

# SKINNY LABELS’ IMPORTANCE FOR DRUG COMPETITION

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## INTRODUCTION

U.S. consumers suffer from high drug prices. A lack of generic competition is one reason why. Congress enacted balanced landmark legislation in 1984 to promote competition and innovation. In the past few years, however, the U.S. Court of Appeals for the Federal Circuit has issued two significant rulings that threaten this balance by allowing brand companies to block generics even when they specifically avoid patents.

Drugs on the market typically have certain uses—known as “indications”—that are protected by patents. But generic manufacturers could decide to enter the market for a use not covered by a drug’s patent. For example, Amarin’s drug, Vascepa, can be used for (1) cardiovascular risk reduction (which reduces the risk of heart attacks and strokes) and also for (2) severe hypertriglyceridemia (high triglyceride levels).<sup>1</sup> In *Amarin*

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1. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370, 1372 (Fed. Cir. 2024) cert. granted sub nom. *Hikma Pharms. v. Amarin Pharma, Inc.*, 2026 WL 120677 (U.S. Jan. 16, 2026) (No. 24-889).

*Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.* (“*Amarin v. Hikma*”),<sup>2</sup> discussed more fully below, Hikma sought to market a generic version for only the second (triglyceride) use.<sup>3</sup> In other words, it “carved out” the first (cardiovascular risk reduction) use from its label, offering a narrower version of the brand’s label known as a “skinny label.”<sup>4</sup> By using skinny labels, generic firms can avoid infringing patents and enter the market earlier, which increases competition and reduces prices.

This Essay first introduces the pharmaceutical regulatory regime, emphasizing the importance of generic competition and the carefully calibrated balance between competition and innovation. It then discusses the Federal Circuit’s recent decisions in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.* (“*GSK v. Teva*”)<sup>5</sup> and *Amarin v. Hikma*,<sup>6</sup> which sharply limited the skinny label pathway. It concludes by highlighting the advantages skinny labels provide as compared to other (litigation-focused) ways generics enter the market.

## I. HATCH-WAXMAN EQUILIBRIUM

In 1984, Congress enacted the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (“Hatch-Waxman Act”) to increase innovation and competition in the pharmaceutical industry.<sup>7</sup>

### A. Generic Competition

The drafters of the Hatch-Waxman Act sought to ensure the availability of “low-cost, generic drugs.”<sup>8</sup> They believed that generic competition would save consumers, the federal government, and state governments millions of dollars each year.<sup>9</sup> In fact, generic competition would “do more to contain the cost of elderly care than perhaps anything else this Congress has passed.”<sup>10</sup>

The Hatch-Waxman Act promotes generic competition through several mechanisms. First, it allows a generic firm to experiment on a

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2. 104 F.4th 1370 (Fed. Cir. 2024) *cert. granted sub nom. Hikma Pharms. v. Amarin Pharma, Inc.*, 2026 WL 120677 (U.S. Jan. 16, 2026) (No. 24-889).

3. *Amarin*, 104 F.4th at 1373.

4. *Id.*

5. 976 F.3d 1347 (Fed. Cir. 2020).

6. 104 F.4th 1370, *reh’g granted, opinion withdrawn* (Feb. 9, 2021), *on reh’g*, 7 F.4th 1320 (Fed. Cir. 2021).

7. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355).

8. 130 CONG. REC. 24,427 (1984) (statement of Rep. Henry Waxman).

9. *Id.*

10. *Id.*; see also Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 42 (2009).

brand drug during the patent term without infringing the patent, which facilitates Food and Drug Administration (“FDA”) testing.<sup>11</sup> Second, the legislation allows a generic manufacturer to rely on the brand firm’s clinical studies rather than undertaking independent safety and efficacy testing.<sup>12</sup> Third, the first generic firm to challenge invalid or noninfringed patents gains a valuable 180-day period of marketing exclusivity.<sup>13</sup>

Finally, the Hatch-Waxman Act provides the opportunity for generic firms to create “skinny labels.”<sup>14</sup> This occurs when generic firms “carve out” patented uses from a drug label, fostering competition on unprotected uses.<sup>15</sup> In particular, section viii of the Act provides that, for “a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection,” the applicant must provide “a statement that the method of use patent does not claim such a use.”<sup>16</sup>

As the Supreme Court has stated, “a single drug may have multiple methods of use, only one or some of which a patent covers.”<sup>17</sup> The Court recognized that the Hatch-Waxman Act “authorize[s] the FDA to approve the marketing of a generic drug for particular unpatented uses; and section viii provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can quickly come to market.”<sup>18</sup> The Court recognized that “[t]he statutory scheme . . . contemplates that one patented use will not foreclose marketing a generic drug for other unpatented uses.”<sup>19</sup>

### *B. Brand Innovation*

In addition to encouraging generic competition, the Hatch-Waxman Act sought to increase brand-firm innovation. Before Congress passed the Act in 1984, the number of new chemical entities entering human testing and new drug compounds and dosage forms entering the market decreased dramatically.<sup>20</sup> This decrease was based in part on FDA requirements that had “delayed commercialization and substantially eroded the effective patent term.”<sup>21</sup>

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11. 35 U.S.C. § 271(e)(1).

12. 21 U.S.C. § 355(j).

13. § 355(j)(5)(B)(iv).

14. See *supra* notes 1–4 and accompanying text.

15. Corrected Brief of *Amici Curiae* 57 Professors Supporting Cross-Appellants, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347 (Fed. Cir. 2020) (Nos. 18-1976, 18-2023).

16. § 355(j)(2)(A)(viii).

17. *Caraco Pharm. Lab’ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 414 (2012).

18. *Id.* at 415.

19. *Id.*

20. Carrier, *supra* note 10, at 43–44.

21. *Id.*

The Hatch-Waxman Act introduced several provisions to encourage brand innovation. As I have previously explained:

It authorized patent-term extensions, with the current extension amounting to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials. It provided for market exclusivity periods not based on patents, such as a four- or five-year period for a company offering a drug with a new active ingredient. And it granted to patent holders an automatic 30-month stay of FDA approval, ensuring that—even without obtaining a preliminary injunction—brand firms would not face generic competition for a period of time.<sup>22</sup>

### *C. Balanced Regime*

The Hatch-Waxman Act’s drafters emphasized the equilibrium between competition and innovation. As I have explained:

Representative Henry Waxman underscored the “fundamental balance of the bill,” and the Energy and Commerce Committee explained that allowing early generic challenges “fairly balanced” the exclusionary rights of patent owners with the “rights of third parties” to contest validity and market products not covered by the patent. Similarly, the Judiciary Committee concluded that it “has merely done what the Congress has traditionally done” in intellectual property law: “balance the need to stimulate innovation against the goal of furthering the public interest.”<sup>23</sup>

Congress did not anticipate that every provision in the Hatch-Waxman Act would promote innovation. As the Federal Circuit recognized in 2003, the legislature “explicitly stated that the incentive . . . for research and development by innovators” was provided by “patent term restoration.”<sup>24</sup> In particular, “[t]here is no evidence that Congress intended to enable an innovator to extend its exclusivity merely by asserting patents on unapproved uses.”<sup>25</sup> As the court colorfully asked: “[I]f an innovator has not made the investment to test and obtain approval of the new use, what investment is to be protected by creating an added incentive?”<sup>26</sup>

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22. Corrected Brief of *Amici Curiae* 57 Professors Supporting Cross-Appellants, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347 (Fed. Cir. 2020) (Nos. 18-1976, 18-2023) (citations omitted).

23. *Id.* (citations omitted).

24. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003).

25. *Id.*

26. *Id.*

## II. FEDERAL CIRCUIT

As shown by two recent cases, the Federal Circuit currently has a very different view on generic competition than it did in 2003.

### A. *GSK v. Teva*

In the first case, *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*,<sup>27</sup> GlaxoSmithKline LLC and SmithKline Beecham (Cork) Ltd. (“GSK”) sued Teva Pharmaceuticals USA, Inc. (“Teva”) for patent infringement.<sup>28</sup> The lawsuit did not allege that Teva *directly* infringed its patents but rather that it *indirectly* infringed—known as induced infringement—by encouraging doctors to infringe.<sup>29</sup>

### 1. BACKGROUND

GSK marketed carvedilol (sold under the name Coreg), which treats hypertension, congestive heart failure (CHF), and post-myocardial infarction with left ventricular dysfunction (post-MI LVD).<sup>30</sup> Teva sought to market a generic version of the drug, but it waited until the patent on the hypertension use expired.<sup>31</sup> At that time, Teva carved out the “indication and prescribing information for treatment of [CHF].”<sup>32</sup> As a result, the skinny label “was only indicated for hypertension and post-MI LVD”—neither of which was covered by a patent.<sup>33</sup> Despite this, the jury found that Teva induced infringement and assessed damages of \$235 million.<sup>34</sup>

The district court granted Teva’s motion for judgment as a matter of law, finding that substantial evidence did not support the verdict because “GSK failed to prove by a preponderance of the evidence that ‘Teva’s alleged inducement, as opposed to other factors, actually *caused* the physicians . . . to directly infringe’ by prescribing generic carvedilol . . . for the treatment of . . . CHF.”<sup>35</sup>

The district court highlighted “many sources of information available to prescribing physicians”<sup>36</sup> and stated that “GSK’s Coreg label and

27. 976 F.3d 1347 (Fed. Cir. 2020).

28. *Id.* at 1353.

29. *Id.*

30. *Id.* at 1349; *Id.* at 1361–62 (Prost, C.J., dissenting).

31. *Id.* at 1349–50.

32. *Id.*

33. *Id.* at 1362 (Prost, C.J., dissenting).

34. *Id.* at 1350–51; *Id.* at 1364 (Prost, C.J., dissenting).

35. *Id.* 1351 (quoting *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 313 F. Supp. 3d 582, 591 (2018)).

36. *Id.*

promotion of carvedilol had already informed physicians about the uses of Coreg” and that “[c]ardiologists testified that they knew of the various uses of carvedilol.”<sup>37</sup> The court observed that “[a] reasonable factfinder could only have found that these alternative, non-Teva factors were what caused the doctors to prescribe generic carvedilol for an infringing use.”<sup>38</sup> As a result, the court concluded that “substantial evidence does not support the jury’s finding on causation, and therefore does not support its verdict that Teva is liable for induced infringement.”<sup>39</sup>

## 2. MAJORITY OPINION

The Federal Circuit reversed. It stated that “[t]he jury received evidence that Teva’s promotional materials referred to Teva’s carvedilol tablets as AB rated equivalents [therapeutic equivalents] of the Coreg tablets.”<sup>40</sup> It also pointed to evidence that “Teva’s 2007 press release remained on [its] website” and two editions of Teva’s Monthly Prescribing Reference “state[d] that they provide ‘high-quality educational tools to serve as convenient, authoritative references in daily use.’”<sup>41</sup>

In addition to these materials, “[w]itnesses for both sides testified that cardiologists knew of carvedilol and the uses established for Coreg.”<sup>42</sup> In particular, “GSK’s witness . . . testified that doctors are ‘completely reliant’ on information provided by the generic producers, and that doctors receive Teva’s product catalogs, visit its website, and read its product guides.”<sup>43</sup> In short, there was “ample record evidence . . . to support the jury verdict of inducement to infringe.”<sup>44</sup> Nor did the court need to confront “a policy debate about whether GSK made enough money from carvedilol in past years, and therefore should not be permitted to enforce its patent on its discovery of this novel method of prolonging life for persons with congestive heart failure,” as this “is a policy matter for Congress.”<sup>45</sup>

## 3. DISSENTING OPINION

Then-Chief Judge Prost, in a critical dissent that was almost twice as long as the majority opinion, pointed out that the majority “exhumes

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37. *Id.*

38. *Id.*

39. *Id.* (quoting *GlaxoSmithKline LLC*, 313 F. Supp. 3d 582 at 597).

40. *Id.* at 1350 n.3, 1353.

41. *Id.* at 1353.

42. *Id.*

43. *Id.*

44. *Id.* at 1355.

45. *Id.* at 1356.

Teva's press releases to establish infringement because they remained on Teva's website after the . . . patent's issuance."<sup>46</sup> But the Chief Judge explained that "[t]he continued presence of the press releases . . . is not probative evidence of inducement," which requires "an affirmative act to encourage infringement" not satisfied by the "passive maintenance of the pre-issuance press releases."<sup>47</sup>

The dissent also found that "GSK did not produce any evidence during the skinny label period upon which a reasonable juror could conclude that Teva *encouraged* doctors to prescribe carvedilol to practice the patented method"<sup>48</sup> as "Teva's press releases and product catalogs" did "not promote treating CHF at all."<sup>49</sup>

Stepping back to the policy consequences of the majority's ruling, the dissent noted that "Congress designed the generic approval system with the express purpose of speeding the introduction of generic drugs to the market as soon as patents allow."<sup>50</sup> Chief Judge Prost made clear that the panel's decision "undermines this balance by allowing a drug marketed for unpatented uses to give rise to liability for inducement and by permitting an award of patent damages where causation has not been shown."<sup>51</sup>

The dissent explained that Teva had acted "as Congress intended," as the company "waited until GSK's patent covering the carvedilol compound expired to launch its product covering two unpatented indications."<sup>52</sup> Chief Judge Prost noted that the majority's holding "is no small matter," as "it nullifies Congress's statutory provision for skinny labels—creating liability for inducement where there should be none."<sup>53</sup> "Contrary to Congress's intent," the dissent continued, "the Majority thereby allows one patented method to discourage generics from marketing skinny labels—thus, slowing, rather than speeding, the introduction of low-cost generics."<sup>54</sup>

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46. *Id.* at 1369 (Prost, C.J., dissenting).

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.* at 1357.

51. *Id.*

52. *Id.* at 1358

53. *Id.*

54. *Id.* The panel subsequently issued a second opinion that focused more directly on the specifics of Teva's conduct; then-Chief Judge Prost reasonably warned that the new opinion "does little to assuage, and even exacerbates, concerns raised by the original." *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1361 (Fed. Cir. 2021) (Prost, C.J., dissenting).

*B. Amarin v. Hikma*

In the second case, *Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc.*,<sup>55</sup> Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Mochida Pharmaceutical Co., Ltd. (collectively, “Amarin”) sued Hikma Pharmaceuticals USA Inc. and Hikma Pharmaceuticals PLC (collectively, “Hikma”) for induced patent infringement.<sup>56</sup>

## 1. BACKGROUND

Amarin marketed icosapent ethyl (sold as Vascepa) for two uses: (1) treating “severe hypertriglyceridemia (‘the SH indication’), a condition in which a patient’s blood triglyceride level is at least 500 mg/dL” and (2) “reduc[ing] cardiovascular risk (*i.e.*, myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization) in patients having blood triglyceride levels of at least 150 mg/dL (‘the CV indication’).”<sup>57</sup> Hikma “sought the FDA’s approval of a ‘skinny label’ for its generic product that would include only the SH indication and not the CV indication.”<sup>58</sup>

After receiving FDA approval for a label referring only to the SH indication, Hikma issued press releases that referred to its product as the “generic version” or “generic equivalent” of Vascepa and provided sales data for the drug.<sup>59</sup> It also marketed the drug on its website, indicating that its version was “AB” rated, which “reflects the FDA’s determination that a generic drug is therapeutically equivalent to a branded drug when the generic drug is used as labeled.”<sup>60</sup>

The U.S. District Court for the District of Delaware “concluded that the warning as to side effects for patients with cardiovascular disease was ‘hardly instruction or encouragement’ to prescribe the drug for the CV indication.”<sup>61</sup> The court further concluded that “[e]ven if [Amarin is] right that Hikma’s label’s silence regarding CV risk reduction communicates to the public that [the drug] can be used to reduce CV risk, ‘merely describing an infringing mode’ . . . does not plausibly induce infringement.”<sup>62</sup>

Regarding Hikma’s public statements, the District Court concluded that “although the press releases may be relevant to Hikma’s *intent* to

55. 104 F.4th 1370 (Fed. Cir. 2024), *cert. granted sub nom. Hikma Pharms. v. Amarin Pharma, Inc.*, 2026 WL 120677 (U.S. Jan. 16, 2026) (No. 24-889).

56. *Id.* at 1374.

57. *Id.* at 1372.

58. *Id.* at 1373.

59. *Id.*

60. *Id.* at 1374.

61. *Id.* at 1375 (quoting *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642, 646 (D. Del. 2022)).

62. *Id.* at 1376 (quoting *Amarin Pharma, Inc.*, 578 F. Supp. 3d at 646).

induce infringement, they did not plausibly evidence ‘an inducing act.’”<sup>63</sup> For the website, “the court determined that Hikma’s advertisement of its product as AB-rated in [a] category . . . broad enough to include infringing uses . . . did not ‘rise to the level of encouraging, recommending, or promoting taking Hikma’s generic for the reduction of CV risk.’”<sup>64</sup> Because the court “found that Amarin’s complaint failed to plead inducement based on either Hikma’s label or public statements, [it] granted Hikma’s motion to dismiss.”<sup>65</sup>

## 2. FEDERAL CIRCUIT

The Federal Circuit reversed. It found that “Amarin’s complaint plausibly pleads that Hikma ‘actively’ induced healthcare providers’ direct infringement, i.e., that Hikma ‘encourage[d], recommend[ed], or promote[d] infringement.’”<sup>66</sup>

The court relied on Amarin’s label “in combination with Hikma’s public statements and marketing material.”<sup>67</sup> In particular, “Hikma’s website promotes its product as AB-rated (i.e., therapeutically equivalent for only the labeled indications)” in a category that is “broad enough to encompass both infringing and non-infringing uses.”<sup>68</sup> And the company’s press releases “consistently referred to Hikma’s product as a ‘generic equivalent to Vascepa®,’ ‘generic Vascepa®,’ or ‘Hikma’s generic version of Vascepa®,’ without any indication that its product was AB-rated.”<sup>69</sup> The press releases also “referred to Vascepa as indicated ‘in part’ for the SH indication.”<sup>70</sup> Taken together, “those statements, according to Amarin, ‘made clear that Vascepa® was indicated for more than one use and then identified its own product as a generic version of Vascepa®.’”<sup>71</sup> The complaint also alleged that “in its press releases, Hikma touted sales figures for Vascepa that Hikma knew were largely attributable to the off-label CV indication.”<sup>72</sup>

The court found it “at least plausible that a physician could read Hikma’s press releases—touting sales figures attributable largely to an infringing use, and calling Hikma’s product the ‘generic version’ of a drug that is indicated ‘in part’ for the SH indication—as an instruction or

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63. *Id.* (quoting *Amarin Pharma, Inc.*, 578 F. Supp. 3d at 647).

64. *Id.* (quoting *Amarin Pharma, Inc.*, 578 F. Supp. 3d at 647).

65. *Id.* (quoting *Amarin Pharma, Inc.*, 578 F. Supp. 3d at 648).

66. *Id.* at 1378 (citation omitted).

67. *Id.* at 1379.

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.*

encouragement to prescribe that drug for any of the approved uses of icosapent ethyl, particularly where the label suggests that the drug may be effective for an overlapping patient population.”<sup>73</sup> The court concluded that “Amarin ha[d] plausibly pleaded that Hikma has induced infringement of the asserted patents.”<sup>74</sup>

In January 2026, the Supreme Court granted certiorari on two issues: (1) “Whether, when a generic drug label fully carves out a patented use, allegations that the generic drugmaker calls its product a ‘generic version’ and cites public information about the branded drug (e.g., sales) are enough to plead induced infringement of the patented use”<sup>75</sup> and (2) “[W]hether a complaint states a claim for induced infringement of a patented method if it does not allege any instruction or other statement by the defendant that encourages, or even mentions, the patented use.”<sup>76</sup>

### III. SKINNY LABEL ADVANTAGES

By treating commonplace activities like referring to drugs as generics, advertising on websites, and issuing general press releases and marketing materials as inducing patent infringement, the two Federal Circuit decisions significantly narrowed the skinny label pathway.<sup>77</sup>

The danger from this constricted view is that the skinny label path to entering the market offers advantages not available elsewhere. In allowing generics to enter the market on unpatented indications, without being subject to infringement lawsuits and an automatic 30-month stay of FDA approval, skinny labeling plays a critical role in expediting generic entry and bringing more affordable medicines to consumers.<sup>78</sup>

For generics seeking to enter the market while a drug is covered by a patent, there are two options. The first route is a “Paragraph IV” certification, which allows a generic to certify that the patent “is invalid or will not be infringed.”<sup>79</sup> But this route has disadvantages.

#### *A. Paragraph IV Disadvantages*

The first shortcoming of a Paragraph IV challenge is that, by definition, it involves litigation. The mere filing of a Paragraph IV certification is treated as an artificial act of infringement, which allows the

73. *Id.* at 1380.

74. *Id.* at 1381.

75. *Hikma Pharms. USA Inc. v. Amarin Pharma, Inc.*, SCOTUSBLOG, <https://www.scotusblog.com/cases/case-files/hikma-pharmaceuticals-usa-inc-v-amarin-pharma-inc/> (last visited Jan. 8, 2026) [<https://perma.cc/45RA-824Z>].

76. *Id.*

77. *See supra* Part II.

78. *See supra* Section I.A.

79. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

brand firm to immediately file suit, even if the generic has not yet entered the market.<sup>80</sup> This litigation tends to be lengthy and costly. The latest figures from the American Intellectual Property Law Association (AIPLA) reveal that for pharmaceutical litigation with more than \$25 million at risk, the median litigation costs are \$3 million.<sup>81</sup>

Second, the brand firm, merely by *filing* a lawsuit, can obtain an automatic 30-month stay of FDA approval.<sup>82</sup> There are multiple patents on each drug, with empirical analyses ranging from 3.5 (in 2005)<sup>83</sup> to 7 (for “tertiary” (device) patents)<sup>84</sup> and 17 (on top-selling prescription drugs).<sup>85</sup> At a minimum, then, the generic must navigate multiple patents for each drug. And for each of these patents, the generic firm must file a Paragraph IV certification claiming the patent is invalid or not infringed or (in what is known as a “Paragraph III” certification) promise not to market its drug before the brand firm’s patent expires.<sup>86</sup> In short, the generic seeking to enter is confronted with protracted litigation or waiting.

Nor is it just the number of patents on each drug that poses a challenge; the patents themselves sometimes have questionable validity. One study found that the Federal Circuit upheld method-of-use patents—the focus of skinny labels<sup>87</sup>—only 29% of the time (as compared to 75% for active ingredient patents).<sup>88</sup> Similarly, another study found that while patents covering a drug’s active ingredient are almost always (92%) upheld in court, those involving secondary patents covering “ancillary aspects of

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80. 35 U.S.C. § 271(e)(2).

81. AM. INTELL. PROP. L. ASS’N, AIPLA 2023 REPORT OF THE ECONOMIC SURVEY 62 (2023).

82. 21 U.S.C. § 355(j)(5)(B)(iii).

83. Lisa Larrimore Ouellette, *How Many Patents Does It Take to Make a Drug? Follow-On Pharmaceutical Patents and University Licensing*, 17 MICH. TELECOMM. TECH. L. REV. 299, 321 (2010).

84. Theodore W. Teng et al., *Tertiary Patents on Drugs Approved by the FDA*, 7 JAMA HEALTH F. 1, 4 (2026).

85. Caroline Horrow, Sarah M.E. Gabriele, S. Sean Tu, Ameet Sarpatwari, & Aaron S. Kesselheim, *Patent Portfolios Protecting 10 Top-Selling Prescription Drugs*, 184 JAMA INTERN. MED. 810 (2024) (figures from small-molecule setting). Even higher figures have been reported for biologics, which are more complex than small-molecule drugs and which are listed in the FDA’s “Purple Book.” E.g., Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 3, 17 n.144 (2018).

86. 21 U.S.C. § 355(j)(2)(A)(vii)(III).

87. See *supra* notes 1–4 and accompanying text.

88. Errol B. Taylor & Fredrick M. Zullo, *Focusing Only on Active Ingredient Patents Ignores Case Law Success Rates: Formulation and Method-of-Use Patents Provide Significant Protection for Medicines*, BLOOMBERG L., Oct. 27, 2011 (reviewing decisions between May 2007 and August 2011). The authors found that brand firms prevailed on 75% of active-ingredient and 40% of method-of-use claims in district courts. *Id.*

drug innovation” are upheld in only 32% of cases.<sup>89</sup>

More generally, there are multiple reasons why patents are often overturned in court, including limited time for examination, incentives to grant patents, and the *ex parte* nature of the patent acquisition process.<sup>90</sup> And as questionable as these patents are, because the FDA exercises only a “ministerial” role over patent listings,<sup>91</sup> they remain in the Orange Book, blocking competition.

When patents are listed in the Orange Book, the generic must wait until the 30-month stay expires before getting final FDA approval to enter the market.<sup>92</sup> And even then, to market its less expensive drug, the generic often must launch “at risk” because the patent litigation extends beyond the 30-month stay.<sup>93</sup> Launching at risk exposes the generic to potentially substantial lost-profit damages, in particular because the brand product sells at a much higher price than the generic.<sup>94</sup> As Judge Prost has explained, “if playing by the skinny-label rules doesn’t give generics some security from label-based liability,” they “simply won’t play” because “[t]he risk is too great.”<sup>95</sup>

### B. Skinny Label Advantages

In contrast to these challenges from the Paragraph IV route, the skinny-label path provides unique advantages. Because a section viii statement does not require the same notification to patent holders as does

89. C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCI. 1386, 1386–87 (2013). For oft-cited general studies, see John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205 (1998) (courts invalidated 46% of patents between 1989 and 1996); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 384–85 (2000) (alleged infringers prevailed in 42% of patent cases that reached trial between 1983 and 1999).

90. See, e.g., Michael A. Carrier, *Response to Senator Grassley’s Questions for the Record*, Sen. Jud. Comm. Hearing on “IP and The Price of Prescription Drugs: Balancing Innovation and Competition,” RUTGERS L. SCH. (May 28, 2019), <https://www.judiciary.senate.gov/imo/media/doc/Carrier%20Responses%20to%20QFRs.pdf> [<https://perma.cc/JJ2Q-D7AR>].

91. FDA, THE LISTING OF PATENT INFORMATION IN THE ORANGE BOOK 5 (2022), <https://www.fda.gov/media/155200/download> [<https://perma.cc/4452-WU3A>].

92. See 21 U.S.C. § 355(j)(5)(B)(iii).

93. See, e.g., Peter Loftus, *Pfizer, Takeda to Get \$2.15 Billion Settlement*, WALL ST. J. (June 12, 2013), <https://www.wsj.com/articles/SB10001424127887324188604578541080995659790> [<https://perma.cc/ER9B-MWJN>].

94. See, e.g., *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) (noting the “risk” of Paragraph IV certification, which is accompanied by “the hazard of sparking costly litigation”); Loftus, *supra* note 93 (reporting settlement relating to at-risk launch of generic Protonix).

95. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) (Prost, J., dissenting from denial of petition for rehearing en banc).

a Paragraph IV certification, litigation is “not usually triggered.”<sup>96</sup> In addition, drug applications based on a section viii statement are not subject to the 30-month stay, ensuring faster FDA final approval so generics can more quickly enter the market.<sup>97</sup> For that reason, the D.C. Circuit has recognized that section viii is “an attractive route for generic manufacturers,”<sup>98</sup> with the D.C. district court agreeing that the pathway offers generic manufacturers “a diminished set of . . . risks.”<sup>99</sup>

The importance of skinny labels for competition has been borne out by recent empirical work. Egilman, Kesselheim, Sarpatwari, and Rome identified 15 brand-name drugs whose first competition between 2015 and 2019 was a skinny-label generic.<sup>100</sup> Of these drugs, the authors found that competition from skinny label generics resulted in “a median of 2.5 years . . . of earlier generic competition” and average prices that were a median of 34% lower than prices in the year before competition.<sup>101</sup> Competition from these 15 drugs alone “saved Medicare Part D nearly \$15 billion from 2015 to 2021” and increased use of the drugs, which “suggest[ed] improved patient access.”<sup>102</sup>

Even though skinny labels introduce earlier competition and save consumers money, generic firms have recently not used them as frequently, most likely because of the Federal Circuit’s restriction of the pathway. Ziaks, Akanegbu, Egilman, and Kesselheim have charted the

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96. SHASHANK UPADHYE, *GENERIC PHARMACEUTICAL PATENT AND FDA LAW* § 26:11 (2020).

97. See Brief for Michael A. Carrier et al. as Amici Curiae in Support of the Petition at 5, *Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC*, 25 F.4th 949 (Fed. Cir. 2022) (No. 22-37) (“The immediate litigation consequences of paragraph IV are not needed for section viii because a carve-out of a method of use, double-checked in the approval process, provides certainty to the generic applicant and the FDA that the drug and its labeling do not infringe.”).

98. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (quotation omitted).

99. *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 73–74 (D.D.C. 2003).

100. Alexander C. Egilman, Aaron S. Kesselheim, Ameet Sarpatwari, & Benjamin N. Rome, *Estimated Medicare Part D Savings from Generic Drugs with a Skinny Label*, 177:6 *ANNALS OF INTERNAL MED.* 833, 833 (2024).

101. *Id.* at 834.

102. *Id.* at 835. Medicare Part D provides prescription drug coverage. *MEDICARE, What’s Medicare Drug Coverage (Part D)?*, <https://www.medicare.gov/health-drug-plans/part-d> (last visited Jan. 4, 2026) [<https://perma.cc/64YH-W4X2>]. For similar findings for biologics in the context of Medicare, see Alexander C. Egilman et al., *Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings*, 183:1 *JAMA INTERNAL MED.* 82, 82–84 (2023), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2798552> (finding \$1.5 billion in savings and 2.5 years of earlier entry on five biologics between 2015 and 2020) [<https://perma.cc/DHF4-MVMM>].

decline of skinny labels after the Federal Circuit’s *GSK* decision.<sup>103</sup> They found that, among brand-name drugs susceptible to the practice, skinny labeling fell from 56% in 2021 to 43% in 2022 to only 20% in 2023.<sup>104</sup>

These concerns led the FDA to include in its 2024 legislative proposals a safe harbor for skinny labeling.<sup>105</sup> In particular, the agency asked Congress to “exclud[e] such labeling from the evidence that can be used to support a claim of patent infringement” and “clarify[] that statements regarding therapeutic equivalence cannot be used as evidence to support an infringement claim.”<sup>106</sup> The FDA was “concerned” that the *GSK* decision “imperils an important statutory marketing pathway that allows earlier generic drug market entry for conditions of use of a drug not protected by a patent.”<sup>107</sup> And it worried that “[w]ithout this change, . . . [the] decision could significantly impact the timely availability of generic drugs.”<sup>108</sup>

Finally, in addition to offering a unique tool to reach the market and significant savings for consumers, skinny labels serve as a microcosm of the regulatory regime’s balance.<sup>109</sup> In particular, they expedite generic entry for non-patented uses while specifically disclaiming patented uses.<sup>110</sup> By definition, then, they promote competition without harming innovation.

#### CONCLUSION

Generic competition is critical to the pharmaceutical regime. In passing the Hatch-Waxman Act, Congress made clear that the goal of regulation is to not only foster innovation but also increase competition. The Act was “designed to speed the introduction of low-cost generic drugs”<sup>111</sup> to “millions of Americans.”<sup>112</sup>

Skinny labels are a critical element of generic competition. Generic firms seeking to enter the market during the term of a brand firm’s patent have a choice: (1) file a Paragraph IV certification and be subject to

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103. Therese J. Ziaks, Chukwubuikem M. Akanegbu, Alexander C. Egilman, & Aaron S. Kesselheim, *Frequency of First Generic Drugs Approved Through “Skinny Labeling,” 2021 to 2023*, 31:4 J. MANAGED CARE & SPECIALTY PHARM. 343, 343 (2025).

104. *Id.* at 343–47.

105. FDA, SUMMARY OF FY 2024 LEGISLATIVE PROPOSALS 3, <https://www.fda.gov/media/166049/download> (last visited Jan. 8, 2026) [<https://perma.cc/D292-9B2V>].

106. *Id.*

107. *Id.*

108. *Id.*

109. *See supra* Section I.A.

110. *See supra* Section I.A.

111. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

112. 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman).

litigation (and an automatic 30-month stay) or (2) carve out the patented indication and file a skinny label. Removing the skinny label option from this determination forces a generic firm to endure lengthy and costly litigation. In other words, it threatens to eviscerate the regime's nuanced equilibrium and increase drug prices without promoting innovation.