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DIRECTORATE FOR FINANCIAL, FISCAL AND ENTERPRISE AFFAIRS
COMMITTEE ON COMPETITION LAW AND POLICY

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Working Party No. 2 on Competition and Regulation

COMPETITION IN THE PHARMACEUTICAL INDUSTRY

-- United States --

This note is submitted by the Delegation of United States to the Working Party No. 2 FOR DISCUSSION at its

English text only

COMPETITION IN THE PHARMACEUTICAL

United States

I. The Pharmaceutical Industry: Market Structure

Market Structure

(1.1) Please describe the market structure of pharmaceutical firms in your country - which firms are active, with what market share, in which therapeutic classes and with what level of R&D (including generic producers). Which firms co-operate to jointly undertake R&D or to jointly market certain products? Is there one or more associations of pharmaceutical manufacturers in your country? Is this association politically important?

1. The U.S. pharmaceutical industry is composed of approximately 700 companies that develop, manufacture and market ethical pharmaceutical products, including proprietary (brand name) and generic medicines.[1] The value of U.S. shipments of pharmaceutical products in 1997 was estimated at nearly $83 billion. Sales from the U.S. operations of the ten largest pharmaceutical companies with operations in the U.S. were about $49 billion in 1997.[2] As noted below, there has been continuing industry consolidation but recent market share figures are not readily available.

2. The most useful sources of data on market share in the form requested are proprietary. Appendix 1 hereto contains available public data on market shares for some therapeutic classes, and public information from private sources listing the firms that are engaged in manufacturing, fabricating or processing drugs in pharmaceutical preparations for human or veterinary use, their profits and their

manufacturers and suppliers of bulk pharmaceutical chemicals), Nonprescription Drug Manufacturers Association (over-the counter drug manufacturers) and Pharmaceutical Research and Manufacturers of America (prescription pharmaceutical firms). These associations represent their members in legislative, regulatory and related matters.

II. Regulation of Supply

Protection of Intellectual Property Rights

(2.1) Please describe the regulatory framework established for the protection of intellectual property rights in the pharmaceutical industry.

7. Article I, Section 8, Clause 8 of the United States Constitution grants Congress the power to create a patent system. A patent for an invention is the grant of a property right to the inventor and is issued by the U.S. Patent and Trademark Office. U.S. patent grants are effective only within the U.S. and its territories and positions. Patents on pharmaceutical products can be issued either on a drug's chemical structure or on its method of manufacture or synthesis. The term of the patent is twenty years from the date on which the application for the patent was filed or, in special cases, from the date an earlier related application was filed, subject to the payment of maintenance fees.[6] Patents confer rights to exclude others from making, using, offering for sale or selling the invention claimed by the patent in the U.S. or importing such invention into the U.S.

8. Under the Drug Price Competition and Patent Term Restoration Act of 1984 and amendments thereto, commonly known as the Hatch-Waxman Act, a holder of a pharmaceutical patent for a new chemical entity never approved by the U.S. Food and Drug Administration ("FDA") is entitled to extend patent protection in order to compensate for delays caused by the FDA's premarket approval process. Those extensions, granted after the drug is approved, equal half of the time the drug spent in clinical testing (usually six to eight years) plus the time FDA spent reviewing its new drug application (usually two years). However, the extension cannot be longer than five years, and the FDA cannot grant a total period of patent protection that exceeds fourteen years after the drug is approved. See Appendix 3 for details. The patent term extension was given to the patent holders in exchange for a provision authorizing generic producers to rely on safety and efficacy testing submitted by the original patent holder, thus expediting FDA approval of lower cost generic drugs by eliminating the need for generic producers to submit their own test data to the FDA.

9. The Food and Drug Administration Modernization Act of 1997 added 6 months of patent exclusivity for drugs requiring further review for pediatric applications.[7]

10. During the FTC's 1995 Hearings on Global and Innovation-Based Competition, the pros and cons of compulsory licensing as a remedy were debated by numerous participants at the hearings. Some argued that antitrust should be more receptive to this remedy. Others asserted, however, that compulsory licensing would stifle follow-on innovation. [8] Compulsory licensing has been a remedy in antitrust actions brought by the Antitrust Division of the Department of Justice alleging unlawful provisions in patent and copyright licenses, in addition to enjoining further enforcement of the offending provisions or entering into similar agreements. See, e.g. United States v. Glaxo Group, 410 U.S. 52, 64 (1973). In that case, the Supreme Court stated that "[m]andatory selling on specified terms and compulsory patent licensing at reasonable charges are recognized antitrust remedies." Id. at 64. The Commission has ordered compulsory licensing in one recent case to restore competition allegedly reduced as a result of a proposed merger. In 1997, the Commission challenged the merger of Ciba-Geigy and Sandoz, alleging that the merger would have given Ciba-Geigy a monopoly in certain patents and trade secrets for the development of gene

therapies, which hold promise for the treatment of some forms of cancer and AIDS. The Commission's consent order required Ciba-Geigy to license certain patents and technologies so that R&D efforts to

requirements; and 6) marketing the generic drug after FDA approval. Establishing bioequivalence typically requires clinical studies with a group of 18 to 36 to establish that the rate and extent of absorption of the generic form does not significantly differ from that of the brand-name drug. The Hatch-Waxman Act (Bolar Amendment) permits the preliminary production and testing of generic drugs prior to the expiration of any relevant patents on corresponding brand name drugs. Thus, generic entrants can receive ANDA approval as soon as the patents expire.

Trade Regulation

(2.3) Please describe any barriers to international trade or investment in pharmaceuticals. Are there restrictions on international trade in drugs by third parties (such as parallel trade or re-imports)? Are there restrictions on mail-order or Internet supply of drugs? Does the regulatory regime distinguish between domestic and foreign firms in any way?

15. Parallel imports are defined as genuine goods produced or sold abroad with the consent of the owner of the applicable intellectual property right – copyright, trademark or patent – that are subsequently sought to be imported into the domestic market without the consent of the intellectual property right owner. Over the past decade, the United States has advocated the need for protection from parallel importation in the copyright and patent laws of our trading partners, a position is consistent with U.S. law. Appendix 2 briefly summarizes U.S. law on parallel imports.

16. The Food, Drug and Cosmetic Act ("FDCA"),[13] enforced by the FDA, to control parallel imports. The FDCA requires manufacturers and sellers of drugs to register with the FDA and comply with FDA rules. It applies also to firms that relabel drugs and covers imports as well as domestically made drugs. The FDCA also prohibits counterfeit drugs from being marketed in the U.S.; this would also applies to parallel imports of such products.[14] Section 801(d) of the FDCA bars the reimportation of prescription drugs made in the U.S. by any person other than the original manufacturer or by the FDA for emergency medical care.

17. Additional record-keeping and registration requirements apply if the drug is a controlled substance. See 21 U.S.C. § § 822, 829, and 841. Sections 5 (prohibition of unfair or deceptive acts or practices) and 12 (prohibition of false advertising of food, drugs and cosmetics) of the Federal Trade Commission Act could furnish bases for a federal enforcement action where an online company makes false or misleading claims about the products or services it provides.

18. The FDA does not distinguish between foreign and domestic products; all pharmaceuticals sold in the U.S. must meet FDA regulatory requirements. Foreign firms shipping to the U.S. must register with the FDA. There is no requirement for domestic manufacture. The U.S. and the EU negotiated in 1997 a pharmaceutical Mutual Recognition Agreement to eliminate regulatory barriers and promote trade between them. They agreed to recognize each other's inspections of manufacturing facilities for human drugs and biologics in their respective regions (previously, inspectors from each area had to inspect every factory in which a drug imported into that jurisdiction was manufactured).

19. Under federal law, prescription drugs may be dispensed only with a valid prescription under the professional supervision of a physician or other practitioner licensed to administer the drug. 21 U.S.C. § 353. A prescription drug that is dispensed without a valid prescription is "misbranded." 21 U.S.C. § 353 (b). The introduction or distribution of misbranded drugs into interstate commerce is prohibited by section 301 (a) of the FDCA.

20. Regarding Internet sales in particular, many government officials and health care professionals are raising concerns about the availability of prescription drugs over the Internet without a valid

formulary). Savings result not only from substitution but also discounts offered to health plans or PBMs by manufacturers of brand-name drugs in exchange for being included on their formulary. PBMs, which represent a large pool of customers, can also negotiate with networks of pharmacies to obtain discounts from the retail price per prescription for the health plan enrollees. Since the late 1980s, those techniques have put downward pressure on prices that PBMs and health plans pay for prescription drugs.

31. The Departments of Veterans Affairs (VA) and Defense (DoD) provide medications and medical supplies to their beneficiaries as an adjunct to their health care delivery systems. The VA utilizes a formulary developed by field-based practitioners to address medication and medical supply needs for its beneficiaries.[24] The VA's formulary process includes the development, promulgation and growing use of pharmacologic treatment guidelines. The guidelines reflect best practices for a predominantly geriatric patient population. The VA does not seek discounts or rebates in exchange for formulary listing (see discussion of private health care in response to 3.3 below). The VA determines what is clinically best for veteran beneficiaries and then contracts for an individual drug or therapeutic class of drugs. DoD utilizes a so-called "core formulary" of items available at its own medical treatment facilities; a larger array of drug products is available to DoD beneficiaries through a retail pharmacy network and mail order provider.

See also response to question 3.3.

Price Control Policies

(3.3) Please describe the operation of the controls on pharmaceutical prices in your country.

32. The U.S. has no direct price controls on pharmaceuticals. With respect to cost containment

35. Under the Medicare program, health insurance provided to the elderly and the disabled, drugs furnished to a beneficiary during an in-patient hospital stay are covered as part of Medicare's payment to the hospital for that stay (i.e., payment based on the appropriate diagnosis related group or DRG). Medicare covers outpatient drugs only in the following situations:

- Drugs Furnished Incident To a Physician's Services: These are injectable or intravenous drugs that are furnished by a physician or under the physician's direct supervision and cannot be self-administered.

- Statutorily Covered Drugs: Examples include immuno-suppressive drugs, hemophilia clotting factors, erythropoietin for trained home dialysis patients, allergens under certain conditions, and certain oral anti-cancer drugs, pneumococcal, influenza and hepatitis vaccines.

- DME Drugs: A very few drugs that are used in conjunction with Medicare-covered durable medical equipment; e.g., inhalation drugs (albuterol sulfate) used with a nebulizer.

36. The Balanced Budget Act of 1997 set Medicare payment based on the lower of the billed charge or 95% of average wholesale price (AWP). In 1998, the total Medicare billed charges were approximately $7 billion for drugs that are paid by Medicare at the lesser of the actual charge or 95% of the AWP.

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Control of Physician Prescribing Practices

(3.4) Please describe the systems in place to encourage high-quality cost-effective physician pr de(pla)12.fce25co107

supervised' by the state. [29] Many states have enacted legislation purporting to confer state action immunity upon health care "networks" that apply to the state for approval of the network's proposed structure and plans. Whether such statutes are able to confer such immunity is, however, open to question.

Market Definition Issues and Barriers to Entry

(4.2) Have you had the occasion to address the definition of the relevant market in the pharmaceuticals sector? Did you find that the relevant product market could be approximated by commonly-accepted therapeutic groups? What techniques did you use to determine whether certain products were effective substitutes? Did you find it necessary to distinguish the market for drugs consumed in hospitals from the market for drugs prescribed by physicians and/or market for over-the-counter (nonprescription) drugs? Was the relevant market national or international?

47. As indicated by the cases discussed below, the U.S. antitrust agencies an courts frequently have addressed market definition issues in the pharmaceuticals sector. We define product and geographic markets on a case-by-case basis, examining demand substitution following the analytical approach set forth in Sections 1.1 and 1.2 of the FTC and DOJ Horizontal Merger Guidelines.[30] The agencies rely on evidence from customers, competitors, medical experts and market data to make this determination. Any distinctions between drugs consumed in hospitals from those prescribed by physicians or non-prescription drugs are made on a case-by-case basis using the standards set out in the Merger Guidelines.

48. The United States typically is the relevant geographic market for finished, prescription drugs because the FDA regulations and U.S. patent and other intellectual property laws impose significant barriers to entry on the introduction of products that do not meet these legal requirements.

49. For an example of how the U.S. authorities define a product market, see the discussion below (responses to questions 4.6 and 4.7) of the FTC's successfully litigated case challenging two separate mergers of the four largest drug wholesalers in the U.S. For a second example, in the FTC's recent (non-merger) case against Abbott Laboratories and Geneva Pharmaceuticals, summarized in our response to question 4.4, below, the complaint identifies terazosin HCL as the relevant product market, alleging that other drugs are not effective substitutes because they have different chemical compositions, safety, efficacy, and side effects. In addition, the complaint alleges little price sensitivity between terazosin HCL and non-terazosin HCL products.

(4.3) Did you consider that the pharmaceutical industry is characterized by barriers to entry/exit? What barriers did you identify?

50. The FTC has alleged high entry barriers in several of its complaints involving horizontal mergers, for an example, those identified for the gene therapy market in the FTC's complaint accompanying a consent order challenging the 1996 merger of Ciba-Geigy and Sandoz to become the merged entity, Novartis:

> Entry into the gene therapy market requires lengthy clinical trials, data collection and analysis, and expenditures of significant resources over many years to qualify manufacturing facilities with the Food and Drug Administration. Entry into each gene therapy market can extend up to and beyond 10-12 years. The complaint further alleges that the most significant barriers to entry include technical, regulatory, patent, clinical, and production barriers. The FDA must approve all phases of gene therapy development, including preclinical and clinical work. No company may reach advanced stages of development in the relevant gene therapy markets without: (i) clinical gene therapy expertise; (ii) scientific research that requires years to complete; (iii) patent rights to all the necessary proprietary inputs in to the gene therapy product sufficient to provide the

company with reasonable assurances of freedom to operate; and (iv) clinical grade product manufacturing expertise, regulatory approvals and capacity to complete clinical development. The necessary proprietary inputs include genes, vectors and vector manufacturing technology, and cytokines, proteins necessary for many gene therapy applications.

51. The FTC's complaint in the *Zeneca/Astra* merger, discussed below, succintly described the barriers to entry as "the difficulty of researching and developing a new product, obtaining FDA approval and gaining customer acceptance."

Anticompetitive Agreements

(4.4) Have you had the opportunity to address questions of explicit or implicit collusion in the pharmaceutical sector? What forms of collusion have you found? Have pharmaceutical manufacturers or pharmacies acted in combinations to attempt to increase (or resist decreases in) pharmaceutical reimbursement rates in health insurance plans?

52. The Commission has brought two case(on h)122596CMo12.3(ta.7( )10.nes)10.(a)-0.3(found)1castF-oCom

connection with this consent, the Commission issued a statement placing pharmaceutical companies on notice that it would consider its entire range of remedies against such agreements in future matters, including possibly seeking disgorgement of illegally obtained profits.

55. The Commission has brought several enforcement actions against pharmacies and pharmaceutical associations for acting in combination to increase or resist decreases in pharmaceutical reimbursement rates in health insurance plans.[33] An example is *Institutional Pharmacy Network*,[34] in which the FTC alleged that five institutional pharmacies unlawfully fixed prices and restrained competition among institutional pharmacies in Oregon, leading to higher reimbursement levels for serving Medicaid patients in Oregon long-term care institutions. The five pharmacies, which provided institutional pharmacy services for 80% of patients in Oregon receiving such services, compete to provide prescription drugs and services to long term care institutions. According to the complaint, the pharmacies formed Institutional Pharmacy Network (IPN) to offer their services collectively and maximize their lever9(ec0amve)11.82(m

the ability to innovate in a relevant market is accumulated in one entity, and substitutes are lacking, competition will suffer. The FTC/DOJ Merger Guidelines recognize that a transaction may lessen competition in such nonprice attributes as "product quality, service or innovation."[43]

63. An interesting example of an innovation market merger is the FTC's 1995 enforcement action in *Glaxo/Wellcome*.[44]

competitive entry to defeat these prices increases is not likely to be timely and effective because entry into these markets is subject to FDA regulation and takes an average of 18 months, but can take even longer.

73. After the parties received notice of the FTC's complaint, they announced that they would drop

NOTES

1 U.S. International Trade Commission, Review of Global Competitiveness in the Pharmaceutical Industry ("ITC report 1999"), Publication 3172, April 1999, at 3-4. An "ethical" product is on that is available only through prescription and can be either brand name or generic.

2 Id. at 3-5

3 *See generally* www.pharma.org/facts/index/html.

4 Standard and Poor's, Industry Surveys - Healthcare: Pharmaceuticals , Dec. 16, 1999 ("Standard and Poor's Industry Survey") at 22.

5 Id. at 24.

6 35 U.S.C. 154 (a) (2)(1994). To accommodate the transition from a 17-year to a 20-year patent term, measured from the date of filing and not issuance, the Uruguay Round Agreements Act provides that any patent that was either in force on, or resulted from an application filed prior to, June 8, 1995 (the effective date of the change in the patent term) will have a term that is 17 years from the year of issuance or 20 years from the date of filing, whichever is longer.

7 Public Law No. 105-115.

8 See Susan DeSanti, "The Intersection of Antitrust and Intellectual Property Issues: A Report from the FTC Hearings," Remarks before the Conference on Antitrust for High-Tech Companies Business Development Associates, San Francisco, February 2, 1996 (www.ftc.gov./speeches/other/desanti1.htm).

9 See *Ciba-Geigy Ltd.*, Dkt C- 3275 (consent order, March 29, 1997).

10 ITC report 1999, *supra* note 1, at 3-13. Using 14.9 years as the base, the approval process

33 See www.ftc.gov/bc/rxupdate.htm for a complete listing of such cases.

34 C-3822 (consent order issued August 11, 1998).

An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development. The close substitutes are research and development efforts, technologies, and goods that significantly constrain the exercise of market power with respect to the relevant research and development, for example by limiting the ability and incentive of a hypothetical monopolist to retard the pace of research and development. The Agencies will delineate an innovation market only when the capabilities to engage in research and development can be associated with specialized assets or characteristics of specific firms.

Id. at 11.

43 Merger Guidelines § 0.1 n.6.

APPENDIX 1-1

PRODUCT LINE SALES AND PROFITS
FOR MAJOR PHARMACEUTICAL COMPANIES

COMPANY	PRODUCT CATEGORY	1998 SALES (MIL. $)	1998 PROFITS (MIL. $)
Abbott Labs	Pharmaceuticals	2,601	1,402
American Home Products	Pharmaceuticals	8,902	2,488
Glaxo Wellcome	Pharmaceuticals	13,230	3,043
Johnson & Johnson	Pharmaceuticals	8,562	3,016
Pfizer	Pharmaceuticals	12,230	3,351
Pharmacia & Upjohn	Pharmaceuticals	6,127	691
Schering-Plough	Pharmaceuticals	7,342	2,261
SmithKline Beecham	Pharmaceuticals	7,701	2,010
Warner-Lambert	Pharmaceuticals	5,604	1,474

Source: Standard & Poor's, Healthcare: Pharmaceuticals Industry Survey

APPENDIX 1 -2

RESEARCH & DEVELOPMENT EXPENDITURES

COMPANY	1998 MIL. $	% OF SALES
Abbott	1,222	10
American Home Products	1,655	12
Bristol-Myers Squibb	1,577	9
Eli Lily	1,739	19
Glaxo Wellcome	1,927	15
Johnson & Johnson	2,269	10
Merck	1,821	7
Pfizer	2,279	17
Pharmacia & Upjohn	1,199	18
Schering-Plough	1,007	12
SmithKline-Beecham	1,508	11
Warner-Lambert	877	9

Source: Standard & Poor's, Healthcare: Pharmaceuticals Industry Survey (December 16, 1999)

APPENDIX 1-3

STANDARD INDUSTRY SURVEYS
& P00RS

Healthcare,
Pharmaceuticals

DECEMBER 16, 1999 / HEALTHCARE: PHARMACEUTICALS THIS ISSUE REPLACES THE ONE DATED JULY 29, 1999. THE NEXT UPDATE OF THIS SURVEY IS SCHEDULED FOR JUNE 2000.
Herman -Saftlas
Pharmaceuticals Analyst

(Excerpt from CURRENT ENVIRONMENT, pages 4-7)

Yet new products in the industry's R&D pipeline are relatively sparse. Part of the problem reflects more competition from biotechnology drugs that have eclipsed conventional drugs in many therapeutic categories. At the same time, FDA approvals of breakthrough products (defined as new molecular entities, or NMEs), have been in a downtrend in recent years. Pharmaceutical NMEs totaled 30 in 1998, down from 39 in 1997 and 53 in 1996.

but long-term fundamentals remain sound

Despite its problems, the domestic pharmaceutical industry is still one of the healthiest and highest-margined industries in the United States. Historically, the industry has rejuvenated itself by developing premium-priced breakthrough therapies that made older drugs obsolete and opened up entirely new markets, and we fully expect that this pattern to persist.

An estimated 50,000 scientists employed by U.S. pharmaceutical companies are currently researching several thousand new compounds to treat cancer, heart disease, AIDS, Alzheimer's disease, and many other diseases. More than one thousand new drugs are now in the industry's R&D pipeline to treat cancer, heart disease, AIDS, mental illness, and other ailments.

The overall drug discovery process is undergoing a transformation, thanks to major advances in biomedical science. New processes have been invented that should help scientists develop growing numbers of compounds that can be used in the battle against major diseases in the years ahead. Some of the new methods that hold much future promise include rational drug design, combinatorial chemistry, and high throughout screening. (See this issue's "How the Industry Operates" section for more details on these methods.)

Strategic alliances proliferate

Rather than engage in costly mergers and acquisitions, many pharmaceutical companies firms have chosen alternative means of maximizing product sales. These include: entering into co-promotion deals with other drugmakers; expanding product odoaernat9(ho)13et

The industry has witnessed a flurry of co-marketing deals as drug companies pool their sales forces to make a greater impact. Most leading drugmakers are also stepping up their joint venture and licensing activities with smaller biotechnology companies to empower their R&D programs. According to Burrill & Co., a private merchant bank, the value of drug biotech partnering deals (in up-front payments and equity investments) was nearly $3.7 billion in the first nine months of 1999.

Cholesterol drugs. The cholesterollowering market is expected to exhibit vigorous growth in the years ahead, as people become more aware of the dangers of elevated blood cholesterol. Total prescriptions written for this class in September 1999 were 20% above the year-earlier level.

The American Heart Association has estimated that over 50% of all American adults have elevated blood cholesterol counts. Persons with high cholesterol are initially advised to change their diets to low-fat foods and to lose weight through exercise. However, if these measures are unsuccessful, physicians often recommend drug therapies. Only about one-fifth of all persons who could benefit from these drugs are currently taking them.

The strongest performer in the cholesterol market has been Warner-Lambert's Lipitor. This drug has shown to be more efficacious than its rivals while maintaining an excellent side-effect profile. Sales of Lipitor are expected to rise from an indicated $3.4 billion in 1999 to more than $8 billion within the next five years. As of September 1999, Lipitor accounted for about 42% all new prescriptions for cholesterol reducers. Other leading cholesterol drugs include Merck's Zocor (21 % of the market) and Bristol-Myers Squibb Co.'s Pravachol (14%).

* **Antihypertensives.** Affecting close to 60 million Americans, hypertension or high blood pressure is a generally symptomless condition that if left untreated can lead to stroke, aneurysm, heart attack, and kidney failure. A large number of drugs with different mechanisms of action are available to treat hypertension.

The largest-selling categories include calcium channel blockers, led by Pfizer's Norvasc, and ACE inhibitors, of which Merck's Vasotec/Vaseretic is the biggest seller. Older groups include products such as beta blockers, diuretics, vasodilators, and others.

The most recent wave of antihypertensives are angiotensin II antagonists, led by Merck's Cozaar/Hyzaar (with about a 50% market share of the angiotensin 11 market as of September 1999). Other leading drugs in this class include Novartis's Diovan/Diovan HCT (27%) and Bristol-Myers's Avapro (15%). Bristol-Myers is expected to soon launch a new antihypertensive called Vanlev. This drug has a unique advantage in that it lowers both diastolic and systolic blood pressure (when the heart relaxes and contracts, respectively), whereas conventional antihypertensives lower only diastolic pressure. (In most cases, the diastolic number is the most significant.)

Gastrointestineffinetabolism agents

This large sector, which includes antiulcer drugs, diabetes compounds, antiobesity agents, oral contraceptives, and related drugs, accounted for 15% of U.S. drug sales in the 12 months through August 1999, based on IMS data. Volume growth for most drugs in this class has been in only the single digits in recent years, reflecting the market's relative maturity and a rising proportion of inexpensive generics in the total mix. However, certain segments such as diabetes treatments are showing above-average growth.

* Antiulcer drugs. This $6.S billion U.S. market comprises older H2 antagonists such as SmithKline Beecham's Tagamet and Glaxo Wellcome's Zantac, as well as newer proton pump inhibitors such as

bacterium responsible for recurrent peptic ulcers. Another popular proton pump antiulcer drug is Abbott Laboratories's Prevacid, which has a 22% market share.

Diabetes drugs. This $3.5 billion market is expected to quadruple over the next several years, fueled by a growing patient population and new breakthrough treatments. Most of the growth should reflect rapid expansion in sales of new drugs for Type 2, or adult-onset, non-insulin-dependent, diabetes. Typically affecting persons who are over 40 or clinically obese, this condition is characterized by the body's inability to make enough insulin or to use it properly. The number of patients suffering from Type 2 diabetes has increased significantly in recent years, to a large extent reflecting unhealthy American diets.

The industry leader in this marker is Bristol-Myers Squibb's Glucophage (with about 32% of the market in September 1999), followed by Pfizer's Glucotrol (15%). Recent entrants include SmithKline Beecham's Avandia and Eli Lilly's Actos.

Type I diabetes is a serious condition in which the body does not produce any insulin. Daily injections of the hormone are necessary for the patients survival. A number of companies are now working on newer noninjectable insulin products, including oral and inhaled formulations.

APPENDIX 2

Parallel Imports

The following paragraphs briefly summarize U.S. law in each of the three major areas of intellectual property rights.

(1) Copyright

The Copyright Act, 17 U.S.C. 106 *et seq.*

reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs." P.L. 100-293, § 2 (1988), reprinted in notes accompanying 21 U.S.C. § 353. The legislative history of this provision elaborates on these concerns. See Prescription Drug Marketing Act of 1987, S. Rep. 100-303, p. 58 (Mar. 18, 1988).

(3) Trademark

i. Genuine Goods Exclusion Act (19 U.S.C. § 1526(a))

This Act prohibits importation of a product "that bears a trademark owned by a citizen of . . . the United States, and is registered in the [PTO] . . . unless written consent of the owner of such trademark is produced . . . ." Treasury Department regulations upheld by the Supreme Court provide an exception where the foreign and domestic trademark owners are the same or subject to common control. See 19 C.F.R. 133.21(c)(1) and (2); K-Mart v. Cartier, Inc., 486 U.S. 281 (1988). Where they are not the same or subject to common control, section 1526(a) bars the parallel imports.

ii. Lanham Act (15 U.S.C. § 1124)

The Lanham Act provides a second statutory basis for protection against parallel imports that are physically or materially different from the products sold under the trademark in the United States. Lever Bros. Co. v. United States, 981 F.2d 1330 (D.C. Cir. 1993). In the context of a case under Section 337 of the Trade Act, the U.S. International Trade Commission has prohibited parallel imports of a trademarked product based on a finding of material differences, and the Administration allowed the order to enter into effect. Inv. No. 337-TA-380 (1997). New Treasury regulations establish a procedure by which Customs will allow importation of physically different products, provided that they are properly labeled as such. 64 Fed. Reg. 9058 (1999).

APPENDIX 3

Patent Term Extension Under 35 U.S.C. 156

The right to a patent term extension based upon regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 St. 1585 (Codified at 21 U.S.C. 355(b),(j),(l), 35 U.S.C. § 156, 271,282) (Hatch-Waxman Act). The act sought to eliminate two

circumstances, the statute authorizes the extension of the term of a patent which claims these federally