Economic Analyses of Patent Settlement Agreements: The Implementation of Specific Economic Tests, the Evaluation of Dynamic Efficiency, and the Scope of Patent Rights

By JAMES LANGENFELD* AND WENQING LI**

PATENT SETTLEMENT AGREEMENTS that involve payments from brand-name drug manufacturers to generic drug manufacturers (so called "reverse payments") have recently attracted a great deal of attention from economists, legal scholars, government antitrust enforcement agencies, and the courts.[1] Some of the agreements are "complete" settlement agreements,[2] where the brand-name manufacturer makes payments to the generic drug companies to completely settle the patent litigation, with specific agreed-upon entry dates for the generics. Others involve "partial" or "interim" settlement agreements, where there are payments from patent holders to would-be generic manufacturers in exchange for the generics not entering the market before a final resolution of patent litigation. These interim

* Director, LECG, LLC, Adjunct Professor at Loyola University, Chicago, School of Law, and former Director for Antitrust in the Bureau of Economics of the Federal Trade Commission. Dr. Langenfeld serves as an expert engaged by defendant pharmaceutical companies in *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000). This Article received no funding from these or other companies and does not necessarily reflect the views of any company or institution, including LECG and the Federal Trade Commission.

** Independent consulting economist, LECG, LLC.

1. *See, e.g.*, James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777 (2002); M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON L. REV. 359 (2002) (including background discussion of the actions by government antitrust enforcement agencies and private plaintiffs, the court decisions on this type of case, and some of the prior research in this area).

2. *See, e.g.*, *In re* Schering-Plough Corp., No. 9297, 2003 FTC LEXIS 187 (2001), *available at* http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf (last accessed Aug. 17, 2004).

settlements do not specify a fixed date for generic entry.[3] This Article examines some of the key economic issues presented in the existing research relating to patent settlements with such payments, and presents some specific economic tests and analyses relating to the competitive implications of interim settlement agreements. In particular, this Article focuses on whether an interim settlement is most likely related to the patent holder's potential under-compensation for patent damages and tests that explanation against the potential for such an agreement to be anticompetitve. An interim agreement is most likely procompetitive and pro-consumer under the following circumstances, which typically can be tested from observable information in a case where under-compensation is an issue:

- The payments from the brand-name manufacturer to the generic are less than the expected under-compensation.
- The patent holder overall is substantially engaged in research, development, and promotion.
- The interim settlement agreement is more cost efficient than formal legal proceedings, such as preliminary injunction or stay pending appeal, at preventing expected under-compensation.

As a general rule, the vast majority of research about patent settlements with "reverse payments" has focused on complete and interim settlements in the pharmaceutical industry.[4] These "reverse payments" and the attendant research in the prescription pharmaceutical industry are not surprising, given the industry's unique regulatory require-

3. *See, e.g.*, Plaintiffs' Complaint, at 4–5, *In re* Abbott Labs. & Geneva Pharms., (No. C-3946) (F.T.C. May 22, 2000), *available at* http://www.ftc.gov/os/2000/05/c3946om plaint.htm (last accessed Nov. 2, 2004); Plaintiffs' Complaint, Hoechst Marion Roussel, Inc., (F.T.C. Mar. 16, 2000) (No. 9293), *available at* http://www.ftc.gov.os/2000/03/hoech standrxcomplaint.htm (last accessed Nov. 2, 2004); *see also* Langenfeld & Li, *supra* note 1, at 780–82 (discussing the difference between the complete settlement agreements and the interim settlement agreements, in which interim settlement agreements are called partial settlement agreements).

4. *See, e.g.*, Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002); Thomas Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069 (2004) [hereinafter Cotter, *Antitrust Implications*]; Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003) [hereinafter Hovenkamp et al., *Anticompetitive Settlement*]; Langenfeld & Li, *supra* note 1; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1033–68 (2004); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 407–08 (2003) [hereinafter Shapiro, *Antitrust Limits*]; Jeremy Bulow, The Gaming of Pharmaceutical Patents 4 (May 2003) (unpublished manuscript, on file with the authors); Keith Leffler & Cris Leffler, *Patent Litigation Settlements: Payments by the Patent Holder Are Anticompetitive and Should Be Per Se Illegal*, RES. L. & ECON. (forthcoming 2004), *available at* http://faculty.washington.edu/kleffler/Research. html (last accessed Nov. 2, 2004); Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation*, 49 ANTITRUST BULL. (forthcoming 2004).

ments and, in particular, the regulations embedded in the Hatch-Waxman Act[5] and the Federal Trade Commission investigations targeting it.

The economics of these agreements can be complex, and vary by the specific type of agreement and the facts of each case. As this Article discusses, there is general agreement that analyzing the impact of any particular settlement should take as a starting point the trade-off between short-run price and long-run innovation competition as optimally determined by the existing patent and competition laws and the statutes of the Hatch-Waxman Act. However, even starting from the same point, there is disagreement over exactly how to model these settlements and whether they are, on balance, anticompetitive or improve overall consumer welfare.

Most economists use probabilistic game theory models to analyze these settlements,[6] but some commentators believe such an approach is not appropriate because of its complexity and the potential problems with developing clear and reliable tests.[7] To see why the analysis is complex, consider agreements that completely settle patent disputes. These agreements, in general, fix a date for generic entry that is before the expiration of the patent. However, since the outcome of patent litigation is uncertain and a generic may be bluffing about entering the market, one cannot pinpoint a date when entry would have taken place absent the agreement. Accordingly, most economists look at entry "but for" the settlement by assigning a probability to the date when entry would have occurred absent the agreement and use the "expected value" of that date as an estimate of the specific date of entry. They then compare that expected entry date to the date in the settlement to determine the impact of the agreement on short-run price competition. Some then look to the strength of the patent and proxies for that strength, such as the size of the "reverse payment," to infer the impact on the consumer welfare.[8]

However, the specific terms of a settlement and specific facts about the market will greatly affect the impact of an agreement on the

5. Pub. L. No. 98-417, 98 Stat. 1585 (1984). For a discussion of the relevant aspects of the Hatch-Waxman Acts, see, for example, Langenfeld & Li, *supra* note 1, at 778–80.

6. *See, e.g.*, Shapiro, *Antitrust Limits*, *supra* note 4; Leffler & Leffler, *supra* note 4, at 3–17; Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, 17 ANTITRUST 70, 70–76 (2003) [hereinafter Shapiro, *Settlements Between Rivals*]; Willig & Bigelow, *supra* note 4.

7. *See, e.g.*, Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, 17 ANTITRUST 68 (2003).

8. *See, e.g.*, Shapiro, *Settlements Between Rivals*, *supra* note 6, at 71–72.

firms involved and on consumers in the long run. As we have shown previously, if banning patent settlement agreements such as ones that involve "reverse payments" deters the probability of a new product coming out by as little as thirty percent, then consumer welfare will likely be reduced.[9] Accordingly, these cases do not lend themselves to overbroad generalizations and should not be condemned as per se illegal or virtually per se illegal.[10] Instead, there needs to be specific, measurable, and economically sound tests for each type of case and fact pattern. As discussed above, this Article provides examples of some specific measurable tests for one type of case and fact pattern, which is when interim settlements with payments from a patent holder to a would-be generic entrant can and cannot be justified by the potential for under-compensation to the patent holder. Similar tests that address the specific settlements and market facts can and should be developed to evaluate accurately the implications of each type of patent settlements with "reverse payments."

I. Existing Research on Patent Settlements in the Pharmaceutical Industry with "Reverse Payments"

Research on the implications of patent settlements in the pharmaceutical industry with "reverse payment" is relatively recent.[11] Such research has been spurred, at least in part, by certain Federal Trade Commission challenges to such agreements that have led to litigation and consents between the FTC and the parties involved.[12] The vast

9. Langenfeld & Li, *supra* note 1, at 803–04.

10. Simplistic arguments, such as forcing firms to choose what might be perceived as potentially less anticompetitive patent-dispute settlements make no sense in this context. For example, some have suggested allowing royalty payments from the generic to the patent holder, but argue that complete and interim settlement agreements with "reverse payments" should be banned. *See, e.g.*, Leffler & Leffler, *supra* note 4, at 1, 8–10, 24. However, royalty agreements can have exactly the same implications for short run consumer welfare as agreements with "reverse payment," since a royalty rate could be set sufficiently high that prices would not fall in the short run—even with entry of the licensee.

11. For an encyclopedic list of the various articles, see Cotter, *Antitrust Implications*, *supra* note 4. The earliest of the articles he lists was published in 2001. *Id.* at 1069 n.1.

12. The FTC has brought complaints against Abbott Laboratories and Geneva Pharmaceuticals, Inc. Plaintiffs' Complaint, *In re* Abbott Labs. & Geneva Pharms., (F.T.C. 2000) (No. C-3946), *available at* http://www.ftc.gov/os/2000/05/c3946omplaint.htm (last accessed Nov. 2, 2004); Plaintiffs' Complaint, Hoechst Marion Roussel, Inc., (F.T.C. 2000) (No. 9293), *available at* http://www.ftc.gov.os/2000/03/hoechstandrxcomplaint.htm (last accessed Nov. 2, 2004); *In re* Schering-Plough Corp., 2003 FTC LEXIS 187 (2001). Some of the private cases include *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000), and *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682 (E.D. Mich. 2000). For an example of the consent agreement reached between the FTC and the parties involved in the patent settlement with "reverse payment," see United States of

majority of the articles are by attorneys, and the rest are by economists. Although some of the research attempts to apply certain economic principals to all such cases, many of the actual economic issues depend on the specific nature of the settlement—such as whether the agreement is a complete or interim settlement.[13]

Consider some of the differences in complete versus interim settlements. In complete settlements there can be litigation cost savings, since this type of agreement presumably terminates costly court proceedings earlier. For interim settlements, litigation cost savings are presumably smaller, because the litigation continues as it would without the settlement.[14] Moreover, complete settlements with a negotiated generic entry date likely lead to a different entry date than would occur with litigation absent the agreement. For interim settlements this may not be the case. The litigation continues with or without an interim settlement, and the potential patent damages for a would-be generic entrant will often deter its entry until the litigation is resolved—even though a would-be entrant may be able to credibly threaten a patent holder with earlier entry.[15]

The economic research typically applies probabilistic models of entry dates, as discussed above, and then predicts the impact on consumer welfare of a complete settlement to what would happen absent the agreement. Most economists recognize there is a trade-off in consumer welfare between short-run competition ("static efficiency") and long-run benefits of encouraging firms to compete to develop new products that benefit consumers ("dynamic efficiency").[16] They take

America Before Federal Trade Commission, *In re* Geneva Pharmaceuticals, Inc., Decision and Order, (F.T.C. 2000) (No. C-3946), available at http://www.ftc.gov/os/2000/05/c3946.do.htm (last accessed Nov. 2, 2004). In the consent agreement, Geneva agreed not to enter similar interim settlement agreements in the future unless it receives a court's approval and notifies the FTC. *Id.* § III.

13. Most of the literature specifically analyzes complete settlement agreements, although some of the principles discussed in this research may apply to other patent settlements. Accordingly, the economic analysis of complete settlements is discussed in this section, realizing that there are typically important fact-specific inquiries and economic issues that are unique to any agreement. The other sections of this Article examine interim settlements and one particularly important aspect of evaluating this type of settlement—the potential for a generic under compensating a patent holder for infringement damages.

14. *See* Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 MINN. L. REV. 1789, 1806 (2003) [hereinafter Cotter, *Refining the Presumptive Illegality*].

15. *See, e.g.*, Blair & Cotter, *supra* note 4, at 523; Shapiro, *Settlements Between Rivals*, *supra* note 6, at 74; Langenfeld & Li, *supra* note 1, at 790.

16. *See, e.g.*, Langenfeld & Li, *supra* note 1, at 786–90; Leffler & Leffler, *supra* note 4, at 17; Shapiro, *Antitrust Limits*, *supra* note 4, at 396.

the existing patent laws, antitrust laws, and the Hatch-Waxman Act as having established the optimal trade-off.[17] However, much of the literature applied to complete settlements, in effect, focuses on changes in short-run competition.[18]

The articles typically assume generic entry would drive prices down in some drug markets,[19] and that earlier generic entry would reduce the costs to consumers. They also assume that the patent holder without generic competition will receive substantially larger profits (or rents from the innovation) than the sum of the profits the patent holder and generic would receive after generic entry, due to a drop in price.[20] Accordingly, there is an incentive for a patent holder and generic to reach an agreement to divide the potentially larger profits without generic entry, but this depends on many other factors. These factors include the likelihood that the patent holder will prevail in its patent litigation against the generic and the relative profits for each firm with and without entry.

By focusing primarily on the short-run competitive issues, the literature tends to analyze whether a complete settlement would change the generic's expected entry date. If a settlement would delay the expected entry date beyond what would be expected without the agreement, then the agreement might be seen as a temporal market allocation—dividing the time remaining on a patent and extending the patent holder's market power in the short run.

Some of the articles then argue that the existence of payments from a patent holder to a would-be generic entrant provides substantial evidence that entry would be delayed by the agreement.[21] In effect, the argument is that there must have been an offsetting consideration for the payment from the patent holder to the generic challenger, and that consideration would likely have been the generic

17. *See, e.g.*, Langenfeld & Li, *supra* note 1, at 788; Leffler & Leffler, *supra* note 4, at 17–19.

18. *See, e.g.*, Leffler & Leffler, *supra* note 4, at 17. Leffler and Leffler recognize that complete settlements can affect dynamic efficiency, but they argue that complete settlements are beyond the patent rights granted to patent holders by Congress. *Id.* at 17–21. For a similar discussion, see Shapiro, *Settlements Between Rivals, supra* note 6, at 73.

19. Market definition and market power are typically hotly debated in the cases. For the purpose of this Article, those issues are not addressed.

20. *See, e.g.*, Leffler & Leffler, *supra* note 4, at 4–6; Shapiro, *Antitrust Limits, supra* note 4, at 407.

21. For example, Shapiro states that the strength of the patent is key to any analysis of whether a settlement harms consumers, and he argues that large payments from a patent holder to a generic implies that the patent is weak. *See* Shapiro, *Settlements Between Rivals, supra* note 6, at 71–72.

deferring its entry beyond the date that would have resulted from a reasonable litigation compromise. Such a delay would result in lower consumer surplus in the short run.

Other authors dispute this logic.[22] These authors argue that agreements with cash payments from a patent holder to a generic can save litigation and other costs, reduce uncertainty for risk adverse firms, and eliminate asymmetric information about the value of the patent.[23] They show complete settlements with payments from a patent holder to a generic could actually lead to earlier entry by the generic.[24] For example, these authors argue that settlement negotiations can be expected to break down frequently under the conditions the authors outline, and these breakdowns can result in a later expected generic entry date than the date that would result from a complete settlement with payments from the patent holder to the generic.[25]

The policy recommendations relating to complete settlement with payments from the patent holder to the generic tend to fall into three categories. Some argue that such treatments should be per se illegal if they involve a payment from the patent holder to a generic.[26] Another group in effect argues that these payments should create a presumption of anticompetitive behavior, although the degree of this presumption may vary by author.[27] The final group believes that these settlements should be analyzed under a full rule of reason, taking into consideration competitive effects and efficiencies from any such agreement.[28] In its *Matter of Schering-Plough Corp.*[29] decision, the Fed-

22. *See* Willig & Bigelow, *supra* note 4; Schildkraut, *supra* note 4, at 1033–68.

23. *See* Schildkraut, *supra* note 4, at 1057–67.

24. *Id.* at 1059–60.

25. *See id.* at 1057–60. A patent holder will be willing to accept entry date earlier than the expected entry date under litigation if the patent holder is risk averse. However, a negotiation without reverse payment may still breakdown if, for example, the generic is cash strapped or is too optimistic about its chance of winning the patent litigation. As a result, the generic wants to enter earlier than the entry dates that are acceptable for the patent holder. A payment from the patent holder to the generic can help bridge the gap between the acceptable entry dates for the generic and the acceptable entry dates for the patent holder and lead to generic entry earlier than that expected under litigation. *See id.*

26. *See, e.g.*, Leffler & Leffler, *supra* note 4, at 2–3, 17.

27. *See, e.g.*, Blair & Cotter, *supra* note 4, at 534–38; Bulow, *supra* note 4, at 1; Cotter, *Antitrust Implications*, *supra* note 4, at 1090–94; Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 4; Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 MINN. L. REV. 712 (2004) [hereinafter Hovenkamp et al., *Balancing Ease*]; Shapiro, *Settlements Between Rivals*, *supra* note 6, at 72.

28. The "rule of reason" approach determines whether the agreement is procompetitive by weighing procompetitive effects of an agreement against the anticompetitive effects. *See, e.g.*, Blair & Cotter, *supra* note 4, at 533–34; Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747

eral Trade Commission chose a rule of reason approach, although it did place great weight on the size of the payments to the generics[30] and may have left open the door for it to take a different approach in the future.[31]

As can be seen from this discussion, there is a great deal of literature and varying policy recommendations on complete settlements. There is less research on interim settlements, and we devote the balance of this Article to explaining and developing specific economic tests that address when interim agreements are likely to be procompetitive and when they are not.

II. The Implementation of an Economic Test to Determine Whether an Interim Agreement Is Procompetitive

Although the research specifically addressing interim settlements is more limited, some of the basic issues raised in the context of complete settlements may have relevance for interim settlements. For example, Professor Shapiro proposes a general standard for evaluating patent agreements, arguing that these agreements should not lead to outcomes where consumer welfare is lower than that under ongoing litigation.[32] He applies that general standard to various types of potential antitrust cases, such as complete settlement agreements with "reverse payments."[33]

Some commentators have specifically discussed interim agreements, but few have presented formal models. Blair and Cotter conclude that interim agreements should not be treated as per se illegal for at least two reasons.[34] First, they reason that the courts do not have sufficient experience in analyzing the effects on competition of this type of agreement and therefore lack the empirical foundation for treating these agreements on a per se basis.[35] Second, Blair and Cotter point out that the generic may not be able to pay the full damages if it

(2002); Willig & Bigelow, *supra* note 4; Schlidkraut, *supra* note 4. Schildkraut even suggests there is a case for per se legality of these agreements if they arguably fit within the scope of the patent. *Id.* at 1035.

29. 2003 FTC LEXIS 187 (2001).

30. *See id.* ¶¶ 7, 25–29, *available at* http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf (last accessed Aug. 17, 2004).

31. *Id.* ¶ 29.

32. Shapiro, *Antitrust Limits*, *supra* note 4, at 396.

33. *Id.* at 407–08.

34. Blair & Cotter, *supra* note 4, at 527; *see also* Cotter, *Refining the Presumptive Illegality*, *supra* note 14, at 1807.

35. Blair & Cotter, *supra* note 4, at 527–28.

enters the market and is found guilty of patent infringement.[36] Therefore, the authors contend that "[i]f the agreements reflect a legitimate effort to protect the returns on a patented product from an infringing rival, this will be pro-competitive as it promotes R&D [research and development], which confers broad social benefits."[37] The authors prefer using a traditional rule of reason analysis or a so called "quick-look approach."[38]

Leffler and Leffler, on the other hand, hold the view that interim agreements are anticompetitive in virtually all cases.[39] According to these authors, the only interesting case concerning interim agreements is when the generic otherwise would have entered the market. They then infer that "[i]n this situation, the challenger expects that the profits from entry (including litigation cost) will exceed the damages if the patent is found valid[,]"[40] and interim agreements are no different in effect than complete agreements.[41] These authors also argue that an interim agreement is similar to a "procedural rule granting patent holders a right to pre-trial exclusion without meeting the standard preliminary injunction rules . . . ."[42] They therefore contend that these agreements provide "a greater reward to patent holders than Congress in fact granted."[43]

We have also contributed to this discussion and generated specific tests to measure when an interim agreement with "reverse payments" is likely to benefit consumers.[44] Consistent with most researchers of either complete or interim settlement agreements, we started our evaluation with the presumption that patent and antitrust laws at any point in time strike an optimal balance between ensuring long-run competition ("dynamic efficiency") and short-run competi-

36. *Id.* at 524–25.

37. *Id.* at 529.

38. *See id.* at 532–38.

39. Leffler & Leffler, *supra* note 4, at 1, 24.

40. *Id.* at 24.

41. *Id.* Based on a simulation, Leffler and Leffler conclude that it is only in rare situations that the existence of complete settlement agreement is necessary for the efficient settlement of a patent dispute. *See id.* at 17. However, it is not clear to us whether the simulation Leffler and Leffler conduct is sensitive to specific assumptions built into the model and whether the simulation which Leffler and Leffler use to study complete agreements can be applied to analyze the interim agreements as well.

42. *Id.* at 25.

43. *Id.* As discussed by Langenfeld and Li and later in this Article, interim agreements are not necessarily beyond the scope of patent holders' patent rights.

44. Langenfeld & Li, *supra* note 1, at 794–97.

tion ("static efficiency").[45] We previously addressed one specific aspect of interim agreements, showing the circumstances under which an interim settlement agreement can serve the purpose of protecting a patent holder's patent right by mitigating the risk of under-compensation.[46] We have also shown that an interim settlement agreement can be procompetitive by providing the appropriate incentive intended by the patent law for firms to make investment in R&D. We found if such agreements were treated as per se illegal, it would weaken patent protection.[47] As a result, a per se treatment of these types of agreements can reduce R&D investment and other innovative activities below optimal level and ultimately reduce consumer welfare, even though there may be a short-term gain in consumer welfare.[48]

To assess whether an interim settlement agreement is procompetitive or anticompetitive in a "truncated rule of reason" or a full rule of reason analysis, we developed a specific economic test.[49] According to this test,

> For the payments from the brand-name to the generic to be considered competitively neutral or procompetitive, the payments should be no higher than the expected under-compensation to the brand-name manufacturer if the generic enters the market. This expected under-compensation is equal to the amount of under-compensation multiplied by the probability that the brand-name manufacturer will prevail in the patent infringement litigation.
>
> On the other hand, if the payments from the brand-name manufacturer to the generic are higher than the expected under-compensation, then those payments could be anticompetitive.[50]

45. *Id.* The presumption that the current laws strike an optimal balance between static efficiency and dynamic efficiency also appears to be adopted by the FTC when it states that "antitrust analysis must accept statutes and regulations as they are, and evaluate restraints in the context of the existing framework." *See In re* Schering-Plough Corp., 2003 FTC LEXIS 187, at *65 (2001).

46. Langenfeld & Li, *supra* note 1, at 788, 794–97. Under-compensation for the patent holder is equal to the profit loss the patent holder would have suffered minus the generic's ability to pay the damages if the generic had entered the market during patent litigation and were found guilty of patent infringement later.

Specifically, we address when both parties will find an agreement mutually acceptable, when the settlement surplus is likely due to potential under-compensation and when it is exclusively due to higher profits from reduced competition. We do not agree with Leffler and Leffler that the only interesting case is when a generic would have entered before the end of litigation. The generic presumably has superior knowledge of its intention and ability to enter. Accordingly, the generic may easily be in a position to bluff a patent holder into believing that the generic would enter, when it would not enter until there was a resolution of the patent dispute.

47. *Id.* at 788.

48. *Id.*

49. *See id.* at 794–97.

50. *Id.* at 797.

This test can be written more formally by assuming p is the probability that the patent holder will prevail in the patent infringement litigation, D is the amount of under-compensation, and S stands for the payments from the patent holder to the generic.

(1) If $p^* D \geq S$, then the payment is consistent with a settlement that addresses under-compensation and so is competitively neutral or procompetitive.
(2) If $p^* D < S$, then payments could be anticompetitive.

One way this test can be implemented is by using public data available at the time of the interim agreement, plus data on the drugs included in the agreement. For example, assume we have information on the payments specified in an interim settlement agreement and an estimation of the under-compensation for the patent holder if the generic had entered the market during patent litigation. One can infer the threshold probability of a patent being upheld so that the patent holder's expected under-compensation is equal to or greater than the patent holder's expected payments. That is, we solve equation (1) for the threshold where an interim agreement is competitively neutral (p^t), based on information about the payments and the amount of under-compensation.[51]

(3) $p^t = S / D$

After obtaining this threshold probability, it can be compared to relevant statistics that provide an objective indication on how likely it is that the patent holder's patent would be upheld. If the threshold probability for under-compensation is smaller than the likelihood that the patent holder's patent would be upheld according to the relevant statistics, then the expected under-compensation is likely to be greater than the expected payments. Hence, the interim settlement is likely to be procompetitive. On the other hand, if the threshold probability for under-compensation is greater than the likelihood that the patent holder's patent would be upheld, then the expected under-compensation is likely to be smaller than the expected payments, and the interim settlement could be anticompetitive.

Based on publicly available information, the interim settlement agreement between Abbott and Geneva ("Geneva Agreement") may be used as an example to illustrate this implementation. According to the Eleventh Circuit description of the Geneva Agreement,[52]

51. For a particular case, the potential value of the under-compensation may be approximated from case specific data.

52. These calculations are provided only as an example and do not dispute or endorse the opinion of the court.

> Abbott agreed to pay Geneva $4.5 million each month until either someone else brought a generic terazosin hydrochloride product to market or Abbott won a favorable decision in the district court on its infringement claim. If Geneva won in district court, Abbott's $4.5 million monthly payments would go into escrow pending resolution of the appeal, with the escrowed funds going to the party prevailing on appeal.[53]

In return, the court's opinion suggested that Geneva agreed not to enter the market with its generic terazosin during the patent litigation.[54]

To illustrate how to implement the expected under-compensation versus expected payments test, we focus on a patent holder's expected under-compensation and expected payments between the district court decision and the Federal Circuit decision in a situation similar to what the Eleventh Circuit described above.[55] Let D represent the estimated amount of under-compensation for the patent holder if the generic had entered the market after the district court decision and were later found liable for patent infringement. Let E represent the total payments the patent holder made into the escrow between the district court decision and the Federal Circuit decision. Define p to be the probability of the patent holder winning the patent litigation at the Federal Circuit.

Since the patent holder would lose only the escrow if it would have lost the patent case at the Federal Circuit, the expected payments made by the patent holder after the district court decision is equal to $S=((1-p)*E)$. The patent holder's expected under-compensation is equal to $p*D$. Therefore, the threshold probability p' in this example can be obtained by solving the following equation:

(4) $p'*D = (1-p')*E$, or
(5) $p' = E/(D+E)$

One can obtain from public sources the relevant statistics that provide information on the likelihood that the Federal Circuit would reverse the district court decision in cases similar to the patent dispute between Abbott and Geneva. For example, the Federal Circuit's own official statistics in 1997 show that the Federal Circuit reversed in

53. Valley Drug Co., Inc. v. Geneva Pharms., Inc., 344 F.3d 1294, 1300 (11th Cir. 2003).

54. *Id.* at 1300.

55. The district court hearing Abbott's infringement suit against Geneva ruled on September 1, 1998 that Abbott's '207 patent was invalid in a summary judgment motion. *See id.* at 1301; Abbott Labs., Inc. v. Geneva Pharms., Inc., 182 F.3d 1315, 1316 (Fed. Cir. 1999). The Federal Circuit affirmed the district court's decision on July 1, 1999. *Valley Drug*, 344 F.3d at 1301.

whole or in part fifty-three percent of the cases from district courts. A survey of every patent decision rendered by the Federal Circuit between April 5, 1995 and November 24, 1997 found that the rate of reversal of claim constructions is 37.3% with respect to the district court and Court of Federal Claims cases.[56] According to a study by Allison and Lemley, thirty-two percent of pre-trial motions in which the patent was declared invalid were reversed by the Federal Circuit.[57] However, Allison and Lemley point out that the Federal Circuit reversal rates reported in their study are biased downward because they have excluded remands by the Federal Circuit from their study.[58] Therefore, taking into account the bias in the reversal statistics in Allison and Lemley, the relevant reversal rate of district court decisions in pre-trial motions should be higher than thirty-two percent.

If the threshold probability calculated from equation (5) is lower than the relevant Federal Circuit reversal rate as suggested by these statistics, then the evidence indicates that the expected under-compensation is likely to be greater than the expected payments, which implies the agreement is likely to be procompetitive. On the other hand, if the threshold probability calculated from equation (5) is higher than the relevant Federal Circuit reversal rate, the evidence suggests that the expected under-compensation is likely to be smaller than the expected payments, which implies the agreement could be anticompetitive.

III. Evaluation of Interim Settlement Agreements' Impact on Dynamic Efficiency

We have also shown that dynamic efficiency from introduction of new drugs can be very significant.[59] Specifically, our analysis showed that if there is only a thirty percent probability that an additional new drug will be deterred for each agreement blocked, a ban on interim settlement agreements will reduce total consumer welfare even though earlier generic entry can generate cost savings in the short

56. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1476 (Fed. Cir. 1998) (Rader, J., dissenting).

57. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 243 (1998). Because the district court ruled that Abbott's patent was invalid in a summary judgment motion, the relevant Federal Circuit reversal rate is the reversal rate for pre-trial motions instead of the reversal rate for all trial court findings, which was also reported by Allison and Lemley. *See id.* at 241.

58. *See id.* at 203; John R. Allison & Mark A. Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLA. ST. U. L. REV. 745, 748, 758–59 (2000).

59. *See* Langenfeld & Li, *supra* note 1, at 803–04.

run.[60] One major reason why interim settlement agreements can be procompetitive is that they can protect the value of a patent holder's patent and encourage R&D investment and other innovative activities. This impact is greater if the patent holder is a research-based firm. Thus, we suggested that the nature of the patent holder's firm should be examined in evaluating an interim agreement's impact on consumer welfare.[61] This can be done by analyzing the firm's overall R&D.[62]

Making an interim agreement illegal would weaken patent protection below the optimal level if the patent holder is a research-based firm that relies on patent protection and if the expected payments to the generic are smaller than the expected under-compensation of the patent holder. Consequently, the loss of dynamic efficiency would likely outweigh the gain from static efficiency, and total consumer welfare is likely to decrease. On the other hand, if the patent holder is not a research-based firm, "it would be less likely that the patent holder has engaged in agreements to protect its intellectual property to enable it to bring out innovative products that will benefit consumers."[63]

However, caution should be exercised when attempting to use other criteria for evaluating an interim settlement agreement's effect on dynamic efficiency. Clearly, adopting economically inappropriate criteria will lead to incorrect conclusions on how an interim settlement agreement affects dynamic efficiency and consumer welfare.

For example, it may be tempting to compare the *ex post* profits the patent holder earned from the patented product before a settlement to the specific R&D cost the patent holder incurred bringing that product to the market.[64] Based on this comparison, one might argue that the larger the profits received by the patent holder prior to a settlement and the smaller the R&D necessary to obtain the patent, the smaller the impact from banning the interim settlement agreement on dynamic efficiency. The reasoning, although incorrect, would be that the patent holder was likely to have collected sufficient profits prior to the agreement to motivate its efforts to innovate, even if competition for this product occurred prior to the end of the pat-

60. *Id.*

61. *Id.* at 808.

62. *Id.*

63. *Id.* at 808–09.

64. Here, "ex post" refers to the time period after the relevant patent has been invented.

ent. There are several reasons why this comparison is economically incorrect in evaluating the settlement's impact on dynamic efficiency. First, it is economically inappropriate to compare profits from the sales of a particular drug covered by the patent in dispute to the specific R&D costs incurred for that drug. Research in the pharmaceutical industry is similar to drilling for oil. There are many dry holes, and the small percentage of cases where oil is found must pay for the dry holes if the search is to continue.

It is important to keep in mind that the development of new drugs is not only a costly enterprise that involves substantial R&D expenditures, it is also subject to substantial *ex ante* risk. Pharmaceutical firms synthesize thousands of chemical compounds for each one that reaches the market,[65] but only one of four drugs that enter clinical trials ultimately is approved by the FDA.[66] The average time between the synthesis of a new drug compound and FDA approval is an estimated 14.2 years.[67] According to a study published in the *Journal Of Health Economics*, only about thirty percent of drugs that reach the market produce revenues in excess of average development costs.[68]

Because of these substantial risks associated with new drug development, it is inappropriate to analyze the profits and R&D expenditures associated with a particular drug in isolation. Instead, a research-based firm's R&D investment must be viewed as a portfolio. A research-based company makes substantial investment in R&D, knowing that much of its R&D investment will not generate revenue. These companies, however, expect that a portion of its R&D efforts will result in successful new drug development, and the profits generated from the relatively small number of new drugs can cover the overall R&D expenditures of the firm. It is the research-based firm's commitment to the *overall* level of R&D expenditures that determines the likelihood of successful new drug development. Absent the overall R&D efforts, research-based firms may not have brought many successful drugs to the market, given the substantial risks involved. Therefore,

65. *See* Joseph DiMasi, *Trends in Drug Development Costs, Times, and Risks*, 29 DRUG INFO. J. 375, 381 (1995) (and the references cited therein).

66. *See* W. KIP VISCUSI, JOHN M. VERNON, & JOSEPH E. HARRINGTON, JR., ECONOMICS OF REGULATION AND ANTITRUST 823 (3d ed. 2000).

67. PHARM. RESEARCH & MFRS. OF AM., PHARMACEUTICAL INDUSTRY PROFILE 2001: A CENTURY OF PROGRESS 17 (2001).

68. Henry G. Grabowski & John M. Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. HEALTH ECON. 398, 399 fig.5 (1994). The authors compared, on an after-tax basis, the average net present value of net revenues to the average capitalized value of R&D cost.

comparing profits from the sales of the drug covered by the patent in dispute to the R&D costs associated with that drug does not provide an economically meaningful measurement of how an interim settlement agreement affects dynamic efficiency.

Second, the patent regime is a forward-looking incentive system, and therefore it is economically inappropriate to compare the *ex post* profits realized from the sales of the product covered by the patent in dispute to the research and development costs associated with the product. The patent regime is an incentive system that provides firms the appropriate incentive to engage in R&D and bring new products to market. The appropriate incentive provided by the patent regime depends on the level of patent protection firms *expect* to receive. A reduction in the level of patent protection firms *expect* to receive will reduce firms' incentive to engage in R&D in the *future* and to undertake *future* innovative activities. As a result, dynamic efficiency decreases. Therefore, the patent regime is essentially a forward-looking incentive system that encourages future R&D investments and future innovative activities. At any point in time, such as when settlement agreements occur, the effect of banning such agreements on dynamic efficiency from that time forward must be considered.

On the other hand, if one only focuses on a particular successful patented product that has already been introduced, then there is no real trade-off between static and dynamic efficiencies. Once a patent has been invented and the associated new product has been brought to the market, the specific dynamic efficiency effects associated with that patent are in the process of being realized because the product now exists and consumers are benefiting from that new product.[69] An *ex post* approach in effect would allow other firms to free-ride on *any* already invented patent that generated profits, hoping that the price for that product would be reduced and short-run consumer welfare would be increased from that time forward.

Under this approach, however, innovative firms would have much less incentive to invest in new products from that time forward, since these firms may not be able to recoup their investments. That is, if firms anticipate that their innovative activities will not be protected once each of their innovations have been accomplished, then not pro-

69. Patent protection can also indirectly affect the extraction of dynamic efficiency from products that have been introduced to the market, for example, through its impact on firms' incentive to market and promote the product after launch. For simplicity, this post product launch effect of patent protection is ignored in the discussion in this section. Taking into account this effect does not change the nature of the analysis.

viding patent protection will clearly discourage firms from engaging in future innovative activities, and this will harm society by reducing dynamic efficiency from that time forward. In fact, if one were to use the *ex post* approach limited to a single patent that has already been invented, it may be impossible to justify *any* patent protection.

Accordingly, the trade-off between static efficiency and dynamic efficiency under the patent regime is a trade-off between current static inefficiency and expected future dynamic efficiency at a given point of time and not retrospectively. It is clearly economically incorrect to engage in an *ex post* analysis limited to a single innovation and the products that contain the specific innovation.

Another criterion that might be erroneously used to evaluate an agreement's effect on dynamic efficiency involves examining consumer benefits generated from the specific patent in dispute. Such an approach might assert that the smaller the consumer benefits from the patent innovation, the smaller any impact on dynamic efficiency from disallowing the settlement. The intuition behind such an erroneous argument would be that an innovation yielding little or no additional consumer benefit related to the specific patent implied few dynamic efficiencies, and any static efficiencies from increased short-run competition would dominate.

However, since the patent regime is a forward-looking incentive system that encourages future R&D investment and innovative activities, the trade-off between static efficiency and dynamic efficiency is a trade-off between *current* static efficiency and *future* dynamic efficiency. Therefore, it is also economically inappropriate to evaluate this trade-off by examining the *ex post* consumer surplus generated from a given patent that has already been invented. The direct consumer benefit from a given patent that has already been invented may be small, and it may be zero if the product was not successful. However, if the level of patent protection is reduced, then it would discourage firms from making future R&D investments that could result in new patents and new products that can generate significant consumer benefits in the future.

Given our analyses of the appropriate economic tests of when an interim agreement is likely or unlikely to be procompetitive and pro-consumer, we now turn to other efficiency implications of interim settlements that relate to when these settlements should be considered within the scope of patent protection.

IV. Interim Settlement Agreement Can Be More Cost Efficient Than Formal Legal Proceedings for a Patent Holder to Protect Itself from the Risk of Under-Compensation

One important issue in evaluating the antitrust implications of interim settlements is whether an interim settlement is within the scope of a patent holder's patent right. For example, in remanding the district court's per se ruling of the Geneva Agreement, the Eleventh Circuit states,

> The effect of the Geneva Agreement on the production of Geneva's infringing generic terazosin product may have been no broader than the potential exclusionary effect of the '207 patent.[70]
>
> . . . .
>
> . . . When the exclusionary power of a patent is implicated, however, the antitrust analysis cannot ignore the scope of the patent exclusion.[71]
>
> . . . .
>
> The appropriate analysis on remand will likely require an identification of the protection afforded by the patents and the relevant law and consideration of the extent to which the Agreements reflect a reasonable implementation of these.[72]

We have shown that if the payments from a brand-name manufacturer to a generic in an interim settlement agreement are within a certain range, the interim agreement can protect the patent holder's patent right by reducing the risk of expected under-compensation. Therefore, the payments are consistent with being within the scope of the patent holder's patent right.[73] Other researchers have argued to the contrary. For example, Leffler and Leffler argue that interim settlement agreements exceed the exclusionary potential of patent holders' patent rights set by the current laws because "the patent holder is obtaining pre-trial exclusion without meeting the preliminary injunction criteria of the Federal Rules."[74]

---

70. Valley Drug Co., Inc. v. Geneva Pharms., Inc., 344 F.3d 1294, 1305 (11th Cir. 2003).

71. *Id.* at 1310.

72. *Id.* at 1312 (citation omitted). The Eleventh Circuit remanded the per se ruling on the settlement agreement between Abbott and Zenith as well. See *id.* at 1300–01 for a discussion of the Abbott/Geneva and Abbott/Zenith Agreements.

73. Langenfeld & Li, *supra* note 1, at 788, 797.

74. Leffler & Leffler, *supra* note 4, at 24 (citation omitted) (also arguing that interim settlement agreements that do not involve payments from the patent holders to the challengers should be permitted—see Leffler & Leffler, *supra* note 4, at n.43). For a similar argument, see Shapiro, *Settlements Between Rivals*, *supra* note 6, at 73.

Obtaining preliminary injunctions are costly and they are uncertain, so risk adverse patent holders in particular may find them not to be the most cost effective way to guard against valid concerns about under-compensation—even if the patent holder had a high likelihood of obtaining a preliminary injunction.[75] When the expected costs of different options to protect a patent holder from the risk of under-compensation are accounted for, an interim settlement agreement can be more cost efficient for preventing expected under-compensation than formal legal proceedings, such as a stay pending appeal. If an interim settlement agreement is more cost efficient than formal legal proceedings at preventing expected under-compensation, then this too suggests that the interim agreement is consistent with it falling within the scope of a patent holder's patent right.

To compare the costs of patent protection through interim settlements to that of alternative formal legal proceedings, public information on the Geneva Agreement may again be used as an example.[76] As an alternative to reaching the interim settlement agreement with Geneva, Abbott had the option of seeking a stay pending appeal after the district decision.[77] To illustrate that interim settlement agreements can be more cost efficient than formal legal proceedings, we analyze the conditions under which an interim settlement similar to the Geneva Agreement would be more cost efficient than a stay pending appeal.

First, assume that the patent holder would be under-compensated if the generic had entered the market during patent litigation and if the patent holder's patent had been found valid later. Figure 1 shows the possible different outcomes if the patent holder seeks a stay pending appeal and the cost for the patent holder associated with each outcome. Figure 2 shows the possible different outcomes under an interim agreement and the cost for the patent holder associated with each outcome.

75. This can be true even when a patent holder is risk neutral, as modeled below.

76. *See* discussion *supra* Part II (regarding the Geneva Agreement).

77. As discussed in Langenfeld & Li, *supra* note 1, at 796, a preliminary injunction does not eliminate the risk of under-compensation.

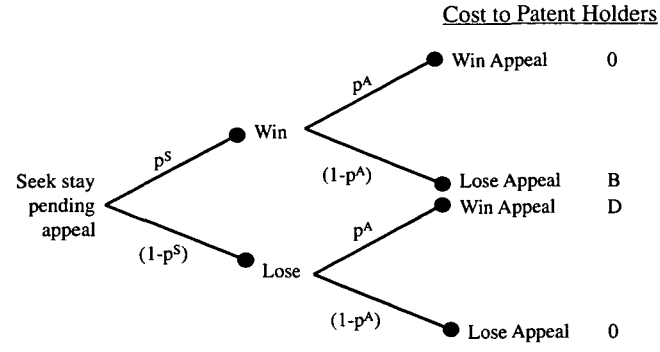

FIGURE 1

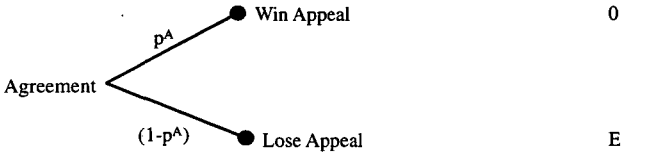

FIGURE 2

The terms in Figure 1 and 2 are defined as follows:

p^S: Probability of patent holder obtaining stay pending appeal
p^A: Probability that the patent holder will prevail in the patent infringement litigation
B: Total amount of bond the patent holder would have been required to post if patent holder had sought a stay pending appeal
D: Amount of under-compensation
E: Total payments by the patent holder made into the escrow between the district court decision and the Federal Circuit decision

From Figure 1, the expected cost for the patent holder of seeking a stay pending appeal is:

(6) $C_S = p^S \cdot (1 - p^A) \cdot B + (1 - p^S) \cdot p^A \cdot D$

The first term on the right hand side in equation (6), $p^S \cdot (1 - p^A) \cdot B$, is the expected value of the patent holder losing the bond it posted if the patent holder obtained a stay pending appeal, but then lost the appeal at the Federal Circuit. The second term in equation (6), $(1 - p^S) \cdot p^A \cdot D$, is the expected under-compensation of the patent holder if the patent holder was denied a stay pending appeal and the generic entered the market after the district court decision, but the patent holder then prevailed in the Federal Circuit.

From Figure 2, the expected cost for patent holder under the interim agreement is:

(7) $C_A = (1 - p^A) \cdot E$

Under the agreement, the only cost for the patent holder is the loss of the escrow if it loses the appeal.

Taking a difference between equations (6) and (7):

(8) $C_S - C_A = (1 - p^A) \cdot (p^S \cdot B - E) + (1 - p^S) \cdot p^A \cdot D$

From equation (8), if the bond the patent holder is required to post, B, is greater than its total escrow payment, E, then equation (8) is greater than zero. This is true even if the patent holder can obtain a stay pending appeal with certainty (i.e., if p^S is equal to 1). That equation (8) is positive implies that it is more cost effective for the patent holder to use the interim agreement to protect itself from the risk of under-compensation, even if the patent holder can obtain a stay pending appeal with certainty. As shown in the Appendix, equation (8) remains greater than zero if p^S is less than 1, as long as the bond the patent holder is required to post, B, is greater than its total escrow payment, E.

In general, the posted bond should cover the profits the generic could have made from its generic drug sales between the district court decision and the Federal Circuit decision if the generic had entered after the district court decision. In most cases, this figure can be estimated, and compared to the size of the total escrow payment. Therefore, given the existence of risk of under-compensation, a sufficient condition for the interim agreement to be more cost effective than a stay pending appeal is that the bond the patent holder would be required to post, B, is greater than its total escrow payment, E, and this can be tested from observable information in any given case.[78]

As this illustrative analysis suggests, an interim settlement agreement can be more cost efficient than a stay pending appeal for the patent holder to protect itself against the risk of under-compensation, even if the patent holder is certain it would win a stay pending appeal. Since most patent cases are settled,[79] settling patent disputes through settlement agreements is typically viewed as a part of a patent holder's right,[80] and the parties involved are encouraged to settle the dispute in the most efficient way. Accordingly, if an interim settlement agreement is demonstrated likely to be more efficient than alternative formal legal proceedings in any given case, then this is another reason why the specific interim settlement agreement should fall within the scope of a patent holder's patent right.

78. Because D is positive if there is risk of under-compensation, (4) can still be positive even if B is smaller than E.

79. *See* Hovenkamp et al., *Anticompetitive Settlement*, *supra* note 4, at 1720.

80. We are not arguing that all patent settlements are within the scope of a patent holder's patent right.

Conclusion

The competitive implications of so called "reverse payments" in patent litigation settlements in the pharmaceutical industry have drawn a great deal of attention and have generated a number of articles in the last few years. The economics of these agreements are complex and vary by the specific type of agreement and the facts each case presents. There is disagreement over when these agreements, on balance, are anticompetitive and when they can improve overall consumer welfare. Accordingly, these cases do not lend themselves to extremely broad generalizations, nor should they be condemned as per se illegal or virtually per se illegal. In this Article we have described and developed some specific measurable tests for determining when interim settlements with payments from a patent holder to a would-be generic entrant can be justified by the potential for undercompensation to the patent holder and when they cannot. Similarly specific tests should be applied to other types of settlements involving "reverse payments" before condemning such agreements.

Appendix

Differentiate equation (8) with respect to p^S:

$$(9)\quad \frac{d(C_S - C_A)}{dp^S} = (1 - p^A) \cdot B - p^A \cdot D$$

The first term in equation (9), $(1 - p^A) \cdot B$, represents the expected premium the patent holder is paying to insure the expected under-compensation, which is $p^A \cdot D$, the second term in equation (9). Since it is only in the holder's economic interest to post the bond if the expected premium is smaller than the expected under-compensation, (8) should be less than or equal to zero.* This implies that $(C_S - C_A)$ is a decreasing function of p^S. In other words, the smaller the p^S is, the larger the $(C_S - C_A)$ is. Since we know that when p^S is equal to 1, (4) is greater than zero, as p^S decreases, $(C_S - C_A)$ will increase. Therefore, $(C_S - C_A)$ is always greater than zero, which implies that the interim agreement is the more cost effective alternative than seeking a stay pending appeal for a patent holder to protect itself from the risk of under-compensation if as the bond patent holder is required to post, B, is greater than its total escrow payment, E.

* Given an estimate of under-compensation and the size of the bond a patent holder is required to post, one can analyze under what conditions a patent holder will be willing to post the bond to insure against the risk of under-compensation.