

STANFORD TECHNOLOGY LAW REVIEW  
VOLUME 16, NUMBER 1 FALL 2012

WHY THE “SCOPE OF THE PATENT” TEST  
CANNOT SOLVE THE DRUG PATENT  
SETTLEMENT PROBLEM

Michael A. Carrier\*

CITE AS: 16 STAN. TECH. L. REV. 1 (2012)  
<http://stlr.stanford.edu/pdf/scopeofthepatent.pdf>

INTRODUCTION.....	1
I. HISTORY OF THE SCOPE TEST.....	2
A. <i>Cardizem – Outside the Scope</i> .....	2
B. <i>Valley Drug – A Calibrated Test</i> .....	2
C. <i>Taxmoxifen – A Shrinking Test</i> .....	3
D. <i>Cipro – The Noose Tightens</i> .....	3
E. <i>Androgel – The Ambiguity Disappears</i> .....	4
F. <i>K-Dur – A Turn Toward Scrutiny</i> .....	4
II. CRITIQUES OF THE SCOPE TEST.....	5
A. <i>Transformed Scope</i> .....	5
B. <i>Assumption of Validity</i> .....	6
C. <i>Inapplicability to Infringement</i> .....	7
CONCLUSION.....	8

INTRODUCTION

One of the most difficult legal issues today involves settlements by which brand-name drug companies pay generic firms to delay entering the market. Such conduct requires courts to consider not only patent and antitrust law, but also the Hatch-Waxman Act, the complex regime governing behavior in the pharmaceutical industry.

Courts have analyzed these agreements by relying on a test that asks if the settlement falls within the “scope of the patent.” They have found, in nearly all

---

\* Professor of Law, Rutgers University School of Law-Camden.

of these cases, that it does. And, as a result, they have concluded that the agreements do not violate the antitrust laws.

This Article shows why the scope test is not appropriate in determining the antitrust treatment of drug patent settlements. It recounts the history of the test, showing its increasing deference over time. And it demonstrates the three primary problems with the test: (1) it involves a transformation that has left the test toothless, (2) it assumes that the patent at issue is valid, and (3) it neglects the issue of infringement.

## I. HISTORY OF THE SCOPE TEST

### A. Cardizem – *Outside the Scope*

The scope test can be traced to the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*.<sup>1</sup> In *Cardizem*, the generic company agreed not to market a generic version of the brand firm's patented blood-pressure drug until it obtained a final determination that the patent was not infringed.<sup>2</sup> Of concern to the court, the agreement prevented the marketing of generic versions of not only the patented drug, but also drugs "not at issue in the pending litigation."<sup>3</sup>

The court found that the brand paid "the only potential competitor \$40 million per year to stay out of the market."<sup>4</sup> And it concluded that the settlement was "a horizontal agreement to eliminate competition" and was "a classic example of a *per se* illegal restraint of trade."<sup>5</sup> The court's punishment of conduct outside the patent's scope was adopted by later courts that used the scope test for different purposes.

### B. Valley Drug – *A Calibrated Test*

The Eleventh Circuit took a calibrated approach to the scope issue in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*<sup>6</sup> In that case, the court reversed the district court's determination that a settlement involving a blood-pressure drug was *per se* illegal.<sup>7</sup> It found that a full analysis of the agreement, which provided "restrictions on infringing products"<sup>8</sup> and the marketing of "any" generic product covering the relevant active ingredient,<sup>9</sup> required

---

1. 332 F.3d 896 (6th Cir. 2003).  
2. *Id.* at 902.  
3. *Id.* at 908 n.13.  
4. *Id.* at 908.  
5. *Id.*  
6. 344 F.3d 1294 (11th Cir. 2003).  
7. *Id.* at 1306.  
8. *Id.* at 1311.  
9. *Id.*

“consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the [a]greements exceed that scope, and the anticompetitive effects thereof.”<sup>10</sup>

In determining whether the settlement provisions resembled a preliminary injunction and stay, the Eleventh Circuit explained that courts must analyze “the likelihood of [the patentee’s] obtaining such protections.”<sup>11</sup> The court remanded for the lower court to determine whether the settlement was a “reasonable implementation” of the “protection afforded by the patents.”<sup>12</sup>

### C. Tamoxifen – *A Shrinking Test*

Courts then imperceptibly shifted from punishing conduct “outside the scope” of the patent to immunizing conduct “within the scope” of the patent. In doing so, the test took a dramatic turn toward deference.

In *In re Tamoxifen Citrate Antitrust Litigation*,<sup>13</sup> the Second Circuit upheld a grant of the defendants’ motion to dismiss regarding a settlement on a breast-cancer-treatment drug. It concluded that as long as “the patent litigation is neither a sham nor otherwise baseless” or beyond the patent’s scope, the patentee can enter into a settlement “to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”<sup>14</sup>

The court concluded that the settlement did not “unlawfully extend the reach” of the patent.<sup>15</sup> Because the brand’s patent “preclude[d] all generic versions of [the drug],” any competing version “would . . . necessarily infringe the patent.”<sup>16</sup> The court also noted that the agreement did not “restrain[] the introduction or marketing of unrelated or non-infringing products,” in contrast to the settlement in *Cardizem*, which “included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market non-infringing products.”<sup>17</sup>

### D. Cipro – *The Noose Tightens*

The Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust*

---

10. *Id.* at 1312; *see also* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005) (focusing on “(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects”).

11. *Valley Drug*, 344 F.3d at 1312.

12. *Id.*

13. 466 F.3d 187 (2d Cir. 2006).

14. *Id.* at 208-09, 213.

15. *Id.* at 213.

16. *Id.* at 214.

17. *Id.* at 213-14.

*Litigation*<sup>18</sup> continued the trend toward deference in affirming a motion to dismiss on an agreement concerning an antibiotic. Its analysis focused on the patent system's right to exclude and the presumption that patents are valid.<sup>19</sup> The court concluded that, in the absence of evidence of fraud before the PTO or sham litigation, the court "need not consider the validity of the patent."<sup>20</sup>

The court found that the agreements at issue only "exclude[d] the defendants from profiting from the patented invention," thus falling "well within Bayer's rights as the patentee."<sup>21</sup> It found that "a patent is presumed to be valid," with patent law bestowing "the right to exclude others from profiting by the patented invention."<sup>22</sup> And it explained that the "essence of the inquiry" was "whether the agreements restrict competition beyond the exclusionary zone of the patent."<sup>23</sup> The court concluded that "all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent."<sup>24</sup>

#### E. Androgel – *The Ambiguity Disappears*

Even though its initial version of the scope test appeared nuanced in its focus on the patent's "exclusionary potential" and "likelihood" of obtaining an injunction, the Eleventh Circuit dispensed with any ambiguity in *FTC v. Watson Pharmaceuticals*,<sup>25</sup> making clear, in upholding a settlement concerning a testosterone drug, that it was lining up behind the version articulated by the Second and Federal Circuits.

The court stated that "[a] patent holder and any of its challengers cannot enter into an agreement that excludes more competition than the patent has the potential to exclude."<sup>26</sup> And it clarified that its use in an earlier case of the phrase "strength of the patent" referred to "the potential exclusionary scope of the patent," which means "the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim."<sup>27</sup>

#### F. K-Dur – *A Turn Toward Scrutiny*

Bucking the march toward deference, in 2012 the Third Circuit in *In re K-Dur Antitrust Litigation* criticized the scope test in reversing the district court's grant of summary judgment.<sup>28</sup> It recognized that the test "assumes away the

---

18. 544 F.3d 1323 (Fed. Cir. 2008).

19. *Id.* at 1333, 1337.

20. *Id.* at 1336.

21. *Id.* at 1333.

22. *Id.* at 1337.

23. *Id.* at 1336.

24. *Id.*

25. 677 F.3d 1298 (11th Cir. 2012).

26. *Id.* at 1308.

27. *Id.* at 1311 n.8.

28. 686 F.3d 197 (3d Cir. 2012).

question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed.”<sup>29</sup> And it observed that “the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny,” explaining that “no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial.”<sup>30</sup> The court concluded by adopting a test by which “the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade.”<sup>31</sup>

## II. CRITIQUES OF THE SCOPE TEST

There are three primary problems with the scope test. First, the version used today has shed any potential nuance in morphing into a test granting automatic legality. Second, the test is based on the crucial assumption that the relevant patent is valid. Third, it cannot address the issue of infringement.

### A. *Transformed Scope*

Although each of the decisions discussed above used the concept of patent scope, the meaning of the test has shifted dramatically. The framework was first articulated in *Cardizem* with the court punishing conduct lying outside the coverage of the patent. The Eleventh Circuit then applied the test by using language that left open the possibility that it would consider whether the patent at issue actually allowed the brand to exclude the generic. In *Valley Drug*, for example, the court explored the likelihood that a patentee would have been successful in obtaining an injunction against infringement.

But the test then shifted toward deference. Such a move was a subtle – and until now unnoticed – shift based on an improper inference drawn from *Cardizem*. The court in *Cardizem* made clear that an agreement covering a product outside the scope of the patent was *per se* illegal. In that case, the agreement applied not only to products covered by the patent but also to unpatented products.

The fact, however, that a settlement reaching a product *outside* the scope of the patent violates the antitrust laws does not mean that one falling *within* the facial scope of the patent is automatically valid. The Second, Eleventh, and Federal Circuits thus used the test for a new and dramatically different purpose. They did not employ the framework to address the easy cases where the settling parties blocked competition on products not covered by the patent.

Instead, they imported the test into the more complex setting of agreements

---

29. *Id.* at 214.

30. *Id.*

31. *Id.* at 218 (providing that presumption could be rebutted by showing that payment (1) was for purpose other than delayed entry or (2) offered some pro-competitive benefit).

that do not reach beyond the facial scope of the patent. These agreements cannot be so easily dealt with. For they might or might not violate the antitrust laws. That depends on whether the patent is valid. But that cannot be determined by the mere existence of the patent.

B. *Assumption of Validity*

The fundamental problem with the court's transformed, simplistic scope test is that it assumes the validity issues that are central to the determination of antitrust analysis. The overriding question in cases analyzing pharmaceutical settlements is whether the patent is valid.

If the patent is valid, then an agreement by which the brand pays the generic to drop its challenge and delay entering the market could fall within the patent's scope and not present antitrust concerns.<sup>32</sup> After all, the brand could rely on the patent itself to exclude competitors before the end of the term.

But if, in contrast, the patent is not valid, then it does not have any scope at all. The patentee is not entitled to pay the generic to drop its patent challenge since, by definition, the patent is not valid. In this setting, the behavior resembles market allocation, one of the most severe anticompetitive harms, with two competitors dividing the market and eliminating competition.

The problem with courts that rely on the scope test today is that they unwittingly assume that the patent is valid. These courts ignore potential indications of patent validity – such as judicial findings of invalidity or substantial payments to generics – in relying on the mere issuance of the patent.

Not every patent issued by the U.S. Patent and Trademark Office, however, is valid. Empirical studies have consistently shown that at least 40% of granted patents that are litigated to decision are invalid.<sup>33</sup> The rate of invalidity is even higher in the present context, with the FTC finding that generics prevailed in 73% of challenges between 1992 and 2000.<sup>34</sup>

Courts that have applied the scope test often address the validity issue by relying on the procedural presumption of Section 282 of the Patent Act, which

---

32. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 66 (2009).

33. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA L.Q. 185, 205 (1998) (finding that 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, 385 (2000) (demonstrating that alleged infringer prevailed in 42% of patent cases that reached trial between 1983 and 1999); University of Houston Law Center, Decisions for 2000-2004, Issue Codes 01-16, 23, 24, <http://www.patstats.org/2000-04.htm> (stating that, in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed).

34. FED. TRADE COMM'N, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16 (2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (providing results for "Paragraph IV" challenges by which generic firms certify that brand firms' patents are invalid or not infringed, seeking to enter before the end of the patent term).

states that patents “shall be presumed valid.”<sup>35</sup> But a presumption of validity is only a procedural presumption governing the order in which proof is presented. It is not substantive evidence of validity.<sup>36</sup> In addition, such a presumption should be entitled to the least amount of deference where parties “enter agreements that prevent validity from even being challenged,” which is especially problematic given the Hatch-Waxman Act’s emphasis on challenges to invalidity and infringement.<sup>37</sup>

### C. *Inapplicability to Infringement*

A final problem with the scope test is that it ignores the issue of infringement. A brand firm must show not only that the patent is valid but also that the generic’s drug infringes its patent. The simplistic version of the scope test cannot resolve that question.

One fundamental difference between validity and infringement is that the patentee bears the burden of demonstrating infringement. For validity, the patentee at least can point to an initial presumption that the patent is valid. In contrast, the Federal Circuit has made clear that “[t]he patentee bears the ultimate burden of proof to demonstrate infringement by a preponderance of the evidence.”<sup>38</sup> For this reason, a court cannot dispose of the issue of infringement by observing the mere existence of the patent.

The *K-Dur* case is instructive in this regard. In that case, one generic claimed that its product did not infringe the brand’s patent because its product lay “outside the range limited by claim 1 of the [] patent.”<sup>39</sup> The other generic claimed that its product did not infringe since it lacked the “coating material with different ingredients” covered by the patent.<sup>40</sup>

These claims were plausible since the brand’s patent did not cover the active ingredient in the patented supplement, but applied only to a weaker formulation that covered a certain type of tablet with a certain percentage of potassium chloride crystals and coating material.<sup>41</sup> So even though the district court “declined to discount the exclusionary power of [the brand’s] patent

---

35. 35 U.S.C. § 282; see *Tamoxifen*, 466 F.3d at 211 (finding that presumption of validity allows parties to settle “weak patent cases” even though “such settlements will inevitably protect patent monopolies that are, perhaps, undeserved”); *Schering-Plough*, 402 F.3d at 1066-67 (relying on presumption in concluding that brand would not suffer antitrust liability for exclusionary activity unless generics were able to prove patent’s invalidity or noninfringement); *Ciprofloxacin*, 544 F.3d at 1337 (asserting that “analysis of patent validity” is not “appropriate in the absence of fraud or sham litigation” since “a patent is presumed to be valid”).

36. See *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983).

37. *Carrier*, *supra* note 32, at 64.

38. *E.g.*, *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008).

39. *In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at \*6 (D.N.J. Feb. 6, 2009), *rev’d*, 686 F.3d 197 (3d Cir. 2012).

40. *Id.* at \*8.

41. *Id.* at \*4.

based on the *possibility* that it was not infringed by the [generic] products,” the issue could not really be resolved by relying on the scope of the patent.<sup>42</sup>

#### CONCLUSION

The scope test applied by courts today cannot resolve the issue of whether drug patent settlements violate the antitrust laws. The test has ventured far beyond its initial version employed for the narrow purpose of punishing conduct reaching products clearly outside the scope of the patent.

The simplistic version used today is employed to give automatic immunity to conduct that might – or might not – be justified. The test assumes issues of validity and infringement that cannot possibly be determined from the mere issuance of the patent. With all potential nuance stripped out of the scope test, courts today are relegated to the role of traffic cops shoeing agreements through an antitrust light always flashing green. The simplistic scope test is not appropriate for analyzing the complex issues presented by drug patent settlements.

---

42. *Id.* at \*25 (emphasis in original).