Practice Point

Nanotechnology licence pitfalls

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Never before has the expression 'size matters' contemplated new combinations of nanotechnology and IP rights ('IPR'). Those looking to protect nanotechnology rights face new and unique challenges, especially when it comes to the licensing and transferring of such rights. The following seeks to highlight potential pitfalls and presents strategies for both licensors and licensees when negotiating licence agreements. Savvy licensors and licensees would be well served by understanding these pitfalls in order to avoid liability and to have maximum protection against future events in this exciting and unique field.

'Nanotechnology' has become a major buzz word in the technology sector. Despite its popularity, however, many find it difficult to fathom working on a scale as small as atoms and molecules. Generally, nanotechnology involves the manipulation of extremely small-scale materials and structures which do not exceed 100 nm.[1] To put that into context, the prefix 'nano' means one billionth. Particles being created are thousandths of the width of a human hair. Therefore, the very fundamental atomic structures of nature are becoming available as modular elements capable of being combined and interlocked in much the same way as a child's building blocks. Some of these atomic building blocks may even be capable of inexpensive molecular self-assembly. The potential uses of nanotechnology seem endless.

The future of nanotechnology is therefore both exciting and unpredictable. During the next few decades, scientists in multidisciplinary fields will make numerous breakthroughs in the study and development of atomic and molecular-scale tools and techniques that will affect our everyday lives. The many potential uses for nanotechnology will include materials and devices capable of use in biomedicine, electronics, information technology, environment and sanitation, energy production, lithography, data storage, optics, aerospace, and molecular robotic manufacturing processes, to name a few.[2]

Key issues

- Nanotechnology is an exciting and unpredictable field with a projected value reaching into the trillions of dollars.
- Certain risks which are unique to the field of nanotechnology may develop rapidly and well before the expiration of a licence agreement.
- In addition to the normal issues encountered with conventional licences, savvy licensors and licensees should consider issues such as government ownership, negative impacts of technology, backlog of patent applications at the USPTO, the difficulty of policing infringement when negotiating licence agreements, and the difficulty of reverse engineering.

Currently, the projected market for nanotechnology products and services is around $300 billion. In the near future, however, the value of current and future licence agreements and joint ventures involving nanotechnology will certainly reach into the trillions of dollars.[3] As a result, IP attorneys and executives who prepare and negotiate these agreements face the formidable challenge of anticipating future events and potential risks that may be unique to this emerging technology. These unforeseen events, which may not exist today, can develop rapidly, well prior to the expiration of existing licence agreements, and companies must be prepared to handle the consequences.

In dealing with licences involving nanotechnology, one should not neglect the normal issues encountered with conventional licences, such as remuneration, exclusivity, transferability, fields of use, territory, and duration. However, when granting or accepting a licence involving nanotechnology, one must contem-

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1 *Oxford English Dictionary.*

2 J D'silva. 'Nanotechnology: Development, Risk and Regulation'. British and Irish Law, Education and Technology Association.

3 T Theis. 'Nanotechnology: A Revolution in the Making'. Accessed on 13 October 2008 at http://domino.watson.ibm.com/comm/research.nsf/pages/r.nanotech.defined.html.

plate certain unique technological factors which have the potential to economically affect the parties to a significant degree. Such factors include the difficulties of reverse engineering, government ownership, negative impacts of technology, backlog of patent applications at the United States Patent & Trademark Office ('USPTO'), and the difficulty of policing infringement.

Trade secrets as an alternative to patent protection

Nanotechnology is unique in that it can be very difficult for competitors to discover the underlying technical principles of an invention simply through an analysis of its structure or function. This is because nanotechnology occurs on a scale that is much smaller than what people are accustomed to. As such, nanotechnology-related inventions, in certain instances, can be safe from reverse engineering.

Given the inherent difficulties in reverse engineering technical advances in certain areas of nanotechnology, patent law may not always be the best available method for protecting nanotechnology-related inventions. In general, in exchange for patent protection, the technology must be disclosed for the world to see, and upon expiration of patent rights, patented inventions fall into the public domain. Thus, if a disclosure is not desirable for any number of competitive reasons, an alternative to pursuing patent protection is to treat the advances in nanotechnology as trade secrets, without publishing them in any form.

Trade secret protection involves protecting ideas simply by keeping them secret. It therefore avoids the effort and expense associated with filing patent applications. Protection can remain for as long as the underlying technology is kept secret. One example of a long-standing trade secret is the formula for *Coca Cola*. Trade secret protection, however, requires continuous diligence, since once the technology is revealed, it is no longer protected. Thus, when the likelihood of reverse engineering a nanotechnology invention is small, licensors and licensees should consider protecting their inventions through trade secrets.

When licensing nanotechnology, it is therefore possible to convey nanotechnology trade secret rights under types of licence agreements known as 'material transfer agreements'. Under these agreements, the licensor shares the materials with the licensee, but does not disclose their composition. A material transfer agreement usually involves a contract between two parties that governs the transfer of tangible materials from one party to the other.[4] The agreement provisions define the respective rights, including IP rights, duties, and obligations of the receiving party with respect to the materials and their derivatives. Under a material transfer agreement, therefore, the recipient has the right to practice the technology but is not entitled to and is prohibited from analysing, reverse engineering, altering or otherwise modifying the materials, and further cannot sell, transfer, disclose or otherwise provide access to the materials to another party without the prior written consent of the transferor. As a result, the underlying structure and function of the licensor's invention remains secret.

While suitable confidentiality and non-compete provisions may give owners of nanotechnology similar protection, this route can carry the risks associated with inadvertent disclosure or misappropriation of these secrets. Protecting trade secrets rights under material transfer agreements therefore offers a more protective alternative that allows the recipient to use the technology without requiring the transferor to disclose what is novel or unique about the material.

Another advantage to pursuing trade secret protection as an alternative to patent law protection is that it is often times easier to obtain an injunction for misappropriation under trade secret law. The chances of early success in seeking a preliminary injunction in a theft of trade secret litigation usually can be greater than in a patent infringement action. This is because, in the absence of a prior favourable court finding of infringement and validity of the same patent, courts may not be as willing to issue preliminary injunctions in relatively complex patent cases, thus allowing wrongdoers to continue infringing. However, courts might be more willing to issue a preliminary injunction in a trade secret case. Because of its potential to prevent wrongdoers from benefiting from a misappropriated technology, trade secret protection may be considered as a viable alternative to protecting owners of nanotechnology against infringement.

Governmental ownership and controls

Another factor that owners of nanotechnology should consider is the possibility, however remote, that the federal government may step in and acquire the technology. Under the Bayh-Dole Act, the government as the funding agency has the right to ignore the

4 A Quick Guide to Material Transfer Agreements at UC Berkeley. Accessed 17 October 2008 at http://www.spo.berkeley.edu/guide/mtaquick.html.

exclusivity of a patent and grant licences on the technology to other parties as long as a few criteria are met. This government right is known as a 'march-in' right.[5] Two of the most important criteria are a failure on the part of the licensor to take 'effective steps to achieve practical application of the subject invention' or to satisfy 'health and safety needs' of consumers. During the anthrax attacks in 2001, for instance, the federal government contemplated marching in and acquiring Bayer's patent rights to the drug ciproflaxin in order to benefit the health and safety of the public. Since a great deal of nanotechnology research and development involves military and national defence applications or public health, it is sometimes funded by various US governmental agencies. Governmental agencies involved in the funding of nanotechnology include the National Science Foundation, the National Institute of Health, and the Department of Defense to name a few. Technology resulting from such government funds, in general, can be subject to government march in rights.

The possibility of losing rights in an invention to the government presents significant risks for both licensors and licensees. For this reason, both parties should conduct significant due diligence into the areas of inventorship and the circumstances surrounding inventive contributions. From the licensee's perspective, if the risk of the government acquiring the technology is high, a licensee may not be eager to accept a licence because the licensee could lose the ability to use the licensed technology. In this situation, a licensee should consider paying less for the licence or ask for a termination clause that would provide contingent relief from certain obligations, such as paying royalties, in the event that the government takes ownership.

From the licensor's perspective, if the risk of the government acquiring the technology is high, licensors may find it difficult to license their technology because licensees may not want to risk losing the right to use the technology. As a result, licensors face losing potential revenues under these circumstances. To offset this risk, a licensor may ask for upfront payments to assure itself of some revenue. A licensor may also ask for a covenant not to sue to protect itself from a possible lawsuit by the licensee in the event that the government acquires the technology. Such provisions would protect the licensee's interests in using the technology as well as the licensor's interests in generating revenues.

On the international front, licensors who wish to license their inventions abroad must take additional precautions to protect their patents. Export control laws require that certain dual-use commodities, software, and technology be authorized by the US government before being exported overseas.[6] These export control laws are designed to protect national security and foreign policy. They apply regardless of whether the technology is protected by patents or trade secrets. Since nanotechnology may involve matters of national security, precautions must be taken to ensure that valuable information is not unlawfully disclosed to others abroad.

Thus, to export nanotechnology or other technical information beyond US borders, a licensor should first explore whether the technology falls within a designated category such that the licensor would need to obtain a foreign export licence from the US government.[7] Failure to do so can subject the licensor to penalties, and may risk invalidating patent protection covering such unauthorized disclosures, or in the event of trade secret protection, may result in significant adverse consequences.[8]

An indemnification clause

Putting aside the exciting potential benefits of nanotechnology, the possible and unknown side effects of the technology can further present difficulties for licensors and licensees. Potentially foreseeable side effects include concerns about toxicity, the environmental impact of nanomaterials, and health risks. Health risks may involve adverse properties of nanoparticles. These include 'nano breach', which can include inhalation, ingestion, or topical absorption of nanoparticles, which may reside in foods, creams, and other consumer products. Health risks may also involve accumulations of nanoparticles within lymph and nervous systems, as well as around hair follicles and in tiny skin folds. These latter risks have given rise to robust research and development in the growing areas of nanomedicine.[9] Although there are no cases on record, owners could conceivably face the possibility of liability for the side effects of their technologies.

From a licensee's perspective, a licensee may not want to risk potential liability for unknown side effects. Even though licence agreements often contain rather limited indemnity provisions which typically protect the licensee in the event of a third party claim, licensees

5 35 USC 203.

6 Bureau of Industry and Security. Accessed on 20 October 2008 from http://www.bis.doc.gov/licensing/exportingbasics.htm.

7 35 USC 184.

8 35 USC 185–186.

9 RA Freitas Jr, 'What is Nanomedicine?' (2005) 1 (1) *Nanomedicine: Nanotech. Biol. Med.* 2–9. Accessed on 17 October 2008 from http://www.nanomedicine.com/Papers/WhatIsNMMar05.pdf.

may demand a broader scope of indemnity to cover, for example, unknown health and environmental-related claims. This form of indemnity may require the licensor to defend and hold harmless the licensee should a court find liability.

While licensees would certainly benefit from this expanded indemnity provision, licensors who are not engaged in the actual commercialization of the licensed technology may not want to expand their indemnity obligations beyond strictly IPR-related areas. In other words, licensors may not be willing to indemnify licensees for any health or physical injuries caused by the nanotechnology. Although neither the US Food and Drug Administration nor the US Environmental Protection Agency has fully formulated standards sufficient to guide and address safety issues relating to nanotechnology, ASTM International, an organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services, along with a number of other US and international organizations, has started to publish certain standards relating to the characterization and handling of nanomaterials.[10]

In addition, some cities including Berkeley, CA, and Cambridge, MA, have devised laws to regulate the use of nanomaterials, requiring users to provide information on any known health or safety risks posed by the nanomaterial, and report on how the materials will be handled, stored, and disposed of.[11] To minimize risks and liabilities, therefore, a licensor may choose to incorporate these standards into the licensing agreement as evidence of best industry protocols. Accordingly, as long as the licensor abides by the standards, the licensor may be able to protect itself against liability for unforeseen side effects.

The cross-licensing imperative

The backlog of patent applications at the USPTO presents additional concerns for licensees and licensors. With the number of nanotechnology-related patent application filings increasing every year, the USPTO is experiencing a significant backlog of patent applications, which has slowed down its ability to examine and process patent applications. A quick search of the USPTO patent applications database, using the term 'nano', resulted in nearly 32,000 hits of published patents. Such a high number means that a nanotechnology-related patent application may not be examined for a number of years after its filing and may not be issued for several more years thereafter. In addition, many nanotechnology-related applications awaiting examination may contain a similar or overlapping scope. This is frequently the case in technology areas which are inundated with new discoveries and constant advances. Nanotechnology is particularly susceptible to this problem because nanotechnology spans a number of disciplines, including chemistry, electronics, biology, and physics to name just a few. Therefore, it may be several years before parties will know precisely who owns what insofar as nanotechnology-related patent rights are concerned.

Circumstances in which parties may have similar or overlapping scopes should encourage those parties to grant cross-licences to existing and future patent rights, so as to eliminate, or at least minimize, the possibility of costly future legal battles. One area currently experiencing increased cross-licensing involves nanotubes. Cross-licensing allows the parties to license among themselves patent rights with a promise not to sue one another. Each party may therefore practice the other party's patent rights without infringing them. Such covenants not to sue can decrease the costs associated with fighting infringement suits. Cross-licensing can therefore offer a viable alternative to litigation for companies whose technologies have an overlapping scope.

Cross-licensing may also be a viable strategy for late-comers looking to enter a technical area where there are existing players. For instance, in the area of nanotube technology, there are a few established players with basic patent rights to nanotube technology. If a late comer enters the market, the late-comer may not be able to practise those basic patent rights without infringing the rights of an existing player.

However, if a late-comer enters the market with its own patent portfolio that fences in an existing player's technology, the late-comer may be able to force a cross-licence with an existing player because the existing player may not be able to expand its technology outwards. In return, the late-comer may need to license back its portfolio to allow the existing player to have access to the surrounding technology. The terms of a cross-licence in this situation may be favourable to the late-comer because of the late-comer's superior bargaining rights.

10 ASTM International Standards Worldwide. Accessed on 27 October 2008 at http://www.astm.org/.

11 'Cambridge considers nanotech curbs City may mimic Berkeley bylaws'. *Boston Globe*. Accessed on 20 October 2008 from http://www.boston.com/business/technology/articles/2007/01/26/cambridge_considers_nanotech_curbs/.

Policing and enforcing nanotechnology patent rights

A further concern for licensors and licensees involves the difficulty of policing and enforcing nanotechnology patent rights against possible infringers. Infringing activity of technology on such a small scale can be particularly difficult to observe, analyse, and police not only because of its size, but also because a vast number of new discoveries and improvements are occurring almost daily across multiple disciplines. Monitoring and policing potentially infringing activities may therefore be overwhelming in the light of all the new developments.

To address some of the difficulties facing companies in policing patent rights, companies entering into technology transfer agreements involving nanotechnology should consider including, among other things, mutual cooperation provisions within the agreement

To address some of the difficulties facing companies in policing patent rights, companies entering into technology transfer agreements involving nanotechnology should consider including, among other things, mutual cooperation provisions within the agreement. Mutual cooperation provisions may require the licensor to initially disclose features of the licensed technology to the licensee. Thereafter, both the licensor and the licensee can continually share with one another critical developments, including improvements, advancements, and/or modifications, of the licensed technology.

Such cooperation may allow both parties to better monitor developments not only of their particular technology, but also of competitors' technologies. Thus, if a third party creates a technology with features or functions within the scope of the licensed technology, the licensor and licensee may have an easier time pursuing a cause of action. Mutual cooperation provisions may, therefore, alleviate some of the burdens affiliated with policing patent rights.

Even though policing patent rights may become easier through the use of mutual cooperation provisions, there remain hurdles to enforcing those rights. Adding to these difficulties are the requirements under the Federal Rules of Civil Procedure, as well as a recent US Supreme Court case. Rule 11 of the US Federal Rules of Civil Procedure requires a meaningful form of infringement due diligence on the part of both counsel and client prior to initiating a patent infringement action. In the case of nanotechnology, however, this requirement can become a significant burden because, as noted above, the very nature of small-scale inventions spanning multiple disciplines makes it difficult to determine if a third party is infringing. In addition, a recent Supreme Court decision has increased the difficulty for a patent holder to file a court injunction to stop an alleged infringer from continuing with the infringing action. In *eBay v MercExchange*,[12] decided on 16 May 2008, the Supreme Court held that a permanent injunction will no longer automatically issue upon a finding of patent infringement. Instead, a four-factor test will need to be applied.

Despite these hurdles in alleging infringement, mutual cooperation provisions can alleviate some of the burden faced by licensors in enforcing patent rights. Mutual cooperation provisions, in part, demand that both parties to the agreement cooperate to protect each other's patent rights. In the event of infringement, these provisions may require that both parties participate in gathering evidence and pursuing court action. Such cooperation can lead to the identification of infringing activity early on, before any significant financial or other harm comes to either licensor or licensee. Moreover, when both parties cooperate in a patent infringement action, the likelihood of success in proving a cause of action can be greater. Mutual cooperation provisions can therefore be helpful in policing and enforcing patent rights.

Technology companies and the legal practitioners representing them should consider and incorporate the foregoing factors into their licensing strategies with respect to nanotechnology-related agreements. In this way, the licence agreements resulting from negotiations will provide maximum protection for future events in this exciting and unique field.

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12 *eBay, Inc. v MercExchange, LLC*, 126 S.Ct. 1837, 547 US 388 (2006).