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Pharmaceutical Patents under Turkish Law

Introduction

Regulations on intellectual property ("IP") rights are crucial for the sustainability of corporate entities. The necessity for the continued innovation of new medicines requires effective protection of IP rights. In terms of pharmaceuticals, patents are considered the most important form of IP protection due to their value as an economic asset to pharmaceutical companies.

A patent is an intellectual property right provided to inventors in exchange for their consent to share the details of the invention with the public. Patents help to establish a legal monopoly and therefore, provide the owner with a negative right to prevent competitors from manufacturing, selling, using, importing the patented goods, basically, prevent them from profiting from the invention without the patentee's consent for twenty years. Even if a pharmaceutical is patented, in order to be manufactured and sold, authorization of the Ministry of Health is required.

Conditions of Patentability

Patent rights are regulated under the Code of Industrial Property (Law No. 6769, "CIP") which has replaced the Decree Law on the Protection of the Patent Rights (Decree Law No. 551). CIP was

adopted in line with the EU acquis as part of Turkey's accession process to the EU and integrated all relevant legislation into a single legal framework. Articles 82-141 of CIP regulates the patent rights in terms of the conditions and the scope of protection, application and priority right, patent objection, term of the protection, annual fees, infringement and termination of patents, right ownership and other relevant matters. According to the legislation, patents can be granted to all drugs on the condition that they meet the basic patent criteria of having novelty, containing an inventive step and being applicable in the industry.

Types and Scope of Pharmaceutical Patents

Fundamentally, types of pharmaceutical patents are divided into two main categories: product patents and process patents.

The most superior type of pharmaceutical patent is product patent. Product patents mainly have a claim on either a molecule or an active substance discovered as a new chemical entity. On the other hand, process patents are granted for the methods used to synthesize the final product and not for the product itself.

The distinction between these two categories has great importance as the scope of the protection varies according to the provided type of patent. Product patent grants the owner an exclusive monopoly, within the framework specified by law, on the manufacture, sale, use and import of the patented drug prohibiting its possession for reasons other than personal needs. On the other hand, process patent authorizes the patentee to claim the prevention of the actual practice of the patented process, proposals made by third parties to others to use the process patent. These types of patents also prohibit the sale, use or import of the goods which are directly obtained by the patented process or keeping such products at hand for commercial or industrial purposes and for other reasons than personal needs.

Formulation patent and indication patent are the other two different types of patents relevant to pharmaceuticals. Indication patent is granted when an alternative/secondary medical use of existing drugs or active substances (or molecules etc.) is discovered. Formulation patent has claims on the pharmaceutical dosage form

of the drug or formulation technology or technique that applies to a variety of drugs. Neither of these patent types provide protection for the active substance.

Bolar Exemption

The activities exempted from the patent protection regarding pharmaceutical IP mainly consist of non-commercial acts but also include experimental activities as well as preparation of prescribed drugs in pharmacies without mass production. According to article 85(3) (c) of CIP, trial practices involving the performances of patented drugs are excluded from patent protection if conducted for regulatory authorization. Aforesaid practices include clinical trials, tests, bioequivalence and licensing studies. The Bolar Exemption, named after the case Roche Products v. Bolar Pharmaceutical, also includes preliminary tests and experiments enabling such processes to be executed. As a result of this exemption, generic companies can complete the technical processes required for the regulatory approvals before the expiration of patent term, therefore launch a generic drug (an equivalent pharmaceutical drug) for a lower cost as the IP protection expires. In this regard, Bolar Exemption functions to balance the interests of corporate entities and the public by encouraging competition between generic and innovative firms.

Data Exclusivity

Data exclusivity is a form of IP protection exclusive to pharmaceuticals. This mechanism prevents third persons from using inventor-generated clinical data for six years within the Turkish-EU Customs Union area, starting from the date of the obtainment of the marketing authorization on a human medicinal product under article 9(a) (3) of the Regulation on Licensing of Medicinal Products for Human Use.

By means of Bolar Exemption, generic pharmaceutical firms can file marketing authorization applications by using the experimental (clinical) data produced by the patentee. Therefore, generic firms can skip particular clinical trials avoiding the costs of drug discovery and development and only test the drugs for safety and efficacy purposes.

Data exclusivity functions as a barrier to these abridged applications, ensuring that no generic firms can make such applications by referring to the clinical data gathered by the patentee.

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