

Patent Execution Strategies

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Abstract

Patents are considered to be enticements for innovation and thereby expected to benefit humanity by making available to the society. Pharmaceutical patents cover products that take a very long time to develop and the patent life is actually closer to 11 or 12 years since federal law requires a company to test its product for safety and efficacy and secure regulatory approval before marketing. Developing countries experience shows that such incentives focus on the market demand rather than the need of the society. This is more obvious in the health related innovation. Therefore, a strong IP protections safeguard should be held against counterfeit, illegitimate and fake pharmaceutical products.

Keywords: Pharmaceutical; Patent; Infringement; Health

Intellectual property is a legal concept which refers to creations of the mind for which exclusive rights are recognized. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets (musical, literary, and artistic works), discoveries & inventions; and design & symbols [1].

The patent protection is the cornerstone of a health and dynamic research environment on any country. The WIPO treaty and several related international agreements are premised on the notion that the protection of intellectual property rights is essential to maintaining economic growth [2]. Unauthorized use of intellectual property rights, called “infringement” with respect to patents, copyright, and trademarks, and “misappropriation” with respect to trade secrets, may be a breach of civil law or criminal law, depending on the type of intellectual property, jurisdiction, and the nature of the action. Patent infringement typically is caused by using or selling a patented invention without permission from the patentee. The extent of protection is defined in the claims of the granted patent.

There is safe harbor in numerous jurisdictions to custom a patented invention for research. This safe marina does not exist in the United States unless the research is done for purely rational purposes, or in order to collect data to prepare an application for regulatory approval of a drug candidate. IP infringements happen for various reasons. They can be due to ignorance of the law, or not appreciating/ caring about the risk, or deliberate infringement, or due to a result of uncertainties in the law. IP rights owners cannot do ample in advance to prevent the bulk of defendants, who are prepared to take a casual from infringing.

The pharmaceutical sector is one of the areas of more speculation and demanding research which repetitively need precise and rationalized information. Global pharmaceutical industry bested US\$ 950 billion in sales with trend to reach US\$ 11.9 trillion by 2016 and they seek constant novelty of their products and processes [3,4]. According to the Organization for Economic Cooperation and Development (OECD), there are four kinds of innovation: product innovation, process innovation, organizational innovation and marketing innovation, as well as a combination of any of the above. The internet has become a critical medium for clinicians, public health practitioners, and laypeople seeking health information [5]. Scrutinizing big data in the pharmaceutical field and specifically for patents, it is possible to observe more than five thousand documents in database like PubMed with the term “patents medicines”. These documents comprise more than 40 years of research involving more than 100 countries, 820 cities worldwide, plus 1600 scientific journals (Lancet, BMJ, JPP, Soc. Sci. Med, etc.) and over 13,700 experts [6]. So, improving health of the people,

mainly in the developing and undeveloped countries depends on the development and disposition of many varieties of health innovations, including novel drugs, vaccines, devices, and diagnostics, also new techniques in process engineering and manufacturing, management approaches, software, and policies in health systems and services [7].

Growing international trade in novel pharmaceutical products has increased the potential for cross border patent disputes. However, there is no consensus regarding the nature, structure and change of patent disputes in the context of international competition. Although patent protection is intended to promise a unifying measure of commercial protection, entrepreneurial practices may influence its efficiency. Thus, there is an urgent need to develop a system of collaborative research culture with public and privately funded research organization for curbing these issues.

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