Patent Pools in Life Sciences

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A patent pool is defined as an arrangement among multiple patent holders to aggregate their patents where all pooled patents are made available to each member of the pool, and standard licensing terms are offered to licensees who are not members of the pool. Typically, a portion of the licensing fees are allocated to each member according to an agreed upon formula.

Patent pools provide a vital mechanism for promoting the development and use of technology and for reducing transaction costs in cases where commercialization of a product or service requires the use of multiple patented technologies. Patent pools played a key role in the development of manufacturing technologies during the industrial revolution, and more recently in the development of the electronics and telecommunications industries. However, with a few limited exceptions, patent pools have not been utilized in the life sciences industry. We discuss the legal requirements for patent pools and explore how technical standards might facilitate the formation of patent pools in the life sciences industry.

The first patent pool, formed in 1856, consisted of sewing machine patents and is customarily called the Sewing Machine Combination patent pool. The Combination patent pool freed its four members to compete with each other in the market place rather than spending most of their time in patent ligation which had until then prevented the sewing machine from becoming a successful commercial product. The 1917 Manufactures Aircraft Association encompassed almost all aircraft manufacturers in the United States. This patent pool is historically important for breaking the hold of the Wright Company and the Curtiss Company, the two major patent holders, on building of new airplanes. New airplanes were needed by the US as it was entering World War 1. Franklin D Roosevelt, then Assistant Secretary of the Navy, helped form this patent pool, which essentially amounted to a compulsory license for national defense since it ensured that aircraft manufacturers had access to essential patents. The 1924 patent pool, now known as the Radio Corporation of America, merged the radio interests of American Marconi, General Electric, AT&T, and Westinghouse, leading to the establishment of standardization of radio parts, airway's frequency locations and television transmission standards. Recent patent pools include patent pools formed around implementation of the digital video disc (DVD) format digital media storage, the MPEG-2 standard for data transmission, and the 1394 ("Firewire") serial bus standard.

CHARACTERISTICS OF PATENT POOLS

An important issue in patent pooling arrangements is the determination of whether a patent is essential. The definition of an essential patent is that it is technically essential, and practically necessary since alternatives are not economically feasible, and that it is essential to the standard or to a device that practices the patent. Thus, for a patent pool in life sciences, a prerequisite is the identification of specific essential patents that are required for the pool. This is difficult to determine in the therapeutic area unless only one drug is available to treat a particular disease. If that is the case, a pool would likely be unnecessary.

Secondly, the determination of a license fee split is potentially the most difficult area for pharmaceuticals. It is very difficult to compare different drugs unless comparator trials have been performed. Even different comparator studies can produce differing results. In addition, different clinical trials with the same drug can produce different results. Thus, it would be difficult to determine the license fee split.

Lastly, the need for inter-operability plays a large part in the success of the patent pools created in the communications sectors. For example, the 3G mobile phone technology patent pool has thousands of patents that have been declared essential for the relevant standards. Patent pools are therefore an effective tool to remove the need to obtain individual licenses necessary to manufacture or operate. Interoperability issue is typically not present in the pharmaceutical industry.

There are several benefits to patent pools. These include the elimination of problems caused by "blocking" patents or "stacking" licenses. In biotechnology, patents to nucleic acids may create blocking patents or lead to stacking licenses, thereby preventing commercial products from entering the market. By creating a patent pool of these basic patents, businesses can easily obtain all the necessary

licenses required to practice that particular technology concurrently from a single entity. Secondly, patent pools can reduce licensing transaction costs and reduce or eliminate the need for litigation. In addition, patent pools can provide incentive for further innovation by enabling its members to share the risks associated with research and development.

On the down side, patent pools may have anticompetitive effects. For example, patent pools inflate the costs of competitively priced goods because certain patents may be considered to be legally blocking, such patents actually cover competitive alternatives to a certain technology, and that the pooling of these patents will expand monopoly pricing. Further, patent pools can be used to shield invalid patents, and force the public to pay royalties on technology that would have become part of the public domain if the patents were actually litigated in court

ANTI-TRUST ISSUES

Patent pools are subject to antitrust scrutiny because of their potential to restrict competition. The Department of Justice (DOJ) has issued *Antitrust Guidelines for the Licensing of Intellectual Property* ("*Guidelines*") for determining whether patent pools comply with the antitrust laws. The DOJ interprets the *Guidelines* as having two overarching requirements: first, a proposed pool must be likely to integrate complementary technologies, and second, the competitive benefits of a proposed pool must be likely to outweigh any competitive harm posed by other aspects of the pooling arrangement. The second requirement effectively limits patent pools to situations where blocking patents, transaction costs and the threat of costly patent litigation pose substantial obstacles to the commercial development of a technology. Assuming a proposed patent pool meets this threshold, the antitrust inquiry focuses on whether the pooled patents cover "complementary" technologies. To assess whether technologies are complementary under the *Guidelines*, the DOJ recommends using an independent expert, typically a licensed patent attorney with the requisite legal and technical expertise, to assess whether each pooled patent is "essential" to complement the other technologies in the pool.

NEGLECTED TROPICAL DISEASES PATENT POOL

While patent pools do exist in the life sciences, they have not been subject to intense scrutiny under the *Guidelines* and they do not have all the indicia of a patent pool. For example, the rationale for creating the GlaxoSmithKline patent pool for neglected tropical diseases, established on February 13, 2009, was to create an interest in and assist with the creation of medicines for serious diseases that have a large social impact but for which there is no commercial interest despite the medical need. GlaxoSmithKline contributed more than 500 granted patents in 80 different patent families to initiate the patent pool. Alnylam joined the patent pool in June 2009 by contributing 1500 issued and pending patents on RNAi technology.

The patents in the patent pool are available for licensing by third parties if two conditions are met: (1) the patents will be applied towards the 16 neglected tropical diseases as defined by the FDA and (2) the therapies will be used in the world's 50 least developed countries as defined by the United Nations. At present, the pool is administered by GlaxoSmithKline, however the intent is to transfer the administration of the pool to an independent 3rd party. It is likely that the license agreement with third parties will be customized for each licensor. The third parties that are likely to request license agreements are likely not-for-profit organizations and public-private partnerships, such as, for example, Medicines for Malaria Venture and TB Alliance, and the like.

The reaction to the patent pool for neglected tropical diseases from both the public and the investor community has thus far been very positive, thus strengthening the position of both GlaxoSmithKline and Alnylam as socially responsible corporations. The existence of the patent pool concretely illustrates to the developing nations that their medical needs are not being neglected, which could help in the efforts to establish IP protection regimes in the developing nations. However, there has not been any licensors yet, and the IP in the pools has not been independently evaluated. Thus, it remains to be seen if the patent pool for neglected tropical diseases will have the same impact as the patent pools have had in the electronics and communication industries.

DIAGNOSTIC PATENT POOLS

An area within the life sciences where patent pools could prove particularly beneficial is the field of diagnostic genetic testing. With the sequencing of the human genome and ready availability of high-throughput screening technologies, genetic testing appears poised for rapid commercial growth. However, the commercialization of genetic testing has been much slower than for many comparable technologies, due largely to the multiplicity of patent rights on the underlying technologies. For genetic testing to be commercially viable, testing procedures must be capable of screening for all of the mutations that are known to be significantly associated with a particular disease or group of diseases. Screening for a single mutation or a subcombination of mutations cannot provide a definitive diagnosis and therefore has limited commercial and clinical value. However, conducting a comprehensive genetic screen often requires navigating multiple, potentially conflicting patent positions on the individual mutations. For example, over 25 mutations are known to have significant diagnostic value for cystic fibrosis (CF) and these mutations are covered by multiple patents with multiple patent holders. In the majority of cases, the cost of negotiating this so-called patent thicket are prohibitive.

One avenue for facilitating the formation of patent pools in the field of diagnostic genetic testing is the adoption of technical standards similar to those in the electronics and telecommunications industries. A major cost of forming and administering a patent pool is the need to obtain expert opinions on whether pooled technologies are essential under the *Guidelines*. The existence of a technical standard can significantly mitigate these costs by simplifying the antitrust analysis and eliminating much of the attendant uncertainty. In addition, testing standards can provide incentives for the development of new technologies by providing objective criteria for technologies that are licensable under a particular pool.

Like other successfully pooled technologies, diagnostic genetic testing is well-suited for the establishment of objective technical standards and has a relatively high degree of inter-operability. A number of efforts have already been made to establish technical standards for genetic testing. The American College of Medical Genetics (ACMG) has issued recommended criteria for testing numerous diseases, including cystic fibrosis (CF), Alzheimer's disease, breast cancer, and colon cancer. For example, the diagnostic standard for CF would require inclusion of all known disease-causing alleles having a minimum frequency of 0.1 in the relevant population. Moreover, recent sequencing initiatives have identified numerous mutations that would need to be tested under such standards in order to definitively screen for most hereditary diseases. This high degree of inter-operability highlights the potential benefits of pooling patents covering individual mutations.

As in the case of the DVD, MPEG-2, and Firewire standards, the adoption of technical standards for genetic testing will likely require a cooperative effort by all of the interested parties. Considering the central role that technical standards have played in the development of the electronics and telecommunications industries, patentees and other stake holders should recognize that establishing such standards could go a long way towards resolving the patent thicket that has thus far prevented genetic testing from reaching its full commercial potential.

CONCLUSION

Patent pools have played an insignificant role in the life science industry. The two major issues have been the determination of essential patents and challenges arising from the distribution of royalties to the members of the pools. Voluntary patent pools that try to address access to medicines have provided good public relations to the industry. However, more effective means for addressing the access issue can be implemented. Patent pools could play a very important role in diagnostics, especially in the field of diagnostic genetic testing where technical standards and inter-operability play an important role.

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