Pharmaceutical Regulatory Affairs 2012: Patent law compliant research methodology in pharmaceutical research - Lachoo Memorial College of Science & Technology, India

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Abstract

Pharmaceutical research is very expensive, time consuming and unpredictable in nature. Research methodology is a plan to carry out the research activities in a logical and systematic manner. Outcome of the pharmaceutical research may be in the form of an inventive product or process, which can be protected from any unauthorized commercial use by acquiring patent rights over it. However, to be patentable the invention shall comply with the requirements of the patent law of the country. Therefore, it is imperative for the researchers to be acquainted with the basic knowledge of the patent regulations, in order to avoid loss of any potential patent rights in due course. The best line of action would be to design a research methodology in such a way that all rules of patentability are followed before, during and after the conduct of the research. Means, a patent law compliant research methodology shall be followed while carrying out the R&D activities. This issue is especially pertinent for small or medium size organizations, where usually well defined patent policy and procedures are not followed. The pharmaceutical sector has unusual prominence in debates about IP policy, and has served as the front line for national and international controversies about the relationship between IPRs, R&D incentives, pricing and access to medicines. Notwithstanding the intensity of debate, on some crucial questions there is relatively little empirical evidence to support policy-making. This paper surveys the empirical literature on intellectual property and pharmaceuticals, discusses methodological issues and key sources of data, and identifies some of the key research issues and major gaps in the literature. The pharmaceutical sector is complex and highly regulated in most economies. Government price controls and purchasing, public and private insurance schemes, restrictions on marketing and promotion, and the involvement of “learned intermediaries” such as physicians and pharmacists powerfully influence demand for pharmaceuticals. On the supply side, stringent product safety review, regulatory oversight of manufacturing, and legal frameworks governing technology transfer between publicly-funded biomedical research institutions and commercial entities play an equally significant role in shaping competition. Importantly, since much of the research on pharmaceuticals has been focused on questions specific to the market institutions and regulatory framework of high-income economies such as the US and the EU, the extent to which this literature provides a firm foundation for evaluating the impact on policy changes in developing countries and countries with economies in transition is therefore unclear. There are three basic requirements of patentability viz. newness, inventive step and industrial applicability, which should be considered while designing a research plan and then carrying out the research. This presentation discusses various approaches that can be incorporated during pharmaceutical research, so that the institute can acquire and enforce the patent rights in an effective manner. India, like many developing countries, only recently began to grant pharmaceutical product patents. Indian patent law includes a provision, Section 3(d), which tries to limit grant of “secondary” pharmaceutical patents, i.e. patents on new forms of existing molecules and drugs. Previous research suggests the provision was rarely used against secondary applications in the years immediately following its enactment, and where it was, was redundant to other aspects of the patent law, raising concerns that 3(d) was being under-utilized by the Indian Patent Office. This paper uses a novel data source, the patent office’s first examination reports, to examine changes in the use of the provision. We find a sharp increase over time in the use of Section 3(d), including on the main claims of patent applications, though it continues to be used in conjunction with other types of objections to patentability. More surprisingly, see a sharp increase in the use of the provision against primary patent applications, contrary to its intent, raising concerns about potential over-utilization.