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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. MERCK & CO., INC., Defendant.	Civil No. 3159

MEMORANDUM OF THE UNITED STATES IN RESPONSE TO THE MOTION OF MERCK & CO., INC. TO TERMINATE THE CONSENT DECREE

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. MERCK & CO., INC., Defendant.	Civil No. 3159

MEMORANDUM OF THE UNITED STATES IN RESPONSE TO THE MOTION OF MERCK & CO., INC. TO TERMINATE THE CONSENT DECREE

Merck & Co., Inc. ("Merck"), the successor in interest to Merck & Co., Inc.[1], the original defendant in this action, has moved to terminate the Consent Decree entered in *United States v. Merck & Co., Inc.* (Civil No. 3159 D.N.J. 1943) on October 6, 1945 ("1945 Consent Decree").[2] A copy of the 1945 Consent Decree is attached as Exhibit A.

After soliciting public comments on the proposed termination, the United States has concluded that this decree is no longer necessary to protect competition and that its continued existence does not otherwise provide any public benefit. The purpose of the decree was to restore competition between Merck and its former German parent, E. Merck. The relationship between Merck and E. Merck, now known as Merck KGaA, has

[1] On November 3, 2009, Merck & Co., Inc. ("Legacy Merck") merged with Schering-Plough Corporation ("Schering-Plough"). As a result of the merger, Schering-Plough—which was renamed Merck & Co., Inc. ("Merck")—became the parent company of both Legacy Merck and the former Schering-Plough operating companies. Legacy Merck was renamed Merck Sharp & Dohme Corp.

[2] Two other defendants were named in the complaint and were parties to the decree. Powers-Weightman-Rosengarten Corporation was dissolved in 1951. George W. Merck died in 1957.

changed dramatically since the 1945 Consent Decree was entered sixty-five years ago. In essence, the competitive problems the 1945 Consent Decree addressed are no longer a cause for concern. Therefore, the United States supports Merck's motion to terminate the 1945 Consent Decree. [3]

I. BACKGROUND

A. The Complaint and the 1945 Consent Decree[4]

The purpose of the 1945 Consent Decree was to restore competition between Merck and its former German parent, E. Merck, by dissolving the "Treaty Agreement" between the two companies and prohibiting various conduct between them. E. Merck is a German company that traces its roots back to a single pharmacy in Germany in 1688. In the early 1800's, Emanuel Merck took over this pharmacy and began industrial production of various organic and inorganic substances. In 1891, his grandson, George Merck, founded a trading company in the United States to sell the German parent company's products here. The German parent company owned a substantial interest in the United States trading company. This trading company was incorporated as Merck & Co., Inc. in 1908 and continued to act as a sales agent for its German parent company in the United States and Canada. Both companies exported to Cuba, the Philippines, and the West Indies and competed for sales there. E. Merck sold the company's products in all other parts of the world.

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[3] The Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)-(h) (the "Tunney Act"), which provides for public notice and comment on antitrust settlements proposed by the United States, does not apply to decree terminations. Merck has provided public notice of its request to terminate the 1945 Consent Decree. As part of this notice, the United States solicited comments regarding the proposed termination. No comments were received.

[4] The following background is taken from the complaint filed in this action, which is attached as Exhibit B.

During World War I, the Alien Property Custodian of the United States seized the interests of E. Merck in Merck. In 1919, George Merck raised funds and purchased the seized assets from the Alien Property Custodian. Since that time, E. Merck has had no ownership interest in Merck. As a result of the war, Merck substantially expanded its manufacturing operations in the United States and developed an export business to Central and South America, countries that E. Merck could no longer export to as a result of the Allied powers blockade of Germany. Once the war ended, Merck ceased exporting to those countries and ceded those countries to E. Merck. In return, E. Merck continued to not make sales in the United States and Canada.

In 1932, the two companies formalized this territorial allocation in a "Treaty Agreement" and agreed to other forms of cooperation, such as cross licensing of patents, sharing new products each developed, and extensive information sharing on improvements to existing and future products. This Treaty Agreement remained in place until the United States challenged it in 1943 in this action. The suit was settled with the entry of the 1945 Consent Decree.

The purpose of the decree was to restore competition between Merck and its former parent company, E. Merck. To achieve that, the primary mechanism was the cancellation of the Treaty Agreement and an injunction preventing Merck and its successors from adhering to the terms of the Treaty Agreement or engaging in conduct to revive the agreement. The decree also prohibits Merck from "entering into, adhering to, maintaining or furthering any agreement" with E. Merck to:

(1) refrain from competing in any market or country;

(2) refrain from competing in the manufacture, sale, distribution, import or export of any chemical or pharmaceutical product;

(3) allocate markets, territories, or customers for the sale of any chemical or pharmaceutical product;

(4) create or observe an obligation to exchange or license rights relating to any chemical or pharmaceutical product;

(5) establish or adopt terms and conditions for licensing patents for any chemical or pharmaceutical product;

(6) establish or adopt terms and conditions for the sale of any chemical or pharmaceutical product; and

(7) fix prices for any chemical or pharmaceutical product.

The decree provides that Merck file with the Assistant Attorney General for the Antitrust Division "notice of their intention to make any agreement or arrangement with E. Merck relating to or affecting the business policy" of Merck. In addition, the decree required Merck to grant patent licenses to anyone who applied for a long list of specific patented processes and not sue anyone for patent infringement based on the same list of patented processes. The decree was entered on October 6, 1945.

B. Developments Since the Entry of the 1945 Consent Decree

Merck and its former parent, E. Merck (now known as Merck KGaA), today are totally separate companies. Both participate in the pharmaceutical business, although Merck KGaA has a very limited presence in the United States. In November 2009, Merck merged with Schering-Plough. The surviving company is still known as Merck & Co., Inc.

In May 2010, Merck advised the Division that it wished to seek termination of the 1945 Consent Decree. To determine whether the Division should consent to the request, the Division required that Merck publish voluntarily, at its own expense and in a form acceptable to the Division, a "Notice of Intention to Seek Termination of the Consent

Decree in *United States v. Merck & Co., Inc., et al.*"[5] The Notice ran in the Wall Street Journal and "The Pink Sheet", a widely read trade publication for the pharmaceutical industry. It described Merck's intention to seek termination of the 1945 Consent Decree and specifically invited any interested persons to submit comments or relevant information about these plans to the Division. The Notice appeared in the August 27 and August 28, 2010 issues of the Wall Street Journal and the August 23 and August 30 issues of The Pink Sheet (both the print and electronic versions).[6] The Notice requested that comments be submitted by October 1, 2010. Although the Division received several requests for copies of the1945 Consent Decree in response to the notice, no comments were submitted. There have been no violations of the consent decree since its entry in 1945.[7]

For the reasons discussed below, the United States has decided to consent to Merck's motion to terminate the 1945 Consent Decree.

II. ARGUMENT

Termination of the 1945 Consent Decree is in the public interest as continuation of the decree is no longer necessary to protect competition. The Treaty Agreement was dissolved more than sixty five years ago. Merck and Merck KGaA continue to be totally separate companies and compete with each other in the pharmaceutical industry. The 1945 Consent Decree has accomplished its principal purpose of restoring competition

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[5] The Notice is attached as Exhibit C.

[6] Copies of proofs of publication from the Wall Street Journal and The Pink Sheet are attached as Exhibits D and E, respectively.

[7] Merck has on two occasions in the last ten years brought to the Division's attention proposed licensing agreements it sought to enter into with Merck KGaA. On both occasions, the Division reviewed the general scope of the proposed licensing agreement and found no conflict with the decree.

between Merck and Merck KGaA. Both companies will remain fully subject to the federal antitrust laws after the termination of the decree. The 1945 Consent Decree is obsolete and no longer needed.

A. Applicable Legal Standard for Termination of the 1945 Consent Decree

This Court has jurisdiction to terminate the 1945 Consent Decree. Section IX of the decree provides that:

> "Jurisdiction of this cause is retained for the purpose of enabling any of the parties to this decree to apply to the Court at any time for further orders or directions as may be necessary or appropriate for the construction or carrying out of this decree, for the amendment, modification, or termination of any of the provisions thereof. . . ."

Under Rules 60(b)(5) and (b)(6) of the Federal Rules of Civil Procedure, "[o]n motion and just terms, the court may relieve a party . . . from a final judgment . . . [when] applying it prospectively is no longer equitable; or (6) for any other reason that justifies relief." *See United States v. IBM Corp.*, 163 F.3d 737, 738 (2d Cir. 1998) (affirming grant of motion by the United States and defendant to terminate antitrust final judgment).

Where, as is the case here, the United States supports a defendant's request for termination of an antitrust consent decree, the reviewing court is responsible for determining whether such termination is in the "public interest." *IBM Corp.*, 163 F.3d 737, 738 (2d Cir. 1998); s*ee also United States v. American Cyanamid Co.,* 719 F.2d 558, 565 (2d Cir. 1983); *United States v. Baroid Corp.*, 130 F.Supp.2d 101, 103 (D.D.C. 2001); *United States v. Loew's Inc.*, 783 F. Supp. 211, 213 (S.D.N.Y. 1992). Exercising "judicial supervision," *IBM*, 163 F.3d at 740, the court should approve a consensual decree termination where the United States has provided a reasonable explanation to support the conclusion that the termination is consistent with the public interest. *Loew's*,

783 F. Supp. at 214. In essence, the court's public interest determination "should look to the elements of that species of antitrust violation to determine whether the present state of affairs is such that dissolution of the decree would be in the 'public interest.'" *IBM Corp.*, 163 F.3d at 740 (citing *American Cyanamid*, 719 F.2d at 565). Deference is usually given to the Antitrust Division's position in light of its antitrust expertise. *Baroid*, 130 F.Supp.2d at 103.

The Division has recognized that obsolete decrees can needlessly burden the parties, the courts, and the competitive process. These considerations, among others, led the Division in 1980 to establish a policy of including in every consent decree a so-called "sunset provision" that, other than in exceptional cases, would result in the decree's automatic termination after ten years.[8] As a result, with rare exception, the only antitrust decrees to which the United States is a party that remain in effect are those entered within the past ten years, or before 1980 when the "sunset" policy was adopted. The Division's policy statements have encouraged parties to old decrees to seek the Division's consent to their termination.[9] In the United States' view, decrees entered prior to 1979

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[8] This change in policy followed Congress' 1974 amendment of the Sherman Act to make violations a felony, punishable by substantial fines and jail sentences. In 2004, Congress increased the statutory maximum penalty for a Sherman Act violation by a corporation to a $100 million fine and by an individual to ten years in prison and a $1 million fine. With these enhanced penalties for *per se* violations of the antitrust laws, the Division concluded that antitrust recidivists could be deterred more effectively by a successful criminal prosecution under the Sherman Act than by a criminal contempt proceeding under provisions of an old consent decree aimed at preventing a recurrence of price-fixing and other hard-core antitrust violations. *United States v. Columbia Artists Mgmt., Inc.*, 662 F. Supp. 865, 867 (S.D.N.Y. 1987).

[9] *See* U.S. Department of Justice, Antitrust Division, DOJ Bull. No. 1984-04, *Statement of Policy by the Antitrust Division Regarding Enforcement of Permanent Injunctions Entered in Government Antitrust Cases* (attached as Exhibit F); and U.S. Department of Justice Press Release, *New Protocol to Expedite Review Process for Terminating or Modifying Older Antitrust Decrees* (April 13, 1999) (attached as Exhibit G).

presumptively should be terminated, unless there are affirmative reasons for continuing them, which we would expect to exist only in limited circumstances.[10]

B. The 1945 Consent Decree's Provisions are Unnecessary Under Current Antitrust Statutes

The presumption in favor of terminating old decrees is especially justified where changes in the law have rendered the decree's provisions unnecessary. Many of the 1945 Consent Decree's provisions prohibit *per se* antitrust violations between Merck and its former parent E. Merck. *E.g. see* Section VI(G)(1) and VI(G)(4). After the passage of decades, judgment provisions that in substance require defendants to abide by the antitrust laws add little, if anything, to antitrust compliance. The remedies available under current antitrust statutes for criminal antitrust violations such as hard-core price-fixing and market allocation are generally more severe than those for contempt of an outstanding judgment and therefore serve as a greater deterrent to resumption of the challenged anticompetitive conduct than the threat of contempt proceedings. *Cf. Loew's*, 783 F.Supp. at 214 (holding that termination of an antitrust decree leaves the parties "fully subject to the antitrust laws of general application").

Section VII of the decree requires Merck "to file with the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice, notice of their intention to make any agreement or arrangement with E. Merck relating to or affecting

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[10] Among the circumstances where continuation of a decree entered more than ten years ago may be in the public interest are: a pattern of noncompliance by the parties with significant provisions of the decree; a continuing need for the decree's restrictions to preserve a competitive industry structure; and longstanding reliance by industry participants on the decree as an essential substitute for other forms of industry-specific regulation where market failure cannot be remedied through structural relief. None of these circumstances is present in this case.

the business policy of either defendant ...." This provision of the decree is no longer necessary to assure that the Division receives notification of proposed business arrangements between Merck and E. Merck (now Merck KGaA). There is no reason to continue to require that Merck provide notification to the Division of proposed business arrangements with Merck KGaA as opposed to any other company. In 1976, Congress enacted the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act"), codified at 15 U.S.C. § 18a, which requires advance notification to the Department of Justice and Federal Trade Commission before the formation of certain joint ventures and prohibits closing the proposed transaction until the expiration of a waiting period, usually thirty days. Thus, the government agencies will have notice of and an opportunity to evaluate significant joint ventures between Merck and Merck KGaA. Moreover, the broad reporting requirements of the 1945 Consent Decree are not consistent with modern antitrust enforcement policy which recognizes that joint ventures and licensing arrangements between companies are often pro-competitive and should be judged under a rule of reason standard.[11] The two companies have operated independently, with no decree violations, for more than 65 years. In reviewing the two proposed licensing arrangements between Merck and its former parent over the last ten years, we have not found that they violated the 1945 Consent Decree or were anticompetitive.

C. Notice Procedures Before Termination of The1945 Consent Decree

The United States believes that advance publication of Merck's plans to seek to terminate the 1945 Consent Decree provided sufficient public notice and opportunity to

[11] *See e.g.* The National Cooperative Research and Production Act of 1993, 15 U.S.C. §§ 4301-06, which applies the rule of reason standard to the antitrust analysis of joint ventures.

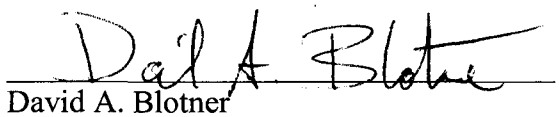
comment on the pending motion to terminate the 1945 Consent Decree. The United States received no comments in response to the notices Merck published. If the Court agrees that no further notice is necessary, the United States requests that the Court enter an order terminating the 1945 Consent Decree. *See* Exhibit A to the Stipulation Between Parties In Support Of The Unopposed Motion Of Merck & Co., Inc. To Terminate The Consent Decree. If the Court, however, concludes that further notice and comment are necessary, the United States requests that the Court enter the stipulated order providing procedures for further notice and comment. *See* Exhibit B to the Stipulation Between Parties In Support Of The Unopposed Motion Of Merck & Co., Inc. To Terminate The Consent Decree. Merck has agreed to follow these procedures, including publication of the appropriate notices, should the Court find it necessary.

III. CONCLUSION

For the foregoing reasons, the United States consents to the termination of the 1945 Consent Decree, subject to its right to withdraw its consent to the motion at any time prior to entry of an order terminating the Decree.

Dated: July 25th, 2011

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing Memorandum Of The United States In Response To The Motion Of Merck & Co., Inc. To Terminate the Consent Decree to be served upon the following attorneys by First Class Mail on July 25th, 2011:

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EXHIBIT A

BB# 0784

Civil Action No. 3159

In the District Court of the United States for the District of New Jersey

UNITED STATES OF AMERICA, AND ALIEN PROPERTY CUSTODIAN, PLAINTIFFS

v.

MERCK & CO., INC., AND POWERS-WEIGHTMAN-ROSENGARTEN CORPORATION, DEFENDANTS

FINAL JUDGMENT

In the District Court of the United States for the District of New Jersey

Civil Action No. 3159

UNITED STATES OF AMERICA, AND ALIEN PROPERTY CUSTODIAN, PLAINTIFFS

v.

MERCK & CO., INC., AND POWERS-WEIGHTMAN-ROSENGARTEN CORPORATION, DEFENDANTS

The plaintiff, United States of America, having filed its complaint herein on October 28, 1943; the defendants Merck & Co., Inc., and Powers-Weightman-Rosengarten Corporation, respectively, having appeared and filed their answer to such complaint denying the substantive allegations thereof; the plaintiff, Alien Property Custodian, having intervened and filed its complaint herein on October 6, 1945; the defendant, Merck & Co., Inc., having filed its answer to such complaint denying the substantive allegations thereof; all parties hereto by their attorneys herein having severally consented to the entry of this final judgment herein without trial or adjudication of any

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issue of fact or law herein and without admission by either defendant in respect of any such issue;

NOW, THEREFORE, before any testimony has been taken herein, and without trial or adjudication of any issue of fact or law herein, and upon consent of all parties hereto, it is hereby

ORDERED, ADJUDGED, AND DECREED, as follows:

I

The Court has jurisdiction of the subject matter herein and of all the parties hereto; the complaint of the United States of America states a cause of action against the defendants under the Act of Congress of July 2, 1890, entitled "An Act to Protect Trade and Commerce Against Unlawful Restraints and Monopoly"; and the complaint of the Alien Property Custodian states a cause of action against the defendant Merck & Co., Inc., under Section 24 (1) of the Judicial Code, as amended (Title 28, U. S. C. Section 41 (1), Section 274 (d) of the Judicial Code, as amended (Title 28, U. S. C. Section 400), and under Section 17 of the Trading with the Enemy Act of October 6, 1917 (40 Stat. 425; Title 50, Appendix, U. S. C., Section 17).

II

As used in this judgment:

1. "E. Merck" means a partnership trading and doing business under that name and style in Darmstadt, Germany, and its partners, and its and each of their agents, employees, affiliates, successors, subsidiaries, representatives, and assigns, and all persons

acting or claiming to act under, through or for them or any of them; provided, that the term "E. Merck" shall not be deemed to refer to or include the Alien Property Custodian by reason of his vesting of any property, interests, or rights of E. Merck; this proviso, however, shall not operate to impair the right of the Alien Property Custodian, as owner of all interests and rights created in E. Merck by virtue of the Treaty Agreement and all agreements amendatory and supplemental thereto, and as owner of all patents, patent applications, processes, and inventions vested in him and referred to herein, to consent to this judgment, to consent to cancellation of said Treaty Agreement and all agreements amendatory and supplemental thereto, and to administer said patents, patent applications, processes, and inventions except as provided in Paragraph X hereof.

2. "Treaty Agreement" means a written agreement, a copy of which is attached hereto and made a part hereof and marked Exhibit A, dated November 17, 1932, between Merck & Co., Inc., and E. Merck.

III

The Treaty Agreement, and all agreements amendatory or supplemental to the Treaty Agreement are hereby cancelled and each of the defendants and each of their directors, officers, agents, employees, representatives, successors, subsidiaries and affiliates, and all persons acting or claiming to act under, through, or for them, are, and each of them and any successor or assign of the Alien Property Custodian, hereby is, enjoined and restrained from the further performance

of any of the provisions of such Treaty Agreement or of any agreement amendatory or supplemental to such Treaty Agreement, and from adopting or following any course of conduct for the purpose or with the effect of reviving or reinstating any of the provisions of said Treaty Agreement or any agreement amendatory or supplemental to such Treaty Agreement. This Paragraph III shall not be deemed to terminate any immunity, as a nonexclusive immunity, held by either defendant on the date of this judgment to manufacture, use, or sell under any existing patent, patent application, process or invention, nor to prevent Merck & Co., Inc., from enforcing or asserting such rights or immunities as it may possess for the use in its business of the name and trademark "Merck" in any form or combination of such name and trademark whatsoever.

IV

Defendant Merck & Co., Inc., its officers, directors, agents, employees, successors, and assigns are hereby ordered and directed to issue to any applicant making written request therefor, a nonexclusive license in the form annexed hereto and marked Exhibit B, under any one or more of the United States Letters Patent and Patents issued under applications for United States Letters Patent, the patent numbers and application numbers of which are listed in subdivision 1 of Exhibit C, attached hereto and made a part hereof, including all continuances, renewals, reissues, or extensions of such patents and patent applications, without any restriction or condition whatsoever, and with-

out royalty or charge of any kind therefor, to make, use, and sell the inventions claimed by the patents and patent applications listed in said subdivision 1 of Exhibit C, for the life of said patents respectively.

V

Defendant Merck & Co., Inc., its officers, directors, agents, employees, successors, and assigns are hereby ordered and directed to issue to any applicant making written request therefor, to the extent that defendant Merck & Co., Inc. has or acquires the power to do so, an unrestricted and unconditional grant of immunity under foreign patents or applications for foreign patents corresponding to the United States Letters Patent and applications for United States Letters Patent listed in Exhibits C and D, attached hereto, to import into, and to sell or to use, and to have imported, sold or used in, any country, any product made in the United States.

VI

Each of the defendants and each of their directors, officers, agents, employees, representatives, successors, subsidiaries and affiliates, and all persons acting or claiming to act, under, through or for them, or any of them are, and each of them hereby is, enjoined and restrained from:

(A) Instituting or threatening to institute or maintaining any suit or proceeding for patent infringement, or to collect royalties (1) based upon any of the United States Letters Patent listed in Exhibits C and D, attached hereto, or issued upon any application

for a patent so listed, or (2) based upon any foreign patent or application for a foreign patent corresponding to the United States Letters Patent or application for United States Letters Patent listed in Exhibits C and D, attached hereto, on account of the importation, sale, or use in any country of any product made in the United States.

(B) Filing any claim or bringing any suit or proceeding under Section 9 of the Trading with the Enemy Act, or otherwise, for the purpose of claiming or recovering any right, title, or interest in and to any such patent or patent application listed in Exhibit D, attached hereto, or any interest therein or thereunder, except in so far as the Alien Property Custodian expressly grants rights therein or thereunder to the defendants, their successors, or assigns, or either or any of them.

(C) Reserving or undertaking to reserve for E. Merck, or any person or persons designated by E. Merck, any right or immunity to use, or to control the use of, in any market or country, any trade-mark, trade-name, or other designation adopted by either defendant for any chemical or pharmaceutical product.

(D) Vesting in E. Merck control over any of the business or over any business policy of defendant Merck & Co., Inc., or of any of its subsidiaries or affiliates.

(E) Claiming or asserting as exclusive any right or immunity received from E. Merck prior to the date of the entry of this judgment, under any patent or patent application or as to any process or invention.

(F) Conditioning in any way the sale or distribution or availability for sale or distribution of any chemical or pharmaceutical product to or by any person, upon such person refraining from reselling or distributing or refraining from exporting for resale or distribution such product in competition with E. Merck at any place in the world.

(G) Entering into, adhering to, maintaining or furthering any agreement, undertaking, plan or program with E. Merck:

(1) To refrain from competing in any market or country or in the manufacture, sale, distribution, importation, or exportation of any chemical or pharmaceutical product, or to allocate markets, territories, or customers for the sale or distribution of any chemical or pharmaceutical product.

(2) To create, or to observe, an obligation to exchange or license under patents, patent applications, inventions, processes, or other rights relating to any chemical or pharmaceutical product.

(3) To establish, adopt, or agree upon terms and conditions to be imposed, observed, or required in the licensing or granting immunities to or by others under patents, patent applications, inventions, or processes relating to any chemical or pharmaceutical product, or in the sale or distribution by or to others of chemical or pharmaceutical products.

(4) To fix, maintain, or determine prices to be quoted or charged by or to, or imposed upon, any other person for any chemical or pharmaceutical product.

VII

Each of the defendants and each of their directors, officers, agents, employees, representatives, successors and affiliates, and all persons acting or claiming to act under, through, or for them or any of them are, and each of them hereby is, ordered and directed to file with the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice, notice of their intention to make any agreement or arrangement with E. Merck relating to or affecting the business policy of either defendant, its successors, affiliates, or subsidiaries. The failure of the Attorney General of the United States or the Assistant Attorney General in charge of the Antitrust Division to take any action following receipt of any information pursuant to this paragraph shall not be construed as an approval of the matter and things so received or informed, and shall not operate as a bar to any action or proceeding that may later be brought or be pending whether pursuant to this judgment or any law of the United States based on things so received or informed.

VIII

For the purpose of securing compliance with this judgment, and for no other purpose, and subject to any legally recognized privilege, duly authorized representatives of the Department of Justice shall, on the written request of the Attorney General, or an Assistant Attorney General, and on reasonable notice to the defendants be permitted (1) access, during the office

hours of said defendants, to all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession of or under the control of said defendants, relating to any of the matters contained in this judgment; (2) without restraint or interference from the defendants, to interview officers or employees of the defendants, who may have counsel present, regarding any such matters; and the defendants, on such request, shall submit such reports on applications for licenses and licensing under Paragraph IV of this judgment, or with respect to any relationship with E. Merck, or on exports or sales for export by the defendants, as may from time to time be reasonably necessary for the enforcement of this judgment; provided, however, that information obtained by the means permitted in this paragraph shall not be divulged by any representative of the Department of Justice to any person other than a duly authorized representative of the Department of Justice except in the course of legal proceedings in which the United States of America is a party or as otherwise required by law.

IX

Jurisdiction of this cause is retained for the purpose of enabling any of the parties to this decree to apply to the Court at any time for such further orders and directions as may be necessary or appropriate for the construction or carrying out of this decree, for the amendment, modification, or termination of any of the provisions thereof, for the enforcement of compliance

therewith and for the punishment of violations thereof.

X

(A) It is adjudged and decreed that all right, title, and interest in and to the patents and patent applications listed in Exhibit D are in the Alien Property Custodian. Subject to the provisions of subsection B of this Paragraph X, this judgment shall not be deemed to affect any right of the Alien Property Custodian or his successors with respect to his ownership of, or to issue licenses or immunities under, any patent, patent application, process, or invention vested in him, or to sell or otherwise dispose of any such patent, patent application, process, or invention, pursuant to the provisions of the Trading with the Enemy Act, as amended, and in accordance with his policy in the administration thereof, or any right of the Alien Property Custodian to royalties or payments accrued prior to the date of the entry of this judgment. Subject likewise to the provisions of subsection B of this Paragraph X, this judgment shall not be deemed to prohibit or restrict in any way the Alien Property Custodian or his successors or assigns from instituting or maintaining any suit or proceeding for patent infringement with respect to patents now or hereafter vested in him or from taking such action with respect to any vested patents, patent applications, processes, or inventions as the national interest may require.

(B) A royalty-free, nonexclusive, unconditional, and unrestricted license under any one or more of the

United States Letters Patent and patents issued under applications for United States Letters Patent, the patent numbers and application numbers of which are listed in the aforementioned Exhibit D, shall be granted by the owner of the title of said patents to any applicant making written request therefor; provided, that so long as ownership of said patents and patent applications is vested in the United States, the department, agency, or officer duly authorized to administer them may, upon a determination that the national interest so requires, withhold, and upon sale or other disposition of any such patents or patent applications, require any subsequent owner thereof to withhold, licenses thereunder from any corporation or other business organization organized under the laws of or having its principal place of business in Germany or Japan, or individuals who are subjects, citizens, or residents thereof, or any corporation, business organization, or individual acting for or on behalf of any such German or Japanese corporation, business organization, or subject, citizen or resident of Germany or Japan; and provided further, that any license issued by a duly authorized department, agency, or officer of the United States may contain the terms and conditions set forth in the form annexed hereto and marked Exhibit E.

Dated October 6, 1945.

FORMAN,
United States District Judge.

We hereby consent to the entry of the foregoing judgment:

Katzenbach, Gildea & Rudner,
KATZENBACH, GILDEA & RUDNER,
Attorneys for Merck & Co., Inc., and Powers-Weightman-Rosengarten Corporation.
By George Gildea.
GEORGE GILDEA.

Tom C. Clark,
TOM C. CLARK,
Attorney General.
Wendell Berge,
WENDELL BERGE,
Assistant Attorney General.
EDGAR H. ROSSBACH,
T. M. M.
United States Attorney.
Herbert A. Berman,
HERBERT A. BERMAN,
Special Assistant to the Attorney General.
Francis J. McNamara,
FRANCIS J. MCNAMARA,
Deputy Alien Property Custodian.
Harry LeRoy Jones,
HARRY LEROY JONES,
Chief, Alien Property Litigation Unit, War Division, Department of Justice.
Raoul Berger,
RAOUL BERGER,
General Counsel to the Alien Property Custodian.

EXHIBIT A

AP 527

E. MERCK AND MERCK & CO., INC.

TREATY AGREEMENT

Dated Nov. 17th, 1932

Duplicate Original

AGREEMENT made this 17th day of November 1932, by and between E. MERCK, an open copartnership with its principal office and place of business in *Darmstadt, Germany,* and *MERCK & CO., INC.,* a corporation *organized and existing under the laws of the State of New Jersey,* with its principal office and place of business at *Rahway, New Jersey,* WITNESSETH:

MERCK & CO., INC., has heretofore succeeded to all the business and property, together with the good will connected therewith, of an agency established by *E. MERCK* for the sale of products under the trade name *"MERCK"* in the *United States and Canada.*

The parties hereto for many years have carried on their respective businesses and trade and each has established a good will in connection therewith. The business of Merck & Co., Inc., and its use of the word "Merck" in connection therewith has been almost exclusively confined to the United States, its territories and dependencies (the word "territories" wherever used herein meaning Alaska and Hawaii and the word "dependencies" wherever used herein meaning Porto

Rico, Virgin Islands, the Panama Canal Zone, Samoa, Guam, and the Wake and Midway Islands) and Canada, while the business of E. Merck and its use of the name "Merck" has been almost exclusively confined to the remainder of the world, except that both parties have business in Cuba, the West Indies, and the Philippine Islands (said Philippine Islands, while dependencies of the United States, are not included in the definition of that word as used herein) in connection with which they have used the word "Merck." The parties hereto have carried on their respective businesses under conditions of mutual cooperation and respect for the rights of the other and they desire to confirm and establish covenants and principles of mutual cooperation and helpfulness in carrying on their respective businesses.

NOW, THEREFORE, the parties hereto hereby *mutually agree as follows:*

1. E. Merck recognizes and confirms the right of Merck & Co., Inc., to the *exclusive use of the word "Merck"* in the United States, its territories and dependencies, and Canada, and the right to use said name jointly with E. Merck in Cuba, the West Indies, and the Philippines, whether said word "Merck" is used alone or in conjunction with or combination with any other word or in connection with any patent or trade-mark or in any other way.

2. Merck & Co., Inc., recognizes and confirms the right of E. Merck to the exclusive use of the word "Merck" in the entire world, except the United States, its territories and dependencies, and Canada, and except in Cuba, the West Indies, and the Philippine Islands, where Merck & Co., Inc., recognizes the right of E. Merck to use said name jointly with Merck & Co., Inc. The right of E. Merck to use the name "Merck"

as herein recognized and confirmed by Merck & Co., Inc., means the right to use said name alone or in conjunction with or combination with any other word or in connection with any patent or trade-mark or in any other way.

3. In case of the merger, consolidation, or transfer of assets by either party, the merged or consolidated corporation or transferee shall succeed only to such rights to use said work "Merck" as are expressly herein recognized and confirmed in the party hereto which so merges, consolidates, or transfers its assets.

4. In case of the abandonment of the use of the word "Merck" by either party as a result of merger, consolidation, or transfer of assets or otherwise, the other party hereto shall thereafter have an unrestricted right to use the name in any part of the world.

5. Either party developing a specialty (hereinafter called the "grantor") shall, except as provided in the last sentence of this paragraph and except in so far as such grantor is prevented by agreements heretofore or hereafter entered into with inventors or other parties having rights acquired prior to or simultaneously with the acquisition by the grantor of its rights therein, offer to the other party hereto (hereinafter called the "grantee") the first right for the sole distribution and/or exclusive manufacture of such specialty in the territory in which the grantee has the exclusive right to use the name "Merck" as hereinabove set forth. In case such offer is accepted, during the first fifteen years after such acceptance, the net profits resulting from the sale of such specialty shall be divided equally between the parties hereto. Said net profits shall be determined by taking the difference between the invoice proceeds on the one side and on the other side the total of manufacturing and adver-

tising expenses, inventor's royalties and a selling commission of 15% to the grantee. In case any loss is incurred in connection with the sale and/or manufacture of such specialty by the grantee, the grantee shall first be reimbursed for said losses out of future profits before any such profits shall be divided hereunder, it being distinctly understood and agreed, however, that the grantor shall, at no time, be responsible for such losses or any part thereof. After the expiration of such fifteen-year period, the grantor shall be entitled to receive only 25% of the profits thereafter resulting from the sale of said specialty, which latter participation of profits shall continue in perpetuity thereafter. The preferential right to market specialties under the provisions hereof is at all times subject to obligations which the grantor may be under to third parties under contracts heretofore made whereby such third parties have preferential rights with respect to the marketing of specialties within territories specified in such contracts.

6. The parties hereto agree to a mutual exchange of information and experience regarding the processes for the manufacture of products now manufactured by both parties, as well as improvements on and technical completion of such processes, but neither party hereto shall be required to give to the other any information or experience in violation of the terms of any agreements heretofore or hereafter entered into with inventors or other persons who acquired rights with respect to such process or with respect to such improvements on or technical completions of the same, prior to or simultaneously with the acquisition of such information or experience by the party hereto. A list of products manufactured by both parties and to which the foregoing obligation applies is attached hereto and made a part hereof. All information of

one party regarding such processes or improvements shall be made available to the other without compensation, except in instances where the exchange results in substantial advantages to the party receiving the information, in which case, the party furnishing the same shall be entitled to appropriate compensation. Such compensation shall be agreed upon between the parties hereto but, in case of their failure to agree, the amount thereof shall be determined by arbitrators, each party to select one arbitrator and the two so selected to choose a third and the decision of such arbitrators or a majority of them shall be final and binding upon the parties hereto. As to processes for the manufacture of products not on the list attached hereto but which may now or hereafter be manufactured by one of the parties hereto, the other party shall have a right to acquire such process from the one having the same (excepting always where such party is prevented from granting such right by reason of obligations to third parties entered into prior to or simultaneously with the acquisition of the rights therein by the party hereto) providing the parties hereto can agree upon the scope of the use of such process and the compensation to be paid therefor and, in any event, upon the same terms upon which the party having such process is willing to sell or convey the right to use the same to third parties. In case of a merger, consolidation, or transfer of assets by either of the parties hereto, the obligations contained in this paragraph 6 shall terminate and cease.

7. The parties hereto agree that, so far as possible, they will, through reports, keep each other fully advised with respect to raw materials, conditions of markets, inventions, and other general information which, in the opinion of either party, may be useful to the other in the carrying on of their or its business.

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8. Insofar as it recognizes and confirms exclusive rights to the use of the name "Merck" this agreement protects the good will of the parties hereto in their respective businesses and is in perpetuity. Except where a different term has been specifically provided in this agreement, the term of this agreement and all obligations hereunder, shall continue for a period of fifty years from the date hereof, except insofar as the same may be terminated in whole or in part by mutual consent. Any future agreements between the parties hereto made pursuant to the terms of this agreement shall continue for such period of time as is provided therein, irrespective of the term of this agreement.

9. It is mutually agreed that in the event that either party hereto institute against the other party any legal proceedings of any nature whatsoever upon a cause of action based upon, arising out of, or in any way connected with the terms, covenants and conditions of this agreement, the party against whom such proceedings are brought, hereby agrees to accept service of process or any other papers necessary to be served to institute such proceedings, and any of the partners of E. Merck, or any of the officers of Merck & Co., Inc., are hereby authorized to accept service of such process or other papers. It is further agreed that, in the event that Merck & Co., Inc., shall institute any such legal proceedings against E. Merck, such proceedings shall be brought only in a court of competent jurisdiction in Germany, in the district in which the partnership of E. Merck has their principal place of business, and in such an event, the interpretation and construction of the terms of this agreement and the rights and liabilities of the parties, arising therefrom, as well as their remedies, shall be governed and determined solely in accordance with the law of

Germany. In the event that E. Merck shall institute any such legal proceedings against Merck & Co., Inc., such proceedings shall be instituted only in a Court of competent jurisdiction of the State of New Jersey, or the United States District Court for the District of New Jersey, and in such event the interpretation and construction of this agreement, and the rights and liabilities of the parties arising therefrom, as well as their remedies, shall be governed and determined solely by the laws of the State of New Jersey.

IN WITNESS WHEREOF, this instrument has been executed on behalf of E. MERCK, party of the first part, by a member of the firm under his hand and seal, and MERCK & CO., INC., the party of the second part, has caused this instrument to be signed by its duly authorized officers and its corporate seal to be hereunto affixed the day and year first above written.

E. MERCK,
By D. KARL MERCK, *A member of the firm.*

MERCK & CO., INC.,
By GEORGE W. MERCK, *Pres't.*

Attest:

OSCAR R. EWING, *Secretary.*

Merck & Co., Inc.
Corporate
Seal
1927
New Jersey

PROCESSES OPERATED BY MERCK & CO., INC. AND E. MERCK, DARMSTADT

Acetamide
Acid Benzoic Reagent
Acid Chromic
Acid Hydriodic
Acid Hydrobromic
Acid Hydrocyanic
Acid Hypophosphorous
Acid Iodic
Acid Iodic Anhydride
Acid Meconic
Acid Oxalic C. P. & Reagent.
Acid Silicic C. P.
Acid Sulphanilic C. P.
Acid Sulphocarbolic
Acid Sulphosalicylic
Acid Sulphuric Aromatic U. S. P.
Aluminum Acetate Solution N. F.
Aluminum Nitrate C. P.
Aluminum Phosphate
Aluminum Sulphate N. F. V. & C. P.
Ammonium Acetate
Ammonium Benzoate
Ammonium Chloride U. S. P., C. P. & Reagent.
Ammonium Chromate
Ammonium Citrate
Ammonium Dichromate
Ammonium Iodide
Ammonium Nitrate, Pure, C. P. & Reagent
Ammonium Oxalate
Ammonium Phosphates N. F., C. P. & Reagent
Ammonium Salicylate
Ammonium Sulphate, Pure, C. P. & Reagent
Ammonium Sulphide, Solution
Ammonium Tartrate
Amyl Nitrite
Amyl Salicylate
Aniline Hydrochloride
Aniline Sulphate
Antimony Chloride Solution
Antimony Sulphurated
Apiol Fluid Green
Apomorphine Hydrochloride
Arsenic Chloride (ous)
Arsenic Iodide (ous)
Barbital
Barbital Sodium
Barium Acetate
Barium Carbonate Pure Precip. C. P. & Reagent
Barium Chloride C. P. & Reagent
Barium Chromate

Barium Nitrate C. P. & Reagent
Barium Sulphate C. P.
Benzene C. P. & Reagent
Benzylsuccinate
Bismuth Betanaphthol
Bismuth Chloride
Bismuth Citrate
Bismuth Hydroxide
Bismuth Nitrate
Bismuth Oxychloride
Bismuth Oxyiodide
Bismuth Salicylate
Bismuth Subbenzoate
Bismuth Subcarbonates
Bismuth Subgallate
Bismuth Subnitrates
Bismuth Subsalicylate
Bismuth Tannate
Bismuth & Ammonium Citrate
Blaud's Mass Powder
Cadmium Acetate
Cadmium Bromide
Cadmium Carbonate
Cadmium Chloride
Cadmium Iodide
Cadmium Nitrate
Cadmium Sulphate
Caffeine Citrated
Caffeine Sodium Benzoate
Caffeine Sodium Salicylate
Calamine Prepared N. F.
Calcium Acetate
Calcium Carbonate C. P. & Reagent
Calcium Chloride Anhydrous C. P. & Reagent
Calcium Chloride Crystals Pure & C. P.
Calcium Chloride U. S. P.
Calcium Iodide
Calcium Lactate Dried
Calcium Lactophosphate
Calcium Nitrate Pure & C. P.
Calcium Sulphate C. P.
Calomel
Calomel Special Fine
Camphor Monobromated
Carlsbad Salt Artificial N. F.
Chlorbutanol
Chromium Salts
Cocaine & Salts
Codeine & Salts
Colchicine
Colchicine Salicylated
Congo Paper
Copper Acetate C. P. & Reagent
Copper Aluminated
Copper Bromide
Copper Chloride C. P. & Reagent
Copper Iodide

Copper Nitrate
Copper Oxide Black
Copper Sulphate U. S. P., C. P. & Reagent
Copper Sulphate Anhydrous C. P.
Copper & Ammonium Chloride
Corrosive Sublimate
Cuprex
Dextrose C. P. Anhydrous
Dextrose Solution Sterilized in ampules
Digitan Powder, Tablets & Tincture
Dionin
Emetine & Salts
Eschka's Mixture
Eserine Salicylate
Ethyl Bromide C. P.
Ethyl Iodide
Ethyl Nitrite
Fibrolysin
Gold & Sodium Chloride
Homatropine & Salts
Hydrastine & Salts
Hydroalcoholic Extract of decocainized coca leaves
Iodine Resublimed Cryst. & Granular
Iodine Trichloride
Iodoform
Ipecae & Opium Powder
Iron Acetate (ic) basic & Solution
Iron Bromide
Iron Carbonate
Iron Citrate Scales & Pearls
Iron Dialyzed
Iron Hypophosphite
Iron Iodide (ous)
Iron Iodide Saccharated
Iron Iodide Syrup
Iron Nitrate Ferric
Iron Oxalate Ferric
Iron Oxalate Ferrous
Iron Oxide Brown Precipitated
Iron Oxide Red Saccharated
Iron Peptonized
Iron Phosphate (ferric) Soluble Scales & Pearls
Iron Phosphate Ferrous
Iron Pyrophosphate Soluble Scales & Pearls
Iron Succinate
Iron Sulphate Ferric Powder & Solution
Iron Sulphate Ferric Basic & Solution

Iron Sulphate Ferrous Gran. U. S. P. & C. P.
Iron Sulphate Ferrous Dried U. S. P.
Iron & Ammonium Citrate Brown Scales & Pearls
Iron & Ammonium Citrate Green Scales & Pearls
Iron & Ammonium Oxalate
Iron & Ammonium Sulphate, Ferric
Iron & Ammonium Sulphate, Ferrous
Iron & Potassium Oxalate
Iron & Potassium Tartrate
Iron & Quinine Citrate Scales & Pearls
Iron & Sodium Oxalate
Lead Acetate Reagent
Lead Chloride
Lead Chromate C. P.
Lead Iodide
Lead Nitrate
Lead Subacetate Solution U. S. P.
Lead Sulphate C. P.
Lime Iodized
Lithium Benzoate
Lithium Chloride
Lithium Citrate
Lithium Iodide
Lithium Nitrate
Lithium Salicylate
Lithium Sulphate
Litmus Paper Red & Blue
Magnesium Bromide
Magnesium Carbonate Heavy
Magnesium Chloride
Magnesium Citrate Soluble
Magnesium Nitrate C. P. & Reagent
Magnesium Oxide Heavy
Magnesium Phosphate Di & Tribasic
Magnesium Salicylate
Magnesium Sulphate Dried
Magnesium & Sulphate Reagent
Magnesium & Ammonium Phosphate
Manganese Carbonate
Manganese Chloride
Manganese Citrate Soluble
Manganese Hypophosphite
Manganese Sulphate Crystals
Mercurial Ointments U. S. P.

Mercury Redistilled U. S. P., C. P. & Reagent
Mercury Acetates
Mercury Ammoniated
Mercury Bisulphate
Mercury Bromide
Mercury Cyanide
Mercury Iodides
Mercury Mass U. S. P.
Mercury Nitrates
Mercury Oleate (25%)
Mercury Oxides
Mercury Salicylate
Mercury Succinimide
Mercury Sulphide Black
Mercury Sulphocyanate
Mercury with Chalk U. S. P.
Methyl Iodide
Methylene Iodide
Methyl Salicylate
Morphine & Salts
Narceine & Salts
Narcotine & Salts
Nickel Chloride C. P.
Oil Ethereal N. F.
Opium Alkaloids
Opium Medicinal
Opium Extract N. F. V.
Papaverine & Salts
Peroxoids
Phenobarbital
Phenobarbital Sodium
Phenylhydrazine Hydrochloride
Pilocarpine Salicylate
Platinic Chloride Solution
Potassa Sulphurated
Potassium Acetate
Potassium Acid Phthalate
Potassium Arsenate Monobasic
Potassium Arsenite Powder & Solution
Potassium Bisulphate
Potassium Carbonate U. S. P.
Potassium Chromate Yellow C. P. & Reagent
Potassium Citrate
Potassium Dichromate C. P. & Reagent
Potassium Iodate
Potassium Iodide
Potassium Nitrate Reagent
Potassium Oxalate Reagent
Potassium Phosphate mono and dibasic
Potassium Sulphocyanate C. P. & Reagent
Quinhydrone
Sodium Arsenate
Sodium Arsenite

Sodium Bisulphate
Sodium Carbonate Anhydrous Pure & C. P.
Sodium Chromate Dried
Sodium Citrates
Sodium Formate
Sodium Hydroxide with Lime
Sodium Iodate
Sodium Iodide
Sodium Malate
Sodium Nitrate Reagent
Sodium Nitrite U. S. P.
Sodium Oleate Acid Mass
Sodium Phosphate Dibasic Anhydrous Reagent
Sodium Phosphate Dibasic large crystals
Sodium Phosphate Monobasic
Sodium Pyrophosphate
Sodium Stearate
Sodium Succinate
Sodium Sulphate U. S. P., C. P. & Reagent
Sodium Sulphate Anhydrous Pure, C. P. & Reagent
Sodium Sulphide Pure, C. P. & Reagent
Sodium Sulphocarbolate
Sodium Sulphocyanate
Sodium Tetraiodophenolphthalein
Sodium Tungstate Reagent
Sodium & Ammonium Phosphate
Spirit Ether Compound
Starch Iodized
Starch Soluble
Strontium Acetate
Strontium Chloride
Strontium Iodide
Strontium Lactate
Strontium Nitrate C. P.
Strontium Salicylate
Stypticin & Tablets
Sulphur Iodide
Tannaform
Thebain & Salts
Theobromine Salicylate True Salt
Theobromine Sodium Acetate
Theobromine Sodium Salicylate
Thiosinamine
Thymol Iodide
Tin metal—granular
Tin Chloride (ous) C. P. & Reagent
Tincture Ferric Chloride
Tincture Ferric Citrochloride
Tincture of Iodine

Traumaticin
Tropococaine Hydrochloride
Tropococaine Hydrochloride Solution in Ampules
Veronal Powder & Tablets
Zinc Metal Mossy, Shot & Sticks
Zinc Bromide
Zinc Iodide
Zinc Nitrate
Zinc Stearate
Zinc Sulphocarbolate

EXHIBIT B

LICENSE

LICENSE, granted this __ day of _____, 19__, by MERCK & CO., INC., a corporation organized and existing under the laws of the State of New Jersey, and having a place of business at Rahway, New Jersey (hereinafter referred to as LICENSOR), to_____ _____, a corporation organized and existing under the laws of the State of _____, and having a place of business at _____ (hereinafter referred to as LICENSEE).

WHEREAS, LICENSOR is the owner of record of the entire right, title and interest in and to the following United States Patent(s): Patent No. _____. Date Granted _____. Inventor _____. Title hereinafter referred to as the Patent(s);

WHEREAS, LICENSOR is required, by the terms of the decree in the case of *United States* v. *Merck & Co., Inc., et al* (No. 3159), entered October __, 1945, in the District Court of the United States for the District of New Jersey, to issue to any applicant making written request therefor, a royalty-free, nonexclusive license under said Patent(s) in accordance with the terms of said decree;

WHEREAS, LICENSEE desires a royalty-free, nonexclusive license under said Patent(s) in accordance with the terms of said decree and has made written request therefor.

NOW, THEREFORE, pursuant to said decree and the foregoing:

1. LICENSOR grants to LICENSEE a nonexclusive License under said Patent(s), including all continuances, renewals, reissues, or extensions thereof, without royalty or charge of any kind therefor, and without any condition or restriction whatsoever, to make, use, and sell the inventions claimed in said Patent(s), for the life of said (Patent(s) respectively.

2. LICENSOR also grants to LICENSEE, to the extent that LICENSOR has or acquires the power to do so, a grant of immunity under foreign patents corresponding to the United States Letters Patent licensed hereunder to import into, and to sell and to use, and to have imported into, sold or used, in any country any products made under this License in the United States.

3. This License is granted without any implied covenants, warranties, representations, licenses, or immunities of any kind on the part of the LICENSOR and without any admission on the part of the LICENSEE as to the enforceability, validity or scope of, or the title to, any of said Patent(s) herein licensed.

IN WITNESS WHEREOF, the LICENSOR has executed this License as of the day and year first above written, and the LICENSEE has accepted the same as indicated hereon.

MERCK & CO., INC.,

By ----------

By ----------

Attest:

Attest:

EXHIBIT C

SUBDIVISION 1

UNITED STATES LETTERS PATENT OF MERCK & CO., INC.

Patent number	Patent number	Patent number	Patent number
2,021,872	2,135,521	2,189,810	2,248,155
2,044,800	2,153,591	2,192,204	2,252,709
2,044,801	2,155,446	2,198,628	2,261,608
2,049,442	2,157,137	2,205,448	2,267,313
2,072,913	2,158,091	2,207,768	2,272,198
2,088,590	2,158,098	2,209,769	2,287,042
2,089,197	2,162,737	2,216,574	2,287,847
2,103,272	2,163,594	2,224,174	2,296,709
2,104,726	2,163,643	2,224,865	2,306,093
2,104,738	2,164,316	2,226,528	2,306,765
2,104,753	2,168,379	2,228,262	2,307,084
2,118,054	2,176,113	2,232,699	2,372,690
2,123,217	2,176,894	2,232,712	2,376,984
2,126,731	2,184,964	2,247,364	Application SN380,668
2,133,999	2,185,237	2,248,078	

SUBDIVISION 2

Upon the expiration of one year and five days from the date of the entry of this decree in the Office of the Clerk of the District Court of the United States for the District of New Jersey, United States Letters Patent Number 2,333,535 shall be deemed to be listed in Subdivision 1 of this Exhibit C.

SUBDIVISION 3

ABANDONED APPLICATIONS FOR UNITED STATES LETTERS PATENT OF MERCK & CO., INC.

Serial number	Date filed	Inventors
6,482	Feb. 14, 1935	Engels Weijlard.
24,908	Jun. 4, 1935	Wallis Fernholz.
30,149	Jul. 6, 1935	Wallis Fernholz.
34,249	Aug. 1, 1935	Wallis Fernholz.
44,469	Oct. 10, 1935	Fernholz.
52,274	Nov. 29, 1935	Stevens Zellner.
96,650	Aug. 18, 1936	Stevens Jackson Engels.
98,404	Aug. 28, 1936	Engels Schnellbach.
113,107	Nov. 28, 1936	Cook.
116,645	Dec. 18, 1936	Engels Stevens.
146,590	Jun. 5, 1937	Bliss Moran.
154,282	Jul. 17, 1937	Jackson.
154,754	Jul. 21, 1937	Weijlard Folkers.
154,755	Jul. 21, 1937	Folkers Major.
155,010	Jul. 22, 1937	Major Folkers.
161,762	Aug. 31, 1937	Major.
164,876	Sept. 21, 1937	Major Zellner.
173,529	Nov. 8, 1937	Engels Weijlard.
180,142	Dec. 16, 1937	Major Jackson.
180,143	Dec. 16, 1937	Folkers.
218,168	Jul. 8, 1938	Burnham Engels Lauer.
228,402	Sept. 3, 1938	Stiller.
233,412	Oct. 5, 1938	Folkers Major.
247,478	Dec. 23, 1938	Keresztesy Stevens.
247,480	Dec. 23, 1938	Keresztesy Stevens.
267,601	Apr. 13, 1939	Harris.
267,602	Apr. 13, 1939	Harris.
267,603	Apr. 13, 1939	Harris.
267,618	Apr. 13, 1939	Stiller.
320,634	Feb. 24, 1940	Van de Kamp Miller.
320,636	Feb. 24, 1940	Tishler Wellman.
322,804	Mar. 7, 1940	Stiller Keresztesy Finkelstein.
327,993	Apr. 5, 1940	Tishler.

Upon the revival or renewal of any application for a patent listed in this subdivision 3 by, or on behalf of, defendant Merck & Co., Inc., such application shall be deemed to be listed in subdivision 1 of this Exhibit C.

EXHIBIT D

SUBDIVISION 1

The following United States Letters Patent and active applications for United States Letters Patent have been vested in the Alien Property Custodian by Vesting Orders Nos. 68, 661, 1249, and 5251.

Patent number	Patent number	Patent number	Patent number
1,894,162	2,145,249	2,190,167	2,245,147
1,935,529	2,145,907	2,190,377	2,259,925
1,941,647	2,149,279	2,212,531	2,259,936
2,078,237	2,160,867	2,212,532	2,274,449
2,085,009	2,163,629	2,221,828	2,289,761
2,086,562	2,170,127	2,229,573	2,296,677
2,094,000	2,176,063	2,229,574	2,343,773
2,098,954	2,182,791	2,230,659	2,345,605
2,114,306	2,182,792	2,235,638	2,354,317
2,119,527	2,183,553	2,235,661	2,358,286
2,127,547	2,189,778	2,235,862	2,358,287
2,133,977	2,189,830	2,235,884	2,359,311
			2,370,015
			Applications SN 331,454, 346,569, 377,673.

SUBDIVISION 2

The following abandoned applications for United States Letters Patent have been vested in the Alien Property Custodian by Vesting Orders Nos. 68 and 5251.

Serial number	Date filed	Inventors
49,822	Nov. 14, 1935	Dalmer, Diehl & Pieper.
171,480	Oct. 28, 1937	Dalmer, Diehl & Pieper.
227,388	Aug. 29, 1938	Thiele.
256,387	Feb. 14, 1939	Rapp & Russow.
266,140	Apr. 5, 1939	Von Werder.
304,389	Nov. 14, 1939	Von Werder.
308,827	Dec. 12, 1939	John.
344,564	July 9, 1940	Zima & Jung.
346,568	July 20, 1940	Zima & Jung.
373,603	Jan. 8, 1941	Von Werder.
375,363	Jan. 21, 1941	Ritsert.
387,542	Apr. 8, 1941	Zima.
403,046	July 18, 1941	Von Keussler.

[SEAL]

EXHIBIT E

OFFICE OF ALIEN PROPERTY CUSTODIAN

WASHINTON

PATENT LICENSE

Number _____

The ALIEN PROPERTY CUSTODIAN, Licensor, acting under the authority of the President of the United States, pursuant to the Trading with the Enemy Act, as amended, and Executive Order No. 9095, as amended, and pursuant to law, HEREBY GRANTS TO _____, Licensee, THIS LICENSE, effective from the date hereof, to make, and sell each of the inventions covered by the _____ ( ) vested United States
(Number of items)
patents and/or applications for United States patents listed in Schedule A and under the "Terms and Conditions," both appended hereto and made a part hereof.

Signed at Washington, District of Columbia, this _____ day of _____, 194__.

James E. Markham,
JAMES E. MARKHAM,
ALIEN PROPERTY CUSTODIAN, LICENSOR.
By ——— ———,
Chief, Division of Patent Administration.
———— ————, *Chief, Licensing Section.*

TERMS AND CONDITIONS

SECTION 1. *Extent of Grant.*—This license is royalty-free, nonexclusive and nontransferable. It does not confer on the Licensee any right to grant sublicenses and cannot be pledged or encumbered except with the written consent of the Custodian. Each patent, patent application, and patent issuing upon such patent application (all hereinafter referred to by the word "patent") hereby licensed has been vested as the property of a national of a designated enemy country and is licensed for the remaining life of the patent beginning with the effective date of this license, unless this license is earlier terminated either in its entirety or as to any specific patent listed in Schedule A, as herein provided.

SECTION 2. *Inventions of Licensee.*—This license does not confer upon the Custodian any rights to or under any invention or patent of the Licensee, past, present, or future.

SECTION 3. *Title and Defenses.*—(a) The Custodian will defend to the full extent of his legal power his authority to issue this license, to vest the licensed patents, and to cut off the rights of the former enemy owners, in any litigation brought against the Licensee, or arising under this license, where the title or authority of the Alien Property Custodian is drawn into question.

The patents covered by this license were vested by the Custodian in the interest of and for the benefit of the United States, and this license is granted by the Custodian, under the direction of the President, in the interest of and for the benefit of the United States under the authority of and in furtherance of the purposes of § 5 (b) of the Trading with the Enemy Act, as amended [§ 301, First War Powers

Act, 1941; 50 U. S. Code, App § 5 (b)]. This license shall be deemed to be an "instruction or direction" that the licensed patent may be used as provided herein, within the meaning of that portion of § 5 (b) which provides that

> no person shall be held liable in any court for or in respect to anything done or omitted in good faith in connection with the administration of, or in pursuance of and in reliance on, this subdivision, or any rule, regulation, instruction, or direction issued hereunder.

The Licensee shall promptly notify the Custodian in writing of any claim or demand made upon, or suit threatened or brought against, the Licensee, which is in any way related to this license.

(b) In any suit or proceeding brought against the Licensee by a former enemy owner of a licensed patent, the Licensee may make any and all defenses which would be available had this license not been granted.

(c) This license is not a warranty that the manufacture, use, or sale of any licensed invention does not infringe valid patents or persons not party hereto.

(d) This license does not confer upon the Licensee any license, implied or otherwise, under any unexpired patent not included in Schedule A, regardless of the ownership of such patent.

SECTION 4. *Reports.*—The Licensee shall keep a record of and shall report to the Custodian the character and extent of his utilization of each licensed patent, including the kind and quantity of products (if any) made, used, or sold under such licensed patent. If there has been no manufacture, use, or sale, such reports shall set forth the manner in which and extent to which this license has been or in the

Licensee's opinion will be useful to the Licensee. The Custodian, upon request in writing by the Licensee and upon a showing that reports under individual patents are not feasible, may authorize the Licensee to make group reports with respect to such patents as cannot feasibly be reported individually. Unless otherwise directed by the Custodian such reports shall be made for the calendar year and submitted not later than January 31st of the following year. Where governmental war secrecy provisions prevent the making of reports required by this section, the Custodian may direct that such reports be submitted after the war.

SECTION 5. *Limitations on Use.*—No licensed patent shall be used in furtherance of any unlawful cartel or combination or in any other way which is contrary to the laws of the United States.

SECTION 6. *Termination.*[1]—(a) The Custodian reserves the power to take such action as the national interest requires, including suspension or cancellation of this license if he determines it to be necessary. The Custodian will not cancel this license except after notice and opportunity for hearing.

(b) If an interest in a licensed patent adverse to that of the Custodian shall be established the Custodian may at his option terminate or renegotiate this license after notice to the Licensee.

(c) This license may be surrendered by the Licensee either in its entirety, or as to any patent listed in Schedule A, by returning it to the Custodian with written request for such cancellation or modification.

[1] Subject to the terms and provisions of the judgment entered October 6, 1945 in the District Court of the United States for the District of New Jersey in Civil Action No. 3159, entitled *United States of America and Alien Property Custodian* v. *Merck & Co., Inc. et al.*

(d) Termination of this license under par. (a), (b), or (c) of this section shall not relieve the Licensee from making reports as required by Section 4, up to the date of termination.

SECTION 7. *Notice.*—Any notice in writing required hereby in connection with this license shall be given to the Custodian at Washington, D. C., and to the Licensee at the address shown upon this license unless a change of such address has been noted upon the records of the Custodian at the request of the Licensee. Notice of hearing, or of termination, or requests by the Licensee for cancellation or modification shall be sent by registered mail.

Licensee _____ License No. _____

SCHEDULE A

Patent No. or serial no.	Inventor and title of invention	Issue date or filing date	Vesting order No.

U. S. GOVERNMENT PRINTING OFFICE: 1945

EXHIBIT B

784

Civil Action No. 3159

IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, PLAINTIFF

v.

MERCK & CO., INC., POWERS-WEIGHTMAN-ROSENGARTEN CORPORATION, and GEORGE W. MERCK, DEFENDANTS

COMPLAINT

HERBERT A. BERMAN
PATRICK A. GIBSON
HAROLD L. SCHILZ
Special Assistants to the Attorney General

FRANCIS BIDDLE
Attorney General

WENDELL BERGE
Assistant Attorney General

CHARLES M. PHILLIPS
United States Attorney

Complaint filed October 23, 1943

IN THE DISTRICT COURT OF THE UNITED STATES

FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. MERCK & CO., INC., POWERS-WEIGHTMAN-ROSENGARTEN CORPORATION, and GEORGE W. MERCK, Defendants.	Complaint Civil No.

To the Honorable the Judges of the District Court of the United States for the District of New Jersey.

The United States of America, seeking equitable relief, by its attorneys, Herbert A. Berman, Patrick A. Gibson, and Harold L. Schilz, Special Assistants to the Attorney General, acting under the direction of the Attorney General, files this complaint against the defendants and complains and alleges upon information and belief as follows:

I. JURISDICTION AND VENUE

1. This complaint is filed and this action is instituted against the defendants under Section 4 of the Act of Congress of July 2, 1890, c. 647, 26 Stat. 209, as amended, entitled "An Act to Protect Trade and Commerce against Unlawful Restraints and Monopolies," commonly known as the "Sherman Antitrust Act"; in order to prevent and restrain continuing violations by defendants, as hereinafter alleged, of Section 1 of the Sherman Antitrust Act.

2. The defendants are inhabitants of the District of New Jersey.

II. DESCRIPTION OF DEFENDANTS

3. The defendant Merck & Co., Inc. (hereinafter referred to as defendant Merck) is a corporation organized and existing under the laws of

the State of New Jersey, with its principal office at 126 Lincoln Avenue, Rahway, New Jersey.

4. The defendant Powers-Weightman-Rosengarten Corporation (hereinafter referred to as P-W-R) is a corporation organized and existing under the laws of the State of New Jersey, having its principal office at 126 Lincoln Avenue, Rahway, New Jersey. The said corporation is a wholly-owned subsidiary of defendant Merck.

5. The defendant George W. Merck has been and is president and a member of the Board of Directors of defendant Merck. His business address is 126 Lincoln Avenue, Rahway, New Jersey, and he resides at R. F. D. 129, West Orange, N. J., within the District of New Jersey. He has participated and now participates in the direction and management of defendants Merck and P-W-R and has approved, authorized, ordered and done some or all of the acts herein alleged to have been performed by defendants Merck and P-W-R and constituting the violations of law herein complained of.

III. THE CO-CONSPIRATORS

6. The following are not made defendants, but are herein named as co-conspirators in the unlawful conspiracy hereinafter alleged:

E. Merck, a partnership trading and doing business under that name and style in Darmstadt, Germany (hereinafter referred to as Merck-Darmstadt);

Dr. Karl Merck, a member of the foregoing firm; C. Loew, a director thereof; and Bernhard Pfotenhauer, a member or representative thereof;

Those corporations, now dissolved, hereinafter described and designated as Merck & Co. of New York, Merck & Co., Inc., and the Merck Corporation.

IV. TRADE AND COMMERCE OF DEFENDANTS

7. Defendant Merck manufactures chemicals and pharmaceuticals for

medicinal and household purposes. It also produces industrial chemicals, including photographic, laboratory and analytical chemicals and agricultural specialties. About 1,200 types of chemicals and pharmaceuticals are produced by said defendant, including synthetic vitamins, narcotics, quinines, certain sulfonamides, arsenicals, bismuths, citrates, iodides, mercurials, and atabrine. It is the largest manufacturer of pharmaceuticals in the United States.

8. Defendant Merck manufactures the above-described products at a number of plants, including plants located at: Rahway, New Jersey; Philadelphia, Pennsylvania; and Elkton, Virginia. It maintains branch sales offices and warehouses in New York, New York, and St. Louis, Missouri. Defendant Merck sells and ships large quantities of its said products throughout the United States and certain foreign countries hereinafter mentioned. Its gross sales have amounted to more than $43,544,000 annually. All but a small part of such sales have been made by defendant Merck in interstate and foreign commerce.

9. Among the chemicals and pharmaceuticals manufactured and distributed by defendant Merck are certain so-called "specialty" drugs. A specialty in the medicinal chemical industry is a product sold under a distinctive name, nearly always a trade-mark name, as distinguished from materials sold under their chemical names; it is usually derived from a patented or secret process. It is usually sold in a small, distinctive unit package as contrasted with bulk chemical sales; and it is usually sold at a higher price than the prices obtained for the bulk chemicals comprising such specialty.

10. Defendant Merck processes and distributes chemicals and pharmaceuticals in the Dominion of Canada through a wholly-owned subsidiary, Merck & Co., Ltd., which has its principal place of business at Montreal, Canada.

11. Defendant P-W-R is now engaged in the sale, distribution, and export to foreign countries of chemicals and pharmaceuticals in the manner

hereinafter described. Defendant P-W-R obtains said commodities for such foreign trade from defendant Merck.

V. BACKGROUND OF THE VIOLATIONS OF LAW COMPLAINED OF

12. Since prior to the year 1891 and continuously to the present time, Merck-Darmstadt has carried on the business of manufacturing, at its plants in Germany, and marketing, at home and abroad, chemical and pharmaceutical products. The said firm has been and is now one of the world's largest manufacturers and distributors of such products, and has carried on a large export trade therein to all markets of the world except as hereinafter described.

13. In the year 1891 one or more of the partners of Merck-Darmstadt organized a partnership in the United States under the name and style of Merck & Co. A corporation with the same name was formed under the laws of New York in the year 1903 to take over the business of said partnership. Merck-Darmstadt owned and retained substantial interests in the said firm and the said corporation (both hereinafter referred to as Merck & Co. of New York).

14. Prior to the First World War, Merck & Co. of New York acted as a selling agency for Merck-Darmstadt. As such sales agent, Merck & Co. of New York agreed to confine all of its distribution and sale of chemicals and pharmaceuticals to the United States, its dependencies, Canada, and the below-mentioned joint territory. Merck-Darmstadt was exclusively allotted the markets for such products in all other countries of the world except for said joint territory. Merck-Darmstadt and Merck & Co. of New York agreed that the Philippine Islands, Cuba, and the West Indies should be joint territory, to which each should be equally free to export.

15. During the First World War the interests of Merck-Darmstadt in Merck & Co. of New York were seized by the Alien Property Custodian of the United States. The interests so seized were thereafter purchased by

Merck & Co. of New York from the Alien Property Custodian on or about August 1919. Funds to finance such purchase were raised by the sale of non-voting preferred stock issued by Merck & Co. of New York, and no outside interests acquired any shares of the voting stock of Merck & Co. of New York upon such acquisition by it of the interests seized by the Alien Property Custodian. During the First World War Merck & Co. of New York expanded its own manufacturing facilities, and since then it and its successors, including defendant Merck, have from time to time greatly increased their manufacturing operations in this country. Since the above-described seizure and acquisition of the interests of Merck-Darmstadt in Merck & Co. of New York, the latter company and its successors, including defendant Merck, have been financially independent of, and have had no corporate affiliation with, Merck-Darmstadt, and they and Merck-Darmstadt, except for the illegal restraints hereinafter described, would have competed in the manufacture and sale of chemical and pharmaceutical products in interstate and foreign commerce.

16. During the First World War, the blockade of Germany maintained by the Allied powers prevented Merck-Darmstadt from shipping its products to South and Central America and other markets of the world. Merck & Co. of New York obtained a considerable export business in sales of chemicals and pharmaceuticals in countries located in South and Central America during that period. Upon the conclusion of the First World War Merck & Co. of New York surrendered its said trade and commerce in such foreign countries, that is, those of South and Central America, and allowed said trade and commerce to revert to Merck-Darmstadt. Merck & Co. of New York and Merck-Darmstadt both thereafter resumed the division of trade territory between them hereinabove described in Paragraph 14.

17. In the year 1927 Merck & Co. of New York merged with the Powers-Weightman-Rosengarten Company, a corporation then existing under the laws of Pennsylvania, the same being the successor of a chemical house founded at Philadelphia, Pennsylvania, in the year 1818. Merck & Co. of New York

and the Powers-Weightman-Rosengarten Company conveyed their assets and businesses to Merck & Co., Inc., a corporation organized under the laws of New Jersey in June 1927. The latter corporation transferred 65-1/2% of its common stock to Merck & Co. of New York, which changed its name to The Merck Corporation, and 35-1/2% of its common stock to the Powers-Weightman-Rosengarten Company. Merck & Co., Inc. thereafter formed defendant Powers-Weightman-Rosengarten Corporation (herein called P-W-R), incorporated under the laws of New Jersey, as a wholly-owned subsidiary of said Merck & Co. Inc. P-W-R's corporate name and entity were kept alive by Merck & Co, Inc. and by defendant Merck, but P-W-R became inactive commercially and remained dormant until it began in 1939 the activities hereinafter described.

13. In 1934 the Merck Corporation and Merck & Co., Inc. reorganized and were consolidated by transfer of their assets, businesses, liabilities and capital stock to a new corporation, defendant Merck, incorporated in that year under the laws of New Jersey.

19. Defendant Merck through the aforesaid reorganization acquired all the rights and assumed all the obligations of its said predecessors, including all rights and obligations created by the hereinafter described Treaty Agreement. All the acts, understandings, and agreements hereinbefore and hereinafter alleged as the acts, understandings, and agreements of said corporations, namely Merck & Co. of New York, the Merck Corporation, and Merck & Co., Inc., have been adopted and continued by defendant Merck.

VI. THE VIOLATIONS OF LAW COMPLAINED OF

20. Defendants and their co-conspirators have been for many years and are now, through their acts hereinbefore and hereinafter complained of, violating Section 1 of the Act of Congress approved July 2, 1890, entitled "An Act to Protect Trade and Commerce against Unlawful Restraints and Monopolies," as amended, commonly known as the Sherman Act, by contracting, combining, and conspiring in restraint of trade and commerce

in chemical and pharmaceutical products among the several states of the United States and with foreign nations as hereinafter set forth.

THE UNLAWFUL CONTRACT

21. On or about November 17, 1932, Merck & Co., Inc. and Merck-Darmstadt made and entered into a contract known as and herein called the "Treaty Agreement," a true copy of which is attached hereto and made a part hereof, marked Exhibit A.

22. By the terms of the Treaty Agreement, Merck-Darmstadt has agreed with defendant Merck that in the sale and distribution of chemicals and pharmaceuticals defendant Merck should have the exclusive right to use the word Merck, either alone or in conjunction with or combination with any other word or in connection with any patent or trade-mark or in any other way, throughout the United States, its territories and dependencies, and Canada. Defendant Merck and Merck-Darmstadt have agreed by the terms of the Treaty Agreement that Cuba, the West Indies, and the Philippine Islands should be joint territory in which each should have the right to use the name Merck jointly with the other. Defendant Merck has agreed with Merck-Darmstadt by the terms of the Treaty Agreement that Merck-Darmstadt should have the exclusive right to use the name Merck in the manner above stated in all other countries other than those hereinabove referred to. The Treaty Agreement provided that the aforesaid exclusive division of trade territory should be in perpetuity. Said Treaty is still in force and effect.

23. By the terms of the Treaty Agreement defendant Merck and Merck-Darmstadt have further undertaken to surrender exclusively to the other in the other's allotted exclusive territory, reserving a defined share in the profits, all new products developed by either in the future as specialties. Specialties, the nature of which is set forth in Paragraph 9

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above, are of great importance in the trade carried on by manufacturers and marketers of chemical and pharmaceutical products. In further implementation of the intent of the Treaty Agreement to eliminate competition between the parties thereto, as hereinafter more fully described, it was also provided therein that the parties should mutually exchange information and experience regarding their respective processes and improvements relating to designated present products and to future products. To like purpose and effect it was further provided that the parties should inform each other respecting raw materials, conditions of markets, inventions, and other general information. It was provided that the term of all the undertakings mentioned in this paragraph should be 50 years from November 17, 1932.

24. Territorial division of the use of the name Merck, as effected by the Treaty Agreement, was not made necessary by any requirement of law in any country, nor have the laws of any country recognized any right in either Merck-Darmstadt or Defendant Merck (or Merck & Co., Inc.) to preclude the other from doing business in such country under such company's own name unless solely by force of the provisions of the Treaty Agreement itself purporting to recognize such an exclusive right.

25. Territorial division of the right to use the name Merck, as effected by the Treaty Agreement, was not necessary in order to prevent confusion as to the identity of the said companies. There was and could be no confusion among chemical and pharmaceutical manufacturers, distributors, wholesalers and retailers, or on the part of the public, as to the identity of products of the two parties to the Agreement. The name of the German company has been and is known and used in the trade as "E. Merck Chemical Works, Darmstadt." The term Darmstadt has always associated that company with a locality so known in Germany with a company there organized and doing business. The name of the American company has been and is known and used in the trade as "Merck & Co., Inc., Rahway, N. J."

Among chemical and pharmaceutical dealers and distributors the use of the name Rahway, N. J., on the labels, letterheads, and order forms of defendant Merck associates it with the locality of that name and identifies it as the American company. The order forms of the American company also recite that it has other offices located in New York, N. Y., St. Louis, Mo., and Philadelphia, Pa. In contrast to those of the American company the labels, letterheads, and order forms of the German company have borne the imprint "E. Merck, Darmstadt, Chemische Fabrik."

26. It was the purpose and intention of Merck & Co., Inc. and Merck-Darmstadt in entering the aforesaid Treaty Agreement to effect complete division of trade territories in the sale and distribution of all chemical and pharmaceutical products made by them and to suppress all competition between them in the United States and in foreign markets. To accomplish such purpose Merck & Co., Inc. (and thereafter defendant Merck) and Merck-Darmstadt planned to sell all such products made by each only under its respective firm or corporate name and have at all times (except for the P-W-R activities hereinafter described) adopted the course of trade, and followed the business practice of identifying substantially all the products of each by the use of its respective company name. Such identification has been invariably practiced by defendant Merck and Merck-Darmstadt by use of labels attached to all packages in which products of the respective companies have been sold, by use of letterheads, order forms, bills of lading, invoices, advertisements and all other written communications wherein each of said companies has invariably utilized its respective company name.

27. Defendants Merck and Merck-Darmstadt have at all times executed and complied with the Treaty Agreement in every respect, and have continued thereby to effect (except for the P-W-R activities hereinafter described) complete territorial division of substantially all of their trade and business. Defendant Merck and Merck-Darmstadt have each at all times

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(except for the P-W-R activities hereinafter described) refrained from all export to and, all trade or business in the other's aforesaid exclusive territory except for shipments of chemicals and pharmaceuticals made into the other's territory at its request. The operation of the Treaty Agreement as here alleged is more fully set forth in the allegations of Paragraphs 33 through 37 below, and the acts of the parties therein set forth have been done in compliance with, and in execution of, the Treaty Agreement.

23. When the Second World War prevented Merck-Darmstadt from exporting chemical and pharmaceutical products into certain of the countries allocated exclusively to it under the aforesaid Treaty, defendant Merck adopted as a purely temporary expedient, for the period of the war, the use of P-W-R as a vehicle of export to such countries, and now sells for export thereto by and through P-W-R and in its name only. The defendants are, with this adaptation to war conditions, continuing to adhere to the Treaty Agreement and are now utilizing P-W-R in order to keep the Treaty Agreement alive and to continue its operation. Defendants now plan to, and have agreed with Merck-Darmstadt to, discontinue all shipments through P-W-R and in its name after the war and to revert to their former practice of selling chemicals and pharmaceuticals only under the name of defendant Merck, and to maintain the territorial division of the entire trade and business of defendant Merck and Merck-Darmstadt, respectively, as hereinabove described. The operation of the Treaty Agreement as here alleged is more fully set forth in the allegations of Paragraphs 38 through 42 below.

29. By reason of the matters and things hereinabove set forth, the said Treaty Agreement is, by its terms, by the business practice observed, by the interpretation placed upon it by the parties and by their intent, and in its operation, a contract in restraint of trade among the several states and with foreign nations in chemical and pharmaceutical products, whereby defendants have been and are now violating, and will, unless therefrom enjoined, continue to violate Section 1 of the Sherman Act.

THE UNLAWFUL CONSPIRACY

30. In addition to the above-alleged unlawful contract, defendants and their co-conspirators, for many years prior to 1932 and continuously at all times thereafter, have also knowingly engaged and are now so engaged, in part within the District of New Jersey, in an unlawful combination and conspiracy to restrain and prevent all competition between defendant Merck and Merck-Darmstadt in the manufacture, sale and distribution of chemicals and pharmaceuticals in interstate and foreign trade and commerce, by agreeing with each other to allocate the United States, its territories and dependencies and Canada to defendant Merck as its exclusive territory, to reserve Cuba, the West Indies and the Philippine Islands as joint territory in which both companies should be free to trade, but at agreed, uniform, and non-competitive prices, to allocate to Merck-Darmstadt as its exclusive territory the rest of the world, to cause each of the said companies to refrain from exporting all pharmaceuticals and chemicals to, and from selling any such products for export to, the other's aforesaid exclusive territory, and to cause said companies to surrender to each other exclusive control, in the other's exclusive territory, of all present and future technological developments and patents and processes; all in violation of Section 1 of the Sherman Antitrust Act.

31. Prior to 1932 the corporate predecessors of defendant Merck had entered into an informal understanding with co-conspirator Merck-Darmstadt, the substantial terms of which are set forth in the preceding paragraph. Such understanding is still in effect between defendants and their co-conspirators. On or about November 17, 1932, co-conspirators Merck & Co., Inc. and Merck-Darmstadt decided to enter into a formal written contract to implement and effectuate the aforesaid conspiracy. Because both of the aforesaid conspirators were aware that a contract providing for a division of sales territory between the two would be in violation of the antitrust laws, they decided to disguise the real agreement between the

parties, notwithstanding the facts alleged in Paragraphs 24 and 25 above, and enter into the aforesaid Treaty Agreement which apportioned the markets of the world in which each was to have the right to use the name Merck.

32. Defendants and their co-conspirators have at all times well known it to be their practice, and they have at all times intended to continue and have continued it as their practice, to conduct all of the trade and business of defendant Merck and Merck-Darmstadt (except for the P-W-R activities hereinafter described) under their own respective names of which the word Merck is in each case a part. Throughout the period of time covered by said conspiracy, defendant Merck and co-conspirator Merck-Darmstadt have, in execution thereof, refrained (except for the P-W-R activities hereinafter described) from all export of chemical and pharmaceutical products into the other's said exclusive territory except for shipments made to the other at its request.

33. Throughout the period from November 17, 1932, to sometime in the latter part of the year 1940 defendants and their co-conspirators, and their officers, agents, and sale representatives, have, as a part of the conspiracy aforesaid and in execution and furtherance thereof, enforced adherence to the aforesaid sales territory restrictions agreed upon between them, and have investigated and policed the operations of defendant Merck and Merck-Darmstadt to prevent violations thereof. As a further part of the conspiracy and in execution thereof defendant Merck and Merck-Darmstadt have each exercised surveillance over the other with respect to any chemicals and pharmaceuticals manufactured by it and sold outside of the territories respectively allotted to it as aforesaid. Such surveillance has also been exercised by sales representatives of Merck-Darmstadt and dealers in Merck-Darmstadt's products in many parts of the world. In some instances when products of defendant Merck have appeared in foreign countries allocated to Merck-Darmstadt, the latter has complained to defendant Merck relative to the same and received from

it assurance that the condition would be corrected, and that any further sales of Merck's products in such foreign nations would be suppressed. During the same period of time, defendant Merck has refused to supply prospective customers outside its Treaty territory with its products and instead has referred to Merck-Darmstadt numerous orders for chemical goods received from buyers located in the foreign countries allocated to Merck-Darmstadt. Merck-Darmstadt has reciprocated by likewise referring to defendant Merck numerous orders for its products from purchasers located in the sales territory assigned to defendant Merck. In many cases those who sought to purchase from one company but were located in territory assigned by the terms of said conspiracy to the other Treaty partner were notified by the recipient of the order that their requests to purchase or their inquiries concerning chemical and pharmaceutical products had been referred to the other Treaty partner for disposition. When such action was taken, the reason given for it to the prospective customer was said to be that the recipient of the order did not export to the country where the order originated.

34. In a large number of instances during the said period of time described in Paragraph 33 defendant Merck has received orders for products which it did not manufacture or was unable to furnish. In such cases, as a part of the conspiracy, the territorial limitations agreed upon have been observed by making shipments of chemical goods from Merck-Darmstadt to defendant Merck, enabling the latter to fill orders originating in the territory assigned to it; and defendant Merck in a number of instances likewise has shipped chemical goods to Merck-Darmstadt to enable it to fill orders it has received from customers located in foreign territory allocated to it.

35. During the said period of time described in Paragraph 33 said territorial restraints have been further effected between Merck and Merck-Darmstadt in some instances where orders from customers located

in territories allocated to one of the Treaty partners were filled by the other Treaty partner, by causing the invoices to be prepared in the name of the Treaty partner to whom the territory was assigned, adjustment then being made between defendant Merck and Merck-Darmstadt for the value of such products.

36. Defendant Merck in furtherance of the said conspiracy during the said period of time described in Paragraph 33 has also sought to persuade and induce a number of buyers of its chemicals and pharmaceuticals to refrain from exporting such products for resale in foreign countries allocated solely to Merck-Darmstadt. To enforce such requests defendant Merck has adopted a policy of refusing to sell its products to buyers suspected by it of exporting the same for resale in the countries assigned Merck-Darmstadt.

37. In the joint sales territories allotted to both defendant Merck and Merck-Darmstadt as aforesaid they have, during the period described in Paragraph 33 above, in furtherance of the conspiracy, eliminated competition between them with respect to certain specialty drugs by equalizing and fixing uniform prices quoted for the same types of products, and have charged purchasers of the so-called "American" and "German" brands of the same types of chemicals and pharmaceuticals non-competitive and uniform prices.

38. After outbreak of the Second World War in 1939 the British Blockade of Germany prevented Merck-Darmstadt from exporting to many foreign countries, particularly Latin American countries. Demand in those markets for products formerly supplied by Merck-Darmstadt increased, especially on the part of dealers and agents representing Merck- Darmstadt. Merck-Darmstadt requested defendant Merck to supply its agents in South and Central America, but insisted that said agreement for territorial division remain in effect. In these circumstances, defendant Merck undertook exports to Merck-Darmstadt's territory in the manner hereinafter

described. On commencement of such foreign trade defendant Merck refused to confine its sales solely to Merck-Darmstadt's agencies, but agreed with Merck-Darmstadt that the former's exports to the latter's exclusive territory would be purely temporary for the period of the war, that the territorial division of their trade remained in effect, that the Treaty Agreement would continue in operation, and that in observance thereof defendant Merck would avoid all use of the name Merck in its exports to Merck-Darmstadt's exclusive territory.

39. In execution of the conpsiracy and to insure its continued observance during the war and its operation thereafter on the original basis, defendants revived the commercial activity of P-W-R and have made and now make all exports to, and sales for export to, Merck-Darmstadt's exclusive territory, undertaken by them as described in Paragraph 38 above, solely through P-W-R and in its name, and defendant Merck continues to abide by the letter of the Treaty Agreement by meticulous and studied avoidance of any such foreign trade, or sales therefor, in its own name, or accompanied by any use whatever of the name Merck. Defendants have adopted such device purely as a temporary expedient during the war; they are thus preventing the development of any good will identified with defendant Merck itself in such foreign trade; and they now intend, and in or about May 1940 agreed with Merck-Darmstadt, that after the war the said trade of P-W-R will be discontinued and abandoned. Defendants and co-conspirators are thereby insuring the continued operation of the conspiracy after the present war has terminated.

40. In execution of the means and methods of adherence to said conspiracy in war-time as alleged in Paragraph 39 above, about November 1939 defendant Merck issued instructions to its agents, employees and representatives that all of its export business should be carried on through P-W-R and under the P-W-R name with the exception of exports to Cuba, the West Indies, Philippine Islands, and Canada, where all of its products

(Over)

might still be and have continued to be sold by defendant Merck under the Merck name. For the purposes aforesaid, defendant Merck since November 1939 has caused defendant P-W-R to handle all sales to Merck-Darmstadt's exclusive territory in the name of P-W-R; to use P-W-R labels, P-W-R price-lists, P-W-R invoices and bill heads, all carrying the address of Powers-Weightman-Rosengarten Corporation as being at "Philadelphia, Pa.", has cuased office correspondence, acknowledgements of orders and other communications to purchasers in Merck-Darmstadt territory to be signed by P-W-R employees, has cuased P-W-R to use a distinct cable address designated as "Poway," and in other respects has concealed from such purchasers of chemicals and pharmaceuticals and from the trade generally any reference to the connection of said defendants Merck and P-W-R.

41. Defendants have sought to discourage exports to foreign nations assigned exclusively to Merck-Darmstadt, by the device of exacting harsh and onerous terms of payment from purchasers therein, while at the same time more liberal methods of payment have been allowed to purchasers of Merck products located in Cuba and the West Indies. Defendants thus are now conducting their P-W-R foreign trade in a manner and upon a basis that recognizes all trade and commerce with foreign nations in Merck-Darmstadt's exclusive territory as being temporary and to be abandoned after the war.

VII. THE EFFECTS OF THE CONTRACT AND CONSPIRACY

42. By establishing and maintaining the aforesaid contract, combination and conspiracy in restraint of interstate and foreign trade and commerce in chemicals and pharmaceuticals, by the various acts hereinbefore alleged, and by understandings, agreements, and contracts to effectuate this purpose, including the Treaty Agreement of 1932, and by the continuation of said conspiracy through the instrumentality of defendant Powers-

Weightman-Rosengarten Corporation as the agent of defendant Merck for export distribution and sales in or for territories unlawfully assigned to Merck-Darmstadt, the defendants herein (1) have unreasonably restricted and restrained export sales and distribution of chemicals and pharmaceuticals; (2) in the joint sales area described in the Treaty Agreement have fixed and maintained arbitrary, artificial, and non-competitive prices for certain chemicals and pharmaceuticals; (3) have unreasonably restricted and limited imports of chemicals and pharmaceuticals into the United States; (4) have unreasonably restrained such trade and commerce among the several States and with foreign nations in violation of the laws of the United States, and defendants are now continuing and will continue the foregoing unless therefrom enjoined by this court.

VIII. DEMANDS FOR RELIEF

WHEREUPON PLAINTIFF DEMANDS JUDGMENT AS FOLLOWS:

1. That the aforesaid contract, combination, and conspiracy in restraing of trade and commerce among the several States of the United States and with foreign nations be adjudged and decreed to be unlawful; and that the agreements, understandings, and practices alleged in this complaint be adjudged and decreed to be in violation of the Sherman Antitrust Act.

2. That observances of the Treaty Agreement of 1932 between Merck & Co., Inc., Rahway, N. J. and Merck-Darmstadt, Darmstadt, Germany, thereafter assumed by defendant Merck, be perpetually enjoined.

3. That the defendants, and each of them, and their officers, directors, employees, agents, representatives, successors, and all persons and corporations acting and claiming to act on behalf of them, be perpetually enjoined from engaging in any acts or practices or entering into

any contracts or understandings, the purpose or effect of which is to carry out, continue, or revive the unlawful combination and conspiracy and the restraints of trade and commerce among the several states and with foreign nations set forth in this complaint.

4. That defendant Merck be enjoined from refusing to fill under its own name any orders from, or for shipment to, any foreign countries at peace with the United States, on the same terms given by defendant Merck to purchasers in Cuba and the West Indies, where such orders are placed by any person who makes appropriate payment or tender of payment, and that defendant Merck be further enjoined from following any policy of discouraging any such trade and commerce with foreign nations in and under its own name.

5. That in respect of the grant or license by Merck-Darmstadt to defendants, or any of them, of any exclusive rights in any patents or processes in effectuation of the Treaty Agreement of 1932 or of the aforesaid conspiracy, this court cancel and terminate the exclusivity of defendant's rights in such patents and processes and cancel and terminate all contracts, agreements, understandings, and grants carrying out the purpose of the Treaty Agreement to accord to defendant Merck exclusive rights in such patents and processes.

6. That defendants be required to file with the Attorney General of the United States, or the Assistant Attorney General in charge of the Antitrust Division, notice of intention to make, accept, or exchange any grant, assignment, or license to or from E. Merck of any patent covering any chemical or pharmaceutical product, or of any patent or secret process for the manufacture of chemicals and pharmaceuticals.

7. That the plaintiff have such other further, general, and different relief as the nature of the case may require and the court may deem proper in the premises.

8. That the plaintiff recover the costs of this suit.

HERBERT A. BERMAN

PATRICK A. GIBSON

HAROLD L. SCHILZ
Special Assistants to the Attorney General
Department of Justice
Antitrust Division
U. S. Court House
Room Nos.
Trenton, New Jersey

FRANCIS BIDDLE
Attorney General

WENDELL BERGE
Assistant Attorney General

CHARLES M. PHILLIPS
United States Attorney

I hereby certify that the foregoing
is a TRUE COPY of the original
on file in my office.

William H. Tallyn, Clerk

per Vera Alexander
Deputy

EXHIBIT A

E. MERCK

and

MERCK & CO., INC.

TREATY AGREEMENT

Dated November 17th, 1932.

HUGHES, SCHURMAN & DWIGHT

100 Broadway
New York

AGREEMENT made this 17th day of November 1932, by and between E. MERCK, an open copartnership with its principal office and place of business in Darmstadt, Germany, and MERCK & CO., INC., a corporation organized and existing under the laws of the state of New Jersey, with its principal office and place of business at Rahway, New Jersey, WITNESSETH:

MERCK & CO., INC. has heretofore succeeded to all the business and property, together with the good will connected therewith of an agency established by E. MERCK for the sale of products under the trade name "MERCK" in the United States and Canada.

The parties hereto for many years have carried on their respective businesses and trade and each has established a good will in connection therewith. The business of Merck & Co., Inc., and its use of the word "Merck" in connection therewith, has been almost exclusively confined to the United States, its territories and dependencies (the word "territories"

wherever used herein meaning Alaska and Hawaii and the word "dependencies" wherever used herein meaning Porto Rico, Virgin Islands, the Panama Canal Zone, Samoa, Guam, and the Wake and Midway Islands) and Canada, while the business of E. Merck and its use of the name "Merck" has been almost exclusively confined to the remainder of the world, except that both parties have business in Cuba, the West Indies and the Philippine Islands (said Philippine Islands, while dependencies of the United States, are not included in the definition of that word as used herein) in connection with which they have used the word "Merck". The parties hereto have carried on their respective businesses under conditions of mutual cooperation and respect for the rights of the other and they desire to confirm and establish covenants and principles of mutual cooperation and helpfulness in carrying on their respective businesses.

NOW, THEREFORE, the parties hereto hereby mutually agree as follows:

1. E. Merck recognizes and confirms the right of Merck & Co., Inc. to the exclusive use of the word "Merck" in the United States, its territories and dependencies, and Canada, and the right to use said name jointly with E. Merck in Cuba, the West Indies and the Philippines, whether said word "Merck" is used alone or in conjunction with or combination with any other word or in connection with any patent or trademark or in any other way.

2. Merck & Co., Inc. recognizes and confirms the right of E. Merck to the exclusive use of the word "Merck" in the entire world, except the United States, its territories and dependencies, and Canada, and except in Cuba, the West Indies and the Philippine Islands, where Merck & Co., Inc recognizes the right of E. Merck to use said name jointly with Merck & Co. Inc. The right of E. Merck to use the name "Merck" as herein recognized and confirmed by Merck & Co., Inc. means the right to use said name alone or in conjunction with or combination with any other word or in connection with any patent or trade-mark or in any other way.

3. In case of the merger, consolidation or transfer of assets by either party, the merged or consolidated corporation or transferee shall succeed only to such rights to use said word "Merck" as are expressly herein recognized and confirmed in the party hereto which so merges, consolidates or transfers its assets.

4. In case of the abandonment of the use of the word "Merck" by either party as a result of merger, consolidation or transfer of assets or otherwise, the other party hereto shall thereafter have an unrestricted right to use the name in any part of the world.

5. Either party developing a specialty (hereinafter called the "grantor shall, except as provided in the last sentence of this paragraph and except in so far as such grantor is prevented by agreements heretofore or hereafter entered into with inventors or other parties having rights acquired prior to or simultaneously with the acquisition by the grantor of its rights therein, offer to the other party hereto (hereinafter called the "grantee") the first right for the sole distribution and/or exclusive manufacture of such specialty in the territory in which the grantee has the exclusive right to use the name "Merck" as hereinabove set forth. In case such offer is accepted, during the first fifteen years after such acceptance, the net profits resulting from the sale of such specialty shall be divided equally between the parties hereto. Said net profits shall be determined by taking

the difference between the invoice proceeds on the one side and on the other side the total of manufacturing and advertising expenses, inventor's royalties and a selling commission of 15% to the grantee. In case any loss is incurred in connection with the sale and/or manufacture of such specialty by the grantee, the grantee shall first be reimbursed for said losses out of future profits before any such profits shall be divided hereunder, it being distinctly understood and agreed, however, that the grantor shall, at no time, be responsible for such losses or any part thereof. After the expiration of such fifteen-year period, the grantor shall be entitled to receive only 25 % of the profits thereafter resulting from the sale of said specialty, which latter participation of profits shall continue in perpetuity thereafter. The preferential right to market specialties under the provisions hereof is at all times subject to obligations which the grantor may be under to third parties under contracts heretofore made whereby such third parties have preferential rights with respect to the marketing of specialties within territories specified in such contracts.

6. The parties hereto agree to a mutual exchange of information and experience regarding the processes for the manufacture of products now manufactured by both parties, as well as improvements on and technical completion of such processes, but neither party hereto shall be required to give to the other way any information or experience in violation of the terms of any agreements heretofore or hereafter entered into with inventors or other persons who acquired rights with respect to such process or with respect to such improvements on or technical completions of the same, prior to or simultaneously with the acquisition of such information or experience by the party hereto. A list of products manufactured by both parties and to which the foregoing obligation applies is attached hereto and made a part hereof. All information of one party regarding such processes or improvements shall be made available to the other without compensation, except in instances where the exchange results in substantial advantages to the party receiving the information, in which case, the party furnishing the same shall be entitled to appropriate compensation. Such compensation shall be agreed upon between the parties hereto but, in case of their failure to agree, the amount thereof shall be determined by arbitrators, each party to select one arbitrator and the two so selected to choose a third and the decision of such arbitrators or a majority of them shall be final and binding upon the parties hereto. As to processes for the manufacture of products not on the list attached hereto but which may now or hereafter be manufactured by one of the parties hereto, the other party shall have a right to acquire such process from the one having the same (excepting always where such party is prevented from granting such right by reason of obligations to third parties entered into prior to or simultaneously with the acquisition of the rights therein by the party hereto) providing the parties hereto can agree upon the scope of the use of such process and the compensation to be paid therefor and, in any event, upon the same terms upon which the party having such process is willing to sell or convey the right to use the same to third parties. In case of a merger, consolidation or transfer of assets by either of the parties hereto, the obligations contained in this paragraph 6 shall terminate and cease.

7. The parties hereto agree that, so far as possible, they will, through reports keep each other fully advised with respect to raw materials, conditions of markets, inventions and other general information which, in the opinion of either party, may be useful to the other in the carrying on of their or its business.

8. In so far as it recognizes and confirms exclusive rights to the use of the name "Merck" this agreement protects the good will of the parties hereto in their respective businesses and is in perpetuity. Except where a different term has been specifically provided in this agreement,

the term of this agreement and all obligations hereunder, shall continue for a period of fifty years from the date hereof, except in so far as the same may be terminated in whole or in part by mutual consent. Any future agreements between the parties hereto made pursuant to the terms of this agreement shall continue for such period of time as is provided therein, irrespective of the term of this agreement.

9. It is mutually agreed that in the event that either party hereto institute against the other party any legal proceedings of any nature whatsoever upon a cause of action based upon, arising out of, or in any way connected with the terms, covenants and conditions of this agreement, the party against whom such proceedings are brought, hereby agrees to accept service of process or any other papers necessary to be served to institute such proceedings, and any of the partners of E. Merck, or any of the officers of Merck & Co. Inc. are hereby authorized to accept service of such process or other papers. It is further agreed that, in the event that Merck & Co., Inc., shall institute any such legal proceedings against E. Merck, such proceedings shall be brought only in a court of competent jurisdiction in Germany, in the district in which the partnership of E. Merck has their principal place of business, and in such an event, the interpretation and construction of the terms of this agreement and the rights and liabilities of the parties, arising therefrom, as well as their remedies, shall be governed and determined solely in accordance with the law of Germany. In the event that E. Merck shall institute any such legal proceedings against Merck & Co., Inc., such proceedings shall be instituted only in a Court of competent jurisdiction of the State of New Jersey, or the United States District Court for the District of New Jersey, and in such event the interpretation and construction of this agreement, and the rights and liabilities of the parties arising therefrom, as well as their remedies, shall be governed and determined solely by the laws of the State of New Jersey.

IN WITNESS WHEREOF, this instrument has been executed on behalf of E. Merck, party of the first part, by a member of the firm under his hand and seal, the MERCK & CO., INC., the party of the second part, has caused this instrument to be signed by its duly authorized officers and its corporate seal to be hereunto affixed the day and year first above written.

E. MERCK,

By Dr. Karl Merck
A member of the firm

Attest:

MERCK & CO., INC.

By George W. Merck
President

Oscar R. Ewing
Secretary

(Seal)

Processes operated by Merck & Co. Inc.

and

E. Merck, Darmstadt

Acetamide
Acid Benzoic Reagent
Acid Chromic
Acid Hydroidic
Acid Hydrobromic
Acid Hydrocyanic
Acid Hypophosphorous
Acid Iodic
Acid Iodic Anhydride
Acid Meconic
Acid Oxalic C. P. & Reagent
Acid Silicic C. P.
Acid Sulphanilic C. P.
Acid Sulphocarbolic
Acid Sulphosalicylic
Acid Sulphuric Aromatic U.S.P.
Aluminum Acetate Solution N.P.
Aluminum Nitrate C.P.
Aluminum Phosphate
Aluminum Sulphate N.P.V. & C.P.
Ammonium Acetate
Ammonium Benzoate
Ammonium Chloride U.S.P., C.P. & Reagent
Ammonium Chromate
Ammonium Citrate
Ammonium Dichromate
Ammonium Iodide
Ammonium Nitrate, Pure, CPP & Reagent
Ammonium Oxalate
Ammonium Phosphates N.F., C.P. & Reagent
Ammonium Salicylate
Ammonium Sulphate, Pure C.P. & Reagent
Ammonium Sulphide, Solution
Ammonium Tartrate
Amyl Nitrite
Amyl Salicylate
Aniline Hydrochloride
Aniline Sulphate
Antimony Chloride Solution
Antimony Sulphurated
Apiol Fluid Green
Apomorphine Hydrochloride
Arsenic Chloride (ous)
Arsenic Iodide (ous)
Barbital
Barbital Soidum
Barium Acetate
Barium Carbonate Pure Precip. C.P. & Reagent
Barium Chloride C.P. & Reagent
Barium Chromate
Barium Nitrate C.P. & Reagent
Barium Sulphate C.P.
Benzene C.P. & Reagent
Benzylsuccinate
Bismuth Betanaphthol
Bismuth Chloride

Bismuth Citrate
Bismuth Hydroxide
Bismuth Nitrate
Bismuth Oxychloride
Bismuth Oxyiodide
Bismuth Salicylate
Bismuth Subbenzoate
Bismuth Subcarbonates
Bismuth Subgallate
Bismuth Subnitrates
Bismuth Subsalicylate
Bismuth Tannate
Bismuth & Ammonium Citrate
Blaud's Mass Powder
Cadmium Acetate
Cadmium Bromide
Cadmium Carbonate
Cadmium Chloride
Cadmium Iodide
Cadmium Nitrate
Cadmium Sulphate
Caffeine Citrated
Caffeine Sodium Benzoate
Caffeine Sodium Salicylate
Calamine Prepared N.F.
Calcium Acetate
Calcium Carbonate C.P. & Reagant
Calcium Chloride Anhydrous C.P. & Reagent
Calcium Chloride Crystals Pure & C.P.
Calcium Chlorine U.S.P.
Calcium Iodide
Calcium Lactate Dried
Calcium Lactophosphate
Calcium Nitrate Pure & C.P.
Calcium Sulphate C.P.
Calomel
Calomel Special Fine
Camphor Monobromated
Carlsbad Salt Artificial N.F.
Chlorbutanol
Chromium Salts
Cocaine & Salts
Codeine & Salts
Colchicine
Colchicine Salicylated
Congo Paper
Copper Acetate C.P. & Reagent
Copper Aluminated
Copper Bromide
Copper Chloride C.P. & Reagent
Copper Iodide
Copper Nitrate
Copper Oxide Black
Copper Sulphate U.S.P., C.P. & Reagent
Copper Sulphate Anhydrous C.P.
Copper & Ammonium Chloride
Corrosive Sublimate
Cuprex
Dextrose C.P. Anhydrous
Dextrose Solution Sterilized in ampules
Digitan Powder, Tablets & Tincture

Dionin
Emetine & Salts
Eschka's Mixture
Eserine Salicylate
Ethyl Bromide C.P.
Ethyl Iodide
Ethyl Nitrite
Febrolysin
Gold & Sodium Chloride
Homatropine & Salts
Hydrastine & Salts
Hydroalcholic Extract of decocainized coca leaves
Iodine Resublimed Cryst. & Granular
Iodine Trichloride
Iodoform
Ipecac & Opium Powder
Iron Acetate ic basic & Solution
Iron Bromide
Iron Carbonate
Iron Citrate Scales & Pearls
Iron Dialyzed
Iron Hypophosphite
Iron Iodide (ous)
Iron Iodide Saccharated
Iron Iodide Syrup
Iron Nitrate Ferric
Iron Oxalate Ferric
Iron Oxalate Ferrous
Iron Oxide Brown Precipitated
Iron Oxide Red Saccharated
Iron Peptonized
Iron Phosphate (ferric) Soluble Scales & Pearls
Iron Phosphate Ferrous
Iron Pyrophosphate Soluble Scales & Pearls
Iron Succinate
Iron Sulphate Ferric Powder & Solution
Iron Sulphate Ferric Basic & Solution
Iron Sulphate Ferrous Gran. U.S.P. & C.P.
Iron Sulphate Ferrous Dried U.S.P.
Iron & Ammonium Citrate Brown Scales & Pearls
Iron & Ammonium Citrate Green Scales & Pearls
Iron & Ammonium Oxalate
Iron & Ammonium Sulphate, Ferric
Iron & Ammonium Sulphate, Ferrous
Iron & Potassium Oxalate
Iron & Potassium Tartrate
Iron & Quinine Citrate Scales & Pearls
Iron & Sodium Oxalate
Lead Acetate Reagent
Lead Chloride
Lead Chromate C.P.
Lead Iodide
Lead Nitrate
Lead Subacetate Solution U.S.P.
Lead Sulphate C.P.
Lime Iodized
Lithium Benzoate
Lithium Chloride
Lithium Citrate

(Over)

Lithium Iodide
Lithium Nitrate
Lithium Salicylate
Lithium Sulphate
Litmus Paper Red & Blue
Magnesium Bromide
Magnesium Carbonate Heavy
Magnesium Chloride
Magnesium Citrate Soluble
Magnesium Nitrate C.P. & Reagent
Magnesium Oxide Heavy
Magnesium Phosphate Di & Tri-basic
Magnesium Salicylate
Magnesium Sulphate Dried
Magnesium & Sulphate Reagent
Magnesium & Ammonium Phosphate
Manganese Carbonate
Manganese Chloride
Manganese Citrate Soluble
Manganese Hypophosphite
Manganese Sulphate Crystals
Mercurial Ointments U.S.P.
Mercury Redistilled U.S.P., C.P. & Reagent
Mercury Acetates
Mercury Ammoniated
Mercury Bisulphate
Mercury Bromide
Mercury Cyanide
Mercury Iodides
Mercury Mass U.S.P.
Mercury Nitrates
Mercury Oleate (25%)
Mercury Oxides
Mercury Salicylate
Mercury Succinimide
Mercury Sulphide Black
Mercury Sulphocyanate
Mercury with Chalk U.S.P.
Methyl Iodide
Methylene Iodide
Methyl Salicylate
Morphine & Salts
Narceine & Salts
Narcotine & Saltes
Nickel Chloride C.P.
Oil Ethereal N.F.
Opium Alkaloids
Opium Medicinal
Opium Extract N.F.V.
Papaverine & Salts
Peroxoids
Phenobarbital
Phenobarbital Sodium
Phenylhydrazine Hydrochloride
Pilocarpine Salicylate
Plantinic Chloride Solution
Potassa Sulphurated
Potassium Acetate
Potassium Acid Phthalate

Potassium Arsenate Monobasic
Potassium Arsenite Powder & Solution
Potassium Bisulphate
Potassium Carbonate U.S.P.
Potassium Chromate Yellow C.P. & Reagent
Potassium Citrate
Potassium Dichromate C.P. & Reagent
Potassium Iodate
Potassium Iodide
Potassium Nitrate Reagent
Potassium Oxalate Reagent
Potassium Phosphate mono and di-basic
Potassium Sulphocyanate C.P. & Reagent
Quinhydrone
Sodium Arsenate
Sodium Arsenite
Sodium Bisulphate
Sodium Carbonate Anhydrous Pure & C.P.
Sodium Chromate Dried
Sodium Citrates
Sodium Formate
Sodium Hydroxide with Lime
Sodium Iodate
Sodium Iodide
Sodium Malate
Sodium Nitrate Reagent
Sodium Nitrite U.S.P.
Sodium Oleate Acid Mass
Sodium Phosphate Dibasic Anhydrous Reagent
Sodium Phosphate Dibasic large crystals
Sodium Phosphate Monobasic
Sodium Pyrophosphate
Sodium Stearate
Sodium Succinate
Sodium Sulphate U.S.P., C.P. & Reagent
Sodium Sulphate Anhydrous Pure, C.P. & Reagent
Sodium Sulphide Pure, C.P. & Reagent
Sodium Sulphocarbolate
Sodium Sulphocyanate
Sodium Tetraiodophenolphthalein
Sodium Tungstate Reagent
Sodium & Ammonium Phosphate
Spirit Ether Compound
Starch Iodized
Starch Soluble
Strontium Acetate
Strontium Chloride
Strontium Iodide
Strontium Lactate
Strontium Nitrate C.P.
Strontium Salicylate
Stypticin & Tablets
Sulphur Iodide
Tannaform
Thebain & Salts
Theobromine Salicylate True Salt
Theobromine Sodium Acetate

(Over)

Theobromine Sodium Salicylate
Thiosinamine
Thymol Iodide
Tin Metal - Granular
Tin Chloride (ous) C.P. & Reagent
Tincture Ferric Chloride
Tincture Ferric Citrochloride
Tincture of Iodine
Traumaticin
Tropococaine Hydrochloride
Tropococaine Hydrochloride Solution in Ampules
Veronal Powder & Tablets
Zinc Metal Mossy, Shot & Sticks
Zinc Bromide
Zinc Iodide
Zinc Nitrate
Zinc Stearate
Zinc Sulphocarbolate

EXHIBIT C

NOTICE OF INTENTION TO SEEK TERMINATION OF THE CONSENT DECREE IN UNITED STATES v. MERCK & CO., INC., ET AL.

PLEASE TAKE NOTICE that Merck Sharp & Dohme Corp. ("Merck"), has submitted a request to the Antitrust Division of the United States Department of Justice ("Antitrust Division") to support Merck in obtaining termination of the Final Judgment entered in *United States v. Merck & Co., Inc., et al.*, Civil No. 3159 (D.N.J. 1943), on October 6, 1945 (the "Consent Decree"). Merck is publishing this notice of its intention to seek termination of the Consent Decree so that any interested persons can submit comments to the Antitrust Division with respect to the proposed termination.

On October 28, 1943, the United States filed a complaint alleging that Merck and E. Merck (a corporation doing business in Darmstadt, Germany that is now known as Merck KGaA) had agreed to allocate customers and territories between themselves in the sale and distribution of chemical and pharmaceutical products made by them, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The suit was resolved in 1945 by entry of the Consent Decree.

The Consent Decree prohibits Merck and E-Merck from, *inter alia*, entering into or furthering any agreement to (1) allocate markets or customers or refrain from competing in the manufacture, sale, distribution, or import/export of any chemical or pharmaceutical product; (2) create or observe an obligation to exchange or license rights relating to any chemical or pharmaceutical product; (3) establish terms or conditions upon which patents relating to any chemical or pharmaceutical product will be licensed or any chemical product will be sold by or to others; and (4) fix prices for any chemical or pharmaceutical product. Merck is seeking the termination of the Consent Decree because the Decree no longer serves the public interest and

inhibits the companies from potentially engaging in procompetitive transactions that would benefit consumers.

Interested persons are invited to submit comments regarding the potential termination of the Consent Decree to the Antitrust Division. Comments must be received by the Antitrust Division by October 1, 2010. Comments should be addressed to Donna M. Kooperstein, Chief, Transportation, Energy, and Agriculture Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street, N.W., Washington, DC 20530.

EXHIBIT D

LEGAL NOTICES

PUBLIC NOTICES

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NOTICE OF CLAIMS BAR DATE AND PROCEDURES FOR RESOLUTION OF DISPUTED CLAIMS AND OBJECTIONS TO PROCEDURES AND PLAN

TO CREDITORS AND INVESTORS IN:

Ariel Fund Limited;
Gabriel Capital, L.P.;
Gabriel Alternative Assets, LLC; and
Gabriel Assets, LLC (together, the "Ariel & Gabriel Receivership Entities")

On July 30, 2010, the New York State Supreme Court (the "Court") signed an Order Setting a Claims Bar Date; Fixing Manner of Notice of the Claims Bar Date; and Establishing Procedures for Resolution of Disputed Claims and Objections to Procedures and Plan (the "Distribution Motion Procedures Order"), pursuant to which the Court has, among other things, set September 20, 2010 at 5:00 p.m. prevailing New York Time, as the last date and time for claimants to submit a proof of claim ("Proof of Claim") against any of the Ariel & Gabriel Receivership Entities identified above (the "Bar Date"). The Bar Date is enforceable notwithstanding any otherwise applicable law that could govern the timing of the assertion of a claim against any of the Ariel & Gabriel Receivership Entities.

A complete set of instructions for submitting a Proof of Claim, a copy of the Distribution Motion Procedures Order, and all other relevant documents are available at www.guidepostpartners.com. Responses to Frequently Asked Questions also appear at www.guidepostpartners.com.

YOUR RIGHTS MIGHT BE AFFECTED BY THE DISTRIBUTION MOTION PROCEDURES ORDER. YOU SHOULD CONSULT AN ATTORNEY IF YOU HAVE ANY QUESTIONS, INCLUDING WHETHER YOU SHOULD SUBMIT A PROOF OF CLAIM.

Dated: August 27, 2010
New York, New York

MEDIA & MARKETING

* * * *

THE WALL STREET JOURNAL.

LEGAL NOTICES

PUBLIC NOTICES

NOTICE OF INTENTION TO SEEK TERMINATION OF THE CONSENT DECREE IN UNITED STATES v. MERCK & CO., INC., ET AL.

PLEASE TAKE NOTICE that Merck Sharp & Dohme Corp. ("Merck") has submitted a request to the Antitrust Division of the United States Department of Justice ("Antitrust Division") to support Merck in obtaining termination of the Final Judgment entered in United States v. Merck & Co., Inc., et al., Civil No. 3159 (D.N.J. 1945), on October 6, 1945 (the "Consent Decree"). Merck is publishing this notice of its intention to seek termination of the Consent Decree so that any interested persons can submit comments to the Antitrust Division with respect to the proposed termination.

On October 28, 1943, the United States filed a complaint alleging that Merck and E. Merck (a corporation doing business in Darmstadt, Germany, that is now known as Merck KGaA) had agreed to allocate customers and territories between themselves in the sale and distribution of chemical and pharmaceutical products made by them, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The suit was resolved in 1945 by entry of the Consent Decree.

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Interested persons are invited to submit comments regarding the potential termination of the Consent Decree to the Antitrust Division. Comments must be received by the Antitrust Division by October 1, 2010. Comments should be addressed to Donna M. Kooperstein, Chief, Transportation, Energy, and Agriculture Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street, N.W., Washington, DC 20530.

EXHIBIT E

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PRESCRIPTION PHARMACEUTICALS AND BIOTECHNOLOGY

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Comparative Effectiveness Research
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Health Care Reform

- **Getting to know HHS: insurance oversight management team is complete** – Top level staffing for the HHS Office of Consumer Information and Insurance Oversight will be complete when former Pennsylvania Insurance Commissioner Joel Ario joins Aug. 30. The OCIIO will oversee implementation of the commercial insurance market expansion and reforms mandated by the health reform law 6

Developments In Deal-Making

- **Deals of the Week: Medco/United BioSource, Aspen/Sigma, Biogen/Knopp** – PBM Medco expanded its capabilities to include drug-outcomes-based research for pharmaceutical companies by purchasing United BioSource this past week, while South Africa's Aspen became a player in Australia through a buyout of Sigma's pharmaceutical operations 9

More Regulatory And Business News

- **FDA Science Board recommends larger nanotech program budget** – Science Board members say $7.3 million agency requested in its fiscal 2011 request for its first dedicated budget for nanotechnology is not enough. Agency should jump on the "leadership moment" to help shape nano standards for the world, Applebaum says. Board discusses ways to reach out for more funding 18

- **Safety problems help AstraZeneca win suit brought by former partner Verus** – Court tosses out Verus Pharmaceuticals' $1.28 billion breach of contract suit against AstraZeneca, concluding the firm had the right to halt development of a pediatric formulation of the asthma drug budesonide before an end of Phase II meeting with FDA. AstraZeneca said safety problems precluded further development. The now defunct Verus, which sold off all its other businesses after forming a partnership with AstraZeneca, plans to appeal the decision 20

- **Business news in brief** – Novartis, with a strong emphasis on detailing its new hypertension drug ***Valturna*** (aliskiren/valsartan), saw its volume of sales calls to doctors, nurses and physician assistants increase by 7 percent during the first half of 2010, in contrast to an overall industry decrease of 1 percent, market analytics firm SDI reports. Johnson & Johnson appoints long-time exec Ajit Shetty to lead a new quality control organization across diverse business units, a move that is a key step to showing it has control over manufacturing issues following recalls of several consumer products. Plus updates on the Novartis/Alcon deal and potential Sanofi-Aventis/Genzyme deal 7

- **Merck recalls losartan tabs** due to labeling error; more recalls 21

- **Bedford receives approval for sumatriptan** subcutaneous injection; more ANDAs 19

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PCORI Should Take Lead On Public CER Inventory, Pharma Groups Tell HHS

Development of a publicly available repository of comparative effectiveness research should grow out of the work of the soon-to-be established Patient Centered Outcomes Research Institute, groups representing pharmaceutical industry interests urged in recent comments to HHS.

The comments reflect a concern with the potential market impact of making CER available through a government-sponsored website, and thus appearing to be eudorsed by HHS, without industry being allowed a formal role in the selection of studies or in how they are presented.

The comments respond to a July 19 request for information from HHS on establishing a public catalog of comparative effectiveness studies that would facilitate access to data for a broad group of stakeholders and also identify gaps in research ("The Pink Sheet," Aug. 2, 2010). The notice came from the office of newly installed Assistant Secretary for Planning and Evaluation Sherry Glied.

Submissions by the Pharmaceutical Research and Manufacturers Association, the National Pharmaceutical Council and the Partnership to Improve Patient Care recall arguments made during the debate over establishing a national CER institute as the health reform bill moved through Congress.

During the debate, industry argued that biopharmaceutical firms should be permitted to participate in the establishment of an institute that would coordinate, direct and serve as a source of CE research. In the end, industry obtained its seat at the table and the health reform law established the Patient Centered Outcomes Research Institute as a public-private entity.

PCORI's governing board, which the statute says will include representatives of private sector companies, is scheduled to be announced by the Government Accountability Office in September ("The Pink Sheet," June 30, 2010). Also next month, GAO will solicit nominees for the institute's methodology committee, which will play a key role in developing and identifying standards for research. The methodology group may include members from private industry.

In its comments, dated Aug. 9, PhRMA says "to help ensure the CER inventory is useful and sustainable, HHS should build it in collaboration with the PCORI created by Congress." PCORI "offers a significant new opportunity for a federally supported CER program that is objective, patient-centered, inclusive of multiple stakeholders, and sustainable over the long-term."

PhRMA suggests that HHS clarify that the inventory will not include HHS recommendations or guidance and will "serve simply as a research database." The group also requests more detailed guidance from HHS on the types of studies and analyses that qualify as CER.

For example, HHS stated the database could include self-reported data from a wide range of sources, including "gray literature," which "are not always subject to rigorous peer review," PhRMA said.

Comments from the National Pharmaceutical Council seek to ensure the data included in the inventory are limited to comparative clinical effectiveness, another major industry concern in the CER debate. NPC is supported by major pharmaceutical firms.

Like PhRMA, NPC recommended that once the PCORI methodology committee has developed research standards, those should be used as the "minimum criteria for studies to be included in an inventory."

In the meantime, NPC suggested that a recently developed framework for evaluating observational CE studies known as the GRACE (Good Research for Comparative Effectiveness) Principles could be used to evaluate such studies for inclusion in the inventory.

GRACE Principles For Observational Data

Released in April, the GRACE principles were developed by Cambridge, Mass.-based Outcome Sciences, a provider of patient registries, technologies and studies to evaluate real-world outcomes, with seed funding from NPC. The principles, which have been endorsed by the International Society of Pharmacoepidemiology, center around three basic questions:

- Were the study plans, including research questions, main comparisons, outcome, etc. specified in advance of conducting the study?

- Was the study conducted and analyzed in a manner consistent with good practices, and reported in enough detail for evaluation and replication?

- How valid is the interpretation of comparative effectiveness for the population of interest, assuming sound methodology and appropriate follow-up?

In separate comments, the Partnership to Improve Patient Care made similar arguments on the need for developing methodological standards for research. "It is our concern that developing this list without the guidelines provided by standardized methods would only be of use to others than patients and doctors and could possibly be used inappropriately," PIPC said.

By developing an inventory in conjunction with PCORI, HHS can "ensure that the diverse perspectives and needs of patients and providers are fully considered as the inventory is developed," the group urged. In this way, "PCORI could address questions like how the inventory will incorporate and assimilate studies on the same interventions that include different outcomes."

Furthermore, PIPC said, it is "very important for CER to consider factors such as patient reported outcomes, quality of life, and productivity, but not all studies evaluate these outcomes."

PIPC is a CER policy group formed in November 2008 with support from PhRMA, the Biotechnology Industry Organization, the Advanced Medical Technology Association and patient and advocacy groups. It is led by former California Democratic congressman Tony Coelho.

PhRMA advises that HHS' initial focus be on developing an inventory of federally funded CER before moving ahead with a catalog of CER by non-profit or private organizations. Currently, "there is not a single public resource that comprehensively documents the projects, locations, funding amounts, status and results of the individual CER projects" being funded by HHS, PhRMA pointed out.

FDA Drug Advertising Rules An Obstacle

The group highlighted one issue that could hamper biopharmaceutical firms from contributing commercially developed research to the HHS inventory – FDA rules on comparative effectiveness claims in drug advertising and communications.

FDA considers drug labeling or advertising misleading if it contains a representation, not approved for use, that a drug is better, more effective, useful in a broader range of conditions or patients, safer or has fewer side effects than "has been demonstrated by substantial evidence or substantial clinical experience," PhRMA noted.

As a result, "we recognize that many comparative studies and evidence syntheses might not meet the FDA's exacting standards for inclusion in a company's professional drug labeling and promotion; however, such studies could nevertheless be considered of high quality and useful in helping to inform decision making," the group maintained.

The trade group asks that HHS work with FDA to consider potential approaches to address the problem and "provide a mechanism to enable manufacturers, which play a prominent role in generating research, to voluntarily provide relevant, reliable, and scientifically valid studies to the database."

In its comments, America's Health Insurance Plans urged HHS to coordinate with FDA to include in the inventory approval notices on new drugs and biologics and approved labeling or product literature provided to FDA or the public. Data supporting Medicare coverage decisions by the Centers for Medicare and Medicaid Services would also be valuable, AHIP said.

Other features of the inventory suggested by the insurers' trade group include:

- Head-to-head comparisons of new drugs to existing drugs that treat the same condition, both within classes and across classes.

- Direct comparisons of pharmacotherapy outcomes with and without prior genetic testing.

- How new treatments work in the real world, for example in populations with co-morbidities, and not only within the research design.

– *Cathy Kelly (c.kelly@elsevier.com)*

HHS CER Catalog May Not Be Sustainable Without Clear Funding Stream – NIH

A Web-based inventory of comparative effectiveness research sponsored by HHS would need dedicated funding to be sustainable, the National Institutes of Health cautions in Aug. 9 comments to the HHS Assistant Secretary for Planning and Evaluation.

"Sustainability should be a main consideration for the design and development of the inventory," NIH Office of Science Policy Analysis Director Lynn Hudson said. The comments were culled from NIH's 27 institutes and centers.

They addressed a recent HHS request for input on establishing a public catalog of CE studies that would facilitate access to data for a broad group of stakeholders and also identify gaps in research ("The Pink Sheet," Aug. 2, 2010).

"Few electronic database resources which are for the public good are sustainable without government support," the comments state. "The federal agencies should underwrite the cost of sustaining and developing the inventory in the same way" as the Library of Medicine's PubMed research database and the National Center for Biotechnology Information's GENSAT database of gene mapping data.

"There is great concern, however, that an inventory that would be created as an unfunded mandate would not be sustainable," the comments assert.

"Creating yet another 'single purpose' resource (inventory) may not necessarily meet the stated goals," NIH says. However, "it makes sense to make it easy for people to find out what kinds of CER-related resources are available – a meta-inventory perhaps."

NIH's ClinicalTrials.gov database of clinical studies is "already, in some sense, an inventory of CER since some clinical trials are CER," the comments continue, suggesting that its database could inform HHS' thinking on the resources needed for a CER inventory.

"The Clinical Trials.gov team are experts on how difficult it is to create a data resource that meets multiple user needs, including real data, etc. They could provide some data about the ongoing cost of maintaining such a resource."

– *Cathy Kelly (c.kelly@elsevier.com)*

Getting To Know HHS: Insurance Oversight Management Team Is Complete

Top level staffing for the HHS Office of Consumer Information and Insurance Oversight will be complete when former Pennsylvania Insurance Commissioner **Joel Ario** joins Aug. 30.

Ario has been appointed deputy director of the office of health insurance exchanges within the OCIIO. He has served as insurance commissioner in Pennsylvania since July 2007.

Ario is the third state insurance commissioner to be tapped for a leadership role in the new office, which should ensure a high level of scrutiny of the insurance industry. OCIIO will oversee implementation of the commercial insurance market expansion and reforms mandated by the health reform law ("The Pink Sheet," May 17, 2010).

The OCIIO is headed by Director **Jay Angoff**, a former Missouri insurance commissioner with a track record of challenging insurance company rates through litigation.

And OCIIO Deputy Director **Steve Larsen** was previously the Maryland insurance commissioner from 1997 to 2003. He now heads the office of oversight within OCIIO.

The OCIIO has four deputy directors. In addition to Ario and Larsen, **Elizabeth Fowler** is deputy director for policy. She joined the office from Capitol Hill, where she played a key role in developing the Affordable Care Act as the top health reform staffer to Senate Finance Committee Chairman Max Baucus, D-Mont. ("The Pink Sheet" DAILY, July 14, 2010).

Richard Popper is deputy director of the office of insurance programs. He previously was executive director of the Maryland Health Insurance Plan from 2002 to 2010. In that role, he was responsible for running Maryland's high-risk insurance pool.

Karen Pollitz is deputy director of the office of consumer support. She is a former professor at the Georgetown University Health Policy Institute. Pollitz also previously served as the assistant deputy secretary for legislation at HHS from 1993 to 1997.

The OCIIO has initiated a number of health reform regulations over the past few months They include: new rules giving consumers the right to appeal health plan decisions; requirements that new health plans cover preventive services, including vaccines, without cost-sharing ("The Pink Sheet," July 19, 2010); and rules defining when plans are considered to be "new" and so unable to claim a grandfather exemption from some insurance market reforms.

The office has also issued requests for input on a number of topics, such as what standards health insurance exchanges should be required to meet, new requirements for the way health plans determine medical loss ratios, and how to conduct health plan premium rate reviews.

– *Cathy Kelly (c.kelly@elsevier.com)*

Business News In Brief

Novartis runs counter to sales call trends for first half of 2010: With a strong emphasis on detailing newly launched hypertension drug ***Valturna*** (aliskiren/valsartan), Novartis saw its volume of sales calls to doctors, nurses and physician assistants increase 7 percent during the first half of 2010, in contrast to industry trends. In a newly issued report, health care market analytics firm SDI announced overall sales calls by pharma companies to clinicians decreased 1 percent during the first six months of the year, compared to the second half of 2009. Based on SDI's findings, Merck sales calls declined 16 percent and GlaxoSmithKline's 7 percent. The industry's biggest company, Pfizer, posted a 2 percent decrease in sales calls during the half-year. At Novartis, a full 19 percent of sales calls were used to discuss Valturna, a combination drug approved by FDA last September that comprises the active ingredients in ***Diovan*** and ***Tekturna*** (*Pharmaceutical Approvals Monthly*, October 2009). With pharmaceutical sales forces being reduced in recent years, the drop in sales calls may be slowing, SDI Associate Director of Syndicated Analytics Jason Fox said, but in-person calls remain the most popular method of informing clinicians of new drugs, second only to product sampling.

Genzyme's sale price speculation: The surfeit of reports regarding Sanofi-Aventis' attempts to purchase Genzyme probably means the two companies are now engaged in discussions, if not actual price negotiations, Bernstein Research analyst Geoffrey Porges suggested in an Aug. 20 note. "The best guess is that these discussions are focused on enhancing Sanofi's understanding of Genzyme's businesses, rather than on deal negotiation," he wrote. "It also seems feasible that the two parties have entered into a confidentiality agreement, or are in the process of negotiating one." Such an agreement might include a standstill clause or require written indication of interest at a certain price, but it also could provide an exclusivity period for Sanofi, Porges added. It would be in Sanofi's interest to keep another bidder from getting involved, as Porges' research of seven prior similar merger deals shows an agreement has been reached at 10 percent to 15 percent above the initial offer, but at 20 percent to 25 percent higher if a second bidder emerges. If Sanofi remains the lone bidder, Porges predicts the French pharma will buy Genzyme at about $76-$79 per share early in 2011, but the price could rise to $83-$86 a share if another bidder comes into play.

Novartis scores modest victories in its bid for Alcon: In mid-August, Novartis scored two modest victories in its efforts to secure 100 percent ownership of ophthalmology specialist Alcon. On Aug. 14, China's Ministry of Commerce conditionally approved the transaction, provided Novartis agrees not to sell a pre-merger ophthalmological anti-infective and halts a sales partnership with a Taiwanese contact-lens maker (PharmAsia News, Aug. 17, 2010). On Aug. 16, the Swiss pharma announced five of its nominees had been elected to Alcon's board of directors, replacing the five Nestle representatives on the board. Despite these small wins, Novartis must still sway to its side independent Alcon shareholders, who own 23 percent of the company and are unhappy with their lower per-share offer. It remains to be seen whether the shareholders' legal claims will hold up well enough to halt the merger; they may also be gambling that Novartis will simply tire of fighting them in order to seal the deal in a timely fashion. If Novartis were to pay independent shareholders $180 a share – the same price offered Nestle – the cost of acquiring the independent shareholders' stake would climb from $9.8 billion to $12.5 billion. Given that Novartis is already on the hook for roughly $40 billion, the pharma could decide the additional money might not be worth a protracted battle with dissidents ("The Pink Sheet" DAILY, Aug. 16, 2010).

J&J creates position focused on quality control: Hit hard by manufacturing problems associated with its pediatric ***Tylenol*** and other over-the-counter medicines, Johnson & Johnson has appointed long-time executive Ajit Shetty to lead a new organization within the health care giant that will guarantee quality production across its diverse business units. The news, announced internally to J&J employees last week, was first reported by the Wall Street Journal. Under the new quality control framework, Shetty will manage the chief quality officers for each of J&J's business groups; the managers of the firm's 120 world-wide manufacturing facilities will also report directly to Shetty's group. One of Shetty's near-term objectives must be overhauling operations at the McNeil Consumer Healthcare Unit's Fort Washington, Pa. plant. This spring the company recalled 1,500 lots of pediatric Tylenol, ***Benadryl, Motrin*** and ***Zyrtec*** liquids manufactured at the site due to potential super-potency or inert particulate matter in suspension. The appointment of Shetty is a key step in J&J's ability to demonstrate to consumers – as well as FDA and Congress, which continue to investigate the company – that it has control over its manufacturing dilemmas ("The Tan Sheet," July 26, 2010).

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Deals Of The Week: Medco/United BioSource, Aspen/Sigma, Biogen/Knopp ...

Each week, "The Pink Sheet" presents commentary on some of the week's most interesting business deals, contributed by the editors of the IN VIVO blog. Visit the blog at http://invivoblog.blogspot.com/.

"The Pink Sheet" presents
Deals Of The Week
From The IN VIVO Blog

Medco/United BioSource: If you have any doubts about the importance of outcomes-based research in the post-health care reform era, look no further than Medco's Aug. 16 announcement that it plans to acquire the Bethesda, Md.-based information services company United BioSource Corp. (UBC) for $730 million. The tie-up gives the pharmacy benefit manager a new business capability – drug outcomes-based research for biopharma companies – that's likely to be a valuable service in today's comparative effectiveness era.

Among other things, UBC is the market leader in designing and conducting risk evaluation and mitigation strategies for new medicines. UBC says it has been involved in the design, implementation and/or assessment of more than 60 REMS and predecessor programs, known as risk minimization action plans. In addition to safety and risk management, UBC focuses on health economics and outcomes research, including drug cost-benefit and cost-effectiveness analyses. UBC also brings Medco the capacity to conduct post-approval research in Europe and Japan.

Medco's deal with UBC is more strategic in nature than recent moves by CVS Caremark and Express Scripts, PBMs which have aimed to add volume by acquiring large chunks of business from insurers. In July, CVS Caremark announced a 12-year contract with Aetna to manage duties previously handled by the insurer's internal PBM covering 9.7 million plan members. That followed Express Scripts' outright purchase of WellPoint's internal PBM, NextRx, which handles pharmacy benefits for about 25 million customers.

Aspen/Sigma: The beleaguered Australian-based health care firm Sigma finally bought its way out of a jam, inking a deal Aug. 16 with South Africa-based Aspen Pharmacare. Under the terms of the deal, Sigma, the largest pharmaceutical manufacturer by volume in Australia, will sell its pharmaceutical group to Africa's largest drug maker for 900 million Australian dollars ($811 million).

In hiving off the branded and generics drug unit and its most profitable division, Sigma once again will become a wholesale distributor; it also will be able to retire its total debt burden of A$785 million ($654 million). Sigma ran into trouble after spending $2.2 billion to acquire generics maker Arrow in 2005, with write-downs associated with that transaction resulting in a A$389 million loss for the 12 months to Jan. 31, 2010.

Interestingly, even though Aspen already has operations in Australia, the company also has committed to a long-term supply, distribution and logistics agreement with Sigma. According to affiliated publication PharmAsia News, opinions about the deal's value vary, in part because the continued relationship between the two companies carries execution risks for Aspen (PharmAsia News, Aug. 17, 2010). There are risks for Sigma as well, including whether the Aussie company's new CEO Mark Hooper can find growth in a generics-free company.

BioMarin/ZyStor Therapeutics: In a move to bolster its orphan drug pipeline, BioMarin Pharmaceutical has acquired enzyme replacement specialist ZyStor Therapeutics of Milwaukee for up to $115 million in upfront and milestone payments. As with many recent buyouts of private startups, the deal is back-end loaded, with a modest upfront payment of $22 million plus a $93 million earn-out.

Under the deal, announced Aug. 17, BioMarin gets ZyStor's ZC-701, a novel therapy to treat the inherited enzyme deficiency Pompe disease, as well as a platform to create additional future enzyme replacement therapies. BioMarin says ZC-701 features a faster development timeline and lower projected development costs than its in-house candidate for Pompe disease, BMN-103. (Both compounds are in preclinical development.)

The deal illustrates the new math currently in operation at many venture-backed companies. In order to advance ZC-701 through proof-of-concept, ZyStor would have had to raise a much larger round of capital; instead ZyStor's backers, chiefly a syndicate of Midwestern venture firms, chose to sell. Given the $22 million upfront, ZyStor

investors got their money back, but only just. The step-up multiple was a meager 1.5x, meaning the deal value was only 50 percent more than the amount of cash raised privately. Add in the earn-out, and the multiple could rise to 7.9x, higher than the average return for private biotechs acquired in 2009.

BioMarin wouldn't discuss the duration of the earn-out or the timing of specific milestones, except to say that one $13 million payment will be made when the first patient is enrolled in ZC-701's Phase III trials.

Biogen Idec/Knopp: In its first deal since new CEO George Scangos took the reins in mid-July, Biogen Idec will pay $80 million upfront to privately held Knopp Neurosciences in exchange for worldwide rights to develop and commercialize KNS-760704 for amyotrophic lateral sclerosis.

The deal comes with significant financial upside for Knopp, including a $20 million upfront payment, Biogen's $60 million equity investment, and potential regulatory and sales milestones of around $265 million. (Yes, there are double-digit sales royalties too – and the smaller biotech retains U.S. co-commercialization rights to the product.)

But the deal is notable for another reason: in an interview with "The Pink Sheet" Daily, Knopp's VP of Business Development Tom Petzinger noted proceeds from the deal will be distributed to the company's investors, which include Saturn Partners, Kramer Capital Partners and LaunchCyte ("The Pink Sheet" DAILY, Aug. 18, 2010).

Does that mean the licensing deal provides Knopp's backers with an exit? Or is this perhaps a share buyback? Deals of the Week's curiosity was sufficiently piqued to warrant a call to Petzinger, who clarified the distribution is not an exit and the shareholders retain all their equity. Rather, as a goodwill gesture to its investors, Knopp is handing back excess cash. No word yet on whether the investors also sought to bestow a similar act of kindness on their limited partners.

Novartis/Quark: Novartis has agreed to pay Quark Pharmaceuticals $10 million for the option to later in-license QPI-1002, a systemically delivered synthetic siRNA currently in Phase II for prevention of acute kidney injury in patients undergoing major cardiovascular surgery and for prophylaxis of delayed graft function in patients receiving kidney transplants.

The companies revealed few details of the Aug. 18 agreement. The exercise fee and milestones for '1002 could reach $670 million but Quark CEO Daniel Zurr was not able to break down those biobucks more specifically or say when Novartis' option kicks in. Of course there are royalties on net sales too – if a drug ever reaches the market. In an interview, Zurr could only say he was "quite happy" with the royalty rate ("The Pink Sheet" DAILY, Aug. 19, 2010).

Also left unanswered is what the tie-up means for Novartis' ongoing collaboration with Alnylam, under which the two companies are developing RNAi candidates in a variety of therapeutic areas. Originally a three-year agreement, Novartis has extended the Alnylam partnership twice for one year, with a termination date coming in October. At that time, Novartis will have to decide whether to non-exclusively license the Alnylam platform and further increase its ownership stake in the RNAi pioneer.

Abbott/SkyePharma: Back in January, FDA declined to approve SkyePharma's ***Flutiform*** fixed-dose combination asthma product, instead issuing a complete response letter. After a June meeting with the agency, it became clear the companies would need to conduct additional clinical trials. In our No-Deal of the Week, the other shoe dropped on Aug. 20, with Abbott backing out of the Flutiform deal (one originally signed by Kos back in 2006 for $25 million upfront and renegotiated slightly by Abbott in 2008), penalty-free.

Skye hasn't given up on the project, according to a statement, but won't be taking home a break-up fee to keep it warm during those cold English summer nights, either. The therapy remains under review in Europe, where – perhaps luckily for Skye – "the regulatory approach is different from the United States," the release notes. If Skye sees a path forward in the U.S. it will try to sign up another marketing partner. For now, nobody seems surprised by Abbott's decision – yet SkyePharma's shares still slid 2.5 percent on the news.

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PRESCRIPTION PHARMACEUTICALS AND BIOTECHNOLOGY

"The Pink Sheet"

Monday, August 23, 2010

From the Web

WHO gives Pfizer vaccine nod for int'l procurement
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Termination of Consent Decree in U.S. v. Merck & Co., Inc.

NOTICE OF INTENTION TO SEEK TERMINATION OF THE CONSENT DECREE IN UNITED STATES v. MERCK & CO., INC., ET AL.

PLEASE TAKE NOTICE that Merck Sharp & Dohme Corp. ("Merck") has submitted a request to the Antitrust Division of the United States Department of Justice ("Antitrust Division") to support Merck in obtaining termination of the Final Judgment entered in *United States v. Merck & Co., Inc., et al.*, Civil No. 3159 (D.N.J. 1943), on October 6, 1945 (the "Consent Decree"). Merck is publishing this notice of its intention to seek termination of the Consent Decree so that any interested persons can submit comments to the Antitrust Division with respect to the proposed termination.

On October 28, 1943, the United States filed a complaint alleging that Merck and E. Merck (a corporation doing business in Darmstadt, Germany, that is now known as Merck KGaA) had agreed to allocate customers and territories between themselves in the sale and distribution of chemical and pharmaceutical products made by them, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The suit was resolved in 1945 by entry of the Consent Decree.

The Consent Decree prohibits Merck and E. Merck from, *inter alia*, entering into or furthering any

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agreement to (1) allocate markets or customers or refrain from competing in the manufacture, sale, distribution, or import/export of any chemical or pharmaceutical product; (2) create or observe an obligation to exchange or license rights relating to any chemical or pharmaceutical product; (3) establish terms or conditions upon which patents relating to any chemical or pharmaceutical product will be licensed or any chemical product will be sold by or to others; and (4) fix prices for any chemical or pharmaceutical product. Merck is seeking the termination of the Consent Decree because the Decree no longer serves the public interest and inhibits the companies from potentially engaging in procompetitive transactions that would benefit consumers.

Interested persons are invited to submit comments regarding the potential termination of the Consent Decree to the Antitrust Division. Comments must be received by the Antitrust Division by October 1, 2010. Comments should be addressed to Donna M. Kooperstein, Chief, Transportation, Energy, and Agriculture Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street, N.W., Washington, D.C. 20530.
Aug 23, 2010

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THE NEWS THIS WEEK Vol. 72, No. 35 August 30, 2010

Drug Development

Keeping Up With FDA's Thinking May Slow Down Drug Development

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At FDA

- **Behind closed doors: FDA's drug safety oversight board will keep its decisions private** – Agency's transparency initiative has led to more detailed public meeting summaries but will not extend to publication of the board's internal recommendations, which will remain non-public, DSOB Executive Director Osborne says. Meeting minutes also will not reflect the amount of debate among DSOB members, he says, adding that stakeholders can "make their own guess" about how spirited the discussion might have been on a particular topic 17

- **The look of FDA's drug safety oversight board** – The board comprises 20 representatives from FDA and eight members from six other federal agencies who provide feedback on the potential and actual effects of drug safety regulatory actions 19

Updates On Deals

- **FTC taking a closer look at Talecris/Grifols merger; HIGPA voices concern** – The Federal Trade Commission has asked for more information from Talecris Biotherapeutics and Grifols regarding their announced merger plans. That transaction has raised red flags with the Health Industry Group Purchasing Association, which expressed concerns that reducing the number of IVIG producers from five to four, if this merger were completed, would create IVIG access issues 26

- **Deals of the Week: Roche/BioImagene, P&G/Somaxon, Roche/Aileron** – During a week when numerous biopharmaceutical companies found themselves in deal-making pickle, Roche prospered with a pair of deals. Meanwhile, Procter & Gamble returned to the prescription drug business with an agreement to co-promote Somaxon's recently approved insomnia drug, Silenor 24

- **Business news in brief** – Long-time CFO Kevin Buchi steps in to head Cephalon as founder and CEO Frank Baldino takes a medical leave-of-absence. Meanwhile, Shire obtains EU approval for its Gaucher disease drug ***Vpriv***, while Cerezyme tells doctors and patients that its Gaucher drug, ***Cerezyme***, will return to full supply next month 27

On Capitol Hill

- **Senate Finance panel key to watch in post-election committee turnovers** – It already looks like there might be substantial turn-over after the next election on the two key Senate panels with jurisdiction over health care: Finance and Health. Finance will likely lose members, and perhaps more significantly, Ranking Republican Charles Grassley is slated to give up his ranking post under Senate GOP procedures 29

More Policy News

- **CDC issues $10 million in comparative effectiveness research awards** – The Centers for Disease Control and Prevention recently issued $10 million in total to four academic institutions to conduct comparative effectiveness research programs. The agency also is planning an additional $20 million in awards to set up specialty cancer registries for use in CER 28

- **Medicare and Medicaid in brief** – CMS is planning to issue guidance on the calculation of average manufacturer price for Medicaid reimbursement after Medicaid funding law tweaks the definition; Medicare Part D donut hole rebate checks are expected to go to about 4 million beneficiaries; more in brief 33

- **Regulatory news in brief** – FDA revises guidance on antibiotic development for skin infections, clarifying when non-inferiority designs can, and can't, be used in skin and skin structure infection trials. Agency also announces public hearing on patient leaflets 20

- **Barr receives approval for clonidine transdermal patch**; more ANDAs 20

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Roche's T-DM1 Early Filing Strategy Backfires As FDA Refuses To File BLA

It hasn't been a swell summer for Roche, and now a bit of near-term pipeline news that could have put the company on a more positive trajectory has fallen flat. FDA refused to file Roche's BLA for breast cancer agent trastuzumab-DM1 (T-DM1), a conjugated version of ***Herceptin***, for accelerated approval, the company announced Aug. 27.

Roche has already faced two significant pipeline setbacks this summer, a disappointing advisory committee review for ***Avastin*** (bevacizumab) in breast cancer and safety issues with taspoglutide for type 2 diabetes. But given the early Phase II data used for the filing, FDA's decision on T-DM1 wasn't entirely unexpected either.

The filing was based solely on the results of a single-arm 110-patient Phase II study, which showed T-DM1 shrank tumors in one-third of women with advanced HER2-positive breast cancer who had received an average of seven prior medicines, including two HER2-targeted agents. While the data were positive, it's not surprising that FDA would want to see more, especially given that the agency is taking a harder look at progression-free survival as an endpoint for breast cancer and how it relates to clinical outcomes.

The regulatory action pushes a potential re-filing and launch out two years, pending the results of an ongoing Phase III trial. Dubbed EMILIA, the trial compares T-DM1 to GlaxoSmithKline's ***Tykerb*** (lapatinib) in combination with capecitabine in people with advanced HER2 positive breast cancer whose disease has worsened after initial treatment. Roche said it expects to resubmit the BLA in mid-2012, which would position the drug for a launch in 2013.

During Roche's investor meeting in March, the company admitted the filing strategy had a lower probability of success than one based on significantly more data. "If we file early, we file on early data and the risk of not succeeding there is higher," acknowledged Jean-Jacques Garaud, head of research and early development.

FDA decided not to file the application because it did not meet the standard for accelerated approval, Roche said, because all the available treatment choices approved for metastatic breast cancer had not been exhausted in the study population.

"We firmly believe in the potential of T-DM1 as a novel HER2 targeted option and remain fully committed to its ongoing development," the firm said in a statement.

Still, Roche did consult with FDA prior to the submission, which suggests the agency offered some positive feedback at that time, and it's not clear why, if at all, the agency then changed its thinking. But certainly FDA must be feeling cautious about moving toward an accelerated approval after its Oncology Drugs Advisory Committee voted against granting full approval of Avastin for first-line treatment of metastatic breast cancer in July, basically nixing FDA's accelerated approval for the indication in 2008. That decision was based largely on the committee's feelings that the drug did not delay disease progression long enough to be clinically meaningful ("The Pink Sheet," July 26, 2010).

The vote in favor of removing the breast cancer indication from Avastin's labeling was a controversial one. If FDA ultimately agrees with ODAC, it will put a pinch on Roche's top-line this year ("The Pink Sheet," July 26, 2010).

"We can't speculate if the Avastin decision had anything to do with this decision," a Genentech representative said. "But FDA continues to make it clear that they want randomized data and overall survival data for approval of new breast cancer drugs."

The case of another problematic accelerated approval, Pfizer's ***Mylotarg*** (gemtuzumab) for acute myeloid leukemia, is also fresh in the agency's mind. Mylotarg was voluntarily pulled from the market by Pfizer in June, 10 years after it received accelerated approval, when it failed in a confirmatory trial ("The Pink Sheet," June 28, 2010).

Roche has a lot riding on T-DM1, an antibody-drug conjugate, or so-called "armed antibody," that attaches trastuzumuab and the chemotherapy DM1 together using a stable linker and is delivered directly to the cancer cells. DM1 and the linker technology are licensed from Waltham, Mass.-based ImmunoGen, which is also banking on the product's success. The approach is expected to offer additional efficacy benefits over Herceptin and also greater tolerability given the targeted delivery of the cytotoxic agent.

Genentech is looking to T-DM1 to drive continued growth of its blockbuster Herceptin franchise and eventually replace Herceptin as the standard of care. Roche is also looking to develop T-DM1 in

combination with another investigational agent, pertuzumab, with the aim of eliminating the need for chemotherapy. Pertuzumab is an HER2 blocker that is believed to work synergistically with Herceptin.

The FDA decision is also a road bump for ImmunoGen, delaying the royalties and milestones the company would receive upon approval and launch. The approval milestones would be in the low double-digits in the millions of dollars, said ImmunoGen CEO David Junius. Until now, the positive Phase II data and praise from Roche have helped validate the company's platform technology and put the company on an aggressive growth track ("The Pink Sheet" DAILY, June 8, 2010).

"We continue to believe in the potential for T-DM1 and don't see FDA's decision as a reflection on that," Junius said during a same-day conference call. "This appears to be a technical issue, not a fundamental one."

Nonetheless, the company acknowledged the financial impact and said it would provide revised financial guidance shortly. The company does not have any immediate plans to reduce its cash burn, Junius added. ImmunoGen had approximately $110.3 million in cash and marketable securities as of June 30.

FDA's refusal to file may dampen general investor enthusiasm for conjugated therapies, but it seems like the decision has more to do with the accelerated approval than the technology itself.

Seattle Genetics, another drug developer working on antibody-drug conjugates, is also partnered with Genentech. But Seattle Genetics said it isn't concerned that the latest action will derail such programs. "We do not believe the FDA's decision on T-DM1 has broader implications for antibody-drug conjugates," the firm said. "In our view, the decision appears to relate to the treatment landscape for metastatic breast cancer rather than more generally applicable principles."

The company's lead program, SGN-35, which combines a CD30 antibody with its ADC technology, is in Phase III for relapsed and refractory Hodgkin's lymphoma patients under a Special Protocol Assessment with FDA. The firm said FDA has agreed the trial design meets the requirements for accelerated approval.

– Jessica Merrill (j.merrill@elsevier.com)

Court Backs FDA Rationale For Approving Generic *Lovenox*

A district court shot down Sanofi-Aventis' arguments against FDA approval of Sandoz's generic ***Lovenox*** (enoxaparin).

It found that the agency had the right to require Sandoz to conduct additional immunogenicity studies of its version of the anticoagulant and to permit Sandoz to use a different manufacturing process than Sanofi.

In an Aug. 25 order, Judge Emmet Sullivan of the U.S. District Court for the District of Columbia denied Sanofi's request for a preliminary injunction to overturn FDA's approval of Sandoz's enoxaparin ANDA. FDA approved the product on July 23 and Sanofi filed suit against the agency three days later ("The Pink Sheet" DAILY, July 27, 2010). The case will proceed, however, despite the ruling on the preliminary injunction.

While the decision is a victory for Sandoz and its marketing partner Momenta, it also could be good news for companies developing biosimilars. Although Lovenox is not a biologic, it is a complex compound that raises some of the same safety, efficacy and comparability issues involved in approval of follow-on biologics. Judge Sullivan backed FDA's rationale for approving Sandoz's product.

For Sanofi, the ruling is gut-wrenching, since it means the company's chances of halting generic competition through legal maneuvering are grim, though not entirely done in. Lovenox is Sanofi's second best-seller. In 2009, the blood thinner generated U.S. net sales of approximately $2.5 billion. Sandoz launched its generic in the U.S. immediately after receiving FDA approval. It told the court it expects to ring up sales of more than $40 million in the next six weeks.

Facing the loss of Lovenox and several other key drugs to generic competition in the near term, Sanofi is looking to acquisitions to buffer its top-line. The company reportedly made a bid for the U.S. biotech Genzyme on Aug. 2, offering around $70 per share, although the speculation has not been confirmed ("The Pink Sheet" DAILY, Aug. 3, 2010).

But merger talks appear to have stalled, with Genzyme said to be balking at the offer. Many biotech analysts contend that Genzyme could sell for significantly more, around $80 per share. Rodman & Renshaw analyst Simos Simeonidis, in an Aug. 26 research note, said the court ruling could put more pressure on Sanofi to speed up talks with Genzyme and go "straight to more meaningful discussions about the price of a potential transaction."

Immunogenicity Studies Not Equivalent

Meanwhile, Sanofi's legal maneuver to block generic Lovenox could provide a lesson for other companies seeking to challenge FDA approvals. One of Sanofi's key arguments was that since FDA required Sandoz to submit additional tests on its product, the application should have been treated as a full new drug application and not an ANDA.

FDA required Sandoz to submit three types of studies comparing the immunogenicity (the potential to elicit an immune response) of its product with Lovenox. They included a comparison of the ability of the two products to bind to and form complexes with chemokine PF4 and characterization of the size and charge of the resulting complexes; studies to understand the amount and nature of potential contaminants; and functional studies to assess potential immunogenic properties.

The court states in a footnote that "while Sanofi repeatedly attempts to characterize the FDA's request for additional data on immunogenicity as impermissible 'safety testing,' the FDA explains that '[t]he additional data sought from Sandoz in this case was limited solely to assuring that Sandoz's manufacturing process would not produce impurities with potential immunogenic effects to any greater degree than Lovenox itself."

"Contrary to Sanofi's implication, FDA did not request or demand anything approaching the type of large-scale clinical safety and efficacy trials mandated for new drugs," the court said.

The court also rejected Sanofi's claim that FDA departed from its precedent in approving ANDAs for complex products not fully characterized. The company had cited the agency's past decisions for hyaluronidase, ***Omnitrope*** and ***Premarin***. For example, for Premarin the agency could not find

active ingredient sameness for synthetic versions of the drug. FDA had argued that its finding of active ingredient sameness is specific to each active ingredient ("The Pink Sheet," Aug. 2, 2010). The court said FDA provided legitimate reasons for deciding that enoxparin should be treated differently than the drugs Sanofi cited.

FDA's Test For "Sameness" Is Reasonable

Sanofi also had argued that since Lovenox is not fully characterized – i.e., all the structures within the drug have not been identified – it is impossible to tell if a generic has the same active ingredients. But the court said FDA's five-part test for determining "sameness" is reasonable. These criteria include equivalence of physical and chemical properties and equivalence of certain aspects of the drug's effect in humans.

"It was similarly reasonable for the FDA to conclude that an ANDA applicant need not use the same manufacturing process as Sanofi," the court stated.

The court rejected Sanofi's claim that it would face irreparable harm if Sandoz is able to continue to market its generic. It said Sandoz also would face significant harm if the court imposed an injunction and that the negative impact on both is "essentially 'a wash.'"

Despite its strong rejection of Sandoz's arguments, the court left the door open for further litigation. "This opinion does not foreclose the possibility that upon a more developed record, Sanofi may be able to establish that there are grounds for overturning the grant of Sandoz's ANDA," Sullivan said.

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Supreme Court Again Asked To Address Generic Firms' Liability For Inadequate Warning Labels

Actavis is making a second appeal to the Supreme Court to consider whether a generic manufacturer can be sued for failing to add safety information to its labeling that is not in the brand's label.

Actavis filed a petition for writ of certiorari with the court in June seeking review of a case in which it was found liable for failing to warn of the risk of tardive dyskinesia from use of its generic version of Wyeth's heartburn drug ***Reglan*** (metoclopramide).

The U.S. Court of Appeals for the Fifth Circuit affirmed a district court ruling that the plaintiff's failure to warn claims were not preempted by the Food, Drug and Cosmetic Act, which requires a generic to have the same label as the brand. Citing the Supreme Court's decision in Wyeth v. Levine, the Fifth Circuit found that Actavis could have changed its label after approval if there was new safety information.

In Wyeth, the court ruled that brand manufacturers could comply with the duty to warn imposed by state law by making a unilateral label change. The issue is of great concern to the generic industry as companies face numerous suits claiming they are liable for inadequate labeling. Since the Wyeth decision, courts have been ruling against them.

The case, Actavis v. Demahy, is similar to another cert petition, Pliva v. Mensing, submitted by Pliva, Teva, UDL Laboratories, Wyeth and Actavis Elizabeth in February ("The Pink Sheet" DAILY, May 25, 2010). The court asked the Solicitor General for the government's views in that case.

"In general the courts have read Wyeth too broadly, as if that decision swept away federal preemption for all drug product liability claims," Actavis states in its recent petition. "The nearly uniform misapplication of Wyeth by the lower courts requires this court's intervention now, before generic drug manufacturers are forced by the threat of liability to abandon their low-cost business model" of providing access to lower-priced drugs.

The petition says that although the Fifth Circuit acknowledged that a generic drug label has to mirror the brand at the time of approval, it concluded that FDA's requirements for approving a generic drug cease to matter after approval. "That conclusion is wrong: a generic drug is required to have labeling that is identical to the brand *at all times*," Actavis stated.

– Brenda Sandburg (b.sandburg@elsevier.com)

FDA Reverses Stance On Bioequivalence Standards For Mesalamine

FDA believes that comparative pharmacokinetic studies, instead of comparative clinical endpoint studies, are best for determining bioequivalence of extended- or delayed-release mesalamine products – a reversal of its previous position.

The policy shift came in the agency's response to a pair of citizen petitions from manufacturers of different formulations of the ulcerative colitis drug – Shire, which markets ***Pentasa***, and Warner Chilcott, which markets ***Asacol*** and ***Asacol HD***.

The citizen petitions, Shire's filed in September 2008 and Warner Chilcott's filed in February, both reference a September 2007 letter from Dale Conner, director of the Division of Bioequivalence I in FDA's Office of Generic Drugs, where he laid out a different position.

"Comparative clinical endpoint bioequivalence studies would be less sensitive, accurate and reproducible than PK studies," FDA says.

In the letter, Conner told Shire's regulatory counsel that "a bioequivalence study with pharmacokinetic endpoints is not useful" for establishing the bioequivalence of generic mesalamine extended-release capsules to brand-name products such as Shire's Pentasa, and that generic drug manufacturers should perform a parallel, three-arm bioequivalence study (investigational generic drug, reference brand-name drug and placebo). In vitro dissolution testing would also be necessary, Conner wrote.

Those comments were the basis of the citizen petitions from each company. However, in FDA's response, CDER Director Janet Woodcock explained that the agency's thinking has evolved and it now recommends PK trials rather than clinical endpoint studies for generic mesalamine, although in vitro dissolution tests are still necessary.

"Having analyzed the available clinical efficacy data for orally administered modified-release mesalamine products ... we conclude that comparative clinical endpoint bioequivalence studies would be less sensitive, accurate and reproducible than PK studies," the response states. "That is, we expect that PK studies will better detect significant differences, if any, in the drug release patterns of test and reference formulations of Pentasa, Asacol or Asacol HD at the sites of drug action."

The reason FDA had thought in 2007 that a PK study would not be adequate to establish bioequivalence had to do with the complexity of the PK profile of mesalamine, which in these formulations is designed to be released topically in the colon rather than systemically.

The thinking was that "the standard PK metrics [of] total area under the plasma concentration versus time curve (AUC) and maximum plasma concentration (Cmax) ... would not distinguish between products with materially different mesalamine release profiles at the sites of drug action so long as the peak concentrations and total amount of mesalamine released throughout the GI tract were not significantly different," the response explains.

However, the agency now believes that if "partial AUC or other profile comparison tools ... [such as] mean residence time and steady-state Cmax" are used instead, a PK study would be adequate for establishing bioequivalence.

Panel Discussion Bears On FDA Response

FDA recently came around to its determination that partial AUC can work for ANDAs for drugs with complex pharmacokinetic profiles, such as those with unusual modified-release properties, and brought the matter up for discussion at its April 13-14 meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee ("The Pink Sheet" DAILY, April 12, 2010).

"The Office of Generic Drugs has recently encountered several review examples of multiphasic modified-release products for which it has concluded that the generic and corresponding reference product may not be therapeutically equivalent (switchable), despite being deemed bioequivalent when the traditional metrics were compared," the briefing package explained. FDA has put out product-specific guidances on bioequivalence requirements for some of those drugs, such as ***Ambien CR*** and ***Ritalin SR***.

While the panel discussion did not touch directly on mesalamine, Lawrence Yu, OGD's deputy director for science, spoke about the use of replicate design studies for highly variable drugs, of which mesalamine is an example.

Replicate design studies provide variability quantification of test and reference products, he explained in a presentation to the panel. This means

comparing the distribution of the test-to-reference ratio to the distribution of the reference-to-reference ratio.

Panel member Arthur Kibbe, Wilkes University, agreed that "in situations where we have issues that are critical to patient care, a replicate study is going to help us a lot more, and that's because we really don't know how reliable batch-to-batch or lot-to-lot innovator is."

Generic substitution should not cause variability in bioavailability, Yu said. "Reference scaled bioequivalence limits (used for highly variable drugs) naturally tighten the CI [confidence interval]. Generic product design should not be more variable than the reference product."

FDA's response on the mesalamine citizen petition draws on this approach, and on a January 2001 FDA guidance on statistical approaches to establishing bioequivalence. "FDA has developed analytical methods that facilitate demonstration of bioequivalence in highly variable drugs," the response states. "The replicated crossover design with an average bioequivalence analysis approach has been available for highly variable drugs to reduce sample size since 2001 and has been used when appropriate for NDAs." It adds that OGD has adopted this approach as well since 2007.

In making this case, FDA rejected the argument in Warner Chilcott's petition that the high variability in plasma concentrations of mesalamine and N-acetyl mesalamine leads to "broad ranges for the critical pharmacokinetic variables for establishing bioequivalence [that] have the potential to undermine the reliability of the bioequivalence determinations in that they may obscure small, but clinically significant differences in drug."

The company further claimed that high systemic plasma concentrations of the drug could be toxic, and said that PK studies should be required to evaluate this risk. FDA replied that there is no evidence of this and rejected the request as moot since the agency has concluded that "ANDA applicants for generic formulations of Asacol and Asacol HD should submit data from PK studies under fed and fasted conditions to show bioequivalence."

FDA Also Denies Request For Guidance

FDA also denied Shire and Warner Chilcott's request to issue a product-specific guidance on establishing bioequivalence of generic mesalamine products at this time, although it may develop one in the future. Warner Chilcott's petition had gone even further than Shire's, requesting that OGD issue such a guidance "prior to approval of any generic versions of such drugs," an idea that the agency rejected out of hand.

"FDA cannot delay review or deny approval to an ANDA or a new drug application on the grounds that FDA has not published bioequivalence recommendations for the relevant product," the response says. "To the extent the Pentasa and Asacol petitions contend that FDA *must* publish bioequivalence recommendations, or that FDA cannot approve applications referencing those products before publishing these recommendations, FDA disagrees and denies these requests."

In a silver lining for the petitioners, FDA agreed with them that in vitro dissolution tests across a range of pHs should be used to show bioequivalence of mesalamine products.

It also acceded to Warner Chilcott's request that the agency not grant waivers for the in vivo bioequivalence testing requirement for Asacol (400 mg) or Asacol HD (800 mg) based on a successful showing of in vivo bioequivalence in the other strength, as while it appears to be a doubling of the dose, the release profile means that the two do not have a linear response.

Implications For Pending Generics?

FDA's new stance against clinical endpoint studies, however, could undermine the position of generic manufacturer Roxane Laboratories, which has a pending ANDA for generic Asacol.

Roxane filed a comment in opposition to Warner Chilcott's citizen petition on the grounds that for Roxane's version of the drug, "in vivo clinical endpoint studies clearly demonstrate that the ANDA product is safe and bioequivalent to the RLD [reference-listed drug]," and FDA should not impose the additional conditions of a PK safety study and an in vitro dissolution test (and not block all ANDAs until it publishes a guidance on mesalamine bioequivalence).

While FDA has indirectly granted some of Roxane's requests, the agency refused to deal with the substance of Roxane's argument, stating in a footnote that it was rejecting the comment because it was filed just three weeks before the response to Warner Chilcott's petition was due and because the comments exceeded the petition's scope.

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Chronic Pain Indications Will Be Harder To Come By, FDA Says

A general chronic pain indication may elude Eli Lilly's ***Cymbalta*** near the finish line because FDA has changed its thinking about the evidence needed to support the claim.

The agency is developing a new regulatory approach for pain indications as well as guidance covering the clinical trial requirements for various analgesic indications.

FDA would not say whether it evaluated the Cymbalta (duloxetine) NDA based on its current thinking because the application is pending. However, it appears the agency used the newly emerging standards to determine that the chronic pain claim it told the company several years ago it could obtain would be scaled back.

Furthermore, it appears a general claim for musculoskeletal pain may not be assured based on comments by members of the Anesthetic and Life Support Drugs Advisory Committee at its Aug. 19 review of the Cymbalta NDA.

Bob Rappaport, director of FDA's Division of Anesthesia and Analgesia Products, said the agency is bridging the gap between the old and new thinking with the Cymbalta application.

"The use of a chronic musculoskeletal indication, rather than a chronic pain indication, for Cymbalta is in keeping with our current thinking and with the criteria for broadened indications as it seems a good intermediary step as we work on guidance for industry," Rappaport said.

"The bar for a general chronic pain claim will be considerably higher, and the current studies completed for Cymbalta do not cover enough painful conditions to allow for the general chronic pain indication," he added.

It is not known when the new guidance will be completed, the agency said. At least eight drugs currently in U.S. clinical trials for a chronic pain-related indication could be affected, according to data from Elsevier Business Intelligence's Inteleos database.

Lilly submitted several positive studies showing Cymbalta's efficacy in chronic lower back pain and osteoarthritis. Coupled with the pain-related indications already approved for the drug – diabetic peripheral neuropathy and fibromyalgia – the new studies were intended to form the basis for a general chronic pain indication.

In 2005, FDA officials told Lilly positive Phase III studies in chronic lower back pain and osteoarthritis were necessary for the general chronic pain indication, but the agency has since changed its thinking.

Rappaport said in the last 10 years the academic community began questioning the appropriateness of broad pain indications for analgesic drugs. Questions were raised about whether enough was known about the drugs to determine if efficacy in one pain condition would translate to another, and some studies confirmed this concern, he said.

The agency has since tried to define the exact number and type of studies needed to justify a general chronic pain indication, while not stifling drug development.

"Our thinking regarding these concerns has evolved over the years and even in recent months and weeks," he said. "As our understanding of the complexities of this situation has developed, we have had to change our requirements to broaden analgesic indications."

The result of the agency's evolving position was its announcement during the Cymbalta meeting that the indication under consideration was chronic musculoskeletal pain, not chronic pain as had been stated in the pre-meeting briefing package.

On the day of the advisory committee meeting, Lilly said it was confident of the data submitted and expected further talks with FDA about the indication. The company would not elaborate after the meeting.

New Requirements, Existing Data

Ellen Fields, clinical team leader in FDA's Division of Anesthesia and Analgesia Products, gave clues as to some of the new requirements during the advisory committee meeting.

"The Pink Sheet"
Monday, August 30, 2010

PUBLISHERS SPOTLIGHT > VIEW ALL

Termination of Consent Decree in U.S. v. Merck & Co., Inc.

NOTICE OF INTENTION TO SEEK TERMINATION OF THE CONSENT DECREE IN UNITED STATES v. MERCK & CO., INC., ET AL.

PLEASE TAKE NOTICE that Merck Sharp & Dohme Corp. ("Merck") has submitted a request to the Antitrust Division of the United States Department of Justice ("Antitrust Division") to support Merck in obtaining termination of the Final Judgment entered in *United States v. Merck & Co., Inc., et al.*, Civil No. 3159 (D.N.J. 1943), on October 6, 1945 (the "Consent Decree"). Merck is publishing this notice of its intention to seek termination of the Consent Decree so that any interested persons can submit comments to the Antitrust Division with respect to the proposed termination.

On October 28, 1943, the United States filed a complaint alleging that Merck and E. Merck (a corporation doing business in Darmstadt, Germany, that is now known as Merck KGaA) had agreed to allocate customers and territories between themselves in the sale and distribution of chemical and pharmaceutical products made by them, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The suit was resolved in 1945 by entry of the Consent Decree.

The Consent Decree prohibits Merck and E. Merck from, *inter alia*, entering into or furthering any agreement to (1) allocate markets or customers or refrain from competing in the manufacture, sale, distribution, or import/export of any chemical or pharmaceutical product; (2) create or observe an obligation to exchange or license rights relating to any chemical or pharmaceutical product; (3) establish terms or conditions upon which patents relating to any chemical or pharmaceutical product will be licensed or any chemical product will be sold by or to others; and (4) fix prices for any chemical or pharmaceutical product. Merck is seeking the termination of the Consent Decree because the Decree no longer serves the public interest and inhibits the companies from potentially engaging in procompetitive transactions that would benefit consumers.

Interested persons are invited to submit comments regarding the potential termination of the Consent Decree to the Antitrust Division. Comments must be received by the Antitrust Division by October 1, 2010. Comments should be addressed to Donna M. Kooperstein, Chief, Transportation, Energy, and Agriculture Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street, N.W., Washington, D.C. 20530.

EXHIBIT F

Appendix 3

Department of Justice

FOR IMMEDIATE RELEASE
FRIDAY, APRIL 27, 1984

AT
202-633-2016

The Department of Justice today issued a policy statement concerning the enforcement and review of outstanding judgments in government civil antitrust cases.

The statement advises that, effective May 1, 1984, the Antitrust Division will lodge in its litigating sections and field offices direct responsibility for both the enforcement of the approximately 1500 existing judgments -- which include consent decrees and also the injunction's resulting from trials -- and the review of those judgments for possible modification or termination.

The statement further advises that the Antitrust Division expects defendants and others bound by outstanding judgments to comply with their terms scrupulously.

The Division will periodically conduct inquiries to determine judgment compliance, and will initiate criminal or civil contempt proceedings to deal with violations. The Division encourages persons with knowledge of possible judgment violations to contact its Office of Operations, Room 3214, Main Building, Department of Justice, Washington, D.C. 20530. Such communications will be accorded confidential treatment.

(MORE)

The statement also confirms that the Antitrust Division will continue its program of considering for possible modification or termination judgments that may have become anticompetitive or for other reasons may no longer be in the public interest. Defendants who believe that their judgments ought to be modified or terminated should contact the Division's Office of Operations and furnish the type of information that the Division needs in order to evaluate such requests, as spelled out in the policy statement.

J. Paul McGrath, Assistant Attorney General in charge of the Antitrust Division, explained that the transfer of judgment responsibility to the Division's litigating sections and field offices will complete a process of decentralizing the Division's judgment activity which began in late 1982 when the Division's Judgment Enforcement Section was dissolved and judgment responsibility was divided on an interim basis among other sections.

McGrath emphasized that the Division is committed to enforcing compliance by judgment defendants, and others bound to outstanding judgments, with the terms of those judgments. When the Division obtains evidence of a violation, he said, it will in appropriate cases bring criminal contempt proceedings. McGrath noted that in 1983 a criminal contempt proceeding was brought against H.P. Hood, Inc., for violating the terms of a 1981 consent decree. Hood did not dispute the charges and was fined in excess of $100,000.

(MORE)

McGrath further emphasized that it continues to be the Division's policy to review for possible termination or modification existing judgments that, with the passage of time and as a result of changed legal or factual circumstances, have now become anticompetitive or for other reasons may no longer be in the public interest.

McGrath said this program, initiated in 1981, has proven successful in identifying judgments that unduly restrict legitimate competitive activity and are no longer justified.

Since 1981 some 400 outstanding judgments have been reviewed for possible termination or modification. Seventeen have been terminated or modified and five others are the subject of pending judicial proceedings looking towards termination.

A copy of the policy statement is attached.

# # # #

Statement of Policy by the Antitrust Division Regarding Enforcement and Review of Permanent Injunctions Entered in Government Antitrust Cases

Effective May 1, 1984, the Antitrust Division will lodge in its litigating sections and field offices direct responsibility for the enforcement of permanent injunctions (hereinafter referred to as "judgments") entered in antitrust actions brought by the Department of Justice, and for the review of such judgments for possible modification or termination.

The Antitrust Division expects defendants and others bound by outstanding judgments to comply with their terms scrupulously. The Division will periodically conduct inquiries to determine judgment compliance, and will initiate criminal or civil contempt proceedings to deal with violations. Persons who have reason to believe that judgment violations may have occurred are encouraged to contact the Division's Office of Operations, Room 3214, Main Building, Department of Justice, Washington, D.C. 20530. Such communications will be accorded confidential treatment.

The Division recognizes that, with the passage of time and as a result of changed legal or factual circumstances, existing judgments may become anticompetitive or for other reasons no longer be in the public interest. The Division seeks to identify such outdated judgments, and in appropriate cases will consent to court applications by defendants to modify or terminate them, particularly where the judgments in question unnecessarily or unduly restrict otherwise legitimate competitive activity. Judgment defendants who believe that their judgments ought to be terminated or modified should so inform the Division, through the Office of Operations, and provide to the Division:

(1) a detailed explanation as to (a) why the judgment in question should be vacated or modified, including information as to changes of circumstances or law that make the judgment inequitable or obsolete, and (b) the actual anticompetitive or other harmful effect of the judgment;

(2) a statement of the changes, if any, in its method of operations or doing business that the defendant contemplates in the event the judgment is modified or vacated; and

(3) a commitment to pay the costs of publication of public notice of the termination or modification proceedings in the trade and business press, as the Division may determine to be appropriate.

EXHIBIT G

Department of Justice

FOR IMMEDIATE RELEASE
TUESDAY, APRIL 13, 1999
WWW.USDOJ.GOV

AT
(202) 514-2007
TDD (202) 514-1888

DEPARTMENT OF JUSTICE ANNOUNCES NEW PROTOCOL TO EXPEDITE REVIEW PROCESS FOR TERMINATING OR MODIFYING OLDER ANTITRUST DECREES

WASHINGTON, D.C. -- The Department of Justice's Antitrust Division today announced a new protocol designed to expedite the review process for parties seeking to terminate or modify outstanding consent decrees. The protocol is effective immediately.

The new protocol is a voluntary procedure which can be utilized by parties seeking to modify or terminate consent decrees that do not contain an automatic termination provision. Most consent decrees entered into before 1980 do not contain such provisions.

A consent decree cannot be terminated or modified except by court order. Prior to making a recommendation to the court, the Division must determine the probable effects of termination or modification on the market at issue in order to make an informed representation to the court that the requested order is in the public interest.

In the past, when the Division has agreed to support termination or modification, it has taken on average about two years between the party's initial request and the filing of the motion. The new protocol is designed to enable parties to expedite the Antitrust Division's review by getting needed information to the Division more quickly.

The new protocol differs from the present decree review process in three ways. First, the party seeking termination or modification will provide its request with the specific information that the Division would normally gather in the course of its review. Having the requesting party

provide this material when it makes its request, rather than having the Division later request the information, is expected to reduce the time needed for the Division to act on the request. **(Please see Attachment)**

Second, the requesting party will contact other defendants bound by the decree and inform them of its intentions. Early involvement by all defendants will further streamline the review process.

Third, at the time the Division opens its review, the requesting party will agree to publish, at its own expense, notice of its intent to seek termination or modification and invite interested parties to provide the Division with relevant information. In determining what notice is appropriate at this stage, the Division will consider the cost of notice to the requesting party. This notice will not replace the notice and comment period that occurs after the motion to terminate or modify is filed with the court. Rather, the intent is that the additional pre-filing publication will cause any interested parties to come forward earlier in the process so that their concerns may be considered and addressed prior to the filing of a motion. The Division will take into account both concerns that are brought to its attention and appropriate inferences that might be drawn if no substantial concerns are raised at that time.

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99-131

ATTACHMENT

INFORMATION TO BE PROVIDED WITH REQUESTS THAT THE ANTITRUST DIVISION SUPPORT TERMINATION OR MODIFICATION OF CONSENT DECREES

1. The identity of the party making the request, its representative for purposes of the request, and the decree that is subject to the request; also the date of the decree's entry and the specific action requested (e.g., termination of the entire decree or a specific modification).

2. Confirmation that the party making the request has not been found in violation of the decree and is not aware of any ongoing decree violation or investigation by the FTC or the Antitrust Division into activities subject to the decree.

3. A statement of the reasons for the request, which may include any factors that the party making the request believes are relevant to the public interest, and which should include the following:

A.
Any legitimate business activities that may be prohibited or impeded by the decree.

B.
Any aspects of the decree that the party believes do not promote competition or the public interest.

C.
Any other burdens, costs or other adverse effects that the decree imposes on the party making the request or on others.

D.
Any changes in the factual circumstances relating to the decree, including changes in any relevant market covered by the decree.

E.
Any relevant changes in the law.

F.
An explanation of why, or to what extent, termination or modification of the decree would not undermine the purposes of the decree.

4. A description of how the party would change its manner of doing business if the decree were terminated or modified.

5. Copies, where applicable, of the party's most recent annual report, financial statement, and SEC Form 10-K.

6. Copies of the party's most recent business, marketing, or strategic plans for any product covered by the decree.

7. The identity (including the name of a contact person, with telephone number and address) of all significant competitors; the party's ten largest customers; and, if appropriate, the party's ten largest suppliers, for each product or service affected by the decree.

8. The identity of any intellectual property at issue in the decree and any licenses pertaining to that intellectual property, together with the expiration or termination date of the intellectual property and any licenses to it.