

IP Risks and Cross-Border Alliances

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It takes astute legal and business planning to create cross border alliances that protect intellectual property.

Thanks to growth in international trade, rapid technological innovation, and a willingness to share intellectual property (IP), the number of corporate cross border alliances has grown steadily. Pharma, in particular, has embraced the concept, because the risks associated with commercialization of pharmaceutical products are so great and because the industry realizes the value of jointly developed IP. In fact, pharma has achieved some of the world’s best cross-border collaborations. The most successful have been formed with careful legal planning that minimizes a company’s chances for jeopardizing the alliance’s greatest asset: the IP that goes into and comes out of it.

“We’re seeing more and more companies trying to aggressively tap into partnership and in-licensing and out-licensing and not letting IP issues get in the way of extending their reach into other companies and doing partnerships,” says Russ Hagey, managing director of the Los Angeles office of Bain & Company, a global business consulting firm, and a leader in its healthcare practice area. “There has been a historic view that IP is the hurdle that has kept people away from wanting to do partnerships and alliances. But with a dearth of good opportunities in a lot of companies’ product pipelines, there’s a willingness to work through whatever historical stumbling blocks may have existed.”

This article examines how pharma companies that employ thorough business and legal planning can protect their intellectual property, as well as any that the alliance develops, and stay focused on what really matters: the opportunities of collaboration.

Where in the World?

Alliances can be structured in several different ways. Several factors, including business, legal, liability, tax, accounting and IP, dictate what the most appropriate form may be. An alliance may be implemented through a jointly owned entity or by contract. But before choosing a structure or even a partner, the initiating company should consider the benefits

and risks of establishing a cross-border alliance in any given country. For a variety of reasons, such as tax incentives to companies that develop IP and commercialize products there, certain countries and regions may be more favorable to the project. Many countries in Asia offer these incentives, such as Singapore and Taiwan. Taiwan, for instance, may allow research and development costs to be deducted from income tax. Most of the countries in Europe also offer such incentives.

“The Irish tax laws will give you a break if you have a manufacturing site there, but the real break comes if you are an Ireland-based company earning royalty income from patents based on R&D that originated in Ireland—and that flow of royalty income is tax-free,” explains Marla Church, former corporate patent counsel for Elan Pharmaceuticals Research, a US subsidiary of Elan, which is headquartered in Dublin. “In the early days, it gave [Elan] an edge in that we had all our R&D in Ireland and all the patents originated in Ireland.”

Once a company targets a country or region for further inquiry, it must get answers to more specific questions that will uncover the potential risks of establishing an alliance there. For example:

- 1 What is the scope of IP protection in the region/country?
- 1 Do the country’s patent laws adequately cover compositions and methods of treatment ?
- 1 If not, are there significant risks for entering the alliance partner’s market?
- 1 Is there sufficient enforcement for violations of IP rights?

Most of the Western European countries and Canada have strong IP protections. Therefore, the IP risks in these countries are relatively low. However, the IP landscape of many other countries that might be considered as a site for a collaborative deal offer IP risks and challenges that should be closely considered before any deal is done. A representative list of such countries and examples of potential concerns related to the IP rights in them are shown in “Table A.”

Some countries, such as China and Argentina, have a history of poor IP enforcement. According to Peter C. Richardson, Pfizer’s senior assistant general counsel and general patent counsel, it can be difficult to determine how courts in these countries will handle patent disputes. He says, “China doesn’t have a lot of history on patent enforcement.

They've enacted laws that provide for patent protection, but not many cases have been litigated. Argentina has a national pharmaceutical industry and they've had a system that tends to favor pharma companies there. They have historically not been ready to grant IP rights in the first place, and enforcing rights has been problematic."

Other countries have requirements that significantly reduce an alliance's value. For instance, there may be a mandate to compensate an employee for developing IP. For instance, in Japan, the Patent Law requires that companies provide "appropriate compensation" for discoveries made by employees. Over the last few years, there have been a number of high-profile lawsuits involving this requirement, and other issues related to the ownership of IP rights.

Worse yet, there may be compulsory license provisions, whereby a government can compel a patent holder to license rights to a third party to produce and sell a product with royalties determined by the government instead of the patent holder and the third party. Developing countries, with low or nonexistent levels of IP protection and limited access to new pharma products, are more likely to enact legislation permitting compulsory licensing under a broad range of circumstances, including loosely defined "national requirements." In the United States compulsory licensing is not permitted except in limited circumstances. Recently, the compulsory licensing provisions of Argentina have been criticized as "overbroad," by allowing the government to compel licenses without a legitimate market rationale. Also, it has been reported that the Ministry of Health in Malaysia has been moving for compulsory licensing of HIV therapies in order to obtain the lowest possible price.

Run a Background Check

Successful alliances ensure that legal and IP issues are addressed up front and that both parties share an understanding of the value of IP before establishing a formal relationship. Because cross-border alliances often include companies with drastically different corporate cultures, it is important to recognize early if differences regarding IP are likely. According to Frederick F. Giarrusso, vice-president of business development for Santen Holding U.S., "It's almost impossible to negotiate with someone who has no idea about, or respect for, IP."

It is likewise imperative to conduct a formal due diligence analysis of the IP. In fact, due diligence analysis, which is the hallmark of avoiding pitfalls in most alliances, may also assist the parties in valuing both the technology and the IP. In certain regions of the world, valuing technology presents specific problems. Melvin Rodriguez, director of Willamette Management Associates' inter-company transfer pricing practice in New York, points out, "It is not easy to do valuations in Latin America because it is difficult to get reliable comparable companies or transaction data. There are few sources of reliable information since few countries require public disclosure of financial information for exchange traded companies. Likewise, Europe tends to be an area of concern because partners outside that region may find that their products are subject to 'gray markets'—loss of protection because products can be sold under a different or similar label by additional distributors in other jurisdictions that seek to enhance free trade."

Taking care of due diligence up front means that alliance partners understand what IP the other party has and that they know whether the partner can make good on the technology or IP they promise. There must be a thorough analysis of the partner's technology. Due diligence also reveals the value of the partner's IP, as well as the strength of the proposed partner's IP portfolio, which may include blocking patents and other important knowledge assets. Blocking patents are especially valuable because they cover the basic components of a pharmaceutical product, or a method of making the product, and therefore block competitors from the market completely. Any investigation should also include a risk assessment to see whether the proposed partner is involved in, or is likely to be involved in, any high-stakes IP litigation. If patents are the alliance centerpiece, companies should consider counsel's opinion addressing potential infringement, validity, and enforceability issues. For instance, if there is any chance that the alliance could be sued for patent infringement in the United States, obtaining a "freedom to operate" opinion can establish the necessary written record to avoid a successful claim of willful infringement.

The due diligence process can also include a search and analysis of state-of-the-art developments in the pharma industry, including a careful review of related and competitive technologies, and a legal analysis of whether the technology and IP can be conveyed to the alliance: that is, whether they are owned by, or are free to be licensed by,

the contributing partner. “You don’t want to enter into negotiations with somebody, get too far down the road, have an agreement, and then find out that the whole thing is going to die because somebody else has the patent rights and they are just going to stop you from developing the product,” explains Richardson. “We often find that we need to do a fair amount of independent evaluation to determine what rights there are and to make sure that there are no third-party rights. We don’t want to be in the position where we take a license and then find out that we can’t market the product because somebody else has a patent and we are unable to negotiate a further license.”

If the alliance will be structured as a co-development deal, the company will want to make sure that the potential partner can deliver what it proposes. The best way to determine a partner’s capabilities is to visit their facilities in-person—especially if the alliance will be structured as an R&D alliance. “You want to see their labs, you want to see how they’re set up, you want to see that they have the equipment necessary to carry out the experiments that they say they are going to do,” cautions Corinne Marie Pouliquen, senior counsel in the Washington DC office of Epstein, Becker & Green. “If you walk in and they have no venting system, that’s not a good thing. I have seen places where they have loose leaf papers flying around the bench and they’re just taking notes. If I think there’s going to be a problem, I will spell it out [in the agreement].”

It also matters who conducts the due diligence. Those doing so should have an in-depth knowledge of the applicable technology and broad knowledge of technology management, implementation, and deployment, ideally including expertise in pharma or a related industry. For some purposes, even companies with sophisticated in-house technological capacities require that independent experts conduct technology assessments to avoid the potentially negative impact of hidden agendas and vested interests.

Although it can be easy to get bogged down in the due diligence process, once it is completed, the alliance members have valuable information about how best to structure the alliance and address any anticipated IP challenges.

Protecting Interests

For a company contributing IP to an alliance, nothing is more important than retaining maximum control over its IP. Likewise, both parties must consider ownership of IP

generated by the alliance. The agreement should be flexible enough to account for changes in the competitive and IP landscape that the alliance is targeting.

“From a cross-border point of view, companies need to keep in mind the importance of arriving at flexible but workable arrangements that meet operational and tax objectives and provide them with the flexibility to adjust to changes in the environment,” notes Rodriguez. For example, such flexibility can help a pharma company deal with some of the dynamic changes being made to the IP landscapes in emerging market countries. Rodriguez further explains, “Flexibility can be understood as having a financial option, but here the option is operational and is embedded in the way the companies structure the transaction. These options are called ‘real options,’ such as the option to abandon a project given some performance criteria or the option to delay a project given the presence or absence of some economic condition in the market place. The ability to build these options ahead of time is of great value to all parties involved. A few companies have cross border arrangements that cannot be abandoned at a reasonable price because they did not include in the negotiations the conditions under which the project would be abandoned and the cost of abandonment.”

Once the alliance begins producing IP, the partners must determine how to protect and manage it. In many instances, pharma alliances should first look to patent protection in each country involved. That will generally allow both parties to fully realize the benefits and protection of their patent rights. The scope of patent protection is not uniform from country to country, however, and in some countries, patent protection may pose more risks than rewards. In a country where enforcement is weak, the cost and difficulty of procuring a patent and the requirement for disclosure of the technology may not be justified. For example, in India, it can take many years to procure a patent in the first place, and in any event, may have very little value because of an uncertain enforcement climate.

It may, in fact, be impossible to obtain a patent under a foreign country’s patent law. Instead, the alliance may want to protect the invention as a trade secret, a form of protection that is at least equal in duration to a patent and that also maintains

confidentiality. Richardson points to China as an example. “China is a young country from a patent law point of view. It has had patent laws for about 10–15 years, so it has had to develop these systems and learn how to operate dispute resolutions and so forth. But the biggest issue in places like China is the long-term predictability. It’s one thing to get a patent, but nobody has had much experience in what that does in terms of market exclusivity.”

Moreover, the alliance should ensure that the party with the responsibility for generating and maintaining the IP is also well versed in proper IP development and documentation. That includes determining who will file patent applications before established bar dates and disclosures. Companies should also maintain accurate records and signed documentation to memorialize the IP production.

Enforce What’s Protected

Vigorous enforcement of the IP by both partners is extremely important. Even with the increased focus on IP protection, countries with weak patent systems generally are less aware of the power that patents and IP could have if they were properly enforced. Fortunately, alliance partners in some of those countries are patent savvy.

“We seek patent protection for companies in more than 130 countries,” explains Richardson. “So we have a whole staff of people who are obtaining patent rights for Pfizer’s inventions. Patents are critical for us to be able to sell Pfizer products. So there’s a huge amount of cross-border work done just for Pfizer. By the same token, we also enforce patents globally. Because once you have a patent, it only means something if you’re prepared to sue somebody who’s copying your product.”

At the same time, such enforcement should be coordinated so the action does not put either partner at a disadvantage. For instance, one partner could irreparably harm a relationship with a third party that is a valuable partner in another collaboration, or the enforcement action might harm other worldwide interests.

“We’ve got close to 300 cases of infringement litigations around the world, in which we are enforcing our patent rights,” says Richardson. “Many of those have a cross-border aspect, because it’s common to have litigation in more than one jurisdiction. So it’s important to tie those together and to have the interaction between the law firms in different countries coordinated by the legal division’s IP group. You can’t be saying one

thing in litigation in one country and something different in another. For patent enforcement, that is not a recipe for success.”

When the Alliance Ends

Alliance partners should start their collaboration with the end in mind, because a well planned termination agreement makes for a smoother transition when it is time for the alliance to part ways.

In China, for example, Rodriguez cautions, it “could be difficult if you do not go with a very clear mind on what the terms of the transaction will be and who is responsible for ownership, development, and exploitation of property. It’s very difficult to be successful in these arrangements if you don’t have any strategies relative to exiting the arrangement.” For instance, deciding which party owns any jointly developed IP should be a top priority. That includes any obligations that survive the termination, such as maintenance of licenses to use the IP that is produced by the alliance and maintenance of its value.

Looking Ahead

Throughout the world, IP is being recognized as the cornerstone of the pharmaceutical industry, even in countries and regions that have historically ignored its importance. As Giarrusso has said, “You can have a factory burn down, you can have a laboratory blow up, all kinds of things can happen. Your computers can go to hell. But if you own IP, you can pull it back together. You’ve got the core to your business. You can always build another building. You can always put up another lab. And you can always straighten up a computer mess.”

Hagey expects cross border alliances to continue to grow in the coming years, despite concerns over IP protection. For starters, increasing numbers of companies need to fill pipelines with good products, which means they will reach beyond their traditional borders. Also, more companies are going to look across borders for talent, as the high tech industry has done to find engineering talent.

Finally, he expects more companies will view alliances as windows into international geographies. Bain's research finds that companies successful in international expansion

use data-driven test market results as a measurement tool to determine likelihood of commercialization before they would invest directly. In other words, because markets have different reimbursement patterns and different national health organizations, companies will use alliance opportunities as the ultimate commercialization test of products in those markets. “Those geographies will provide growth options in the future,” he says “and you've got a range of companies that are going to be willing to make the long-term bet.”

Glossary of IP Terms

There are four general types of intellectual property (IP): patents, trademarks, copyrights, and trade secrets.

Patents recognize the economic importance of inventions. For an invention to qualify for patent protection, it must be novel, include an inventive step (be non-obvious), and be commercially applicable. An inventor creates a potentially valuable product and society provides a limited period of exclusive rights to the invention in return for public disclosure of information about the invention.

A trademark is a word, phrase, number, logo, etc., used to distinguish goods and services of one trade from those of another. Trademarks are meant to provide consumer protection both by providing product identification and avoiding consumer confusion about the source of the good or service.

Copyrights provide protection for authors of creative works, such as books, music, and software.

Trade secrets are ideas, information, or know-how, such as a manufacturing process or business method, which is used in a business, and which gives that business a possible advantage over competitors who do not know or use it.

Table A

The “Special 301” provisions of the Trade Act of 1974, require the U.S. Trade Representative (“USTR”) to identify foreign countries that deny adequate and effective protection of IP rights. Each year the USTR reviews and analyzes data related to IP

protection policies in various foreign countries. As part of this analysis, the USTR accepts submissions from industry groups such as the Pharmaceutical Research and Manufacturers of America (“PhRMA”).

After conducting an annual review, the USTR submits a proposed designation for those countries found to have insufficient IP protections. The worst performers are designated as “Priority Foreign Countries.” The other designations are: Continued Monitoring Countries, Priority Watch Countries, and Watch List Countries (least problematic).

	Recommendation from PhRMA “Special 301” Submission for 2003	Examples of Potential Concerns Related to IP Rights
Argentina	Priority Foreign Country	Pharmaceutical product patents were not allowed until 2000. It has been reported that there is a significant backlog of pending applications directed to commercially significant products. Patent protection for “second uses” of known compounds is not available. Argentine pharmaceutical firms continue to produce and export unlicensed copies of patented products. Industry estimates that the lack of adequate patent protection results in annual losses of \$750 million.
Brazil	Priority Watch List	Inefficient patenting system – the government issued only 2 non-pipeline pharmaceutical patents in 2002, out of 18,000 regularly filed pending pharmaceutical applications.
China	Continued Monitoring	To redress the loss of patent life to regulatory delay, many countries have adopted systems of patent term restoration, giving back to the patent owner some time lost to regulatory requirements. The U.S., Japan and the European Union provide up to five years

		of restoration. No such term is available in China. Growing presence of counterfeit pharmaceutical products. Industry estimates that lost sales are in excess of \$800 million.
Hungary	Priority Watch List	Significant barriers to the effective enforcement of IP rights exist, including weak and inconsistently applied penalties for IPR violations. For instance, it has been found that it is very difficult to obtain preliminary injunctions necessary to stop a counterfeiter.
India	Priority Watch List	Does not currently provide patent protection for pharmaceutical products. India's Patents Office is essentially non-functional, having a backlog of over 30,000 unprocessed applications.
Taiwan	Priority Watch List	Insufficient legislation protecting regulatory data. Reported to have increased activity of counterfeiting of pharmaceuticals.

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