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PATENT TERM EXTENSIONS FOR PHARMACEUTICAL PRODUCTS

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TABLE OF CONTENTS

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INTRODUCTION

Patent protection is essential to the innovative pharmaceutical sector. Innovative companies require the guaranteed period of market exclusivity afforded by patents in order to sustain drug prices and thereby recoup research and development (R&D) expenditures and finance the development of new products.

Like other inventions, medicines are entitled to patent protection if they meet the requirements set out by the patent-granting authority. Unlike many other products, however, medicines are required to undergo a strict regimen of tests and evaluations in order to determine their safety and efficacy before they can be sold commercially. Much of this testing takes place after a patent for a drug has been applied for so that there is a lag between the invention of the drug and its sale to the public. Conducting pre-clinical and clinical trials and meeting government-imposed regulatory requirements consume part of the period of patent protection and result in a shorter period of market exclusivity for pharmaceutical sector products than for the products of many other industries.(1)

Innovative companies have responded to this disadvantage by lobbying vigorously for measures to strengthen the patent system and for changes to the regulatory process in order to decrease the time involved in obtaining market approval for a drug.

Over the past few years, several industrial countries have made provision for extending the life of pharmaceutical patents to compensate for the erosion of the length of patent terms by the time necessary for regulatory approval procedures. This paper describes measures taken in a number of countries to broaden patent protection for pharmaceutical products.

UNITED STATES

In most countries, including the United States, the basic patent term is 20 years from the date on which a patent application is filed. Until recently the standard patent term in the U.S. was 17 years from the date of the granting of a patent. The recent change aligns U.S. law with the provisions of the Uruguay Round Agreements under the General Agreement of Tariffs and Trade (GATT).

A. *The Drug Price Competition and Patent Term Restoration Act of 1984*

In the early 1980s, innovative drug manufacturers in the United States, arguing that regulatory delays reduced the effective life of their patents, began to push for an extension of the patent term. A number of bills to lengthen the patent term were introduced in Congress, but all met with substantial opposition from consumer and other groups.(2) At the same time as opposing increased patent protection for brand-name drugs, the generic drug sector and consumer groups rallied support for reforms that would allow generic drugs to be sold as soon as possible after the relevant patents had expired.

The issues of patent term extension and early market entry for generic drugs were addressed in the *Drug Price Competition and Patent Term Restoration Act of 1984* (the "Restoration Act").(3) This Act provided for an abbreviated application for the approval

of generic drugs so that they would be available in a shorter time after the expiration of a patent. In order to expedite market entry, generic manufacturers were allowed to use an unexpired drug patent for the purpose of preparing their application for Food and Drug Administration (FDA) approval, without risking legal action for patent infringement.(4)

For the brand-name drug manufacturers, the most important provisions of the Restoration Act were those that provided for an extension of a drug's patent term based upon the time taken to satisfy FDA regulatory requirements.

A number of conditions have to be met before an extension is granted. First, the patent term cannot have expired before an extension application is submitted. Second, the term must never have been extended before. Third, the product must have been the subject of a "regulatory review period" before it was sold to the public. Fourth, the request for an extension must follow the regulatory review period applicable to the first commercial marketing of the drug. Fifth, the patent extension application must be submitted within 60 days after the approval of a new drug application by the FDA.(5)

The extension of the patent term is limited by the difference between 14 years and the number of years remaining in the patent term after the drug has been approved for sale. The maximum allowable extension is five years. Thus, if there are 11 years remaining on the patent after the drug product has been approved for sale, the length of the extension cannot exceed three years, even if the regulatory review period was longer than three years.

An applicant for a patent term extension is required to pursue the marketing approval process with due diligence. If it can be shown that the applicant has not done so, the regulatory review period for determining the length of a patent extension will be reduced by the length of the period in which the applicant delayed pursuing market approval.

B. *The Orphan Drug Act*

Passed in 1983, the *Orphan Drug Act* (ODA)(6) was designed to deal with the lack of financial incentives for drug manufacturers to develop drugs for individuals with rare illnesses. Under the Act, a drug can be designated an "orphan" drug if it will be used to treat a condition or disease that affects fewer than 200,000 persons in the United States or where the condition affects more than that number but there is no reasonable expectation of recovering from U.S. sales the development costs and the cost of making the drug available in the U.S. market.

The ODA provides a number of incentives to drug manufacturers. These range from grants for clinical testing and tax credits for clinical research and development costs to seven years of market exclusivity from the time a product is approved for particular condition.

JAPAN

Provisions to extend the term of pharmaceutical patents in Japan became effective on 1

January 1988. The legislation provides that the patent term can be extended for up to five years from the original expiration date of the patent.(7)

THE EUROPEAN COMMUNITY

In 1992, the Council of the European Communities adopted Regulation No. 1768/92(8) to provide for the creation of supplementary patent protection for medicines. The Regulation provides that pharmaceutical patents can be extended for a maximum period of five years.

The Regulation sets out a number of conditions applicable to an extension. In order to obtain supplementary protection, the patent for the medicine must be in force and a valid authorization to market the medicine must exist. A medicine will be entitled to only one supplementary patent certificate and an application for supplementary protection must be filed within six months of the date on which a patentee receives authorization to market the medicine.

AUSTRALIA

To implement its obligations under the agreements arising from the Uruguay Round of the GATT, Australia introduced a standard 20-year patent term in 1995.

According to the draft report of an inquiry into the pharmaceutical industry in Australia, the Australian government is considering a patent restoration period for pharmaceutical products. The preferred option is an effective patent life of 15 years, running from the date on which a product receives market approval.(9)

CANADA

In Canada, the standard patent term is 20 years from the date on which a patent application is filed. Canada does not have patent extension legislation pertaining to pharmaceutical products.

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(1) It is estimated that the development and regulatory approval process takes an average of 8 to 12 years.

(2) Ronald L. Desrosiers, "The Drug Patent Term: Longtime Battleground in the Control of Health Care Costs," *New England Law Review*, Vol. 24, Fall 1989, p. 133-134.

(3) Public Law No. 98-417, 98 Stat. 1585 (1984).

(4) Ellen J. Flannery and Peter Barton Hutt, "Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984," *Food Drug Cosmetic Law Journal*, Vol. 40, No. 3, July 1985, p. 308.

(5) Suzan Kucukarslan and Jacqueline Cole, "Patent Extension under the Drug Price Competition and Patent Term Restoration Act of 1984," *Food and Drug Law Journal*, Vol. 49, No. 3, 1994, p. 511.

(6) Public Law No. 97-414, 96 Stat. 2049 (1983).

(7) J.W. Baxter, John P. Sinnott, William Joseph Cotreau, *World Patent Law and Practice*, Matthew Bender & Co. Inc., Vol. 2, p. 16-48.

(8) Council Regulation (EEC) No 1768/92, *Official Journal of the European Communities*, No L/182/1. Regulations are binding and directly applicable to all community members; they are comparable to national laws.

(9) Australia, Pharmaceutical Industry Inquiry, *Draft Report Overview*, 1995.