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Pharmaceuticals is Engulfed in an Incredible Patent Thicket- An Analysis

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ABSTRACT *Patent thickets are sets of overlapping property rights that occur in fragmented tech- nology markets, and increase the costs of commercializing innovations due to transaction Costs, double marginalization, complement problem, and the possibility of hold-up and prolonged litigation. Patent thickets inhibit innovation, one is led to conclude that industries and/or governments need to design different policies which effectively discoverage the creation of patent thickets. It constrain innovation, the inability to systematically detect patent thickets allows for continuation of this intangible reality in the future.*

Introduction:
Patents are exclusive property rights in intangible creations of the human mind. They exist only as provided in the laws of sovereign states, and can be enforced only to the extent that application has been made and a patent granted covering the territory of an individual state. Patent rights are limited in duration, with the global standard being 20 years from the date of application. The new product, article of manufacture or process described in the patent application must be something that has never been previously disclosed anywhere in the world and something that would not be obvious to a person ordinarily skilled in the field involved. Determinations of whether these requirements have been met are made by comparing the claims of the patent applicant against the body of published literature in the field, including previously issued patents. This process is called examination, and it assures that no one is able to claim patent rights on anything that already is existence.

Patents work differently indifferent industries. In the electronic industry patents are often shared among competitors through pooling or cross licensing. This sharing is necessary because a given product often contains many patented technologies. However, in the pharmaceutical, chemical and biotechnology industries the patent normally equals the product, and protects the extensive investment in research and clinical testing required before placing it on the market. Patent protection for chemical and pharmaceutical products is especially important compared with other industries because the actual manufacturing process is often easy to replicate and can be copied with a fraction of the investment of that required for the research and clinical testing. The extensive cost required to produce a new pharmaceutical product has meant that private sector investment in pharmaceutical innovation has been disproportionately directed to products meeting the needs of patients in developed countries, particularly in the United States, which combines strong patent protection with a market free of price controls.

Patent system and pharmaceuticals:
Until the TRIPS Agreement in 1994 many developing countries provided no patent protection for pharmaceutical products. And, while 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.

Effective use of the patent system in the 20th Century gave rise to commercial enterprises that advanced the progress of medical science beyond anything known in prior history. While public funding of the training of scientists and basic research vastly expanded the understanding of human pathology as the century progressed, it was the profit incentive operating through pharmaceutical companies accountable to investor shareholders, which provided desperately needed new therapies to patients. By the decade of the 1980s patent dependent pharmaceutical companies developed more than 92% of all new drugs.

Challenging patents:
Brand-name drug companies have used a number of strategies to extend the period of market exclusivity on their drugs, and prevent generic competition. This may involve aggressive litigation to preserve or extend patent protection on their medicines, a process referred to by critics as "ever greening". Patents are typically issued on novel pharmacological compounds quite early in the drug development process, at which time the 'clock' to patent expiration begins ticking. Later in the process, drug companies may seek new patents on the production of specific forms of these compounds, such as single enantiomers of drugs which can exist in both "left-handed" and "right-handed" forms, different inactive components in a drug salt or a specific hydrate form of the drug salt. If these patents are granted they shall 'reset the clock' on patent expiration. These sorts of patents may later be targeted for invalidation by generic drug manufacturers.

Problems regarding pharmaceutical patents:
The pharmaceutical industry is one of three technology-based industries in which the patent virtually equals the product. The others are the chemical industry (including agricultural chemicals) and the biotechnology industry, whose innovations span the spectrum from engineered plant varieties to human pharmaceutical therapies. These three industries are much different than other patenting industries such as computers and electronics. While responsible for many patent filings the computer and electronics industries are characterized by extensive use of other techniques for managing inventions, including the use of trade secrecy and the pooling of patents with those of competitors to accommodate government and industry technical standards. Most importantly, unlike industries which produce products requiring expensive and complex manufacturing infrastructures, the patented products of pharmaceutical companies can be easily and cheaply replicated by copiers with little capital investment. Since capital investment in the pharmaceutical indus-

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try disproportionately is directed 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.

Legal issues relating to patenting pharmaceuticals:
When India acceded to the WTO in January 1995, it agreed to bring its patent laws into compliance with TRIPS within ten years from the day it was accepted into the WTO. At that time, India's patent law did not protect compositions of matter. Knowing that by 2005 the necessary legal framework would exist under which composition of matter applications could be examined; India established a patent office "mailbox" into which patent applications for products were deposited. The patent office held the applications for examination until after revised patent laws were promulgated. Now that the laws have been enacted, the applications are being removed from the mailbox and reviewed in the order in which they were deposited. The patent term for mailbox patents will be calculated from the date of deposit.

The delay between the deposit of an application in the patent office mailbox and the issuance of the patent has consequences on the ability of the patent owner to institute infringement actions. A patentee cannot institute a patent infringement action against an entity or company that has been producing and manufacturing a patented product before 2005 and who continues to manufacture the product on the date of the patent grant. Typically, the infringer is a generic drug manufacturer that manufactured the now-patented product while the patent application for the product sat in the mailbox. This provision is essentially a compulsory license to the manufacturer. The only remedy available to the patent holder is a reasonable royalty. The 2005 Amendments to the Patent Laws and a Shift toward Innovation and Outsourcing currently, more than twenty percent of the world's generic pharmaceuticals are produced in India. With the recent changes to India's patent laws, the historically generic pharmaceutical companies will likely shift their focus toward innovation. As there is a shift toward innovation, research and development outsourcing will become an important issue. Manufacturing costs are estimated to be fifty percent below manufacturing costs in Europe and the United States. Moreover, India has the largest number of U.S. FDA approved plants outside the United States and Indian manufacturers are now required to be compliant with Good Manufacturing Practices. In contrast to its historic position, India's current patent system supports innovation and the protection of patent rights while simultaneously protecting the dominant generic market.

Conclusion:
Patents may be an inefficient or defective property right if technologies are complex and patent standards are low. This is because patents do not, in fact, convey exclusive ownership over the relevant productive assets when a single technology involves large numbers of patents. The patent race model and the prospect model of patents depend on the crucial assumption that a productive innovation uniquely corresponds to just a single patent.

Patent thickets inhibit innovation; one is led to conclude that industries and/or governments need to design different policies which can effectively discourage the creation of patent thickets. Patent thickets constrain innovation, the inability to systematically detect patent thickets allows for the continuation of this intangible reality in the future.

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