

REPORT OF THE SECTIONS OF ANTITRUST LAW AND INTELLECTUAL PROPERTY LAW ON THE DRUG COMPETITION ACT OF 2001

The views in this Report are presented on behalf of the Sections of Antitrust Law and Intellectual Property Law (“the Sections”). They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association (“ABA”) and should not be construed as representing the position of the ABA.

This Report provides the Sections’ comments on S. 754, the “Drug Competition Act of 2001,” (“the Senate Bill”) and a House bill (H.R. 1530), which apparently was based on an earlier version of the Senate bill (“the House Bill”). In October, 2001, the Judiciary Committee ordered that the Senate Bill be reported favorably to the Senate, although at the time of this writing a Committee report has yet to be issued. Because the status of the House Bill is unclear, this Report focuses principally on the Senate Bill.

BACKGROUND AND SUMMARY

The proposed legislation is intended to facilitate federal antitrust enforcement by giving the Federal Trade Commission (FTC) and the Department of Justice (DOJ) early, confidential access to certain agreements made in settlement of patent disputes between manufacturers of brand-name pharmaceuticals and their potential generic competitors. The Senate Bill requires notification of agreements between a company that owns or controls a listed patent for a brand name drug (or holds the “New Drug Application” under the Food and Drug Administration’s rules), and any company seeking to manufacture a generic version of that drug (but has not yet entered the market), where the agreement concerns the manufacture, marketing, or sale of either the brand name or generic version of the drug, or where the agreement relates to the 180-day period of limited protection from competition under the Hatch-Waxman Act. The stated purpose of the notification is to ensure that enforcement agencies have an early opportunity to consider whether such agreements may violate existing antitrust laws.

The Senate Bill reflects a particular concern with whether certain agreements reached during patent litigation between brand name and generic drug firms may constitute an abuse of the Hatch-Waxman Act. The Hatch-Waxman Act provides incentives for patent challenges by firms seeking to make a generic version of a patented brand name drug. The generic firm that is first to file with the FDA an “Abbreviated New Drug Application” (“ANDA”) containing a “paragraph IV certification,” thereby certifying that the target patent is invalid or not infringed by the generic firm, receives generic marketing exclusivity for a 180-day period upon the occurrence of a triggering event (and upon final FDA approval). The first filer’s 180-day marketing exclusivity is triggered either by (1) the start of commercial marketing of the generic drug, or (2) a court decision finding the patent to be invalid or not infringed.

The FTC already has numerous investigative tools at its disposal to obtain, analyze and challenge as unlawful patent litigation settlement agreements in the pharmaceutical industry. The

Commission is currently using its investigative powers under Section 6(b) of the FTC Act to obtain information on these very types of agreements from all of the principal branded and generic pharmaceutical manufacturers.¹ Indeed, the FTC staff already has alleged that three such agreements violate the antitrust laws.² This existing ability to obtain industry-wide information and pursue its ongoing investigations of agreements reached between brand name and generic drug applicant firms suggests that the FTC's ability to detect, investigate and remedy unlawful patent settlement agreements is more than adequate.

The Senate Bill is nevertheless designed to provide earlier notice to the agencies of these and other agreements in order to facilitate future enforcement efforts in this area.

In sum and in relevant part, the Senate Bill provides:

- If a brand-name drug company and a generic-drug ANDA applicant enter into an agreement which relates to the 180-day marketing exclusivity period or which concerns the manufacture, marketing, or sale of either the brand name drug or its generic equivalent, then both companies must file a copy of the agreement (or a complete written summary of any oral agreement), along with copies of any other contingent or related agreements, with the FTC and the DOJ. "Purchase orders for raw material supplies," equipment and facility contracts, and employment or consulting contracts are specifically exempted. (Section 5, the Act's operative Section)
- Filings must be made within ten business days of the execution of the agreement to be notified. (Section 6)
- Filings are entitled to confidentiality protections that parallel protections provided in the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. §18a(h). (Section 7)
- Non-compliance with any provision of the Act may subject the party to a penalty of up to \$11,000 per day. Failure to comply with the Act's requirements may also result in ordered compliance by a federal court, and/or other appropriate equitable relief, including a decree of unenforceability (against the party that failed to file) for the duration of the non-compliance, upon application by one of the antitrust enforcement agencies. (Section 8)

¹ The Commission is seeking information about any such agreements from 30 branded manufacturers, and 70 generic manufacturers, 66 Fed. Reg, 12519 (Feb. 27, 2001) ; is largely in possession of that information today; and is beginning to analyze it.

² See Geneva Pharmaceuticals, Inc., Dkt. No. C-3946 (May 22, 2000) (consent order); Hoechst Marion Roussel, Inc., Dkt. No. 9293 (May 8, 2001) (consent order); Schering-Plough Corp., Dkt. No. 9297 (March 30, 2001) (complaint).

- The FTC, with the concurrence of the DOJ, may issue rules defining the Act's terms, which may create exemptions from the Act and which may prescribe other necessary and appropriate rules to effectuate the purposes of the Act. (Section 9)
- Actions taken to comply with the Act will not create a presumption of wrongdoing. (Section 10)

Notably, the Senate Bill contains procedural, not substantive, changes in the law.

SUMMARY OF COMMENTS

The absence of any existing reporting requirement for ANDA patent case settlements has not prevented the FTC from challenging three such settlements within the last two years. Although the legislation arguably is unnecessary, the Sections recognize that Congress nevertheless may choose to enact a filing requirement. The Sections are concerned, however, lest the current carefully circumscribed draft bill become more burdensome and expensive as it passes through the legislative process and eventually through the development of implementing regulations.

If Congress believes that requiring notification of ANDA patent case settlement agreements may provide a fuller opportunity for the enforcement agencies and the courts (including the FTC's law judges) to fashion substantive rules in this still-emerging area of the law, the Sections believe the Senate Bill reflects a far better, and more balanced, approach, and that the House Bill should be modified to more closely track the clarified version of S. 754 which we propose.

Given the substantial and ongoing investigation and debate in this area and the lack of consensus on which, if any, agreements involving generic drug ANDA applicants should be considered illegal, the Sections also recommend that the legislation be limited in time.

COMMENTS

The Sections Have Reservations About The Potential Burden Of The Legislation.

The current version of the Senate Bill (S. 754) requires only that the text of a relatively narrow class of patent litigation settlement agreements be filed. In that respect it parallels 35 U.S.C. §135(c) which requires that patent interference settlement agreements be filed with the United States Patent and Trademark Office ("PTO"). That filing program has been in effect for almost forty years. During that time the settlements have been made available to the enforcement agencies with no fees whatsoever payable upon timely filing and, currently, a fee of \$130.00 for late filing.

Given the far more burdensome version of the House counterpart, the Sections are concerned lest the final version of the legislation become more burdensome as it comes closer to enactment. This concern is based partly on experience with the Hart-Scott-Rodino program, in which a

purportedly modest premerger reporting program evolved over time into a massively burdensome one,³ prompting Congress to modify the process in an effort to alleviate some of those burdens.

Congress Should Consider Several Modifications To The Senate Bill.

The Senate Bill is generally clear and straightforward. However, certain language may introduce confusion in defining reporting requirements. The Sections therefore recommend the following changes for consideration:

- The “Purposes” section of the Senate Bill (Section 3) indicates that notification is required of all agreements between companies owning patents on branded drugs and companies who could make generic versions of these drugs. However, the operative language in Section 5 makes clear that only certain agreements are to be notified. It is focused in its definition and limitations (by excluding certain types of agreements, *e.g.*, those involving raw material suppliers), and appropriately so. We recommend that the Purposes section be conformed to the operative language in Section 5.
- The reference in Section 5 of the Senate Bill to excluding “purchase orders for raw material supplies” from the notification obligation is somewhat vague. Purchases of raw materials can be made through means other than purchase orders, and active ingredients should be specially included in the exclusion. The Sections believe the language should be changed to “purchases of Active Pharmaceutical Ingredients (or API’s) and other raw materials” so as to remove any ambiguity concerning whether suppliers of API are deemed “raw material” suppliers.
- The Senate Bill appropriately exempts those agreements notified to the DOJ and FTC from Freedom of Information Act disclosure. The Senate Bill nevertheless allows for subsequent disclosure of all such agreements in “any administrative or judicial action or proceeding.” This is too broad, and can provide an “end-run” around the FOIA exemption. It permits the FTC or DOJ to produce the confidential agreements to any plaintiff, without further confidentiality protections. Because plaintiffs can already obtain the agreements, where so

³ Initially, the HSR program was enacted without any filing fees; now it provides for fees ranging from \$45,000 for the smallest filed transactions to \$280,000 for transactions valued at more than \$500 million. In addition, the scope of requests for additional information under the HSR Act, which Congress intended to limit to “the very data that ... has already been assembled and analyzed by [the merging parties]” soon required production of hundreds of file boxes of documents. *See* 122 Cong. Rec. 30,878 (1976) (remarks of Congressman Rodino), quoted in J. Sims & D. Herman, “The Effect of Hart-Scott-Rodino on Merger Practice: A Case Study in the Law of Unintended Consequences Applied to Antitrust Legislation,” 65 *Antitrust L.J.* 865, 879 (1997). Behind these burdens looms the further possibility of waiting periods, which will interfere with judicial calendars and the litigation process.

ordered, directly from the companies in litigation and subject to appropriate confidentiality protections, this provision allowing for direct production is unnecessary and unwarranted. The Sections suggest as an alternative, that disclosure be allowed “in any administrative or judicial action or proceeding in which the Federal Trade Commission or Department of Justice is a plaintiff or complainant, or upon the order of any court of competent jurisdiction.”

Legislation Should Be Modeled On The Current Senate Bill, Rather Than The House Bill.

The House Bill, H. 1530, closely resembles an older version of the Senate Bill, and may no longer be under active consideration. The Sections believe that the current version of the Senate bill is far superior to the current version of the House bill. The House bill contains the following shortcomings which are remedied by the Senate bill:

- H.R. 1530 would require more agreements to be notified, and has a more burdensome notification procedure. The “Purpose” section explains that the bill is designed to require disclosure of all agreements between companies owning patents on branded drugs and companies who “could” make generic versions of these drugs. This language, its definition of “Agreement,” and the operative language give the bill much wider application than just patent settlements. The bill would presumably require disclosure of numerous other types of agreements, such as licenses and supply agreements, that do not raise any potential competitive concerns.
- H.R. 1530 also would require an explanation of whether the parties believe the agreement would “in any way interfere with the production, manufacture or sale of the generic version of the drug in question.” This stands in contrast to other antitrust notification laws, such as the Hart-Scott-Rodino Antitrust Improvements Act, which require basic notification only, unless and until the agency requires additional information. The Sections believe it would be unfair, unduly burdensome, and wasteful to require parties to provide notice beyond that set forth in the Senate Bill, as a matter of routine for every agreement they reach, without regard to whether those agreements might raise any legal questions or are determined to be worthy of further investigation. The Agencies have sufficient investigative tools (including subpoena power and civil investigative demands) to probe any agreements they wish to investigate more thoroughly.
- The burden imposed by H. 1530 would be exacerbated by the requirement that the explanatory material be submitted along with the agreement within 10 days of signing. Like other litigation settlements, patent litigation settlements are often reached on the eve of trial - - many times with significant pressure from the trial court judge. Parties in the throes of final trial preparation who engage in time-consuming and heated settlement discussions cannot simultaneously be preparing a detailed report analyzing the competitive aspects of the settlement for an agency filing. The Senate Bill strikes a sensible balance in this regard. It requires a filing be made quickly -- within 10 days of the executing of the agreement -- but

requires only that the agreement itself be filed and any other related agreements between the parties, or written descriptions of “non-textual” (i.e., oral) agreements.

- H. 1530 expands the definition of “antitrust laws” to include Section 5 of the Federal Trade Commission Act. Since the term “antitrust laws” appears in many other provisions dealing with antitrust procedures and remedies, the implications of such an expansion would be far-reaching. Such a change could, for example, be interpreted to confer private rights of action under Section 4 of the Clayton Act, 15 U.S.C. §15(a), for violations of Section 5 -- a right which does not currently exist and may not be desirable. This provision has wisely been stricken from the current Senate bill.
- H.R. 1530 contains no FOIA protections, and is therefore at odds with similar notice laws (*see, e.g.*, the Hart Scott Rodino Antitrust Improvements Act) and would force companies into the untenable and unacceptable position of having to place their trade secrets and other confidential information at risk of public disclosure in order to meet compliance requirements.
- H.R. 1530 is unfairly punitive. Unlike the Senate Bill, which contains an \$11,000 per day penalty for non-compliance, H.R. 1530 contains a \$20,000 per day penalty for failing to comply with any provision. This is higher than HSR Act penalties, for no reason. Further, if the parties reasonably believe their agreement would not limit competition and so state, they may be penalized long after the fact if the Commission disagrees. This improperly places notifying parties at risk of penalty simply for stating their position about the competitive effects of the subject agreement.

For these reasons, among others, the Sections believe that, if Congress decides to enact a reporting requirement, the legislation should be modeled after the Senate Bill, rather than the House Bill.

The Undeveloped Nature of the Law In this Area Makes a Sunset Provision Appropriate.

The legal implications of ANDA patent litigation settlements and other agreements between brand-name and generic pharmaceutical companies involve complex, unresolved questions at the interface of antitrust, intellectual property and FDA law. Such agreements also implicate the important judicially-recognized public policy favoring the settlement of litigation. The Sections believe any need to require early notice of agreements as to which there is no academic, agency, or judicial consensus of possible anti-competitive harm may be fairly short-lived.⁴ Further, there is a broad, ongoing FTC study under Section 6(b) of the FTC Act regarding various pharmaceutical industry practices, and ANDA patent litigation settlement agreements in particular, that has not yet been completed.

⁴ In this regard, the Sections note that the principal class action cases in this area (involving patent litigation settlements) have yet to run their course.

A principal purpose of the FTC's industry-wide Section 6(b) study is to "examine the use of agreements between pharmaceutical companies, and any other strategies, that may delay generic drug competition."⁵ The Commission's report, when it issues, will provide Congress with far more information than is now available about agreements which are the target of this legislation. This will allow Congress to determine whether there are problems that warrant continuation of the kind of reporting program proposed in the legislation, and if so, how that program ought to be modified or restructured.

Therefore, if Congress decides to implement the stated, and limited, goal of the Senate Bill -- to give federal antitrust enforcers early notice of certain agreements with generic drug applicants, to allow further study and facilitate enforcement actions where appropriate -- the Sections do not believe such an obligation should be perpetual. Congress should retain the flexibility that a sunset provision provides so that it can tailor future legislation to meet more refined concerns.

Specifically, the Sections recommend that the effective period of the Senate Bill be limited to three years. During this three-year period, the FTC should be required to report back to Congress annually on its experiences and enforcement history. At the end of the three years, and after the benefit of these annual reports and further agency and court exploration of this area, Congress can then decide whether to modify the law, make the law permanent, or let the law expire.

Conclusion

While the Antitrust Law and Intellectual Property Law Sections have concerns about the potential burden of the legislation, the Sections believe that it can be improved by clarifying certain of its provisions. At the same time, the Sections believe that, given the present state of flux in the law relating to pharmaceutical patent litigation settlements, and the lack of information about the dimensions of the problem, Congress should consider a sunset provision which would trigger a review in three years and, if warranted by experience within that time, a more permanent extension of the law.

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⁵ FTC Press Release, "FTC to Study Generic Drug Competition," Oct, 11, 2000, p. 2.