting Excess Patent Claims and Prior Art* (2013) [hereinafter FCAC Model Order].

60. Ibid., pp. 1–2.

61. Ibid., pp. 6–7.

62. Jason Rantanen, "The Disappearing Federal Circuit Advisory Council Model Orders," *Patently-O*, Aug. 12, 2013. https://patentlyo.com/patent/2013/08/the-disappearing-federal-circuit-advisory-council-model-orders.html; see, e.g., *Unwired Planet, LLC v. Google, Inc.*, No. 3:12-cv-504, slip op. p. 2 (D. Nev. Aug. 30, 2013) (citing FCAC Model Order, p. 2). https://www.courtlistener.com/recap/gov.uscourts.nvd.90092.147.0.pdf; Menell et al., § 2.1.3.1, https://www.fjc.gov/sites/default/files/2017/PCMJG3d_2016_final.pdf.

63. General Order Adopting Model Order Focusing Patent Claims and Prior Art to Reduce Costs, Gen. Order No. 13-20 (E.D. Tex. 2013). https://www.txed.uscourts.gov/sites/default/files/goFiles/13-20.pdf.

64. S. 1416, Affordable Prescriptions for Patients Act of 2019 (APPA), 116th Congress (as reported from committee, June 28, 2019).

bill's efforts to increase competition in biologics markets.[65] Nevertheless, Sen. Cornyn himself intended this approach to be a watered-down version.[66] An earlier, stronger legislative proposal to make biologic patent thicketing an unfair method of competition actionable by the Federal Trade Commission was originally proposed and altered in committee.[67] Several industry biotechnology groups praised the bill as reported out of committee, insofar as that bill did less with respect to patent thicketing than the original.[68] As a result, several organizations characterized the reported amendment as one that "loses a lot of teeth" compared to the original version.[69] The bill subsequently became caught up in a larger wave of legislative efforts on drug pricing toward the end of 2019, and ultimately did not make further progress due to the presidential impeachment trial and subsequent COVID-19 pandemic.[70]

METHODS

The data collection for this study began with compiling a list of biologics litigation actions in federal district courts. The initial source of the list was the law firm Goodwin Procter's online database of cases under the BPCIA. That list was supplemented with cases identified through searching judicial opinions for "BPCIA" and "biologics patent," and cases listed as related in the dockets of cases already found. Neither appeals in the Federal Circuit or Supreme Court, nor administrative actions in the USPTO or the U.S. International Trade Commission were included, since those cases have distinct requirements and consequences that render them less informative for BPCIA policy. Related and consolidated cases were treated as discrete cases, because judges often consolidated cases involving unrelated parties, patents or products.

Information for each case, including the list of litigated patents, was identified using data from Unified Patents' litigation portal; that data was reviewed for errors and corrected by hand. This information was further combined with docket sheet information for each case, retrieved from the CourtListener docket service. The USPTO's PatentsView service was the source of bibliographic data on each patent. Application numbers and dates of patent applications in each patent's priority chain were collected from a PatentsView bulk data file, supplemented by hand for missing data. The FDA Purple Book was the source of approval dates for biologics; where several approval dates were given, the earliest was used, as later dates appear to be supplemental approvals for particular indications.

For each case, the initially filed complaint was reviewed to assess the nature of the litigation, in particular whether the lawsuit fell under the BPCIA, whether the lawsuit was an infringement action or one for declaratory judgment, and what the reference product and/or allegedly infringing product were. Non-BPCIA cases included litigation prior to the biosimilar applicant's aBLA filing,[71] lawsuits involving biologics patent holders that were not the reference product sponsors,[72] a direct patent infringement lawsuit[73] and one grandfathered under pre-BPCIA law.[74]

For cases under the BPCIA, it was then determined which of the three phases of litigation the case was brought under. A difficulty in doing so is that the parties often did not make clear the statutory basis for the suit; moreover, the litigants almost always accused each other of failing to comply with the elements of the patent dance. Only lawsuits where the complainant specifically recited completing the BPCIA list exchange procedure within 30 days of filing of the complaint or where the required (but often forgotten) notice of the lawsuit was published in the Federal Register were categorized as Phase 1.[75] A suit was considered to be brought under the BPCIA penalty provisions for failing to complete the patent dance only where the complaint explicitly listed those statutory provisions or alleged that the biosimilar applicant had failed to furnish certain information entirely (as opposed to the applicant tendering information that the reference product sponsor deemed insufficient). All other BPCIA litigation was considered to be Phase 2 so long as the biosimilar applicant had transmitted the required notice of commercial marketing, alleged to have occurred in every such case reviewed.

Because the date of the initial 3A patent list production is relevant to the APPA, dates were identified based on the

65. See, e.g., Elliott T. Dube, "Cornyn, Running for Re-Election, Gets in Pharma's Crosshairs," *Bloomberg Law*, June 12, 2019. https://news.bloomberglaw.com/health-law-and-life-sciences/cornyn-running-for-re-election-gets-in-pharmas-crosshairs-1; Letter from David Certner, AARP, to John Cornyn and Richard Blumenthal, United States Senate, June 18, 2019, p. 1. https://www.aarp.org/content/dam/aarp/politics/advocacy/2019/06/061819-endorsement-letter-for-cornyn-blumenthal-patent-bill-final.pdf.

66. Alex Ruoff, "Drug Industry Notches Win as Senator Rethinks Patent Measure," *Bloomberg Government*, June 18, 2019. https://about.bgov.com/news/drug-industry-notches-win-as-senator-rethinks-patent-measure.

67. S. 1416, Affordable Prescriptions for Patients Act of 2019 (APPA), 116th Congress sec. 2(a), § 27(a)(11), (b)(1).

68. See, e.g., Bell. https://bioutah.org/senate-judiciary-committee-approves-modified-drug-patent-measure; John Conrad, "The Affordable Prescriptions for Patients Act (S. 1416)," *iBIO*, July 1, 2019. https://ibio.org/the-affordable-prescriptions-for-patients-act-s-1416.

69. Florko. https://www.statnews.com/2019/06/21/pharma-win-congress-patents.

70. Owermohle. https://www.politico.com/newsletters/prescription-pulse/2019/10/25/patent-thicket-bill-caught-in-price-reform-tug-of-war-781485.

71. See, e.g., *Sandoz, Inc. v. Amgen Inc.*, 773 F.3d 1274 (Fed. Cir. 2014). https://scholar. google.com/scholar_case?case=413931286222629256.

72. See, e.g., *Merck Sharp & Dohme Corp. v. Genentech, Inc.*, No. 2:16-cv-4992 (C.D. Cal. July 5, 2016). https://patentdocs.typepad.com/files/merck-v-genetech.pdf.

73. *Janssen Biotech, Inc. v. Celltrion Healthcare Co*., No. 1:16-cv-11117 (D. Mass. June 14, 2016). https://patentdocs.typepad.com/files/janssen-v-celltrion-1.pdf.

74. *Sanofi-Aventis U.S. LLC v. Mylan NV*, No. 1:17-cv-181 (N.D.W. Va. Oct. 26, 2017). https://www.courtlistener.com/recap/gov.uscourts.wvnd.42174/gov.uscourts.wvnd.42174.1.0.pdf.

75. PHSA § 351(*l*)(6)(C).

complaints reviewed. In most cases, the date was recited in the complaint itself. In the handful of cases that did not state the 3A list date, a date was determined based on a related case involving the same parties and allegedly infringing biosimilars, or estimated based on other information in the complaint. For any estimates, final dates erred on the side of later dates.

In total, 52 cases and 154 litigated patents were identified. A summary of the number of cases found by BPCIA phase is given in Table 1.

TABLE I: NUMBER OF BIOLOGICS LITIGATION CASES BY BPCIA PHASE

Case Type	Count
Phase 1	22
Phase 2	7
Incomplete patent dance	10
Not BPCIA	13

RESULTS

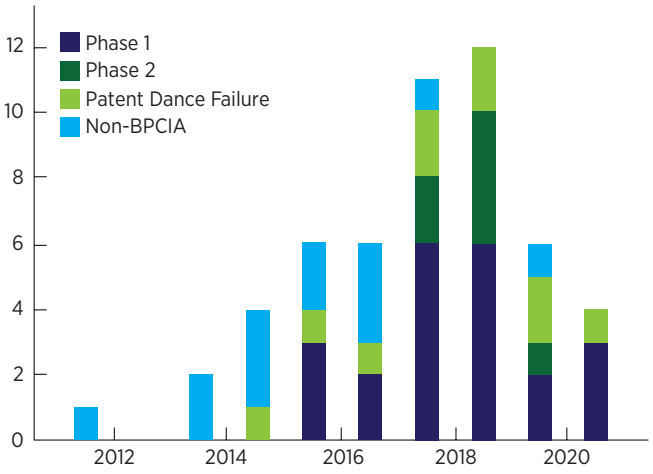
Volume of Patents and Litigation

To assess the nature of biologics litigation and the effect of potential limits, a summary of overall characteristics of that litigation is helpful. Figure 1 shows the number of cases filed each year, broken down by BPCIA phase. Unsurprisingly, few cases were filed immediately after the BPCIA's passage in 2010, since a lawsuit under the statute can only arise after an application for approval of a biosimilar has been filed. Sandoz filed the first such application in 2014.[76] Thus, all biologics litigation prior to 2015 was not under the BPCIA, with the exception of the case between Amgen and Sandoz.[77]

The number of BPCIA cases increased gradually in 2015 and 2016, and then jumped dramatically in the next two years, falling again in 2019. There are several possible explanations for the 2017–2018 spike, including the Supreme Court's 2017 decision in *Sandoz v. Amgen*, which may have induced earlier litigation; the introduction of APPA in 2019, which may have discouraged high-volume filing; and the activity of one particular litigant, Genentech, which filed a large number of cases in that time frame.

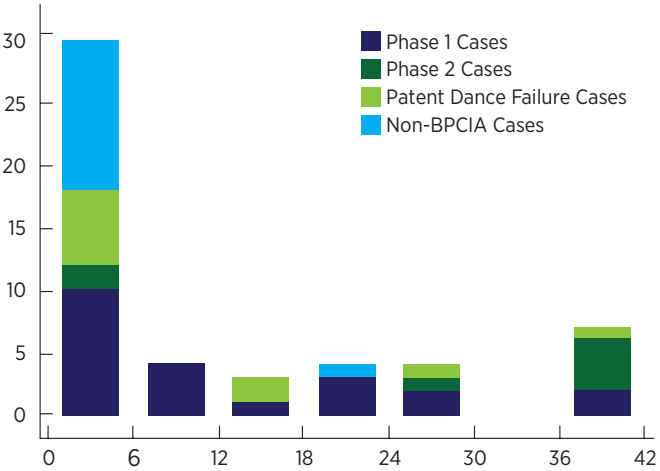
Figure 2 shows the number of patents litigated per case, for BPCIA and non-BPCIA cases. As the chart shows, the vast majority of cases involve only a small number of asserted patents, including cases where a failure in the patent dance occurred—a notable finding given that the reference product

FIGURE I: NUMBER OF BPCIA CASES PER YEAR



sponsor in such a situation may assert an essentially unlimited number of patents. Additionally, the 7 lawsuits with over 30 patents asserted were all brought by Genentech or declaratory judgment actions against Genentech, suggesting that the high end of patents per lawsuit are the result of one particular outlier litigant. This summary result provides at least some support for imposing limits on the number of patents litigated in biologics cases: Any such limit would have little effect on the majority of cases, largely serving instead to reduce a limited subset of especially aggressive litigation campaigns.

FIGURE 2: HISTOGRAM OF PATENTS LITIGATED IN BPCIA AND OTHER BIOLOGICS CASES

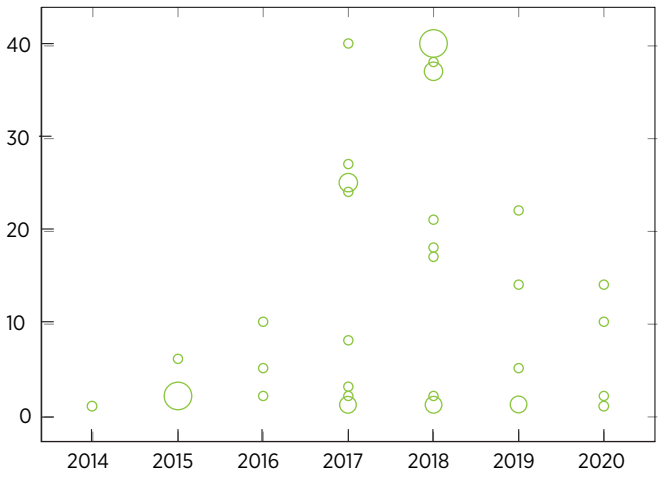


In Figure 3, each circle represents one or more BPCIA lawsuits, with the size of the circle indicating how many lawsuits it represents. The circles are plotted along the vertical axis to indicate the number of patents involved in the filed cases. For example, in 2018 there were three lawsuits involving 40 patents each.

76. Stephen Barlas, "FDA Accepts Its First Biosimilar Application," *Pharmacy and Therapeutics* 39:10 (2014), p. 660. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4189690.

77. Complaint, *Amgen Inc. v. Sandoz Inc.*, No. 3:14-cv-4741 (N.D. Cal. Oct. 24, 2014). https://www.courtlistener.com/recap/gov.uscourts.cand.281722.1.0.pdf.

FIGURE 3: PATENTS LITIGATED PER BPCIA CASE BY YEAR



Although the number of patents litigated per BPCIA case is generally small, the trend is toward larger and more complex cases, as seen in Figure 3. Prior to October 2017, when Genentech and Amgen began several suits against each other, no BPCIA case exceeded 10 patents asserted. Thereafter, 18 cases, or 69 percent of all the BPCIA cases filed since October 2017, have put 10 or more patents at issue.

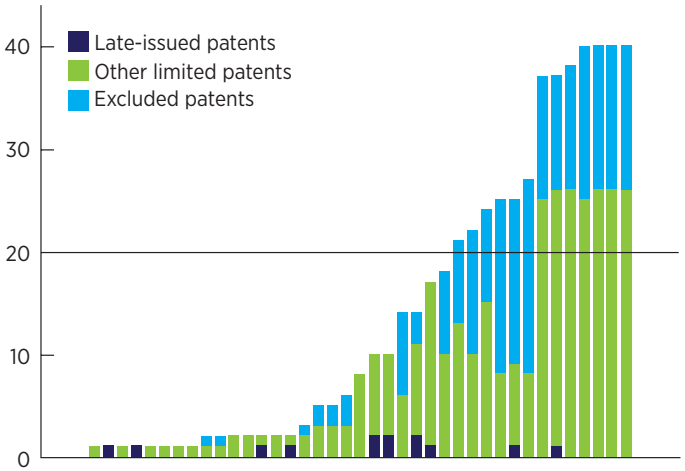
Additionally, there are several reasons to believe that the number of litigated patents per case will continue to rise. Most of the BPCIA cases filed to date have been Phase 1 cases, in which the biosimilar applicant has substantial control over how many patents are litigated.[78] Phase 2 cases are likely to become more frequent in view of the *Sandoz* decision making such cases easier to bring, and Figure 1 suggests that Phase 2 cases are being brought more frequently. Since the number of patents litigated in Phase 2 is not constrained as it is in Phase 1, the volume of patents per case is likely to increase in the future.[79] There are also signs that litigants are becoming more aggressive in patent assertion. For example, AbbVie has stated in several of its Phase 1 lawsuit filings that it holds an "estate" of between 60 and 80 patents on the biologic Humira, and "will assert the remainder of the patents" in a "second wave" of litigation.[80]

The data above thus suggests that the APPA's approach of limiting the number of litigated biologics patents could be beneficial, at least conceptually. The predominance of low-volume BPCIA cases indicates that biologic patent holders are frequently satisfied asserting their rights in just a few patents, suggesting that patent litigation limits on the whole would not be disruptive to the industry. Especially indicative of this are the patent dance failure and non-BPCIA cases, since the patent holder is free to sue on every patent at its disposal, and yet the majority of these cases involved six or fewer patents.[81] At the same time, outlier cases involving large volumes of patents are likely to increase over time, such that cutting down on the subset of unusually complex, costly biologics lawsuits would potentially be a welcome reform.

Effect of Proposed Litigation Limits

That biologics litigation limits are helpful in principle does not, of course, mean that the particular numerical limits chosen in APPA are the right values. Applying those limits to prior biologics litigation, as done in Figure 4 below, suggests that in fact the limits in the proposed legislation are too permissive and would likely not have much effect on the biosimilars industry. Within the figure, each bar represents a single lawsuit, and the bars are sorted by the total number of litigated patents.

FIGURE 4: PATENTS LITIGATED IN BPCIA CASES BY APPA CATEGORIES



As described above, the APPA constructs three categories of litigated biologics patents: patents excluded from limitations, late-issued patents (up to 10), and other limited patents (up to 20, along with late-issued patents). Figure 4 shows how those categories would have applied to past BPCIA litigation. Cases where the APPA would have decreased the number of patents in the lawsuit are those where the green bar is higher than the horizontal 20-patent cutoff line. Cases where the blue bar exceeds the cutoff line are unaffected, because patents in that bar are excluded from the APPA's limits. In computing the number of excluded patents, it is assumed that every patented method of manufacturing is used by the reference product sponsor, as the APPA requires

78. Public Health Service Act (PHSA) § 351(*l*)(5)(B)(ii), 42 U.S.C. § 262.

79. PHSA § 351(*l*)(9)(A).

80. Complaint, *AbbVie Inc. v. Amgen Inc.*, No. 1:16-cv-666 (D. Del. Aug. 04, 2016). https://www.courtlistener.com/recap/gov.uscourts.ded.59985.1.0.pdf; see, e.g., Complaint, *Abbvie Inc. v. Sandoz Inc.*, No. 3:18-cv-12668 (D. N.J. Aug. 10, 2018). https://www.courtlistener.com/recap/gov.uscourts.njd.381520/gov.uscourts.njd.381520.1.0_1.pdf.

81. PHSA § 351(*l*)(9).

of excluded patents.[82] This seems a fair assumption, since the sponsor likely uses its own inventions and can always start using them for purposes of complying with the statute.

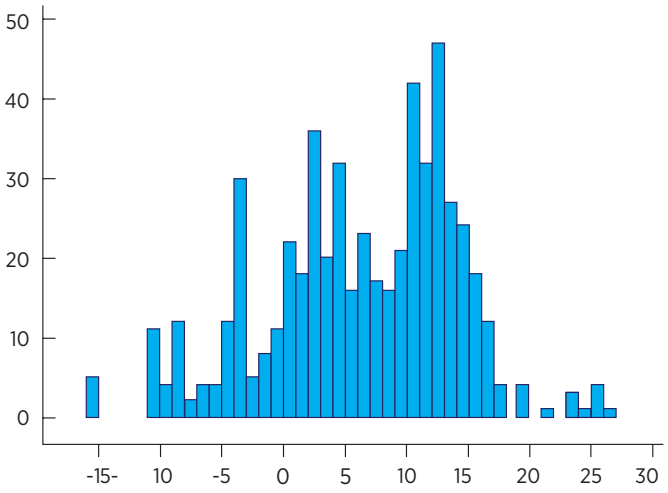
As Figure 4 shows, the proposed limit of 20 patents and 10 late-issued patents would have virtually no effect except on the seven most heavily litigated cases, and even then, would only reduce the number of litigated patents by 5–6 patents, or 13–16 percent of the total patents litigated. The limit on late-issued patents is even less impactful: no case involved more than two such patents, far less than the limit of 10 in the APPA.

As explained previously, it is arguably a virtue of the APPA's approach that the bill would not affect most biologics litigation and thus would minimally disrupt industry practices and expectations. But the fact that the APPA's effect is so minor means the bill cannot achieve its purposes. Cutting down complex litigation by a mere 16 percent will likely have a negligible effect on cost disincentives for biosimilar development. To be sure, increased occurrences of Phase 2 litigation in the future might be more affected by the APPA's current numerical limits, but the effect will likely be modest at most.

The ineffectiveness of the bill's litigation limits is largely a result of the excluded patents category. As a reminder, the APPA excludes from its limitations any patents issued within four years of FDA approval of the reference biologic product.[83] As Figure 4 shows, that exclusion would place a large portion of litigated patents outside the reach of the proposed law. Among the top 10 cases by number of litigated patents, between 30 and 70 percent of their litigated patents would be excluded and thus subject to no litigation limits under the APPA.[84]

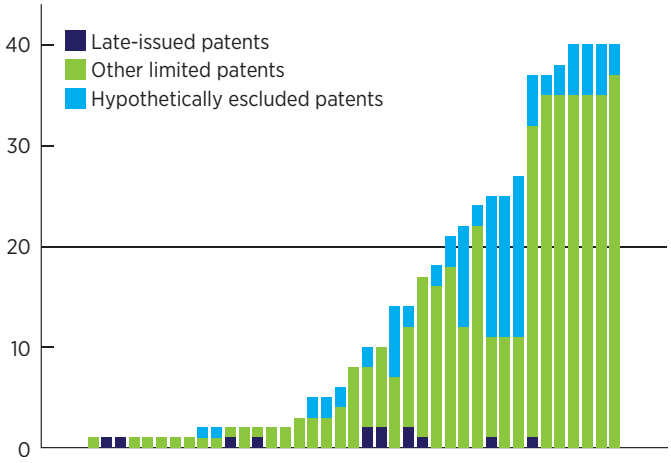
A natural improvement would be to modify the APPA so that it excludes fewer patents from its limitations. Altering the four-year cutoff would be one approach, but in practice such an alteration would have only moderate effects. Figure 5, which plots patent filing dates relative to the FDA approval dates of their respective biologics, reveals a wide diversity in the relationship between those dates: some patents are filed decades after the relevant approval date, but some are filed a decade or more before approval.

FIGURE 5: DIFFERENCE IN YEARS BETWEEN PATENT ISSUE DATE AND BIOLOGIC APPROVAL DATE



Decreasing the exclusion threshold to the date of FDA approval, rather than four years after approval, only tips one more patent lawsuit over the APPA limits, although many more patents in the highest-patent-volume cases are now subject to the bill's limits. This is shown in Figure 6. Removing the exclusion rule altogether renders thirteen BPCIA cases subject to patent limitations.

FIGURE 6: PATENTS HYPOTHETICALLY LITIGATED IN BPCIA CASES



Reducing the limit on how many patents may be asserted—currently 20 in the APPA—could also increase the effectiveness of the bill. For example, one may extrapolate from the Federal Circuit Advisory Council's model order that eleven is a reasonable limit. The model order imposes a limit of 32 patent claims.[85] Assuming conservatively that the patent holder asserts three claims per patent—any less would invite a substantial risk of the asserted claims being deemed invalid or not infringed—that limit allows for eleven patents

82. S. 1416, Affordable Prescriptions for Patients Act of 2019 (APPA), 116th Congress sec. 3(a)(2), § 271(e)(7)(B)(iii)(II) (as reported from committee, June 28, 2019).

83. S. 1416, sec. 3(a)(2), § 271(e)(7)(b)(iii)(*I*).

84. S. 1416, sec. 3(a)(2), § 271(e)(7)(b)(iii)(*I*).

85. FCAC Model Order, p. 6.

asserted, rounding up.[86] That limit would trim the number of patents asserted in the seven patent-heaviest cases by up to 41 percent, and it would impose limitations on three more cases. Nevertheless, the overall effect of more stringent litigation limits is modest: Even eliminating the APPA's four-year exclusion provision entirely and dropping the patent limit to eleven leaves 22 cases untouched, or 56 percent of the population.

ANALYSIS AND RECOMMENDATIONS

The above results suggest that there are useful and effective ways of strengthening the APPA, such as removing the exclusion of patents issued within four years of FDA approval and reducing the number of patents that may be litigated from the current value of 20. Without those changes, the bill will likely have minimal teeth and thus minimal effect on biosimilar entry and drug pricing. Appropriate changes could render the bill a powerful tool against aggressive and costly litigation without upsetting the bulk of biologics lawsuits involving reasonably-sized numbers of patents. A qualitative review of BPCIA and other biologics lawsuits further suggests several ways of strengthening the bill.

First, the bill should impose limits on patent claims asserted, not the number of patents. A single patent may contain dozens or hundreds of claims, so even a case involving a small handful of patents can end up being unmanageably complex.[87] The Federal Circuit Advisory Council model order, the Eastern District of Texas general order and other authorities impose limits on patent claims, not patents, and the APPA should do the same.

The bill should also be clarified as to how it applies to multiple lawsuits between the same parties. In several of the lawsuits reviewed, the reference product sponsor filed a subsequent lawsuit against a biosimilar applicant, for example because the sponsor had obtained new patents.[88] The limits in the APPA do not appear to be cumulative across multiple lawsuits involving the same parties, which could open a backdoor to unlimited patent litigation. This could be fixed by replacing the phrase "the reference product sponsor may assert in the action" with "the reference product sponsor may assert in all actions against the subsection (k) applicant."[89] The phrase "an action for infringement under this section" should also be clarified to encompass all patent infringement actions.[90]

The APPA might also be expanded to apply to non-BPCIA litigation. The bill only applies to biologics patent litigation between a reference product sponsor and a biosimilar applicant, but many biologics patent lawsuits do not fit that pattern. In several (non-BPCIA) cases, the patent holder was a university-affiliated foundation,[91] and one case involved a biosimilar manufacturer suing another biosimilar manufacturer.[92] The framework of the APPA is closely tied to the BPCIA so incorporating its principles to non-BPCIA cases is nontrivial, but it is worth contemplating whether litigation limits on those cases may be appropriate as well.

Finally, the limits on the number of patents (or claims) asserted could be applied not just to litigation, but also to the patent dance itself. A large fraction—10 out of 39—of BPCIA lawsuits have been brought after a failure of the patent dance. That failure likely arises in part because it is too time-intensive and costly for the biosimilar applicant to review the reference product sponsor's 3A patent list and prepare a "detailed statement" of the applicant's legal positions on those patents, which the statute requires to be done in just 60 days.[93] Multiple authorities already support imposing patent volume limits once the patent holder has received "documents sufficient to show the operation of the accused instrumentalities."[94] It would be analogously appropriate to require a reference product sponsor to produce a limited subset of the 3A patent list for which a detailed statement is required, because the sponsor should have already received documents sufficient to show the operation of the accused instrumentalities at an earlier stage of the patent dance.[95]

CONCLUSION

The findings of this study suggest that, while the approach taken in the APPA is promising, there is more work to be done to make the bill effective at narrowing biologics litigation and lowering drug prices. That conclusion should not be

86. Michael K. Henry, "How Many Claims Should My Patent Have?", *Henry Patent Law Firm*, July 13, 2019. https://henry.law/blog/how-many-claims-should-my-patent-have.

87. See, e.g., *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, p. 1309 (Fed. Cir. 2011).

88. See, e.g., Complaint, *Amgen Inc. v. Accord BioPharma*, No. 0:18-cv-61828 (S.D. Fla. Aug. 07, 2018), https://www.courtlistener.com/recap/gov.uscourts.flsd.532845/gov.uscourts.flsd.532845.1.0.pdf.

89. S. 1416, sec. 3(a)(2), § 271(e)(7)(A).

90. Ibid.

91. Complaint, *AbbVie Biotechnology Ltd. v. The Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, No. 1:11-cv-2541 (S.D. N.Y. April 13, 2011). https://www.courtlistener.com/recap/gov.uscourts.nysd377897.1.0.pdf; Complaint, *AbbVie Inc. v. The Kennedy Trust Rheumatology Research*, No. 1:13-cv-1358 (S.D. N.Y. Feb. 28, 2013). https://www.courtlistener.com/recap/gov.uscourts.nysd.408439.1.0.pdf; Complaint, *Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, No. 1:14-cv-2256 (S.D. N.Y. Mar. 31, 2014). https://orangebookblog.typepad.com/files/celltrion-v.-kenne-dy-trust-sdny.pdf.

92. Complaint, *Coherus Biosciences, Inc. v. Amgen Inc.*, No. 1:19-cv-139 (D. Del. Jan. 24, 2019). https://www.courtlistener.com/recap/gov.uscourts.ded.67543/gov.uscourts. ded.67543.1.0.pdf.

93. PHSA § 351(*l*)(3)(B)(ii)(*I*).

94. FCAC Model Order, P. 6; see also Menell et al., § 2.1.3. https://www.fjc.gov/sites/default/files/2017/PCMJG3d_2016_final.pdf.

95. PHSA § 351(*l*)(2)(A).

taken as a discouragement. The interest and member support that the bill has attracted to date suggest that this bill presents an opportunity to advance, and the findings presented above suggest that even substantial strengthening of the bill would not have the sorts of widespread effects on industry that would justify opposition.

Indeed, there is a perhaps unexpected insight from the data relating to the politics of the APPA and biologics litigation. Traditionally, one might expect a clear division between the brand-name pharmaceutical industry, which holds patents and would oppose limitations on patent litigation, and the generic manufacturing industry at the receiving end of patent lawsuits. That is not so in the biologics world; companies like Amgen[96] and AbbVie[97] have found themselves on both sides of patent lawsuits, and brand-name stalwart Pfizer has been repeatedly sued as a biosimilar-manufacturing defendant.[98] Complex industry relationships produce more nuanced politics, giving rise to a unique opening for legislation that, written correctly, could powerfully reduce litigation-based entry barriers, enhance competition, and improve access to key medical treatments for all Americans.

ABOUT THE AUTHOR

Charles Duan is a senior fellow for technology and innovation policy at the R Street Institute, where his research focuses on intellectual property policy and its effects on innovation. He is the author of *A Five Part Plan for Patent Reform* (2014)..

96. See, e.g., Complaint, *Amgen Inc. v. Sandoz Inc.*, No. 3:16-cv-2581 (N.D. Cal. May 12, 2016). https://patentdocs.typepad.com/files/amgen-v-sandoz-1.pdf; Complaint, *Genentech, Inc. v. Amgen Inc.*, No. 1:18-cv-924 (D. Del. June 21, 2018). https://www.courtlistener.com/recap/gov.uscourts.ded.65599/gov.uscourts.ded.65599.10.0.pdf.

97. See, e.g., Complaint, *Abbvie Inc. v. Sandoz Inc.*, No. 3:18-cv-12668 (D. N.J. Aug. 10, 2018). https://www.courtlistener.com/recap/gov.uscourts.njd.381520/gov.uscourts.njd.381520.1.0_1.pdf; Complaint, *AbbVie Biotechnology Ltd. v. The Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, No. 1:11-cv-2541 (S.D. N.Y. April 13, 2011). https://www.courtlistener.com/recap/gov.uscourts.nysd.377897.1.0.pdf.

98. See, e.g., Complaint, *Genentech, Inc. v. Pfizer Inc.*, No. 1:19-cv-638 (D. Del. Apr. 05, 2019). https://insight.rpxcorp.com/litigation_documents/13300221; Complaint, *Amgen Inc. v. Hospira, Inc.*, No. 1:20-cv-561 (D. Del. Apr. 24, 2020). https://www.courtlistener.com/recap/gov.uscourts.ded.72014/gov.uscourts.ded.72014.1.0.pdf; Pfizer, "Pfizer Completes Acquisition of Hospira," Press Release, Sept. 3, 2015. https://www.pfizer.com/news/press-release/press-release-detail/pfizer_completes_acquisition_of_hospira.