

Testimony of
THEODORE C. WHITEHOUSE
of
Willkie Farr & Gallagher LLP
on behalf of
TEVA PHARMACEUTICALS USA, INC.
Concerning
H.R. 1706,
“Protecting Consumer Access to
Generic Drugs Act of 2009”

Before the
Subcommittee on Commerce, Trade, and Consumer Protection
of the
Committee on Energy and Commerce
of the
United States House of Representatives

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SUMMARY

- This testimony is submitted on behalf of Teva Pharmaceuticals USA, Inc., the largest *generic* pharmaceutical company in the US and the company with the most experience with Hatch-Waxman Paragraph IV patent challenges.
- Based on its considerable experience with Hatch-Waxman litigation, Teva strongly believes that settlements of those cases are an absolutely necessary part of the Hatch-Waxman process and that it is essential to have an adequate range of terms over which to bargain to reach necessary and pro-consumer settlements like those in which Teva has engaged. Recent analysis by prominent economists supports this belief.
- Teva's settlements have brought major benefits to consumers by making possible the present and future launch of products an aggregate of at least 80 years before the expiration of relevant patents, thereby saving consumers more than \$67 billion. H.R. 1706 as currently drafted would ban the very settlement terms that have enabled Teva to bring generic drugs to market years before they might otherwise have become available to consumers.
- Teva does not believe that legislation like that embodied in H.R. 1706 is necessary or desirable. However, recognizing the concerns raised by the FTC and in Congress with respect to perceived anticompetitive abuses in particular settlements, Teva has worked and will continue to work with members and staff in both houses of Congress to develop and refine legislative options that do not severely restrict the kinds of settlements that help to bring products to market for the benefit of consumers.
- The outcome of pharmaceutical patent litigation may be more uncertain today than it has been in the past and the need for the flexibility to settle when circumstances warrant is more important than ever.
- Alternative forms of legislation providing for expedited review of settlements before they become effective, either by the court handling the patent litigation or by the FTC through a process similar to current Hart-Scott-Rodino merger review procedures, would be less potentially disruptive to the Hatch-Waxman process than a ban on particular kinds of settlement terms.
- H.R. 1706 imposes too stringent a limitation on settlements. At a minimum, it needs to be revised to allow for the kinds of settlements by which Teva has brought great benefits to consumers.
- The provisions of H.R. 1706 relating to forfeiture of the 180-day exclusivity for first filers are at least unnecessary and potentially very damaging to the core incentives underlying the Hatch-Waxman process by, among other things, causing a forfeiture of exclusivity before anyone has been cleared to enter the market.

Chairman Rush, Ranking Member Radanovich, and members of the Subcommittee, good morning. My name is Theodore Whitehouse and I am a partner in the law firm of Willkie Farr & Gallagher LLP, specializing in litigation with a particular focus on antitrust law. I have had the privilege of serving for several years as an antitrust lawyer for Teva Pharmaceuticals USA, Inc. (“Teva”), a leading pharmaceutical company that participates in both the generic and the branded sides of the industry. Teva appreciates the opportunity to appear and be heard on the important issues being considered here today.

Teva is in the business of bringing low-cost generic drugs to market as soon as possible. Teva believes that the ability to reach reasonable and pro-consumer settlements in Hatch-Waxman patent litigation is absolutely essential to Teva’s efforts to bring low-cost generic drugs to market as soon as possible. From a consumer welfare standpoint, settlements that result in bringing products to market sooner and with more certainty than might otherwise have been the case are a good thing. As a practical matter, settlement is more likely to be achieved if the parties have the ability to bargain over a variety of terms than would be the case if the parties are forced to bargain over only one issue. Because H.R. 1706 would, in Teva’s view, unduly restrict the terms over which parties to Hatch-Waxman litigation may bargain to reach a settlement, Teva does not support H.R. 1706 as currently drafted.

In the testimony that follows, I propose to elaborate on these points and focus on specific concerns with the proposed legislation. I will begin by noting

that Teva believes that legislation providing for expedited prior review of patent settlements by a court or the Federal Trade Commission (“FTC”) would be preferable to legislation categorically banning certain kinds of settlements. I will then explain how H.R. 1706 in its current form would unnecessarily ban some of the kinds of provisions that Teva has found to be necessary and useful in reaching pro-consumer settlements in the past. Finally, I will address briefly the provisions of H.R. 1706 that would amend the Food, Drug, and Cosmetics Act (“FDCA”) so as to impose additional restrictions on the availability of the 180-day period of marketing exclusivity that is a crucial component of the incentive structure on which the entire Hatch-Waxman process depends.

I. TEVA AND ITS POSITION ON THESE ISSUES

Teva and its affiliates together constitute the largest *generic* pharmaceutical company in the world and the largest pharmaceutical company of any kind in the United States in terms of number of prescriptions filled. One result of that status is that Teva is the most active initiator of Paragraph IV Hatch-Waxman patent challenges and therefore has a lot of experience with litigating and settling the patent infringement cases that often result from challenging the patents on branded drugs. Based on that experience, Teva strongly believes that the ability to settle such cases is an absolutely necessary part of the Hatch-Waxman process.

Teva’s experience confirms that it is essential to have an adequate range of terms over which to bargain in order to reach necessary and pro-consumer settlements. Given that the parties are likely to disagree about the relative

strengths of their respective cases, a negotiation for settlement limited to only one variable is highly likely to fail because the parties will not be able to reach the agreement about the relative strength of their cases that is necessary to reach agreement on that one variable. The ability to negotiate over multiple variables increases the likelihood that the parties' differences can be bridged.

Teva believes that the Hatch-Waxman process works very well under the existing law as interpreted by the courts. The process is producing the savings to consumers, third-party payers, and the government that it was supposed to produce. Teva does not believe that legislation of the sort reflected in H.R. 1706 is necessary or desirable and is, therefore, opposed to H.R. 1706. However, Teva is very aware that there is strong sentiment from some members of Congress and elsewhere that action by Congress is needed to address perceived anticompetitive abuses in particular settlements. Teva worked closely with members and staff of the House and the Senate in the last Congress, and plans to continue to work constructively with members and staff of both houses in the current Congress, in an effort to ensure that legislation motivated by a desire to ban what are perceived as bad settlements does not also ban good, necessary, and socially beneficial settlements.

II. THE HATCH-WAXMAN PROCESS

The Hatch-Waxman amendments to the FDCA were intended to promote the introduction of low-cost generic drugs for the benefit of consumers. A central feature of those amendments is a process that enables generic drug companies to challenge the patents claimed to protect brand-

name drugs. That process is designed to encourage generic companies to incur the expense and risk of designing around patents or facing patent litigation by certifying to a belief that the branded drug company's patents are not a legitimate obstacle to generic competition, either because the generic company's proposed product does not infringe or because the patents are invalid or unenforceable. That is called a Paragraph IV certification. The Hatch-Waxman amendments offer the first generic company to make a Paragraph IV certification a 180-day period of marketing exclusivity as the incentive to identify opportunities to enter into the market before the expiration of the brand company's patents listed in the Food and Drug Administration ("FDA") Orange Book.

Under the Hatch-Waxman amendments, submitting a Paragraph IV certification often results in a patent infringement lawsuit being brought by the branded company against the generic company. Because patent litigation is expensive and can consume a large amount of the time of key company personnel -- and the resources of generic companies are, of course, finite -- generic companies must have the flexibility to reevaluate their position in Paragraph IV litigations as those cases proceed. Such reevaluation may lead reasonably to the conclusion that the prospects for success, when balanced against the costs of litigation and the other potential products to which the resources being consumed by the litigation might more productively be directed, are such that the case should be settled.

In this regard, Teva takes issue with Professor Hemphill's assertion that Congress intended in Hatch-Waxman to promote litigation.¹ Congress intended Hatch-Waxman to promote increased availability of generic drugs to consumers. While the initiation of litigation is a necessary instrument to pursuing that goal for many branded products, losing -- or walking away empty-handed from -- litigation does not further that goal. In particular cases, the statutory goal of Hatch-Waxman is more readily served by a timely and appropriate settlement than by continuing to litigate.

III. TEVA'S EXPERIENCE WITH HATCH-WAXMAN LITIGATION

Teva has been involved in more Hatch-Waxman Paragraph IV litigation than any other generic company and therefore has substantial experience with litigating and settling such cases. Teva has litigated many cases to final judgments, but Teva believes that it is essential that it be able to settle these cases where appropriate. Taking away the ability to settle and redirect efforts to other, more promising alternatives will make generic companies less willing to commit to Paragraph IV patent challenges with respect to some products. That result would be detrimental to consumers' interests in timely availability of generic drugs.

Much of the criticism of settlements in Paragraph IV cases is based on an implicit assumption that, but for the settlement, the generic company would have ended up winning the case. Any such assumption would be unreasonable and unfounded. There is no evidence of any pattern or practice

¹ C. Scott Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1612-16 (Nov. 2006).

of generic companies surrendering on the brink of victory or anything of the sort; Teva certainly has not done so. There are prominent recent examples of cases in which generic companies have ended up losing their cases and in those cases consumers would likely have been better off with a settlement than with having to wait out the expiration of the patent before generic competition could begin. For example, in the Plavix (clopidigrel bisulfate) litigation, Apotex and the brand company tried to settle on terms that ultimately contemplated entry at least six months prior to patent expiration but were prevented from doing so by the FTC and a consortium of state attorneys general. With Plavix sales averaging over \$360 million per month in 2008, consumers and taxpayers would have saved many millions of dollars if Apotex had been able to settle on those terms. Instead, Apotex went forward with the litigation and ultimately lost the case.

Teva's experience makes clear that it is not easy to settle Paragraph IV cases. An artificial and unnecessarily restrictive limit on the terms available to be negotiated in such settlements will increase the likelihood that cases will be litigated rather than being settled on terms that are more favorable to consumers than a loss by the generic company.

Teva's practical experience in this regard is consistent with formal economic analysis. A recent and thoughtful paper by three leading economists confirms that pro-consumer outcomes in Paragraph IV patent litigation are more likely if the parties to those litigations have a sufficient number of terms

over which to bargain, and that restricting parties to negotiating only over an entry date will prevent otherwise pro-consumer outcomes.²

In my testimony before this Subcommittee in May 2007, I provided some data on consumer benefits from Teva's actual experience. Those figures showed that, between 1999 and 2007, Teva launched, pursuant to settlements, ten generic products on which it was the first generic firm to challenge the branded company's patent. Each of the ten settlements provided for entry earlier than the expiration of the patents, permitting launches of products an aggregate of 83.4 years before patent expiration, and brought and will bring over \$67 billion in savings to consumers. In five of its ten settlements, Teva brought its product to market in the same year as the settlements were reached. In four of its settlements, Teva secured the additional consumer benefit of early market entry on a product not at issue in the litigation being settled.

A settlement of the Paragraph IV litigation can often be the most pro-consumer outcome available to a generic company. Any settlement that produces some form of early entry is going to be preferable from a consumer perspective to a loss of the litigation by the generic company and the consequent delay of entry until the patent expires. Further, as noted above, some of Teva's settlements have produced pro-consumer results that could not have been obtained from litigating the case to judgment, such as (1) early entry

² See Brett Dickey, Jonathan Orszag, and Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry* (Dec. 2008), a paper funded by the Pharmaceutical Research and Manufacturers of America (PhRMA).

on products in addition to the one in suit, (2) protection for consumers in the event that the brand company undertakes to convert the market to another product, and (3) obtaining a comprehensive release and covenant not to sue covering all patents on the product at issue, not just the patent in suit, thereby assuring entry without further litigation.

One argument that has sometimes been advanced in the recent discussions about patent settlements is that generic companies are so likely to win Paragraph IV challenges that they have no good reason to settle. That argument is typically based on statistics purportedly showing that, in the early years of Hatch-Waxman litigation, generic companies won over 70 percent of such cases. If this statistic was ever accurate, it is certainly not so today.

Paragraph IV cases today involve more difficult issues than they typically did even just a few years ago and may be more difficult and more expensive for generic companies to win. Paragraph IV litigation used to be primarily focused on issues of infringement but, in recent years, the predominant issues involve validity of the patents. In 1999, only 18 percent of Teva's Paragraph IV litigations were primarily focused on invalidity issues and 82 percent of those cases were focused primarily on issues of noninfringement. By contrast, in 2005, those percentages literally flipped, with invalidity cases accounting for 86 percent of the total and noninfringement cases accounting for 14 percent. That is very significant because, in general, invalidity cases are more difficult and expensive to win than are noninfringement cases. Also, an increasing proportion of the cases being litigated involves challenges to the basic

compound patent rather than intrinsically easier issues involving more peripheral patents. During this same period, Teva believes that brand companies have become more sophisticated in their patenting and patent litigation strategies. What this means is that there is greater uncertainty about the outcome when Paragraph IV litigation is initiated than there used to be and a greater need to be able to reassess and move on to other more promising opportunities when events in the litigation make that advisable.³

IV. POTENTIAL LEGISLATIVE ALTERNATIVES REGARDING PATENT SETTLEMENTS

As Teva understands the situation, the introduction of H.R. 1706 and the convening of this hearing today reflect a concern that some settlements of Paragraph IV Hatch-Waxman litigation have not been procompetitive or otherwise in consumers' best interests. To the extent that there is a problem that requires legislative attention, Teva is aware of at least two broad categories of solutions that have been advanced to address it. The first category of solutions would involve establishing formal procedures (in addition to those that already exist under the 2003 MMA amendments to Hatch-Waxman) to ensure that some responsible public official or agency has an opportunity and an obligation to evaluate the competitive effects of a proposed settlement before

³ Teva's view that patent litigation is becoming more difficult and complex is corroborated by recent remarks before a March 18, 2009 Federal Circuit Bar Association/George Washington University Law School symposium by Chief Judge Michel of the United States Court of Appeals for the Federal Circuit. Mike Scarcella, *Clerk Call*, Legal Times, Mar. 23, 2009 (Patent cases are more complex now than in 1993.).

it becomes effective. The second category of solutions -- exemplified by H.R. 1706 -- would categorically ban certain kinds of settlements.

A. Formal Court or Agency Expedited Review Procedures

The first category of potential measures to address the perceived problem of bad patent settlements -- and the one that seems least likely to disrupt the existing and successful Hatch-Waxman process -- involves mechanisms to ensure that settlements are reviewed by a court or administrative agency on an expedited basis to ensure that they conform to the standards already established in the antitrust, patent, and Food and Drug laws. One approach that has been suggested would be for the court before which the litigation being settled is pending to have an explicit mandate to review the settlement to ensure that it is lawful. The court before which the case is pending is in the best position to assess the relative strengths of the parties' respective cases and to determine whether the settlement reasonably reflects those and other relevant factors.

An alternative or supplement to court review would involve more formal expedited review processes before the FTC. Already, as a result of the 2003 MMA amendments,⁴ all settlements of Paragraph IV Hatch-Waxman litigation are required to be filed with the FTC and the Antitrust Division of the Department of Justice. In Teva's experience, all such agreements are carefully reviewed by lawyers and economists at the FTC. A potential legislative approach that has been suggested would be for the FTC to have a more formal

⁴ Pub. L. No. 108-173, 117 Stat. 2066 (2003).

and structured review process for patent settlements, perhaps involving procedures similar to the Hart-Scott-Rodino procedures that have long governed large corporate mergers.⁵ Under that kind of process, parties to a settlement of a Paragraph IV litigation would have to file their settlement agreement and it would not become effective for a reasonable period of time so as to let the FTC review it before it could be actually carried out by the parties.

Teva believes that, if Congress concludes that legislation is needed to address bad settlements of Paragraph IV litigation, serious consideration ought first to be given to establishing mechanisms to ensure that all settlements are given timely review by the courts or the FTC. Teva believes that such mechanisms could adequately and non-disruptively address any perceived problems with bad patent settlements. Teva and others have previously suggested draft legislative language that would establish such mechanisms.

B. Comments and Suggestions on H.R. 1706

H.R. 1706, like similar legislation pending in the Senate,⁶ would broadly prohibit certain kinds of patent settlements (so-called “reverse-payment” settlements), subject to limited exceptions. The legislation would broadly ban any settlement in which any form of benefit flows to or through the generic company with only limited exceptions. Among other things, this means that all ten of the pro-consumer Teva settlements that I described earlier as having brought more than 80 years of time off the relevant patents and over \$67

⁵ 15 U.S.C. § 18a (2009); 16 C.F.R. §§ 801-803 (2009).

⁶ S. 369, 111th Cong. (1st Sess. 2009)

billion in savings to consumers would have been prohibited had H.R. 1706 been the law.

The legislative approach reflected in H.R. 1706 implicitly assumes that the parties to Paragraph IV litigation can reach pro-consumer settlements with only a very limited number of terms over which to bargain -- essentially, limited only to an agreement to entry on some date prior to the expiration of the patent in issue and waiver of damages for launches at risk that precede an unfavorable judgment in the patent litigation. Teva's experience is that restricting the terms of a potential settlement too narrowly will reduce the likelihood that any settlement will be reached and will thus create an undesirable risk that entry will not occur at all before patent expiration. Teva strongly urges that any legislation in this area at least allow for the sorts of pro-consumer settlements to which Teva has been a party.

As currently drafted, H.R. 1706 would allow a settlement to be based on early entry only with respect to the patent and product in suit. That limitation is likely to be a significant problem for at least two reasons.

First, as a litigator, I can tell you that it is typical for the parties on opposite sides of litigation to have very different views of the strength of each of their cases. In those circumstances, a negotiation for settlement limited to only one variable has a high likelihood of failure because the parties will not be able to reach the consensus about the strength of their respective cases necessary to agree on that one variable. The ability to work with more variables increases the likelihood that the parties' differences can be bridged.

Second, branded drug companies often have strategic reasons that have nothing to do with the merits of the pending patent infringement lawsuit for refusing to negotiate generic entry earlier than a date that is too late for fully competitive entry as to the product in suit. Under those circumstances, a settlement based only on the entry date prescribed by the brand company for the product in suit would make little sense but a settlement providing also for early entry on some other product might make for a commercially sensible settlement that is in the best interests of consumers.

H.R. 1706 desirably provides for settlements to include a waiver of damages for prior marketing of the ANDA drug. We understand this provision to be intended to address, for example, the situation in which a generic company launches at risk on the basis of a favorable lower court decision and then finds it necessary to settle following an unfavorable ruling on appeal. Teva has had actual experience with such a situation and strongly supports making provision for it in any legislation on this issue. However, Teva's experience suggests that broader language is necessary to make clear that settlements may permissibly include a complete release and covenant not to sue as to all patents on the product in suit so as to eliminate the risk that the branded company will settle and then later brandish other patents not asserted in the initial suit as a means to forestall generic entry. Also, consistently with the point as to other drug products in the time-off-the-patent provision, above, Teva believes that the release provision should clearly allow a full release and covenant not to sue as to such other products.

As many of those present are well aware, branded drug companies have recently adopted a strategy of releasing so-called “authorized generics” during the 180-day period of market exclusivity provided by the Hatch-Waxman law to the first filer of a Paragraph IV ANDA. The purpose and effect of such product releases by the branded companies are to diminish the value of the 180-day first-filer exclusivity to generic companies with the obvious goal of discouraging generic companies from pursuing the patent challenges that the Hatch-Waxman amendments were designed to encourage. To mitigate the effects of this undesirable practice, Teva believes that any legislation on these issues should specifically allow the parties to a settlement of a Paragraph IV litigation to agree through the means of an exclusive license for a limited duration that the branded company will not engage in this undesirable practice. Such a license is, of course, permissible under the current law.

Teva’s experience also makes clear that generic companies should have the opportunity to purchase finished product from the brand company for sale by the generic company as part of a settlement. Such purchases have no apparent anticompetitive potential and are an important means for dealing with uncertainties about timely FDA approval of ANDAs.

Section 3 of H.R. 1706 contemplates FTC rulemaking to establish other potential carve-outs from the general prohibition. Teva supports that idea but also believes that it would be desirable to give the FTC specific authority to approve settlements on a case-by-case basis, notwithstanding the general

prohibition, to avoid undue delay and to ensure that pro-competitive settlements are not blocked.

V. PROVISIONS OF H.R. 1706 RELATING TO FORFEITURE OF EXCLUSIVITY

In addition to the provisions directed to settlements of Paragraph IV Hatch-Waxman litigation, Section 4 of H.R. 1706 contains proposed amendments to core provisions of Hatch-Waxman amendments codified in the FDCA. Those proposed amendments to Hatch-Waxman are not limited to -- or necessarily related to -- settlements, and Teva believes that they could have substantial negative effects on the carefully balanced incentive structures that are at the very heart of the Hatch-Waxman process.

As noted previously in this testimony, the Hatch-Waxman amendments to the FDCA provide that a generic company that is the first to challenge a brand company's patent on a drug is entitled to 180 days of market exclusivity when it brings the generic product to market. The particular provisions of the FDCA that are proposed to be amended⁷ are very complex and deal with the circumstances under which a generic company entitled to 180 days of first-to-file exclusivity may lose, or forfeit, that exclusivity. It is important to note at the outset that the law as it exists today already addresses the situation in which a settlement agreement is held to be unlawfully anticompetitive: Under that circumstance, exclusivity is already required to be forfeited.⁸

⁷ 21 U.S.C. § 355(j)(5)(D)(i)(I)(BB) (2009).

⁸ 21 U.S.C. § 355(j)(5)(D)(i)(V) (2009).

Under current law, the first applicant forfeits its 180-day generic exclusivity period if it fails to commence commercial marketing within a specified time following certain enumerated events. This “commercial marketing” forfeiture provision attempts to strike a balance between avoiding forcing the first applicant to launch at risk of patent damages and allowing the first applicant to wait indefinitely to begin marketing, while retaining its exclusivity rights. In general terms, the provision states that the first applicant will not be forced to launch its product at risk of patent damages in order to maintain its 180 days of exclusivity unless the first applicant or another applicant with tentative ANDA approval has obtained a final court decision (or a settlement order or consent decree that enters a final judgment that includes a finding) that each of the relevant patents is invalid or not infringed.⁹ In essence, therefore, the statute provides that a first applicant is not required to make the difficult choice between launching at risk or forfeiting its 180-day exclusivity unless and until all of the patent barriers that were subject of the first filer’s Paragraph IV certification have been removed with respect to at least one tentatively approved ANDA product.

Section 4 of the proposed bill would expand the failure to market forfeiture provision, by providing that the mere dismissal of a declaratory judgment action for lack of subject matter jurisdiction, whether with or without prejudice, could lead to a forfeiture. This represents a dramatic and dangerous

⁹ The existing failure to market provisions also include the situation in which the NDA holder withdraws the listed patent from the FDA’s Orange Book.

departure from current law. Under this proposed amendment, for the first time, the first applicant could effectively be forced to launch its product at the risk of massive patent damages in order to maintain its 180 days of exclusivity, even though none of the patent barriers has been removed with respect to any ANDA applicant, and irrespective of whether the first applicant is in litigation with the NDA holder or has settled its case.

This amendment is clearly unnecessary, given the recent decisions of the U.S. Supreme Court and the Court of Appeals for the Federal Circuit favoring declaratory judgment jurisdiction in the Hatch-Waxman context.¹⁰ Even Apotex, Inc., an outspoken proponent of this forfeiture provision, has acknowledged that, “[t]he January 2007 Supreme Court Ruling in the *MedImmune v. Genentech* case appears to have resolved the inability of generic companies to obtain declaratory judgments when branded companies decline to sue generics for patent infringement”¹¹

In addition, the proposed amendment would strongly discourage first applicants from ever filing their own declaratory judgment actions, for fear that a judicial determination that the court lacks subject matter jurisdiction would work a forfeiture of their own 180 days of exclusivity. And, it would create a

¹⁰ See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, n.11 (2007); *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 527 F.3d 1278 (Fed. Cir. 2008); *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007).

¹¹ Apotex, Inc., *Patent Settlements Between Brand and Generic Pharmaceutical Companies: Parked Exclusivity & Lack of Incentive for Subsequent Generic Filers to Fight On Are the Problems, Not “Reverse Payments”* at 6 n.3.

perverse incentive for subsequent applicants to encourage challenges to the justiciability of their own declaratory judgment actions, because a dismissal for lack of subject matter jurisdiction would constitute the simplest, least expensive, and most immediate path for working a forfeiture of the first applicant's exclusivity -- as contrasted with the far more expensive and difficult task of actually having to prevail in a final court decision on the merits that is no longer subject to appeal.

More fundamentally, the proposed amendment ignores the critically important legal distinction between a dismissal for lack of subject matter jurisdiction -- which does not address the merits of the underlying patent dispute -- and a final court decision finding that a patent is invalid or not infringed. There may be public policy justifications for a rule that a first applicant cannot sit on its 180-days of exclusivity after it or a subsequent filer has obtained a judicial determination that all of the patents that were the subject of the first applicant's Paragraph IV certification are invalid or not infringed with respect to at least one tentatively approved ANDA. There is, however, no basis in either law or logic to force a first applicant to lose its exclusivity or risk potentially catastrophic patent damages, merely because a court determines that its or another applicant's declaratory judgment action does not satisfy the Constitutional prerequisites for judicial resolution.

The second proposed amendment to the forfeiture provisions of the FDCA -- captioned subsection DD -- seems to contemplate stripping the first filer of an ANDA of the exclusivity it has earned if some other applicant for authority

to make the same generic drug purchases or otherwise obtains from the brand company and files with the FDA a covenant not to sue. The circumstances under which that would be a fair and appropriate result are not apparent to Teva.

CONCLUSION

Teva appreciates the opportunity to be heard today and welcomes the opportunity to maintain a continuing and constructive dialogue on these important issues with Members and their staffs.

Thank you.