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Review Article

Comparative Evaluation of Patent Term (Beyond 20 Years) in Developed and Developing Countries

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Abstract

Patent is an exclusive right granted for 20 years in exchange of complete discloser of the innovation. Different countries have their different patent laws. The main objective is comparatively evaluation of the patent term extensions granted in developed countries like US, Europe, etc and developing countries like India. Study the strategies used by these countries for extending the patent term. Study of patent laws and their amendments, different cases and conditions and thus analyse the facts and understand eligible conditions in which an extension can be granted. Extension of a patent term is to compensate the regulatory delay which occurs during the approval process of marketing authorisation for the patent, due to which the patentee is unable to enjoy the monopoly. Thus patent term extension encourages innovators to invest in the researches and bring out innovations. Here comparitive evaluation of patent term extension between developed and developing countries is discussed and all pros and cones are evaluated which would be helpful in drafting the policies of patent term extension for countries like India.

Keywords: Patent; Patent Term Adjustment; Patent Term Extension; Supplementary Protection Certificate.

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Introduction

Introduction To Intellectual Property Rights

Intellectual property (IP) pertains to any original creation of the human intellect such as artistic, literary, technical, or scientific creation. Intellectual property rights (IPR) refers to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time.[1]

Introduction to Patent

A patent is a legal right granted by a government that confers upon the creator of an invention the sole right to make, use, and sell that invention for a set period of time (usually 20 years)[1]. The purpose of patent system is to encourage inventions and promotion of technological innovation and to the transfer and dissemination of technology [2]. Patents are territorial and will only give the inventor rights in the country in which a patent is granted [3].

History of Pharmaceutical Patents

Until the TRIPS Agreement in 1994 many developing countries provided no patent protection for pharmaceutical products. The countries that have joined the WTO have obligated themselves to provide such protection; least developed countries are not required to meet this obligation until 2016. The continuing lack of patent protection for pharmaceutical products makes it very difficult to establish research-based industries in most developing countries. Most medical research in these countries takes place in the public sector. The lack of

any means of patenting these inventions and the related lack of experience in licensing them to the private sector, suppresses the development of commercial enterprises focused on alleviating the disease burdens common to developing countries. There are promising developments in countries such as India and Brazil that are beginning to use patents to develop commercial pharmaceutical industries that produce products directed at local diseases and available at price that patients in those countries can afford. These efforts show that developing countries have the capacity to build research-intensive pharmaceutical industries capable of operating profitably in the conditions of the local market. However, for such local industries to take root and grow, effective patent protection must be made available, the commercialization of publicly funded research must be encouraged, and compulsory licensing must be kept to a minimum. As a result of the GATT-TRIPs negotiations, the length of the patent term has been subsequently amended as twenty years from the first filing date of an application [2].

Patentability Criterias

- Novelty – The invention must never have been made public anywhere before the date on which an application for a patent is filed.
- Inventive Step – The invention must be sufficiently different from existing products or processes in a non-obvious way.
- Industrial application – It must be possible for the invention to be actually made or used [3].

Indian Patent System

The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted. The present Patents Act, 1970 came into force in the year 1972, amending and consolidating the existing law relating to Patents in India. The Patents Act, 1970 was again amended by the Patents (Amendment) Act, 2005, wherein product patent was extended to all fields of technology including food, drugs, chemicals and micro organisms. After the amendment, the provisions relating to Exclusive Marketing Rights (EMRs) have been repealed, and a provision for enabling grant of compulsory license has been introduced. The provisions relating to pre-grant and post-grant opposition have been also introduced. An invention relating to a product or a process that is new, involving inventive step and capable of industrial application can be patented in India. However, it must not fall into the category of inventions that are non-patentable as provided under Section 3(d) and 4 of the (Indian) Patents Act, 1970. In India, a patent application can be filed, either alone or jointly, by true and first inventor or his assignee [4].

Non Patentable Inventions as Per Section 3(d)

(a) An invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) The mere discovery of a scientific principle or the formulation of an abstract theory (or discovery of any living thing or non-living substances occurring in nature);

(d) The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or mere new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant ; Explanation- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

(e) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

(g) A method of agriculture or horticulture;

(h) Any process for the medicinal, surgical, curative, prophylactic,diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(i) Plants and animals in whole or any part thereof other than micro-organisms but including seeds,

varieties and species and essentially biological processes for production or propagation of plants and animals;

(j) A mathematical or business method or a computer programme per se or algorithms;

(k) A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(l) A mere scheme or rule or method of performing mental act or method of playing game [4];

(m) A presentation of information;

(n) Topography of integrated circuits;

(o) An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

(p) Inventions relating to atomic energy and the inventions prejudicial to the interest of security of India [5].

Special Problems of Pharmaceutical Patents

Huge capital investment has to be done in pharmaceutical industry for laboratory research and clinical trials rather than the manufacturing of the final product, thus patent exclusivity seems to be the only effective way to protect and receive a return on that investment. This is because pharmaceutical industry is heavily regulated by government agencies to assure the safety and efficacy of products. In the United States, the Food and Drug Administration performs this function. Much of the investment in new drugs is in the clinical trials which are necessary to satisfy safety and efficacy regulators. The lengthy time period between patent filing and placing a product on the market means that pharmaceutical manufacturers receive far shorter periods of patent exclusivity than is the case for other patent dependent industries [2].

Different Wways for Extending Patent Term

Patent term Adjustment (PTA) (USA) (As per 35 U.S.C. 154)

It is the day-by-day adjustment of patent term due to delays caused by the US patent and trademark office during the Prosecution of a US patent application. The total PTA is an addition to the 20-year lifespan of a US patent [5,9]. Since the term of a design patent is not affected by the length of time prosecution takes place, there are no patent term adjustment provisions for design patents. Adjustment information appears on the face of a patent [6,7]. For example, US Patent No. 6,399,594 was subject to an adjustment of 18 days, as depicted in Figure 1.

Patent Term Extension (PTE):(As per 35 U.S.C. 156)

It often takes many years to develop a commercially available medicine from the initial chemical compound made in the laboratory. During this period, when the compound is under clinical testing and regulatory approval, the patent's life is ebbing away [7]. Often, by the time a drug is brought to market over half of the patent life has expired. To act as an incentive to develop and bring new drugs to market, many countries have implemented a legal framework that allows the extension of pharmaceutical patents. An originator can, under certain circumstances, gain a further period of patent exclusivity to exploit a product commercially [10]. Such extensions can be of enormous commercial value, protecting a product at the height of its revenue stream. These extensions are known as patent term extension. Patent term extension is available to compensate for regulatory delays. Maximum patent term extension granted is 5 years. An application for a patent term extension can be made within six months of the issue of the patent. Patent term extension is available in the US, Japan, Israel, Australia, Taïwan, Korea and in some other countries for products subject to a regulatory approval [11] (Figure .2).

Criteria for Patent Term Extension (For US):[8]

a) Patentee or its agent must file an application for PTE that includes detailed statements about the activities undertaken to secure FDA approval.

b) Applicant must establish that the product was subjected to regulatory review period before its commercial marketing or use.

c) The applicant must show that the product permitted is either the first permitted commercial marketing or the use of the product after such regulatory review

d) Patent has not yet expired.

e) Patent term has not been previously extended.

Supplementary Protection Certificate (SPC)(Europe)

It is same as Patent term extension. It is a sui generis intellectual property (IP) right available for various regulated, biologically active agents, namely human

or veterinary medicaments and plant protection products.[11] Created by, and are governed by, an EU Regulation. It has a lifetime of 5 years. One supplementary protection certificate per product. An application for a supplementary protection certificate can be made within six months of the issue of the patent. The duration of a supplementary protection certificate is determined on the basis of the period of time between the registration of the basic patent and the granting of the first licence for the product within the European Community. Five years are deducted from that period of time. For example, there is a period of ten years between the registration date and the date of issue of the licence; the supplementary certificate will be valid for five years [12] (Figure 3).

A Certificate shall be Granted if:[13]

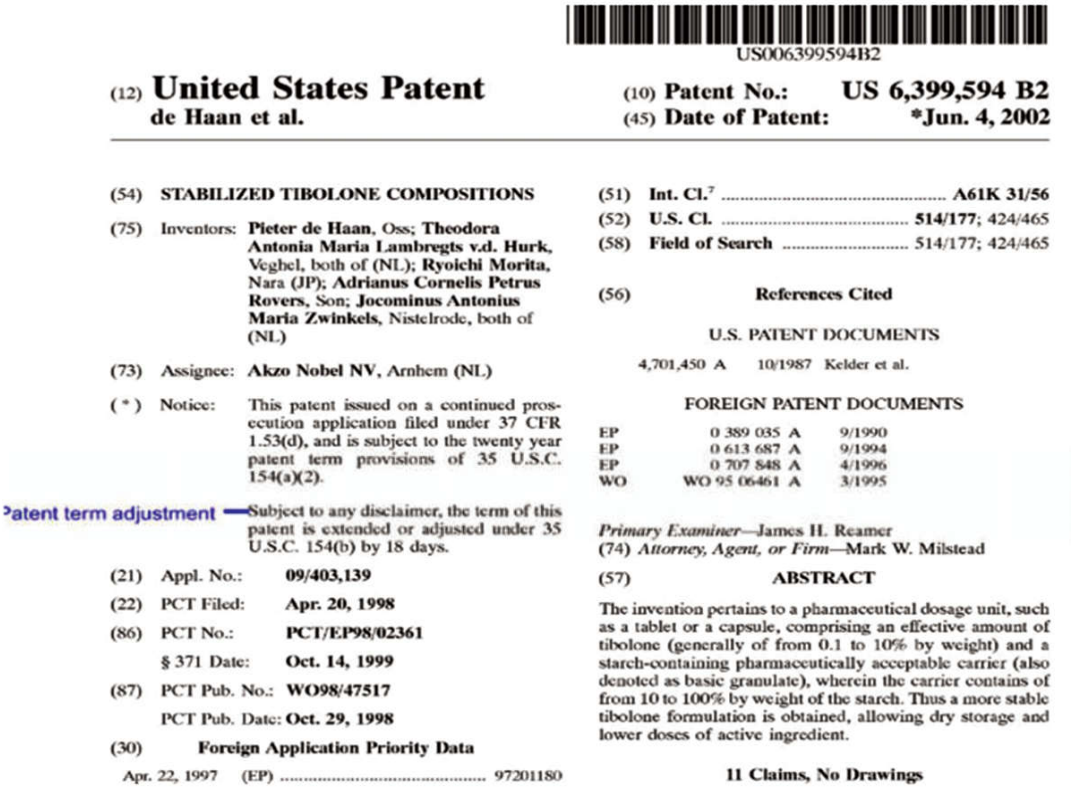
a. The product is protected by a basic patent in force;
b. A valid authorisation to place the product on the market as a medicinal product has been granted;
c. The product has not already been the subject of a certificate;
d. The authorisation referred to in point b) is the first authorisation to place the product on the market as a medicinal product.

Purpose of Extension of Patent Term

Capital investment in the pharmaceutical industry disproportionately related to laboratory research and clinical trials rather than the manufacture of the final product, patent exclusivity is the only effective way to protect and receive a return on that investment [13]. The purpose of the system for patent term extensions is to restore the period during which the patented invention was unable to be worked because it is necessary to obtain approvals or any other dispositions under a law [2].

Data Exclusivity (DE)

Data Exclusivity (DE) or exclusivity of registration data is the period of non-reliance and non-disclosure that is provided to new chemical entities, pharmaceutical compositions, and agrochemical registration data or test data. It is for a limited period of time when the drug regulatory authorities do not allow the test data of the originator to be used to register the generic version. Discovery and development of a new molecule takes about 8 to 10 years and costs millions of dollars, generating the test data takes about 50% of the time and expense. This data becomes very important at the time of obtaining marketing approval from regulatory authorities.



US006399594B2

(12) **United States Patent**
de Haan et al.

(10) **Patent No.: US 6,399,594 B2**
(45) **Date of Patent: *Jun. 4, 2002**

(54) **STABILIZED TIBOLONE COMPOSITIONS**

(75) Inventors: **Pieter de Haan**, Oss; **Theodora Antonia Maria Lambregts v.d. Hurk**, Veghel, both of (NL); **Ryoichi Morita**, Nara (JP); **Adrianus Cornelis Petrus Rovers**, Son; **Jocominus Antonius Maria Zwinkels**, Nistelrode, both of (NL)

(73) Assignee: **Akzo Nobel NV**, Arnhem (NL)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Patent term adjustment — Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 18 days.

(21) Appl. No.: **09/403,139**
(22) PCT Filed: **Apr. 20, 1998**
(86) PCT No.: **PCT/EP98/02361**
§ 371 Date: **Oct. 14, 1999**
(87) PCT Pub. No.: **WO98/47517**
PCT Pub. Date: **Oct. 29, 1998**

(30) **Foreign Application Priority Data**

Apr. 22, 1997 (EP) 97201180

(51) **Int. Cl.**[7] **A61K 31/56**
(52) **U.S. Cl.** **514/177**; 424/465
(58) **Field of Search** 514/177; 424/465

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Primary Examiner—James H. Reamer
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(57) **ABSTRACT**

The invention pertains to a pharmaceutical dosage unit, such as a tablet or a capsule, comprising an effective amount of tibolone (generally of from 0.1 to 10% by weight) and a starch-containing pharmaceutically acceptable carrier (also denoted as basic granulate), wherein the carrier contains of from 10 to 100% by weight of the starch. Thus a more stable tibolone formulation is obtained, allowing dry storage and lower doses of active ingredient.

11 Claims, No Drawings

Fig. 1: Front page of US6399594 illustrating patent term adjustment

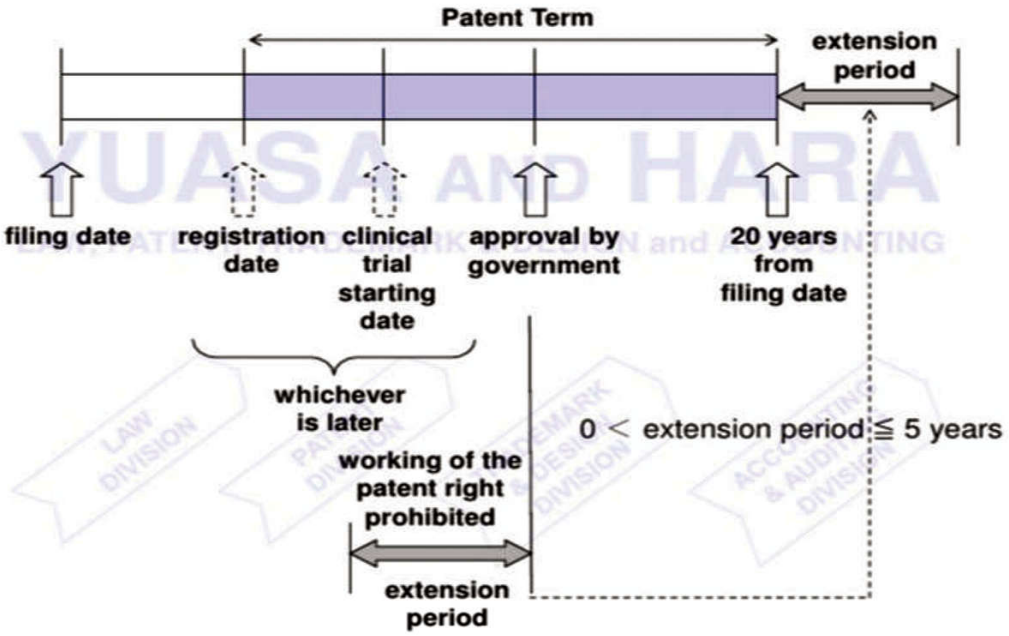

Fig. 2: Timeline of entire patent term with PTE

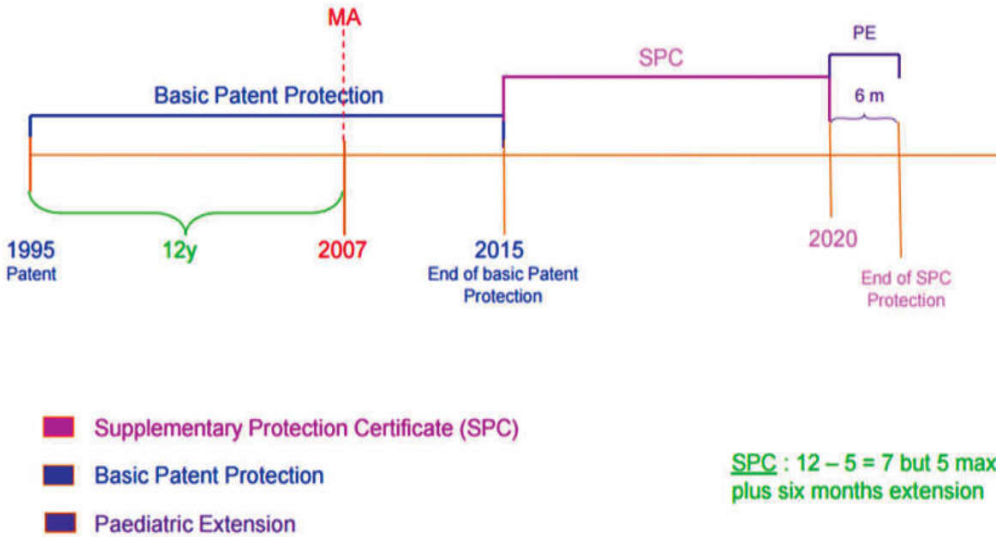

Fig. 3: Timeline of entire patent term with SPC

Data exclusivity provides the originator with rights to preclude third parties from relying on the data to obtain marketing approval for a specific period of time. However, it does not prevent third parties from generating their own data [14].

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