International Patent Protection: Important Considerations and Trends in the Nanotechnology Industry

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ABSTRACT

Many nanotechnology companies have limited intellectual property budgets in the short term, but the potential for global markets for their products and services in the long term. As a result, a coherent and targeted international filing strategy is critical. Here we present an analysis of the relative costs and important considerations related to the pursuit of foreign patent protection and examine trends in foreign filing strategies across the nanotechnology industry.

***Keywords*:** nanotechnology, patent, international, strategy, cost.

1 INTRODUCTION: THE COST OF INTERNATIONAL PROTECTION

Obtaining and maintaining a patent for a single invention in fewer than 10 countries can cost hundreds of thousands of dollars over the life of the patent. [1] Thus, it is not surprising that very few inventions are protected by patents worldwide. However, at least some level of international patent protection is often necessary to provide the competitive edge needed to compete in the global marketplace. Unfortunately, many entrepreneurs in emerging technologies, such as nanotechnology, find themselves faced with the task of developing an international patent strategy on a limited budget with little understanding of the costs and considerations involved in building an international patent portfolio.

This paper describes briefly the mechanics of obtaining patent protection outside of the United States, and compares the cost of filing a patent application in a number of countries in which U.S. inventors frequently file patent applications. This paper further discusses some recent trends in the filing of foreign patent applications by U.S. inventors across all technologies generally and within the field of nanotechnology specifically. Finally, this paper considers a number of factors relevant to the analysis of the need and availability of foreign patent protection for nanotechnology inventions.

2 THE MECHANICS OF OBTAINING INTERNATIONAL PROTECTION

This section briefly discusses the protocol used by U.S. inventors or companies to obtain foreign patents. It is not intended to describe in detail the U.S. or foreign patent laws. Rather, it is intended to provide a broad overview of the steps involved in seeking foreign patent protection.

For purposes of illustration, the mechanics of obtaining international patent protection are described for the typical scenario, in which a U.S. company files a patent application with the U.S. Patent Office. Within one year of filing the initial U.S. patent application, the applicant has the option of filing the application directly in each country or region where patent protection is desired, or filing an "international" patent application under the Patent Cooperation Treaty ("a PCT application"). The filing of a PCT application has the advantage of centralizing the initial review (or "prosecution") of the patent application with a single body. However, once the initial period of review has ended (in the present scenario, 30 months from the filing date of the initial U.S. patent application), the applicant must file the application separately in each country or region (e.g., Europe) where patent protection is desired. Thus, although seeking foreign patent rights through the PCT may create an additional international filing fee up front, it delays the deadline for the payment of the filing fees in each individual country and region. For this reason, many U.S. inventors and companies choose to file through the PCT and, for this reason, the PCT model is used as the basis of the present international patent filing scenario.

The costs associated with prosecuting a patent application through the PCT can be broken down into three categories: (1) the costs associated with the preparation, filing and examination of the PCT application; (2) the cost of obtaining a patent from

NSTI-Nanotech 2007, www.nsti.org, ISBN 1420061828 Vol. 1, 2007

each country or regional patent office after the application has undergone initial examination under the PCT and entered into such countries and regional patent offices; and (3) the costs associated with maintaining the patent (referred to as annuities) in each country. The costs in the first category include governmental and attorneys' fees associated with preparing and filing the PCT application and associated documents, examination of the PCT application by the examiner, and reviewing and responding to communications from the examiner. The costs in the second category include the governmental and attorneys' fees associated with filing the application separately with each patent office, examination of the application by each patent office, reviewing and responding to communications from each patent office, issuance of the patent by each patent office and, if necessary, the associated translation costs. Annuities are fees that are paid to each patent office at set intervals in order to keep the patent in force in each country. If a patent owner decides that a patent is no longer of value, he may discontinue payment of the maintenance fees and allow the patent to expire prior to its full twenty-year term.

Figure 1 illustrates the costs associated with obtaining a patent in various foreign countries, assuming that the application is initially filed as a PCT application, in accordance with the scenario described above. The numbers in the graph represent the three cost categories discussed above. This graph provides only a rough approximation of the costs of obtaining a foreign patent. The costs for obtaining a patent in Germany, the United Kingdom and France are based on the assumption that the application was filed with the European Patent Office and subsequently "validated" in each of these three countries, rather than being filed directly in each of the three countries after the initial examination under the PCT. Thus, the costs listed in category (3) for these European countries includes the cost of validation (and for Germany and France, translation) as well as annuities. The present scenario assumes that examination of the patent application goes smoothly and is based on typical fee schedules supplied by foreign associates. However, the fees charged by U.S. and foreign attorneys can vary significantly and the governmental fees and exchange rates upon which these calculations are based are subject to change. In addition, the governmental fees for a patent application are affected by the size and number of claims in the application. For purposes of illustration, the costs in Figure 1 assume a 30-page patent application with 25 claims and 5 pages of figures.[i] The costs may increase for patent applications that differ significantly from these parameters. For these reasons, the costs shown in Figure 1 are, at best, rough estimates and may, in some cases, significantly under-represent the actual cost of obtaining a particular patent in a given country.

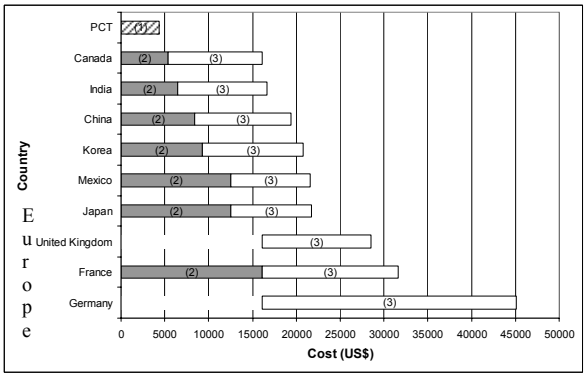


Figure 1

3 INTERNATIONAL FILING TRENDS

When deciding in which countries to file foreign patent applications, one may obtain some guidance by analyzing international filing trends.

Statistics for the number of patent applications filed with patent offices around the world are published yearly by the World Intellectual Property Organization (WIPO), the international body responsible for administrating the PCT. In the most recent report, which includes statistics through the end of 2004, WIPO reported that the six most popular countries or regions in which to file patent applications (determined by the number of non-resident filings) are the United States, Europe, China, Japan, Canada and Korea. [2]

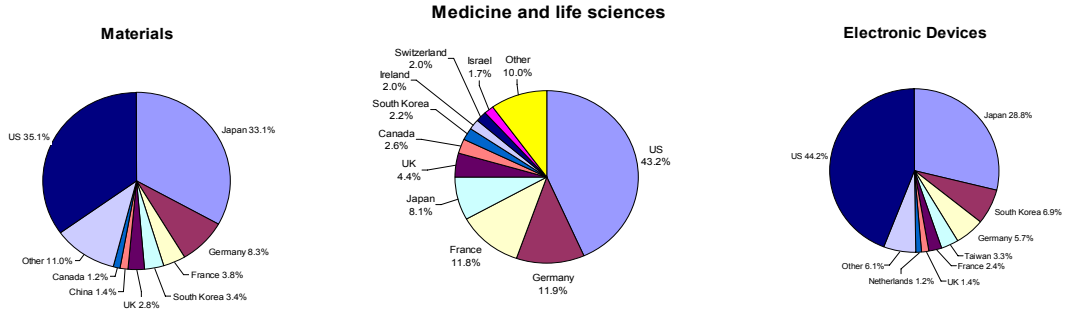
A recent article based on data collected by the Nanotechnology Researchers Network Center of Japan[ii] notes that trends within nanotechnology differ from the general trends reported by WIPO. [3] This article provides an analysis of nanotechnology patent filing trends based on country and technical field. Nanotechnology patents were identified from the list of patent publications released by international patent offices using a keyword search, followed by screening to confirm that the claimed subject matter was, in fact, nanotechnology-related. Nanotechnology-related patents included those dealing with: the development or alternation of materials at the atomic or molecular level; manipulation or processing at the nano-scale; and the use of nanotechnology techniques. The patents were then classified by application. The results are provided in figure 2, which shows the percentage of nanotechnology patent applications filed in various countries for the three largest applications –

materials, medicine and life sciences, and electronic devices.

Not surprisingly, the countries in which nanotechnology patent applicants choose to file patent applications vary significantly depending upon the nature of the invention. In the areas of materials and electronic devices, filings in the U.S. and Japan account for a large majority of worldwide patent filings. U.S. patent filings also dominate the patent landscape in the area of medicine and life science, followed by filings in Germany and France.

Of course, while statistics regarding international filing trends may provide some basic level of guidance, the appropriate international filing strategy for any particular patent application will depend on the specific nature of that application. With this in mind, the remainder of this discussion focuses on some important factors to consider when making decisions about filing foreign patent applications.

Figure 2



4 INTERNATIONAL FILING CONSIDERATIONS

Critical to the development of a coherent international filing strategy is an understanding of the scope of protection offered by a patent. A patent provides the right to exclude one's competitors from making, using, selling, offering to sell, or importing a patented product or process in the territory covered by the patent. In addition, a patent confers the right to prevent one's competitors from importing a product made by a process patented in the territory covered by the patent, even if the product itself is not covered by a patent in that territory. In assessing the value of these rights, the owner of an invention needs to consider a variety of business, legal and practical factors.

Business Factors: Perhaps the most important business factors in determining where to file a patent application are the location and size of current and future markets for the patented technology. When assessing the value of a potential future market, it is important to remember that a patent has a limited 20-year term. In addition to pursuing protection in countries having a market for the technology, patent applicants should consider pursuing protection in countries in which the technology is likely to be manufactured, distributed, marketed or transported, either by the patent owner or the patent owner's present and future competitors.

Other important business considerations include whether the patented invention represents core technology for which exclusivity is highly desirable or necessary for a successful business venture; how easily a competitor could design around the patented invention; how easily a competitor could copy the invention in the absence of patent protection; how easily infringement of the patent could be detected; and the likely life-span of the technology.

Legal Factors: Although the patent laws of most industrialized countries and the 120+ PCT member countries, are similar in many respects, some important differences may affect an applicant's ability to obtain protection for an invention from country to country.

One such difference is the effect of public disclosure on patent rights. The United States provides a one-year grace period for an inventor to file a patent application after the first public disclosure of the invention. Although a few other countries also offer grace periods under certain very limited circumstances, most countries do not offer patent protection for inventions that have been publicly disclosed prior to the filing of a patent application. Prior public disclosures are frequently an issue for inventions developed at universities and other non-profit institutions. Therefore, any nanotechnology company that licenses an invention from a university or non-profit should verify the availability of foreign patent rights up front.

Restrictions on patentable subject matter also differ among countries. The U.S. patent statutes are quite liberal with regard to which types of inventions may be patented. Other countries are more restrictive. Examples of subject matter for which patent protection is not available in all countries include methods of medical treatment, business

NSTI-Nanotech 2007, www.nsti.org, ISBN 1420061828 Vol. 1, 2007

methods, software, and some types of biotechnology. While none of these subject matter areas is generally applicable across all sectors of nanotechnology, specific applications of nanotechnology could fall under one of more of these categories. For example, patents claiming methods of treating or handling embryos using micro- or nanofluidic devices may be difficult to obtain in countries or regions, such as Europe, that restrict the right to patent methods of medical treatment.

Notably, there is at least one instance where foreign patents may be helpful or even necessary to protect the rights to an invention patented in the U.S. This instance involves patents claiming methods for screening or identifying compounds, analytes and the like, where the result of practicing the method is "information" rather than a "product." In *Bayer AG v. Housey Pharmaceuticals* 340 F.3d 1367 (Fed. Cir. 2003), the Court of Appeals for the Federal Circuit (CAFC) held that the section of the U.S. patent code that provides for an infringement action against a party that imports a product into the United States that is made by a process patented in the United States is limited to the importation of physically manufactured goods and does not apply to the importation of information generated by a patented process. Thus, for inventions involving methods of producing information (e.g., methods of using certain nanodiagnostic devices), consideration should be given to obtaining patents in countries possessing the technological infrastructure and capabilities for carrying out the methods.

Practical Factors: In addition to the business and legal considerations discussed above, myriad practical matters should be considered when deciding whether to file a patent application in a given country. These include the ability to enforce a patent in that country, the competency and efficiency of the country's patent office, the regulatory environment of the country, and the country's level of industrialization. A detailed analysis of these practical considerations is beyond the scope of this discussion. However, an assessment of these and other factors is presented in the General Accounting Office's Report to Congressional Requesters on International Trade: Experts' Advice for Small Businesses Seeking Foreign Patents ("the GAO Report"). [1] Based on this assessment, the report lists Australia, Canada, the Netherlands, the United Kingdom, and the United States as countries with patents of "high practical value." Belgium, Finland, France, Germany, Ireland, Israel, Italy, Korea, New Zealand, Singapore and Sweden are listed as countries with patents of "medium practical value." Included among those countries reported to have patents of "low practical value" are several South American countries, several European countries, China, India, Japan and Mexico. Of course these practical factors are highly subject to change over time. In fact, at the time the GAO Report was published, China and Japan were already taking significant steps to improve the value of their patents. More recently, India has begun undergoing significant patent reforms. Therefore, if the business and legal considerations described above weigh in favor of obtaining a patent in a country with a low practical value rating, it may be worth the cost of filing in that country. Indeed, Figure 2 and the discussion in section 3, above, indicate that many patent applicants believe this to be the case.

5 CONCLUSIONS

The decision to seek patent protection outside of the United States involves many factors, including cost, business strategy, international patent laws, and practical considerations. While an exhaustive analysis of these factors is beyond the scope of this paper, it is hoped that the preceding discussion provides a basic framework within which to begin developing a coherent foreign patent strategy.

REFERENCES

[1] United States General Accouting Office Report to Congressional Requestors, GAO-03-910 (June 2003).

[2] WIPO Patent Report, Statistics on Worldwide Patent Activities, published by the World Intellectual Property Organization (2006).

[3] Daisuke Kanama, *Patent Application Trends in the Field of Nanotechnology*, 21 Science & Technology Trends Quarterly Review 77 (Oct. 2006). Available at: http://www.nistep.go.jp/achiev/ftx/eng/stfc/stt021e/qr21pdf/STTqr2105.pd

[i] The number of claims in the Korean and Japanese patent applications was reduced to 5 because these countries impose a heavy fee per claim.

[ii] The Nanotechnology Researchers Network Center of Japan is part of the Nanotechnology Support Project of the Ministry of Education, Culture, Sports, Science and Technology.