

the ANDA First Filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity).

Paragraph II.A. bars agreements in which the first company to file an ANDA agrees with the NDA Holder not to relinquish its right to the 180-day exclusivity period (as interpreted by the courts at the time of the agreement). Paragraph II.B. prohibits the ANDA First Filer from agreeing not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The order recognizes, however, that even these types of agreements, in the context of certain licensing arrangements, might not raise competitive concerns. Accordingly, conduct otherwise falling within the conduct described in Paragraph II would not be prohibited where the ANDA First Filer agrees to license and introduce a competitive product to the market, its 180-day exclusivity right is not extended, and the Commission is provided notice.

Paragraph II's focus on agreements between an NDA Holder and the ANDA First Filer does not mean that the Commission believes that there is no risk of competitive harm in other types of agreements. In particular substantial competitive concerns could arise from an agreement in which a generic company (other than the ANDA First Filer) agrees with the NDA Holder to refrain from marketing a non-infringing product. Given the variety of circumstances in which the restraints may arise, however, and the possibility that some legitimate justifications might exist for such arrangements, the Commission believes that it is appropriate at this time to limit the bans in Paragraph II to the described agreements between NDA Holders and ANDA First Filers.

Paragraph III covers certain private agreements involving payments from the NDA Holder to the ANDA First Filer during patent infringement litigation. Generally, the Respondents can enter into such arrangements only if (a) the agreement is presented to the court and embodied in a court-ordered preliminary injunction, and (b) the following other conditions are met: (i) Along with any stipulation for preliminary injunction, Respondents provide the court with a copy of the Commission's complaint, order, and the analysis to Aid Public Comment in this matter, as well as the proposed agreement; (ii) at least 30 days before submitting the stipulation to the court, they provide written notice (as set forth in Paragraph V of the order) to the Commission; and (iii) they do not oppose Commission participation in the

court's consideration of the request for preliminary relief.

This part of the proposed order is designed to enhance the court's ability to assess the competitive implications of such agreements. This remedy, in addition to facilitating the court's access to information about the Commission's views, may also make the process more public and thereby may prompt other generic drug manufacturers (or other interested parties) to participate.

Paragraph IV addresses private agreements in which an ANDA First Filer agrees with the NDA Holder not to enter the market. Such situations would include agreements that are part of a final settlement of the litigation, and situations in which no litigation has been brought. In these circumstances, there may be no judicial role in ordering relief agreed to by the Respondents. Thus, the order requires that the Respondents notify the Commission at least 30 days before entering into such agreements. Such notice will assist the Commission because of the potential for competitive harm that these agreements may create. Absent the order, there may be no effective mechanism for the Commission to find out about such agreements.

The form of notice that the Respondents must provide to the Commission under Paragraphs II, III and IV of the order is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, the Respondents are required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the order requires the Respondents to identify, among other things, all others who have filed an ANDA for a product containing the same chemical entities as the product at issue, and the court that is hearing any relevant legal proceedings involving either party. In addition, the Respondents must provide the Commission with all documents that evaluate the proposed agreement.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The order will expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed order and the comments received and will

decide whether it should withdraw from the proposed order or make the proposed order final.

By accepting the proposed order subject to final approval, the Commission anticipates that the competitive issues alleged in the complaint will be addressed. The purpose of this analysis is to facilitate public comment on the agreement. It is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

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FEDERAL TRADE COMMISSION

[File No. 002 3331]

Microsoft Corporation; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before May 3, 2001.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Michael Ostheimer, FTC/S-4002, 600 Pennsylvania Ave., NW., Washington, DC 20580 (202) 326-2699.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the

allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for April 3, 2001), on the World Wide Web, <http://www.ftc.gov/os/2001/04/index.htm>. A paper copy can be obtained from the FTC Public Reference Room, Room H-130, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Microsoft Corporation ("Microsoft").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves alleged misleading representations about Pocket PC handheld computers ("Pocket PCs")—personal digital assistants ("PDAs") which feature Microsoft's Windows CE operating system, including Hewlett-Packard Company's Jornada Pocket PC and Compaq Computer Corp.'s Pocket PC. This matter concerns allegedly false and deceptive advertising claims made in advertisements regarding the ability of Pocket PCs to access the Internet and email accounts.

According to the FTC complaint, Microsoft falsely claimed that Pocket PCs contain everything that consumers need to access the Internet and their email accounts, at anytime and from anywhere. In fact, in order to access the Internet and their email accounts using Pocket PCs, when away from their computers ("remotely"), consumers

must purchase and carry a separate modem or similar device that in most cases must be connected to a land telephone line or a mobile telephone; and moreover, many mobile telephones currently in use in the United States are not compatible with Pocket PCs. The complaint also alleges that in representing that consumers can use Pocket PCs to access the Internet and their email accounts, at anytime and from anywhere, Microsoft failed to disclose or failed to disclose adequately that in order to access remotely the Internet and their email accounts, consumers must purchase and carry a separate modem or similar device. The complaint alleges that the failure to disclose this material fact is a deceptive practice.

The proposed consent order contains provisions designed to prevent Microsoft from engaging in similar acts and practices in the future. Specifically, Parts I and II address representations regarding any PDA or handheld Internet or email access device that requires the use of an additional device or connection to a telephone land line in order to access the Internet or email accounts remotely ("covered devices").

Part I of the proposed order prohibits Microsoft from making any misrepresentations about the ability of any covered device to access the Internet or email accounts, or about any performance characteristic of any covered device affecting access to the Internet or email accounts.

Part II of the proposed order prohibits Microsoft from making any representation about the ability of any covered device to access the Internet or email accounts unless Microsoft discloses, clearly and conspicuously, any other products (such as a modem, mobile telephone, or adapter) or Internet or email access services (other than general-purpose ISP service, as defined in the order) that consumers must purchase in order to access the Internet or email accounts.

Parts III through VI of the order require Microsoft to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the commission of changes in corporate structure, and to file compliance reports with the Commission. Part VII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of

the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,
Secretary.

Concurring Statement of Commissioner Orson Swindle

I voted to accept both of these consent agreements for public comment, because the proposed consent orders are adequate relief for the violations alleged in the complaint. Nonetheless, I have strong reservations about the use of unenforceable "voluntary" consumer education. In each of these cases, staff negotiated with the proposed respondent to achieve a consumer education campaign that is being undertaken wholly outside the confines of the order. Consumer education remedies sometimes pose difficult issues and Commissioners may disagree as to whether a particular consumer education remedy is appropriate and reasonably related to the complaint allegations. Yet the solution for such disagreements is not simply to excise such remedies from the legally enforceable obligations that respondents are undertaking in settlement. If consumer education is important enough to include in negotiations, there likely is some impact on what is achieved in negotiating the terms of the consent order itself. Moreover, to the extent that the FTC promotes such "voluntary" consumer education initiatives in our efforts to publicize the consent agreements, we may see many more deep-pocketed respondents seeking to add a bit of "voluntary" and unenforceable consumer education to a broader promotional campaign in exchange for a weaker order than might otherwise be negotiated.

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FEDERAL TRADE COMMISSION

Cigarette and Smokeless Tobacco Reports; Request for Public Comment

AGENCY: Federal Trade Commission.

ACTION: Request for public comments.

SUMMARY: The Federal Trade Commission ("FTC" or "Commission") is soliciting comments to help it determine whether to continue to issue reports on the sales, advertising and promotion of cigarettes and smokeless tobacco products, as well as the formats for any such reports.

DATES: Written comments must be received on or before June 11, 2001.