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BY FAX AND FIRST-CLASS MAIL

Federal Trade Commission
Office Of The Secretary
600 Pennsylvania Ave., N.W.
Washington, DC 20580

Abbott Laboratories and Geneva Pharmaceuticals, Inc., File No. 981-0395

Comment on Proposed Consent Order

I. Introduction

This comment urges the Commission to clarify a number of issues raised by its recent enforcement actions challenging pharmaceutical patent settlements. The Commission's press release recognizes that "the appropriate parameters of permissible conduct in this area" are now uncertain and that "there may be market settings in which similar but less restrictive arrangements could be justified." Accordingly, the Commission has invited wide-ranging comment on the subject of patent settlement agreements.¹

Understandably, the Commission's actions and analysis are limited to the facts of the cases before it. However, the proposed consent orders settling charges against Geneva Pharmaceuticals, Inc. and Abbott Laboratories, glossed by the Commission's administrative

¹ The Commission's March 16, 2000 Press Release states: "We anticipate that the development of a full factual record in the administrative proceeding, as well as the public comments on these consent orders, will help shape further the appropriate parameters of permissible conduct in this area, and guide other companies and their legal advisers" (emphasis added).

Complaint against Hoechst and Andrx, have created a climate of uncertainty about settlement practices and provisions that were previously thought to be lawful and frequently pro-competitive.

The need for clarification is underscored by the Commissioners' Statement accompanying the consent orders. There the Commissioners raise the prospect of severe remedies, including "disgorgement of illegally obtained profits," in future enforcement actions against "arrangements comparable to those addressed in the present consent orders." With this specter of huge monetary penalties looming over patent settlements, it is critically important for the Commission to provide more certainty about the specific features of the Abbott-Geneva and Hoechst-Andrx settlements that might trigger future enforcement actions, so that patent litigants can have a better understanding of how the Commission might analyze settlements presenting different facts.²

II. The Critical Allegations Underlying The Commission's Recent Enforcement Actions.

The Commission's two recent enforcement actions challenge agreements to settle patent litigation between the owner of a pioneer drug patent and the first company to file an Abbreviated New Drug Application ("ANDA") to market a generic version of the patented drug (the "First ANDA Filer"). The Commission's complaints appear to center on five key facts present in those cases:

- An agreement that the First ANDA Filer will delay commercial marketing of its generic version for some period of time;
- Payment of a substantial amount of money from the patent owner to the First ANDA Filer;
- An agreement that the First ANDA Filer will not market non-infringing products;
- An agreement that the First ANDA Filer will not waive or assign the Hatch-Waxman 180-day exclusivity, allegedly creating a "bottleneck effect" that prevents entry by other competitors; and

² Numerous other settlement agreements with first ANDA filers have been reported in the press, but have so far not resulted in Commission challenges. If the Commission has decided that certain settlement agreements do not warrant challenge, it would be helpful for patent litigants and their legal advisers to understand the Commission's analysis in reaching that conclusion.

- An agreement not to dismiss the litigation.

It is not at all clear how the Commission would view other patent settlements that do not involve all of these elements or that involve some or all of these elements in a different factual context. What is clear is that parties trying to structure future patent settlements to avoid Commission challenge will find the legal and economic analysis articulated in the Commission's recent actions insufficient to guide their actions. This difficulty is compounded by assumptions that appear to underlie the Commission's analysis and may run counter to accepted settlement practices and judicial policies. If this is the case, the Commission should articulate these assumptions more clearly and present its analysis more fully.

III. Summary of Comments

The following comments do not take a position, one way or the other, on the merits of the two cases brought by the Commission. They are rather intended to point out the difficulties faced by companies trying to structure future settlements of patent litigation that will comport with the antitrust laws, the Commission's enforcement intentions, the policies underlying the patent laws, and judicial policies favoring settlement of litigation. The comment focuses on five areas of difficulty:

- The Commission's inadequate discussion of elimination of risk as a positive benefit in patent settlements.
- The need to clarify the types of benefits which may be inherently suspect if received by the alleged infringer in a settlement.
- The extent to which the Commission sees competitive concerns in settlements in which the alleged infringer does not any receive payment or receives payment that does not exceed its risk-adjusted anticipated profits.
- The extent to which the Commission's consent order, despite its literal language, intends to prohibit settlement of legitimate patent disputes that are not the subject of the litigation at hand.
- The extent to which the Commission sees an antitrust difference between interim settlements of pending litigation and final settlements.

IV. Significant Issues Requiring Commission Clarification

A. The Commission Should Expressly Recognize The Importance of Eliminating Risk As A Positive Benefit In Patent Settlements.

Settlement of patent litigation eliminates risk on both sides. In doing so, it promotes more innovation and investment by the patent owner. And in allowing the generic competitor who challenges a patent the flexibility to craft a litigation solution that may permit entry without risk, a patent settlement may also increase the likelihood of generic competition.

1. Importance To Patent Owner of Eliminating Risk

For the patent owner, a litigation settlement eliminates the risk that the patent will be held invalid, unenforceable, or not infringed. Litigation is an imperfect process, with unpredictable results. The vagaries of judges and juries will produce erroneous results in a certain percentage of cases. Holders of strong patents will occasionally lose when in fact they should win. The risk of an unjust result to the patent owner is increased by the law of collateral estoppel, under which the patent owner suing multiple infringers must win every case, while the infringers need only win once.³

The elimination of this kind of risk has potential pro-consumer benefits that operate directly in the short term and indirectly in the long term. In the short term, elimination of risk may encourage the patent holder to devote more resources to marketing efforts, including efforts to educate physicians and consumers about the benefits of the product, and to developing improvements to the patented product. In the long run, a legal system which discourages patent settlement agreements will promote uncertainty about the value of patent rights and discourage investment in research.⁴

³ A finding of invalidity or unenforceability in a single case will preclude the patent owner from relitigating that issue against any other infringer or licensee. *See Blonder-Tongue Laboratories, Inc. v. Univ. of Illinois Fdn.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). The infringer, on the other hand, is not bound by any adverse finding on those issues in a previous case in which it is not in privity with the losing party. *Blonder-Tongue, supra*.

⁴ *See generally*, R. Blair & T. Cotter, "An Economic Analysis of Seller and User Liability In Intellectual Property Law," 68 U.Cin.L.Rev. 1, 17-19 (1999).

2. Importance To Generic Competitor of Eliminating Risk

Eliminating risk is equally important to the generic competitor. In addition to sizable litigation costs, the generic competitor faces enormous risks. If it decides to launch its product prior to a final decision on the merits of the infringement suit, the generic competitor risks a huge potential damage exposure,⁵ in addition to a possible final injunction forcing the product off the market. This risk is substantial even if the generic competitor wins in the district court. In more than fifty cases in the last three years alone, infringers who have prevailed in the district court on the grounds of patent invalidity, unenforceability or non-infringement have suffered reversal on those issues in the court of appeals.⁶

On the other hand, if the generic competitor delays launch pending a final decision in the litigation, it risks a long, drawn-out battle, with uncertain prospects of success. More importantly, a First ANDA Filer runs the risk of losing its 180-day exclusivity period if it does not launch following a district court decision of invalidity or non-infringement.⁷

3. Need For Clarification

The Commission's abbreviated discussion of efficiencies in the Abbott-Geneva matter does not refer to the benefits of eliminating these kinds of risks. The Commission may

⁵ The patent owner can recover not only lost profits, measured either by lost sales or price erosion, but also prejudgment interest "where necessary to afford the plaintiff full compensation for infringement." *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654 (1983); D. Chisum, *Chisum on Patents* § 20.03(1). These damages could easily run into the hundreds of millions of dollars for a significant drug. In addition, the damage award may be trebled, and attorney's fees added, if the infringement is found to be willful. 35 U.S.C. §284. Infringement damage awards in the hundreds of millions of dollars are not unprecedented. *See Polaroid Corp. v. Eastman Kodak Co.*, 17 U.S.P.Q.2d 1711 (1991) (\$800 million damage award).

⁶ *See* cases cited in Appendix.

⁷ Differing case law and FDA positions have created confusion about when a First ANDA Filer's 180-day exclusivity period starts. The FDA's current position is that it starts with a favorable *final* decision (after all appeal rights are exhausted) for ANDAs filed before March 30, 2000 and with a favorable *district court* decision for ANDAs filed after that date. *See* fn. 19, *infra*. The courts are split on the question. *Compare Granutec, Inc. v. Shalala*, 139 F.3d 889 (4th Cir. 1998) (180 days runs on final decision) *with Mylan Pharmaceuticals, Inc. v. Shalala*, 81 F.Supp.2d 30 (D.D.C. Jan. 4, 2000) (180 days runs on district court decision).

have felt this was not a significant factor in the context of the interim settlement in that case.⁸ On the other hand, patent settlements can be structured which eliminate risk and facilitate entry, although in some cases that entry may be delayed. By remaining silent on the benefits of eliminating litigation risk, the Commission may be deterring certain kinds of beneficial settlement agreements. It is therefore important for the Commission to articulate its views on the possible benefits of risk elimination in interim and final settlements.

Underlying the Commission's discussion of efficiencies is a sense that the elimination of risk, if it is entitled to any consideration at all, is far less important than forcing an adjudication of patent rights. The Commission's rejection of efficiencies in Abbott-Geneva discredits interim settlements in part because they avoid judicial resolution of the merits. It is unclear whether this was a significant element in the Commission's analysis of interim settlements. Even less clear is the extent to which the Commission views avoiding judicial resolution -- the very purpose of all settlements -- as a negative factor in final, as opposed to interim, settlements.

An enforcement stance that puts too high a premium on adjudicative resolution may not represent the soundest policy. To begin with, it is clearly contrary to the strong judicial policy favoring settlement of litigation, and particularly patent litigation. In the words of one court:

Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld whenever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute.⁹

⁸ The Hoechst-Andrx settlement agreement did give Andrx an option which would have allowed it to sell a once-a-day diltiazem, thus eliminating the risk that if it lost the litigation, Andrx would have been off the market altogether until Hoechst patent expired.

⁹ *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976); *see also Bradley v. Chiron Corp.*, 136 F.3d 1317, 1322 (Fed. Cir. 1998); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 476 (Fed. Cir. 1991); *Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979); *General Tire & Rubber Co. v. Firestone Tire & Rubber Co.*, 349 F.Supp. 333, 344-45 (N.D. Ohio 1972). In this regard, one might question the Commission's suggestion in the two recent cases before it that the settlement of litigation produced only "private benefits to both parties." Clearly, the conservation of judicial resources is a public benefit.

By impelling generics to make an irrevocable, “if you file an ANDA, you must litigate to the bitter end” decision, such an enforcement stance might also discourage generic competition. Limiting the generic competitor’s settlement options will make it difficult for the generic competitor to cut its losses once the litigation is underway. This all-or-nothing wager on the litigation outcome effectively increases the generic competitor’s cost and risk of filing an ANDA and challenging the pioneer patent, and may deter some generic manufacturers from taking that risk.

An antitrust principle that penalizes settlements also diminishes the value of the patent holder’s intellectual property by running up litigation costs and increasing risk and uncertainty. The long-range effect will be to decrease investment in innovation and marketing investment in new products and thus run counter to the principles underlying the patent and antitrust laws.¹⁰

B. The Commission Should Clarify What Constitutes A Suspect Payment of Value To The Alleged Infringer.

The Commission’s recent enforcement actions target the payment of substantial amounts of money to the alleged infringer as a critical element of the asserted violation. Consistent with this allegation, the Abbott-Geneva consent order and the Notice of Contemplated Relief accompanying the Hoechst-Andrx Complaint would require notification to the Commission of any settlement in which the alleged infringer agrees not to market the alleged infringing product and receives “anything of value” from the patent owner.¹¹ The Commission’s treatment of this issue raises two questions.

The first relates to the receipt by First ANDA Filers of non-monetary consideration that may be considered “something of value,” but could be pro-competitive. An example would be a license under the patent that permits a generic competitor to enter at a later date, but still before the patent expires. Such a license would clearly be valuable to the licensee.

¹⁰ See R. Blair & T. Cotter, *supra*, note 4.

¹¹ The Abbott-Geneva Complaint suggests that the concern is with payments in excess of the First ANDA Filer’s projected profits from entry (and thus a possible sharing of monopoly rents attributable to exclusion of later ANDA filers). However, the Hoechst-Andrx complaint contained no such allegation. The Commission might want to clarify whether the concern is with payments in excess of the First ANDA Filer’s expected return from marketing the infringing product (which may be easier to characterize as sharing of monopoly rents from the exclusion of others) or with payments that do not exceed the First ANDA Filer’s expected return (which could more easily be characterized as a compromise of a legitimate, disputed claim in which the alleged infringer is compensated for giving up the possibility that it would have defeated the claim for injunctive relief and been able to enter).

It would also confer significant efficiency and competitive benefits by eliminating the generic competitor's exposure to the risk of an injunction and damages and permit competition earlier than if the generic competitor had lost the litigation. The Commission's treatment of Andrx's option to take a later license in the Hoechst-Andrx complaint,¹² raises the question whether the Commission's negative views on the option for a deferred license are limited to the particular context of that agreement, or proceed from a more general hostility to deferred licenses in any context. This uncertainty should be clarified, since, as discussed below, deferred licenses are generally lawful and may be pro-competitive.

A second issue concerns the following dilemma. As part of an agreement to permit early entry by the generic at some future date within the patent term, the patent owner may grant a royalty-bearing license or agree to supply the generic competitor with the patented product or its active ingredient. Normally, setting a low royalty rate or transfer price would be viewed as pro-competitive. Consistent with this view, paragraphs 25 and 35 of the Hoechst-Andrx Complaint suggest that high license fees in such a setting would make the generic competitor's entry "competitively less significant than entry without the requirement to pay such fees." Yet if the royalty or supply is too low, the patent owner could then be charged with paying "something of value" to the generic competitor in the form of an indirect subsidy for "staying off the market."

The proposed Abbott-Geneva consent order does not condemn outright all payments of value where the alleged infringer delays its product launch; it merely gives the Commission an opportunity to review such agreements. As a remedy for a past violation of the law, this may be entirely appropriate. But other patent litigants trying to craft settlements need the Commission to rectify the inconsistency in an approach which seems hostile to arrangements both for being too generous and for being not generous enough to the alleged infringer.

C. The Commission Should Clarify Its Position With Respect To Licenses for Later Entry Where The Generic Competitor Receives No Payment.

1. Absent A Hatch-Waxman "Bottleneck" Effect, Licenses For Later Entry Within The Patent Term Are Presumptively Lawful And Often Pro-Competitive.

One potentially pro-competitive method of settling patent litigation is to give the potential infringer a license to enter at some future date within the patent term. This represents a compromise between the possibility that the patent owner might win, keeping the generic off the market altogether, and the possibility that the generic competitor might win and enter the market sooner.

¹² Complaint, *Hoechst Marion Roussel, Inc., et al.*, Dkt. No. 9293, ¶¶ 25, 35 (March 16, 2000).

Regardless of the “external” effect of the Hatch-Waxman Act, in which a First ANDA Filer’s delayed entry could also delay entry by later-ANDA-filing generic competitors, such an arrangement would be pro-competitive as against the possibility that the generic competitor (1) would not have risked entry prior to a final court decision, or (2) may have entered before final resolution but then lost the litigation and been forced off the market for the rest of the patent term.

More importantly, such a license would generally be considered lawful under existing case law. A license that allows the licensee to practice the patented art at a later date within the patent term, but does not restrict the licensee’s conduct outside the scope of the patent, is simply a license of less than all of the patent owner’s rights -- in this case of the right to practice the patented art for the entire life of the patent.¹³ As such, it operates entirely within the scope of the patent. The Court of Appeals for the Federal Circuit has clearly stated that such restrictions cannot constitute patent misuse or an antitrust violation unless they have been declared per se unlawful by the Supreme Court. As to patent misuse, the Court’s position is unequivocal:

Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [misuse] inquiry.¹⁴

And if that ends the misuse inquiry, it also ends the antitrust inquiry. Where the Federal Circuit determines that a patent holder’s conduct within the scope of the patent “does not amount to patent misuse, the same conduct cannot support a judgment that [the defendant’s] conduct violated the Sherman Act.”¹⁵

Following these precedents, the Federal Circuit would likely find that deferred licenses which operate wholly within the scope of the patent are lawful.¹⁶ If so, the only

¹³ Because (absent the Hatch-Waxman effect) the only restriction from a delayed license within the patent term operates wholly within the scope of the patent, it is analogous to a field-of-use or territorial restriction, which seldom create antitrust problems.

¹⁴ *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992); *see also B. Braun Medical, Inc. v. Abbott Laboratories*, 124 F.3d 1419, 1426 (Fed. Cir. 1997).

¹⁵ *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 873 (Fed. Cir. 1997), *cert. denied*, 525 U.S. 815 (1997).

¹⁶ Moreover, a deferred license does not necessarily mean delayed entry. Given the length of time of most patent cases to get to trial, the frequency with which initial decisions favoring the infringer are overturned on appeal, and the ensuing time required for a

potential antitrust problem with settlements incorporating this type of license arrangement would have to stem from either (1) the fact that the license arises out of a litigation settlement in which validity and infringement are at issue, or (2) the Hatch-Waxman effect.

With respect to the settlement context, it is clear that the patent owner has a legal right to sue an infringer, so long as the suit is not “objectively baseless.”¹⁷ It would seem anomalous to guarantee the right to bring such a suit and then deny the ability to settle it for relief that does not exceed what the patent owner could have received if it had continued the suit and won.

As for the Hatch-Waxman effect, this occurs solely in the pharmaceutical industry where a marketing delay by the first ANDA filer may delay entry by later potential entrants. For reasons discussed in the next section, this should not automatically condemn a deferred license settlement.

2. Where The ANDA First ANDA Filer Receives No Payment Or Other Valuable Consideration, A Delayed License Should Not Be Unlawful.

a. The Critical Differences Between Settlements In Which The First ANDA Filer Receives Payment And Those In Which No Payment Is Received.

There is a vast difference between a settlement in which the patent owner gives money or other consideration to the First ANDA Filer and one in which it does not. Where the First ANDA Filer receives payment or other valuable consideration and delays commercial marketing, the possibility exists that the payment could represent a sharing of monopoly rents attributable to the exclusion of other generic competitors from the market.¹⁸ This skews the First ANDA Filer’s incentives in a way that a settlement without such a payment would not. Absent such consideration, the First ANDA Filer will agree to a settlement based solely on a risk-reward evaluation of the odds of winning or losing its case. The better the odds of winning, the less inclined the generic will be to settle for any later entry; the worse its odds, the more inclined it

retrial, such a license could well result in entry sooner (and with much less uncertainty) than if the generic competitor had successfully defended the infringement suit.

¹⁷ *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*, 508 U.S. 49, 60-61 (1993).

¹⁸ Payment of consideration to the generic does not in every case constitute a sharing of monopoly rents. It would depend on the extent to which the consideration does not represent payment for other legitimate benefits received by the patent owner or as partial compensation for the generic competitor’s giving up a percentage chance of winning the litigation.

will be to accept a license for later entry. This is a standard compromise -- the hallmark of any litigation settlement -- in which the settlement falls within the range of potential outcomes. It does not involve the sharing of any rents stemming from the exclusion of other competitors.

b. Delay In First-Filer's Entry Does Not Always Delay Generic Competition.

As the Commission has noted, a settlement that delays the First ANDA Filer's entry into the market can operate as a "bottleneck" delaying entry by other generic competitors. This is accomplished by a provision in the Hatch-Waxman Act which prohibits the FDA from issuing its regulatory approval to later-filing generic applicants until 180 days after the earlier of two triggering events. One is commercial marketing of the First ANDA Filer's approved drug. The second is a "decision of a court in an action ... holding the patent ... invalid or not infringed...." 21 U.S.C. §355(j)(5)(B)(iv)(II).¹⁹

While a settlement which delays the First ANDA Filer's entry prevents operation of the "commercial marketing" trigger, it does not prevent the "adverse court decision" trigger. Later ANDA filers are therefore able to trigger the 180-day exclusivity period by successfully litigating their own case on validity and infringement. If the later-filer's suit is proceeding more quickly than the suit against the First ANDA Filer and the later filer wins, the settlement with the First ANDA Filer will not cause any delay in the entry of later-ANDA-filing generic competitors.²⁰ There will be no anti-competitive "bottleneck."

The Commission might also comment on how the FDA's proposed new rules on the 180-day exclusivity period would, if promulgated, affect the antitrust analysis. Under the

¹⁹ In this regard, it is worth noting the Food and Drug Administration's recent announcement that for ANDAs filed after March 30 of this year it will interpret the Hatch-Waxman provision requiring it to issue ANDAs to subsequent filers upon a court decision that the patent is invalid and not infringed, as referring to a district court decision, rather than a final decision after all appeals are exhausted. 65 Fed. Reg. 16,922-23 (March 30, 2000). As to ANDAs issued prior to March 30, 2000, however, the FDA will adhere to its former practice of issuing subsequent ANDAs only after a final decision. For ANDAs subject to the new rule, this means that the First ANDA Filer faces a dilemma if it wins in the district court. If it launches immediately, it runs the risk of massive damages if the decision is overturned on appeal (a not infrequent phenomenon, *see* Appendix). If it does not launch, it will lose some or all of its 180-day exclusivity. This would increase the incentive of the generic competitor to settle rather than litigate.

²⁰ Of course, if the later filer loses, it would never have been able to enter in the first place, so any delay in the "commercial marketing" trigger would have had no adverse competitive effect.

FDA proposal, when a subsequent generic has tentative approval and is prevented from entering only by the 180-day exclusivity period, there will be a 180-day trigger period after which the 180-day exclusivity period will begin to run regardless of whether there has been a court decision or the First ANDA Filer has launched.²¹ The Staff has suggested that this provision would mitigate the “bottleneck effect,”²² but neither the Staff nor the Commission has indicated how it would affect the antitrust analysis.

c. Possible Adverse Consequences of Effectively Forcing First ANDA Filers To Waive Their Exclusivity As A Settlement Condition.

The parties could eliminate the Hatch-Waxman effect of their settlement altogether if the First ANDA Filer agrees as part of the settlement to waive its 180-day exclusivity right. While this may seem like an elegant short-term solution, the long-run implications of such a requirement are less clear. Congress believed that the 180-day exclusivity created a valuable incentive for generic competitors to challenge pioneer patents. Assuming Congress was correct, this incentive will become less effective in the future should the Commission begin to require a waiver of exclusivity in any settlement short of a license for immediate entry.²³ If the effect of the Commission’s enforcement policy will in fact be to force the First ANDA Filer to surrender this right, the Commission should only do so after evaluating its effect on the incentives built into Congress’ statutory scheme.

²¹ 64 Fed. Reg. 42873 (Aug. 6, 1999).

²² “By adding another triggering event -- tentative approval for a second generic drug -- that is not within the control of either the first-filing ANDA applicant or the branded company, the Proposed Rule would reduce the ability and incentive of generic and branded companies to enter into agreements that can forestall generic competition.” “Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission,” *In re: 180-day Beneric Drug Exclusivity for Abbreviated New Drug Applications*, <http://www.ftc.gov/be/v990016.htm>, p. 5.

²³ Although one could argue that the only purpose of the incentive was to encourage generic competitors to litigate to final resolution, the Commission might ask itself whether the best model for promoting earlier generic competition is in fact one that forces the generic competitor to litigate to the death, with the risk of fewer generic entrants if they lose, or one that may promote more entry with a self-calibrating settlement mechanism that will produce earlier entry the stronger the generic’s case. See discussion at pp. 10-11.

d. Importance of Relying On Credible Evidence To Determine The Probability of Generic Entry.

One of the key facts underlying the Commission's competitive analysis in the two recent cases was its factual determination that the generic competitor would have entered earlier if there had been no interim settlement agreement. While such a conclusion may have been warranted on the facts of those cases, in assessing the likelihood of generic entry prior in future cases, the Commission should distinguish between litigation posturing and real probability of entry. The only credible evidence of when the generic was likely to enter is tangible steps to launch, not mere declarations that the alleged infringer "has a strong case" against the patent owner or a paragraph (iv) certification to the FDA that the generic product does not infringe a valid patent. Such self-serving declarations are not credible, simply because no infringer would ever admit (externally or internally) to having a weak patent case, which would expose the infringer to treble damages for willful infringement. *See* 35 U.S.C. §284.

e. Summary

The circumstances under which the Commission should condemn a settlement which grants the First ANDA Filer a late license within the patent term, particularly where the First ANDA Filer receives no money or other suspect consideration, will depend on numerous variations in fact patterns and complex policy cross-currents. To the extent possible, the Commission should provide guidance on how it intends to treat these complexities going forward. At a minimum, it should make clear that in many of these variations, which involve lesser restraints than those presented in Abbott-Geneva and Hoechst-Andrx, it will not seek disgorgement-type relief.

D. The Commission Should Clarify Its Position On Settlements Of Patent Disputes Outside The Context of Pending Litigation.

Read literally, Paragraph II.B. of the Abbott-Geneva proposed consent order would prohibit parties from settling genuine patent disputes before they are in litigation. Presumably the Commission did not intend to create such a rule, either for Abbott or Geneva or anyone else. Indeed, the Analysis To Aid Public Comment ("AAPC") suggests that the Commission's concern is with agreements not to market "non-infringing" products, *i.e.*, products that do not infringe *any* intellectual property owned by the plaintiff, not just the intellectual property that may be the subject of that particular litigation.²⁴ The Commission should confirm that it sees nothing inherently wrong with the settlement of genuine patent disputes that are not currently in litigation.

²⁴ This reading of the Paragraph II of the consent order finds further support in the AAPC's statement that the notification procedures of Paragraph IV were intended to apply to "situations in which no litigation has been brought."

E. The Commission Should Clarify The Apparent Distinction Being Drawn Between Interim Settlements And Final Settlements.

The Commission has devised a potential intervention mechanism for interim settlements, with no corresponding mechanism relating to final settlements. The AAPC bases the distinction on the assumption that there is necessarily judicial involvement in an interim settlement, but not in a final settlement. The basis for this assumption is unclear, since there is no requirement that an interim settlement which avoids the need for a preliminary injunction be presented to the court for approval. The question then arises whether the Commission's different treatment of interim and final settlements in the consent order stems from a belief that interim settlements in this context have more anti-competitive consequences than final settlements. If so, the rationale for this view should be clarified for the benefit of parties entering into final patent settlements.

V. Conclusion

The Commission's enforcement action against the Abbott-Geneva and Hoechst-Andrx interim settlements, and its underlying competitive analysis, raise a number of questions about provisions in settlement agreements that have traditionally been viewed as lawful and often pro-competitive. Additionally, the Commission has warned that it might seek massive monetary penalties for future settlements "comparable to those addressed" in the Abbott-Geneva consent orders. For the reasons discussed, the Commission has not made clear what it means by a settlement "comparable to those addressed" in those orders.

The threat of severe penalties for conduct which is not clearly defined puts the parties wanting to settle patent litigation in an untenable position. Whether the Commission decides to issue a final consent order in the Abbott-Geneva matter or not, it should use the occasion to provide as much clarification as possible of its competitive analysis. At a minimum, it should provide more definitive guidance on the types of settlements that might warrant an enforcement action for substantial monetary sanctions.

Respectfully submitted,

Stephen A. Stack, Jr.

APPENDIX

Optical Disc v. Del Mor, 2000 WL 354753 (Fed. Cir. Apr. 7, 2000)

Affirmed in part, reversed and remanded in part.

Helifix, Ltd. v. Blok-lok, Ltd., 2000 WL 354763 (Fed. Cir. Apr. 7, 2000)

Affirmed in part, reversed and remanded on invalidity issue.

Ransomes, Inc. v. Great Dane Power Equip., Inc., 2000 WL 347931 (Fed. Cir. Apr. 4, 2000)

Reversed and remanded non-infringement holding.

IMS Tech., Inc. v. Haas Automation, Inc., 2000 WL 306986 (Fed. Cir. Mar. 27, 2000)

Remanded non-infringement holding.

Clearstream Wastewater Systems v. Hydro-Action, Inc., 2000 WL 306989 (Fed. Cir. Mar. 27, 2000)

Vacated and remanded non-infringement holding.

Vivid Tech., Inc. v. American Science and Engineering, Inc., 200 F.3d 795 (Fed. Cir. 1999)

Reversed and remanded summary judgment on non-infringement.

Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374 (Fed. Cir. 1999)

Reversed invalidity holding.

Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322 (Fed. Cir. 1999)

“System” claim not invalid for obviousness.

Overhead Door Corp. v. Chamberlain Group, Inc., 194 F.3d 1261 (Fed. Cir. 1999)

Reversed in part non-infringement holding.

Micro Chemical v. Great Plains Chem., 194 F.3d 1250 (Fed. Cir. 1999)

Seiko Epson Corp. v. NU-KOTE Int’l., Inc., 190 F.3d 1360 (Fed. Cir. 1999)

Reversed invalidity holding.

Nova Biomed. Corp. v. I-Stat., 1999 WL 693881 (Fed. Cir. 1999)

Reversed summary judgment on equivalents and remanded.

Bickerstaff v. DR Shrink, Inc., 1999 WL 693884 (Fed. Cir. 1999)

Reversed summary judgment on non-infringement.

Antonious v. Spalding & Evenflo Co., Inc., 1999 WL 777450 (Fed. Cir. 1999)

Affirm non-infringement, reversed invalidity.

Suntiger, Inc. v. Scientific Research Funding, 189 F.3d 1327 (Fed. Cir. 1999)
Reversed summary judgment on invalidity.

Oney v. Ratliff, 182 F.3d 893 (Fed. Cir. 1999)
Reversed and remanded summary judgment for invalidity.

Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999)
Reversed and remanded summary judgment on invalidity.

Hockerson-Halberstadt v. Converse, Inc., 183 F.3d 1369 (Fed. Cir. 1999)
Reversed and remanded invalidity holding.

Smiths Indus. Med. Syst. v. Vital Signs, Inc., 183 F.3d 1347 (Fed. Cir. 1999)

Burke, Inc. v. Bruno Indep. living AIDS, 183 F.3d 1334 (Fed. Cir. 1999)
Vacated and remanded non-infringement holding.

Lenclo Racing Co. v. Jolliffe, et al. 1999 U.S. App. Lexis 14239 (Fed. Cir. June 29, 1999)
Affirmed in part, reversed and remanded in part.

Pitney Bowes v. Hewlett Packard, 182 F.3d 1298 (Fed. Cir. 1999)
Vacated and remanded non-infringement holding.

Scaltech, Inc. v. Retec/Tetra, 178 F.3d 1378 (Fed. Cir. 1999)
Vacated and remanded summary judgment on invalidity.

GE v. Nintendo, 179 F.3d 1350 (Fed. Cir. 1999)
Reversed invalidity for anticipation.

Termslogic Corp. v. Teleengineering, 1999 U.S. App Lexis 8238 (Fed. Cir. Apr. 30, 1999)
Vacated and remanded invalidity holding.

Karlin Tech. v. Sofamol Danek Group, 177 F.3d 968 (Fed. Cir. 1999)
Reversed non-infringement holding and granted summary judgment for infringement.

AT&T Corp. v. Excel Communications, 172 F.3d 1352 (Fed. Cir. 1999)
Vacated and remanded invalidity holding.

Sagh Controls v. Talon, 1999 U.S. App. Lexis (Fed. Cir. Jan. 27, 1999)
Vacated and remanded invalidity holding.

Personalized Media Communications v. U.S. I.T.C., 161 F.3d 696 (Fed. Cir. 1998)

Reversed and remanded in part on invalidity and non-infringement holding.

Donnelly Corp. v. Gentex Corp., 1998 U.S. App. Lexis 22382 (Fed. Cir. Sept. 11, 1998)
Reversed invalidity holding.

Strub v. Axon Corp., 1998 U.S. App. Lexis 20245 (Fed. Cir. Aug. 18, 1998)
Reversed invalidity holding.

Unidynamics Corp. v. Automatic Products International LTD, 157 F.3d 1311 (Fed. Cir. 1998)
Affirmed in part, vacated and remanded in part non-infringement.

DH Technology, Inc. v. Synergystex International, Inc., 154 F.3d 1333 (Fed. Cir. 1998)
Vacated and remanded issue of whether patent lapsed.

Glaxo, Inc. v. Torpharm, Inc., 153 F.3d 1366 (Fed. Cir. 1998)
Vacated and remanded summary judgment on non-infringement.

Mantech Enviro. Corp. v. Hudson Enviro. Serv., 152 F.3d 1368 (Fed. Cir. 1998)
Vacated and remanded summary judgment of non-infringement holding.

State Street Bank & Trust v. Signature Financial Group, 149 F.3d 1368 (Fed. Cir. 1998)
Reversed and remanded invalidity holding.

Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380 (Fed. Cir. 1998)
Vacated and remanded judgment of unenforceability.

Ranpak Corp. v. Storopack, Inc., 168 F.3d 1316 (Fed. Cir. 1998)
Judgment of non-infringement affirmed in part, vacated and remanded in part.

Trimedyne, Inc. v. Surgical Laser Technologies, Inc., 155 F.3d 574 (Fed. Cir. 1998)
Summary judgment of non-infringement affirmed in part and reversed and remanded in part.

Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309 (Fed. Cir. 1998)
Summary judgment of non-infringement affirmed in part and reversed and remanded in part.

Wanlass v. Fedders Corp., 145 F.3d 1461 (Fed. Cir. 1998)
Vacated and remanded summary judgment of unenforceability.

Rockwell International Corp. v. U.S., 147 F.3d 1358 (Fed. Cir. 1998)
Vacated and remanded summary judgment of invalidity.

Solomon v. Kimberly-Clark Corp., 155 F.3d 567 (Fed. Cir. 1998)

Vacated and remanded summary judgment of non-infringement.

Marquip, Inc. v. Fosber America, Inc., 155 F.3d 567 (Fed. Cir. 1998)

Vacated and remanded summary judgment of non-infringement.

Litton Systems, Inc. v. Honeywell, Inc., 140 F.3d 1449 (Fed. Cir. 1998)

Vacated and remanded judgment as a matter of law on invalidity and non-infringement.

Hall and WBX Partners v. FADR International, Inc., 152 F.3d 945 (Fed. Cir. 1998)

Vacated and remanded summary judgment of unenforceability on equitable grounds.

Derrick Manufacturing Corp. v. Southwestern Wire Cloth, Inc., 152 F.3d 944 (Fed. Cir. 1998)

Reversed and remanded judgment of unenforceability on equitable grounds.

Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH, 139 F.3d 877 (Fed. Cir. 1998)

Vacated and remanded summary judgment on invalidity.

Storz Instrument Co. v. Alcon Laboratories, Inc., 135 F.3d 777 (Fed. Cir. 1998)

Vacated and remanded summary judgment on invalidity.

Kamyr, Inc. v. Clement, 135 F.3d 775 (Fed. Cir. 1998)

Vacated and remanded summary judgment of non-infringement.

High-Tech medical Instrumentation, Inc. v. New Image Industries, Inc., 135 F.3d 774 (Fed. Cir. 1998)

Vacated and remanded summary judgment of non-infringement.

Bell & Howell Document Management Products Co. v. Altek System, 132 F.3d 701 (Fed. Cir. 1997)

Vacated and remanded denial of patentee's request for preliminary injunction.

Cabinet Vision v. Cabinetware, 129 F.3d 595 (Fed. Cir. 1997)

Vacated and remanded judgment of unenforceability on equitable grounds.