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Review Article

Approach Followed in the Pharmaceutical Industry for Extension of Patent Term

Jharana Mallick* and Debashrita Sahoo,

Vision College of Pharmaceutical Sciences and Research, Boduppal, Uppal, Hyderabad, Andhra Pradesh, India.

ABSTRACT

The rationale of this paper is to talk about approach followed to extension patent term by the pharmaceutical companies. Market exclusivity acquired through patents can give way higher prices and profits for pharmaceutical products. Therefore, pharmaceutical companies use a variety of strategies to enhance market exclusivity of their products. Some of the strategies discussed in this paper include one-year extension of time to file for patent under the Paris convention, patent term restoration allowed by the Waxman-Hatch Act, orphan drug exclusivity, pediatric exclusivity, and the 30-month stay provision and so on. Even though, the strategies discussed in this paper are for the United States, they may be also applicable to most European countries, Australia, New Zealand, Japan, and Canada with minor modifications as similar pharmaceutical regulations exist in these countries.

Keywords: Patent, Pharmaceutical companies, Waxman-Hatch Act.

INTRODUCTION

The new set of challenges stem from the deeper implications of the imminent product patent regime. As R&D costs of developing new drugs are very high. The costs of reproducing pharmaceutical drugs are very low[1]. Therefore, very few companies will be willing to make huge investments in pharmaceutical R&D without patent protection. Patents also support higher economic growth as the pharmaceutical industry provides high paying jobs which in turn lead to higher economic growth[2].

The rationale objective of this paper is to discuss various approach followed to extension patent term by the pharmaceutical companies in the United States with a view to maintain market exclusivity of drugs. This paper is categorized into various sections by highlighting briefly about the Drug Price Competition and Patent Term Restoration Act of 1984 or Waxman-Hatch Act of 1984 followed by the patent-term extension strategies, background and the generic approval status. Finally we close this paper with conclusions.

The generic drug approval process

The Waxman-Hatch Act allowed generic manufacturers to perform functions needed to obtain approval of generic version of a patented drug during the life of a patent without charge of patent infringement. However, the submission of an ANDA is considered as an act of patent infringement so that the questions relating to the validity, enforceability and infringement of patents can be resolved before a generic drug is introduced[3]. This Act requires the listing of patents relating to each approved New Drug Application in the "Orange Book" maintained by the FDA[4]. The potential generic manufacturer should indicate in the ANDA any of the following four intents (called certifications) relating to each patent in the Orange Book that:

- I patent information on the drug has not been filed;
- II the patent has already expired;
- III the date on which the patent will expire; or
- IV the patent is invalid or use or sale of the drug will not infringe the patent.

The FDA will approve the ANDA filed with paragraphs I and II certifications. For paragraph III certification, the FDA will approve the ANDA only after the listed patents expire[5]. When the potential generic manufacturer indicates paragraph IV certification, the FDA should send the copy of the ANDA to the patent owner. The patent owner has 45 days from the date of the receipt of the ANDA

to execute patent infringement suit. If the patent owner executes the patent infringement suit in the timely manner, the patent owner immediately gets a 30 month stay from the FDA from approving the generic version of the drug. The FDA should then wait until

- Court finds that the listed patent is either invalid or not infringed;
- The listed patent expires if the court finds the listed patent is valid;
- Court orders or thirty months from the date on which the patent owner received the copy of the ANDA elapse.

Every time a new patent is added in the Orange Book, the brand manufacturer gets a 30-month stay from approving the ANDA[6]. However, the 30-month stay obtained for each patent runs concurrently. Currently, the brand manufacturer can only get one 30-month extension. The first generic manufacturer who files ANDA with paragraph IV certification is rewarded with 180-day market exclusivity, if its generic drug is approved[7].

RESULT AND DISCUSSION

Market exclusivity acquired through patents can yield higher prices and profits for pharmaceutical products. Therefore, the pharmaceutical companies use a variety of strategies of to increase market exclusivity of their products[8]. The Paris convention, patent term restoration allowed by the Waxman-Hatch Act, orphan drug exclusivity, pediatric exclusivity, and the 30-month stay provision represent some strategies to maintain market exclusivity and delay introduction of generics.

Table 1: Summary of Market Exclusivities (patent-term extension strategies)

Description	Description	Duration	ANDA Filing
Patents	Compound, medical use,process, formulation	20 years from the date of filing.	Before patent expires
Patent Term Restoration	To make up for time lost in clinical testing and FDA approval time	Maximum 5 years for the lost time. Time from NDA approval until patent expiry may not exceed 14 years.	Before patent expires.
The Paris Convention	Patents	Allows an inventor who files for patent in any member nation one year to file patent in any other member nation	
Waxman-Hatch Exclusivity	Drug (new chemical Entity) approved by the FDA	5 years from the date of drug approval (plus ANDA approval time).	Only after market time expires
Waxman-Hatch Exclusivity	Drug (Not a new chemical entity) approved by the FDA	3 years from the date of drug approval (plus ANDA approval time).	Only after market time Expires
Orphan Drug Drugs	Indications less than 200,000 US patients	No approval of same drug for same indication for 7 years	
The 30 month stay provision	Brand-name drug manufacturer against whose drug ANDA with paragraph IV certification has been filed and brand-name company sues for patent infringement.	Until (1) the date patent expires, (2) court decision, (3)30 months from the date of receipt of notice of the paragraph IV certification Note: ANDA –Abbreviate New Drug Application NDA – New Drug Application	Currently, only one stay is allowed

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