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# Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments

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## Correspondence

# Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments

Herbert Hovenkamp,<sup>†</sup> Mark D. Janis,<sup>††</sup>  
and Mark A. Lemley<sup>†††</sup>

As Daniel Crane suggests,<sup>1</sup> law must often choose between simple rules that are prone to error and more complex rules that are more accurate but harder to administer.<sup>2</sup> Often, but not always. Sometimes the simple rule gets it right. The rule of presumptive illegality adopted by the Sixth Circuit in the case of pharmaceutical exclusion payments<sup>3</sup> is such a case.

Crane argues that exclusion payments will sometimes be socially optimal and should therefore be judged under the rule of reason. In short, he argues that presumptive illegality is overinclusive.<sup>4</sup> Crane's argument fails on two levels. First, his

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1. See Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 MINN. L. REV. 698 (2004) [hereinafter Crane]; see generally Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 750 (2002) (arguing that the optimal rule should yield the lowest net social cost by balancing interests in competition, innovation, and settlement).

2. See, e.g., RICHARD A. EPSTEIN, *SIMPLE RULES FOR A COMPLEX WORLD* (1995) (arguing for simple rules over more complex legal standards).

3. See, e.g., *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003) (finding exclusion payments in pharmaceutical patent settlements illegal per se). *But see* *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003) (rejecting per se illegality); *Schering-Plough Corp.*, No. 9297, at 96 (FTC June 27, 2002) (same), available at 2002 WL 1488085.

4. He also argues that our proposed rule of presumptive illegality is underinclusive because it does not reach anticompetitive settlements that do not

substantive justifications for exclusion payments are unpersuasive. Second, while he emphasizes that a rule of presumptive illegality would burden settling firms with transaction costs, he ultimately favors a solution that would increase, not reduce, those costs.

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involve exclusion payments. See Crane, *supra* note 1, at 700–02. This argument is somewhat at cross-purposes with the general thrust of his paper. Most of his argument is devoted to explaining why the narrow rule of presumptive illegality we propose will impose significant costs on patentees. See *id.* at 703–08. Part I, by contrast, urges broadening that rule, which on his analysis would presumably increase those costs still more. See *id.* at 700–02. Perhaps Crane is attempting a sort of *reductio ad absurdum*: If you make exclusion payments illegal, you must make other kinds of settlements illegal, and, therefore, courts should throw up their hands and make none of it illegal.

In any event, Crane's argument fails because pharmaceutical exclusion payments do have significantly different characteristics than any other kind of settlement. In part, these characteristics result from the odd structure of government regulation in the pharmaceutical industry, in which paying off the first generic to file an abbreviated new drug application (ANDA) can prevent entry not only by that generic, but also by all subsequent generics as well. In addition, an exclusion payment aligns the generic's incentives with the patentee's; they are dividing up a monopoly to which the patentee may not have been entitled. By contrast, other forms of settlement, such as a delayed entry agreement, do not align the incentives in this way.

Nor is the reduction in payment by the generic that Crane discusses economically equivalent to an exclusion payment. An accused infringer would have to pay damages to the patentee only if it had been selling products in the marketplace before it was determined to be infringing. See 35 U.S.C. § 284 (2000) (providing that damages shall be awarded in an amount "adequate to compensate" the patentee for the infringer's past infringement). This virtually never happens in the pharmaceutical context because the Hatch-Waxman rules cause litigation to occur before generics are approved by the FDA. If the accused infringer has been selling products, society will already have benefited from the uncertainty of the patent during the period of competition. A settlement in which the infringer agrees to depart the market in exchange for a reduced damage payment would occur only when the patent looked valid enough and the infringement had been occurring for long enough that the validity-discounted value of the damages payment exceeded the expected net present value to the infringer of continuing to sell in the market. Even then, the patentee would not have an incentive to cut such a deal unless there was reason to think it could exclude others from entering as well, perhaps because entry required a long lead time. This confluence of events could happen, but is less clearly anticompetitive than an exclusion payment.

At the end of the day, Crane is probably right to say in Part I that some settlements that do not involve exclusion payments are also anticompetitive. The fact that antitrust law must make a detailed inquiry into the merits of the patent dispute in those cases, see Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1728 (2003), does not, however, mean that it should make an unnecessary inquiry into the merits of cases involving exclusion payments. Such an inquiry would be required only if there were reason to believe that exclusion payments were good for society. As we discuss in Part I *infra*, no such case has been made.

## I. ARE EXCLUSION PAYMENTS GOOD FOR SOCIETY?

Crane's article repeats a number of arguments that pharmaceutical companies and their supporters have made in an effort to justify the facially anticompetitive practice of paying generic providers not to enter the market and, in the process, to exclude others as well.<sup>5</sup> We have explained in detail elsewhere why exclusion payments are particularly problematic in the context of Hatch-Waxman litigation.<sup>6</sup> Assertions that patentees are entitled to treat their patents as free from uncertainty, or that they will not receive the proper incentives unless allowed to exclude competitors on the basis of dubious patents, simply misunderstand the structure of the patent system.<sup>7</sup> Patents are not rights to exclude, but to try to exclude, and determining the validity and scope of a patent is something that we mainly leave to the courts.<sup>8</sup> We will not go over those old disputes again here.

Crane does offer some purportedly procompetitive justifications for settlements that involve exclusion payments. None of his justifications are persuasive. First, Crane argues that discouraging settlements will prolong patent litigation,<sup>9</sup> and that prolonging litigation will "freeze inventive activity for years" because of uncertainty over whether the infringer can enter the market.<sup>10</sup> He argues that because damage awards normally ex-

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5. See Crane, *supra* note 1, at 705–08.

6. See, e.g., 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 7.4d3 (forthcoming 2004); Hovenkamp et al., *supra* note 4, at 1749–63.

7. Crane generally avoids falling into this trap, but cannot resist occasional forays in this direction. See Crane, *supra* note 1, at 705. He suggests that "[b]y severely limiting patent settlements, the authors' rule would undermine a major goal of patent law, that of encouraging investment in innovation." *Id.* He also argues that the Hovenkamp-Janis-Lemley proposal would "reduce the value of the patent and therefore the incentive to engage in inventive activity." *Id.* at 705–06.

8. See, e.g., Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 391–92 (2003). Mark Lemley has explained elsewhere why we cannot rely on the Patent and Trademark Office (PTO) to weed out bad patents. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1495–96 (2001). In fact, we do not depend on the PTO, since forty-six percent of all patents litigated to judgment are declared invalid. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998).

9. See Crane, *supra* note 1, at 703–04. We do not agree with his premise. As we explained in our original article, patentees and accused infringers are generally free to settle by granting a license, or by delaying entry during the term of the patent. Hovenkamp et al., *supra* note 4, at 1760–63.

10. Crane, *supra* note 1, at 706.

ceed a defendant's profits in patent cases, infringers will have an incentive not to enter the market until the litigation is concluded.<sup>11</sup> Crane also asserts that an early settlement will encourage the defendant to engage in design-around activity earlier than it otherwise would.<sup>12</sup>

We are skeptical that defendants in ordinary patent infringement cases behave as Crane predicts. While Crane may theorize that potential infringers will stay out of the market for fear of massive damage liability, that is not the way things work in the real world. Most patent defendants are unaware of the patent until after they have started selling goods, in part because the law encourages them not to read patents.<sup>13</sup> When they are sued, our experience in litigation makes it abundantly clear that they do not drop out of the market pending resolution of the suit. If they engage in design-around activity, they do so while litigating the suit, rather than waiting until it is resolved.

Whatever the problems with the "freezing invention by infringers" argument in general, it is simply nonsensical in the context of Hatch-Waxman litigation. In Hatch-Waxman cases, the context in which every exclusion payment case so far has arisen,<sup>14</sup> defendants are generally aware of the patent, because such patents are listed in the Orange Book.<sup>15</sup> Defendants are required by law to stay out of the market while patent litiga-

11. See *id.* at 705–06.

12. See *id.* at 706.

13. Parties have a duty to avoid infringing patents of which they become aware or to obtain an opinion of counsel that the patent is invalid. See *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389–90 (Fed. Cir. 1983). A party who fails to comply with the duty is subject to charges of willful infringement and the possibility of enhanced damages. See *Vulcan Eng. Co. v. Fata Aluminum, Inc.*, 278 F.3d 1366, 1378 (Fed. Cir. 2002) ("When it is found that the infringer acted without a reasonable belief that its actions would avoid infringement, the patentee has established willful infringement, which may be accompanied by enhanced damages."). As a result, many companies actively discourage their engineers from reading patents to avoid triggering this duty. See Mark A. Lemley & Ragesh K. Tangri, *Ending Patent Law's Willfulness Game*, 18 BERKELEY TECH. L.J. (forthcoming 2003).

14. Hovenkamp et al., *supra* note 4, at 1751 ("Conceptually, the problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent. Practically, the problem of exclusion payments has arisen in antitrust law primarily in the pharmaceutical industry because of its unique patent rules.").

15. See 21 U.S.C. § 355(b)(1) (2000) (setting out the listing requirement for new drug applications (NDAs)). The FDA also publishes the listings. *Id.* § 355(j)(7)(A)(iii).

tion proceeds and cannot begin selling a pharmaceutical product arguably covered by a patent without first giving the patentee an opportunity to file suit.<sup>16</sup> The patentee can obtain at least one, and possibly an unlimited number of mandatory thirty-month injunctions freezing the defendant's activity.<sup>17</sup> Indeed, even a generic who wants to design around a patent is stuck waiting under the Hatch-Waxman system: any product asserted to be bioequivalent is subject to the stays.<sup>18</sup> We need not fear that continuing patent litigation will paralyze generic pharmaceutical defendants into inaction; the law already paralyzes them. Furthermore, the settlements Crane defends make that paralysis permanent, at least during the term of the patent. The idea that a settlement in which a generic agrees not to make the patented product or to try to design around that product will somehow increase inventive activity by generics is perverse.

Crane's second justification for exclusion payments is even more perverse. He adopts the argument of pharmaceutical patent owners that restricting settlements will increase barriers to entry, since entering firms will know that they have to litigate a suit to judgment rather than settling.<sup>19</sup> Like his first argument, this wrongly assumes that prohibiting exclusion payments will prevent settlement altogether rather than simply channeling it into other forms.<sup>20</sup> It also wrongly assumes that the costs of litigation are a significant percentage of the cost of entering a market.<sup>21</sup> While patent litigation is not cheap,<sup>22</sup> it is

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16. See *id.* § 355(j)(2)(A)(vii).

17. See *id.* § 355(j)(5)(B)(iii). Under the statute, patentees have been able to obtain an unlimited number of thirty-month stays by sequentially listing new patents in the Orange Book covering the same product, a practice known as "evergreening." See, e.g., Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 *IDEA* 227, 239 (2001); Christine S. Paine, Comment, *Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production Through Patent Layering*, 33 *SETON HALL L. REV.* 479, 506-07 (2003); Frederick Tong, Comment, *Widening the Bottleneck of Pharmaceutical Patent Exclusivity*, 24 *WHITTIER L. REV.* 775, 787-88 (2003). The FDA changed its regulations in June 2003 to permit no more than one thirty-month stay, and to restrict the ability of patent owners to list packaging or other incidentally related patents in the Orange Book. See *Applications for FDA Approval to Market a New Drug*, 68 *Fed. Reg.* 36,676, 36,676-77 (June 18, 2003) (to be codified at 21 *C.F.R.* pt. 314).

18. See 21 *U.S.C.* § 355(j)(2)(A)(iv) (2000).

19. See Crane, *supra* note 1, at 706.

20. See *id.* at 705-06.

21. See *id.*

a tiny fraction of the amount of money that is at stake in the cases we are discussing. More to the point, this justification is perverse because in the pharmaceutical industry the settlement in question, an exclusion payment, prevents entry altogether, not just by the settling firm, but by any other generic as well.<sup>23</sup> It is hard to see how a settlement indefinitely forbidding entry by any generic can possibly be justified as a way of reducing barriers to entry.

Third, Crane argues that if patentees cannot make exclusion payments, they will instead settle by licensing the generic companies and that licenses may not be procompetitive because they permit the patentee to control the licensee's price, quantity, or sales territory.<sup>24</sup> Although it is certainly true that some license agreements have anticompetitive provisions, licensing is generally a procompetitive practice.<sup>25</sup> Where anticompetitive provisions do arise, antitrust law can and does deal with them. They do not justify a blanket ban on licensing. More to the point, Crane's argument once again fails to account for the realities of the pharmaceutical industry. Whatever the competitive problems with particular license provisions in other industries, where companies locked in a patent dispute over one

22. See Lemley, *supra* note 8, at 1502 (citing the median cost of litigation through trial and appeal as \$1.5 million per side).

23. This results from a loophole in Hatch-Waxman, which grants generic exclusivity for 180-days to the first generic company to file an abbreviated new drug application (ANDA). See 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Thus, if the first generic company does not enter the market, every other potential entrant is bottled up behind them.

24. See Crane, *supra* note 1, at 707.

25. See, e.g., U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 2.3, 5 (1995). The guidelines state the following:

Licensing, cross-licensing, or otherwise transferring intellectual property (hereinafter "licensing") can facilitate integration of the licensed property with complementary factors of production. This integration can lead to more efficient exploitation of the intellectual property, benefiting consumers through the reduction of costs and the introduction of new products. Such arrangements increase the value of intellectual property to consumers and to the developers of the technology. By potentially increasing the expected returns from intellectual property, licensing also can increase the incentive for its creation and thus promote greater investment in research and development.

*Id.*; see also DAVID J. TEECE, MANAGING INTELLECTUAL CAPITAL 136 (2000) ("Licensing usually leads to faster and more complete diffusion of the innovation, including uses outside the original field, possibly leading to new applications and further innovation. . . . This allows broader use and increases society's returns to the innovation.").

component may compete with each other in selling other components or larger products, a settlement with a license is almost certainly better for competition than the alternative of an exclusion payment, which prevents any generic from entering the market at all.

Finally, Crane argues that a generic company might injure the patentee by free riding on its promotional efforts.<sup>26</sup> This concern seems overstated. Unlike a franchise arrangement, for example, the generic will not be selling products branded with the patentee's name. Trademark law generally deals adequately with the problem of generics capturing goodwill from patent owners.<sup>27</sup> If there are concerns, the patentee could generally resolve them by licensing; nonprice restrictions designed to prevent free riding are routinely upheld under the antitrust laws.<sup>28</sup> If the patentee thinks generic competition is so harmful that no license provisions would suffice, it can choose not to settle and to attempt to exclude the generic company altogether. It should not have the option, however, to do so if the patent is invalid or not infringed.

In the end, Crane's objections to presumptive illegality depend on his belief that "many" exclusion payments that exceed litigation costs are socially desirable. We do not believe he has proven his case. One can easily give reasons why exclusion payments are anticompetitive: they invoke a government regulation to exclude all competitors from a market, even in circumstances where entry would be likely absent the payments. Pharmaceutical companies have labored mightily to come up with good reasons to justify paying generics to stay out of the market, but neither they nor Crane have come up with a persuasive justification. Absent some reason to think a significant number of procompetitive settlements will be wrongly forbidden, presumptive illegality is the right rule.

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26. See Crane, *supra* note 1, at 708.

27. See generally Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455 (2002) (explaining how pharmaceutical patent owners can rely on trademarks to differentiate their products after patent protections expire).

28. See 8 PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW* ¶¶ 1611–19 (2d ed. 2004) (explaining that courts apply a rule of reason to vertical nonprice restrictions).



## II. HOW MUCH INQUIRY SHOULD GO INTO DETERMINING LITIGATION COSTS?

Crane's other objection to our proposed rule of presumptive illegality is much narrower. He does not contend that our decision to limit exclusion payments to litigation costs is wrong.<sup>29</sup> Rather, he argues that we are too narrow in our definition of litigation costs.<sup>30</sup> He would expand the definition to include indirect costs such as lost productivity among employees who are deposed or who search for documents,<sup>31</sup> the cost associated with risk aversion among stockholders,<sup>32</sup> and other unquantified but no less real costs.<sup>33</sup>

Crane is right to suggest that these are real costs of litigation, and in an ideal world with perfect information our rule would take account of them. In our rather less than ideal world, however, the cost and difficulty associated with collecting this information would prevent it from being worthwhile. Consider three points: First, the costs that he identifies, while real, are difficult if not impossible to quantify. Legal fees are billed by the hour, and out-of-pocket expenditures are fairly easy to estimate. It is harder (though not impossible) to estimate employee time diverted into the lawsuit, and harder still to try to quantify the effect of risk aversion on corporate behavior and shareholder value. Under Crane's approach courts would have to quantify these things in determining the legality of a settlement, but there is no reason to believe courts will do a particularly good job of valuing these intangible costs.

Second, if courts expand the litigation costs calculus to include intangible losses a company might suffer from litigation, it is far too tempting to add impermissible "costs" into the mix. Risk aversion is an obvious example.<sup>34</sup> It is true that the cost of risk aversion should be considered a cost of litigation for which a generic might want to be compensated. Uncertainty itself, by contrast, is not a permissible value in exclusion payments.<sup>35</sup> If a patent is worth \$1000 if valid, and is sixty percent likely to be

29. See Crane, *supra* note 1, at 703-05.

30. See *id.*

31. *Id.* at 703-04.

32. *Id.* at 704.

33. See *id.* at 704-05.

34. *Id.* at 704 (arguing that risk aversion could be considered a cost of continued litigation).

35. See Hovenkamp et al., *supra* note 4, at 1760 n.177 (explaining that uncertainty should not be included as a value in exclusion payments).

valid, the expected value of the patent is \$600. Risk aversion might reduce that value to \$550. A proper calculation of indirect litigation costs to include in an exclusion payment could take account of the \$50 in risk aversion, but could not take account of the \$400 by which the uncertainty of the outcome reduced the value of the patent. That \$400 is not part of the value of the patent, and it is precisely what the patentee is attempting to capture by entering into an anticompetitive settlement. In theory, courts could calculate the expected values with and without risk aversion and determine the proper size of an exclusion payment accordingly. In practice, that will never happen, in part because it is too tempting to call any uncertainty a "cost" of litigation.<sup>36</sup>

Finally, including unquantifiable indirect litigation costs will make it virtually impossible for the parties to a settlement to know *ex ante* whether or not their settlement is legal. Legality can be determined under Crane's proposal only by waiting to see how risk averse an agency or court thinks the parties are and what value it puts on lost productivity. If Crane is truly concerned with the transaction costs that a legal rule will impose on patentees, he should favor the bright-line rule of presumptive illegality we propose rather than a legal standard that casts a cloud of uncertainty over a wide range of legal settlements.

### III. ALLOCATING THE COSTS OF UNCERTAINTY

Crane argues that our presumptive illegality rule will increase uncertainty in patent litigation. Ironically, however, Crane's own approach will create far more uncertainty than ours. He does not argue for a rule of *per se* legality, and indeed seems at various points to acknowledge that exclusion payments may sometimes be anticompetitive. Instead, he appears to favor a case-by-case analysis of the merits of each patent suit and the cost structure of both parties in order to decide whether a particular exclusion payment was warranted.<sup>37</sup> This

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36. Indeed, Crane himself falls into this trap, suggesting that we should include losses to the patentee that result from "making marketing, research and development, and other business planning difficult while the outcome of the case remains uncertain." Crane, *supra* note 1, at 704. For a similar argument against *per se* illegality of settlement agreements, see Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation* (manuscript, on file with authors).

37. See Crane, *supra* note 1, at 708-10.

inquiry will be more intrusive than simply litigating the patent suit to conclusion: under Crane's regime, settling parties will have to litigate the merits of the patent suit along with their indirect costs and a host of other antitrust issues before anti-trust agencies and appellate courts with no particular expertise in evaluating patent disputes. Crane invites us to imagine being in-house counsel and having to explain to senior management "that by settling a patent infringement lawsuit they will presumptively become criminals . . . unless they can persuade a jury that they likely would have won the patent infringement lawsuit anyway."<sup>38</sup> Every proposal, including Crane's, however, will place this burden on patentees who enter into a settlement involving an exclusion payment. Our proposal differs from the others only in that it makes the rules clear up front.

Presumptive illegality will, it is true, discourage the use of exclusion payments. If Crane is right that we are not properly accounting for litigation costs, it may even overdeter their use. Antitrust rules, however, are all about comparing error costs. Neither Crane nor anyone else has offered any real reason to believe that exclusion payments serve any significant social purpose, such that we should worry about overdetering them.

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38. *Id.* at 709.

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