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September 26, 1999

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20857

Re: Proposed Regulations Relating to 180-Day Generic Drug Exclusivity

Dear Sir or Madam:

I was counsel to the Generic Pharmaceutical Industry Association (GPIA) in 1984 and participated in the creation of the provisions of the 1984 Drug Price Competition Act relating to the 180 days of generic exclusivity accorded to ANDAs containing paragraph IV patent certifications. Although, I have retired from the practice of law and no longer represent GPIA or any generic drug manufacturers, I am submitting these comments in the public interest in the hope that they will assist the FDA in adopting final rules which will maximize the purpose for which the 180-day exclusivity was established while minimizing the abuses of that statutory privilege.

The FDA's commentary on the proposed regulations recognizes that the 180-day exclusivity provisions of the 1984 Drug Price Competition Act require the promulgation of regulations which seek to (1) maximize the availability of generic drugs at the earliest moment allowed by law, (2) maximize the potential for the 180-day exclusivity to act as an incentive to assert patent challenges which will accelerate the onset of generic competition, and (3) minimize the potential for the misuse of the 180-day exclusivity to thwart generic competition. The proposed regulations do not meet these goals in at least three major respects as follows:

(a) The complicated set of proposed rules with respect to "triggering events" appears to confuse cause and effect. Experience has shown that the existence of an ANDA that is approvable but for a prior exclusivity is not the true cause of delay. Rather, in almost every case, the delay has resulted from an agreement between the first paragraph IV challenger and the patent owner that prevented the challenger from triggering the 180-day exclusivity. In actuality, the first paragraph IV challenge had terminated without producing either of the only two triggering events (judgment or marketing) contemplated by the statute. FDA's refusal to promulgate rules which terminate the first challenger's claim to exclusivity after the paragraph IV challenge is terminated or modified by agreement serves to promote collusive settlements which pervert the fundamental purpose of the exclusivity provision in a manner that was clearly not intended by Congress. That abuse can be regulated without inquiry into the substance of private agreements. The alternative of providing a 180-day trigger period, which actually delays generic competition for an extra six months is unnecessary.

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(b) It is totally unrealistic to believe that patent challenge litigation can be concluded in 30 months. Therefore, the provisions which make it possible for a legitimate paragraph IV challenger to lose its exclusivity if a second ANDA is approved, even though litigation is not completed, will serve as a disincentive to future patent challenges. Indeed, it creates the distinct possibility that a patent owner will collude with subsequent challengers in order to coerce the first challenger into a choice between an unfavorable settlement and a belated empty victory from which no profit can be deprived.

(c) Limiting the availability of the 180-day exclusivity solely to the first ANDA containing a paragraph IV challenge suffers from precisely the same defect (in the opposite direction) as the "successful defense" approach. It is simply not supported by the language of the statute and undermines the incentive that the 180-day exclusivity was intended to provide.

In summary, it appears that the judicial rejection of the FDA's "successful defense" scheme has caused the FDA to become overly protective of the rights of the first challenger at the expense of the real objectives of the statute. By promulgating reasonable regulations that would deprive ANDA applicants who enter into agreements with patent owners from acquiring any residual exclusivity benefits, most delays would disappear. The 180 days of additional delay which the FDA proposes to set aside for "triggering events" ought to be used to provide 180-days of exclusivity for subsequent bona fide challengers, thereby creating the maximum incentive for eliminating wrongfully listed patents and a disincentive for settlements which discourage early generic competition.

The FDA Must Promulgate Rules Which Will Eliminate Residual Exclusivity Benefits When Patent Challenges Are Terminated By Agreement

The FDA's proposed new regulations provide that when a judgment is entered against a patent challenger, the challenger must immediately amend its ANDA to delete the paragraph IV challenge and, in so doing, lose any claim to the 180-day exclusivity. Presumably, this rule would also apply to a settlement that results in a Consent Judgment acknowledging patent validity and infringement although the FDA commentary and proposed regulations do not specifically address this question. Yet, under the FDA's proposal, the termination of litigation by way of a dismissal, with or without prejudice, would not require the challenger to delete a paragraph IV certification from its ANDA. There is no logical reason for this difference.

Any termination of litigation that, on its face, leaves the challenged patent in full force and effect is the practical equivalent of a judgment adverse to the patent challenger. In either case, the challenge to the patent is no longer being asserted. Moreover, it is a common litigation practice for the Answer to a Complaint asserting patent infringement to assert a Declaratory Judgment counterclaim. Thus, as a practical matter, litigation resulting from a patent challenge can not be dismissed without the consent of the paragraph IV challenger. In short, termination of litigation is the equivalent of an admission that the allegation of patent invalidity, unenforceability or non-infringement that was asserted in the original paragraph IV certification has been withdrawn. Further, termination of litigation is a public event and does not require the FDA to delve into the nature of any private agreement between the parties. Therefore, the FDA should promulgate a regulation which requires an ANDA applicant to delete a paragraph IV certification from an ANDA whenever litigation is terminated by dismissal without a judgment adverse to the patent owner unless it can be demonstrated that there is no agreement between the parties and the challenger is in the same position as an applicant who was never sued for infringement.

There remains for resolution the question of how to deal with agreements between a patent challenger and patent owner that are consummated before any challenge litigation commences. This is a simple matter and would also not require the FDA to delve into the substance of private agreements. The FDA must promulgate a rule which simply states that "any agreement between a patent owner and a challenger with respect to a challenged patent terminates the challenge and requires the ANDA applicant to immediately delete the paragraph IV certification from an ANDA". If an agreement between an alleged challenger and patent owner has been consummated before a paragraph IV certification is actually filed, the paragraph IV certification alleging a belief that that the challenged patent is invalid, unenforceable or not infringed is clearly a false, if not fraudulent, statement. If an agreement is consummated during the 45-day time period following certification, maintaining the paragraph IV certification constitutes the deliberate continuation of a knowingly false statement in an ANDA. Therefore, the FDA need only promulgate rules that reinforce the general requirement of truthfulness in dealings with a federal agency. Such a rule would not require the FDA to delve into the substance of private agreements. For example, the FDA could require the applicant, through a duly authorized officer, to affirmatively represent that "there are no agreements between the applicant and the patent owner with respect to the patent(s) which are the subject of the paragraph IV certification". Such a statement should accompany the original certification and could be required at other critical junctures, e.g. the expiration of the 45 day period in the event no litigation is commenced; after the filing of a second ANDA containing a paragraph IV certification, etc. In short, no certification could be filed or maintained without the positive assertion of the absence of any agreement. The failure of an applicant to submit the appropriate representation would constitute a waiver of paragraph IV rights and the statutory criminal penalties for false statements in proceedings before a federal agency would certainly discourage any misrepresentation as to the existence of an agreement.

Regulations to Accelerate the Loss of Exclusivity As a Result of Triggering Events Are Unnecessary and Unfair

The promulgation of regulations depriving challengers who have entered into agreements with patent owners of any claim to exclusivity would eliminate the primary cause of delay in triggering the onset of the 180-day exclusivity period thereby eliminating the need for special "triggering" rules. However, as the FDA has recognized, a potential for delay could still exist, in those situations where a second challenger is not sued and obtains approval before litigation on the first challenge is concluded. This is not a real problem for at least two important reasons. First, if patent owners can not use settlements with prior challengers as a means of blocking approval for subsequent ANDAs, there is likely to be a drastic reduction in the number of situations in which subsequent challengers are not also sued for infringement. Second, the second challenger is in a position to create its own "triggering event" by commencing a declaratory judgment action and seeking an early judgment on the merits of its own case. Under the regulations, any judgment affecting the patent would be a triggering event. In those situations where, for example, the second challenger has a clearly meritorious case of non-infringement whereas the first challenger's case is uncertain, a declaratory judgment proceeding could be commenced and completed by the second challenger during the 30 month period following the first challenge.

Experience has shown that 30 months is not a sufficient time to complete patent challenge litigation. For example, the successful challenge to MODURETIC in the mid-1980 took 48 months. Court calendars have become more clogged in the last decade and cases take longer to complete. This writer is aware of only one case in the entire history of the statute (the cyclobenzaprine case) where a trial and appeal were actually completed within 30 months. The economic incentive to challenge patents would be undermined if exclusivity can be lost in the middle of the battle due to

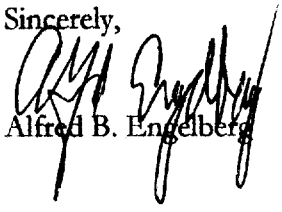
the approval of a subsequent ANDA. Indeed, the statute was expressly written to prohibit such a resultand the proposed regulation clearly undermines the language and purpose of the statute. Moreover, patent owners could use such a rule to enter into collusive agreements with subsequent challengers or licensees (including their own generic subsidiaries) as a means of depriving the first challenger of any economic incentive to continue with litigation. The primary purpose of the exclusivity rule was to provide an incentive to challenge non-meritorious patents that serve to prevent the early onset of generic competition. Even if there is a possibility of some delay in competition in some situations, the FDA can not arbitrarily deprive a bona fide challenger of the incentive that motivated the challenge without completely undermining the purpose of the statute.

Limiting Exclusivity to the First Challenger Undermines the Purpose of the Statute

The proposed FDA regulations display a willingness to delay any generic competition for up to 180-days to create a "triggering period" which benefits the first challenger at the expense of the public even in situations where the paragraph IV challenge has been terminated by private agreement. Yet the FDA is unwilling to provide a 180-day exclusive marketing period as an incentive for a subsequent bona fide challenger after the first challenge terminates as a result of a private settlement. Logic would dictate that subsequent ANDA applicants be specifically encouraged to challenge patents which have been the subject of private agreements that do not produce generic competition. The statute was intended to provide an incentive for challengers and not to protect a first challenger who has abandoned the challenge. Because most of the "triggering periods" contemplated by the FDA's proposed regulations would arise in cases where the first challenger and patent owner have settled and terminated any challenge, the 180-day "triggering" period that the FDA contemplates could, in fact, be better utilized as a 180-day period of exclusivity for a subsequent bona fide challenger. The FDA could accomplish this result by promulgating a rule which terminated any paragraph IV rights when litigation is settled or dismissed and retaining the possibility of exclusivity for a subsequent challenger.

The exclusivity provision enacted by Congress is clearly flawed in that it did not foresee many of the circumstances in which the availability of exclusivity might thwart rather than promote generic competition. However, until Congress decides to fix or eliminate the provision, the FDA is required to regulate in a manner that promotes the apparent purpose of the statute. That objective can not be accomplished by construing the statute in an extreme fashion that overly protects only the "successful litigant" or the "first challenger". Rather FDA must take a middle road that provides the maximum incentives to any bona fide challenger and eliminates any benefit from settlements which do not benefit the public.

Sincerely,



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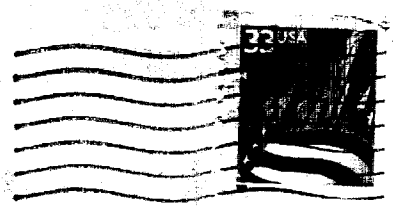

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