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BRICs Bound? Bring Protection! Tips on Obtaining a Granted Patent for Medical Devices

Filing a patent in Brazil, Russia, India or China may not be simple, but it is a vital step in protecting your intellectual property.

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Brazil, Russia, India and China—known collectively as the BRICs—are increasingly important markets for medical device companies. However, many of these companies are rightly concerned about theft of their valuable intellectual property (IP) in these countries. The most common form of protection for innovative medical devices is a patent. A granted patent is a territorial legal right that enables the holder to exclude others from practicing, manufacturing and selling the invention claimed in the patent within the relevant territory. Thus, in order to obtain patent protection, it is necessary to file a patent application in each country of interest, while prosecuting each application to grant (taking all necessary steps to obtain a granted patent).

To obtain patent protection in the BRIC countries, it is necessary to file a patent application in Brazil, Russia, India and China, and to prosecute the application to grant of a patent.

Many medical device companies are wary of the process, but with the help of an experienced patent agent/attorney, the process can be completed relatively smoothly. Here are a few of the key issues companies should



consider when obtaining patent protection in the BRIC countries.

How much will it cost?

Budgeting for international patent costs can be challenging, given the differences between the patent systems and requirements of the BRIC countries. Some important aspects include the relatively high cost of filing a patent application in China, Brazil and Russia because of translation expenses. Any responses to enquiries from the examiner (office actions) also will have to be translated, thus raising the cost of prosecution. In our experience, this means that the cost of filing and obtaining a patent in these three countries is similar to what it

costs to obtain a European patent and a little more than in the United States.

India is an exception. Patent applications are filed and prosecuted in English. Furthermore, filing and prosecution costs in India are quite reasonable, lower than costs in Europe.

How long will it take to obtain a patent?

Once granted, patents have a lifetime of 20 years from the date when the original patent application was filed

(with some exceptions in a few countries). However, because of constant technological improvements and developments, the life cycle of a medical device is typically shorter than 20 years. Therefore, when filing a patent application, it is important to consider the length of time a granted patent could protect your medical device.

For example, if a patent application only protects a particular iteration of the medical device, with an expected post-approval market lifetime of five to 10 years, it may be important to avoid lengthy prosecution and reduce costs.

One important point involving the BRIC countries is that it is possible to speed up prosecution—and obtain a patent more

quickly—if examination is requested as soon as possible. For example, examination may be requested in Brazil 60 days after publication (which occurs 18 months from the priority date) and must be requested before 36 months have elapsed from the filing date. (If filing is performed through the Patent Cooperation Treaty application process, publication would occur after entry to the national phase.) Clearly, requesting examination as soon as permitted accelerates consideration of the application by the Brazilian examiner.

On the other hand, Brazil has a significant backlog of unexamined applications. It has been estimated that this backlog can cause delays of up to six to seven years in obtaining a granted patent. This delay compares very unfavorably with the European Patent Office, which has a delay of about four years. However, the entry of an application to the examination “queue” depends upon when examination is requested, so requesting examination as early as possible would reduce the overall delay of the start of examination from the date of filing of the application.

Prosecution delays in China, meanwhile, are at least no longer than at the European Patent Office, while delays in India are rising significantly. (A dispute between Indian examiners and the Indian Patent Office will cause delays to increase through 2012.) China has a utility model option, similar to Germany, which offers a lower cost, more rapid method of obtaining protection for a medical device, although the scope is narrower than what is covered by a regular patent. Thus, when selecting countries in which to file your medical device patent application, it is important to consider any prosecution delays.

Are there any postgrant requirements?

Apart from the requirement to pay regular (typically yearly) fees, some of the BRIC countries also have postgrant requirements that must be fulfilled to avoid cancellation of the granted patent. India, for example, requires filing of a yearly postgrant statement of working, describing the commercial

exploitation in India of the invention disclosed in the patent. If commercial exploitation does not occur within three years of receiving the granted patent, a third party could request a compulsory licence of the patent. Selling the medical device in India, directly or through a licensee, may be sufficient to fulfil this requirement.

What about enforcement of a granted patent?

Patent enforcement can be arduous and expensive regardless of the country involved. The BRIC countries can be particularly difficult for a number of reasons.

First, these countries typically have a much shorter history of patent case decisions (as opposed to European countries or the United States, for example) or may, in fact, lack a case law tradition. In England, the earliest patent law (Statute of Monopolies) was passed in 1624, whereas China's earliest patent law dates all the way back to . . . 1984! China also lacks the tradition of following previous court precedents, known as *stare decisis*, so that earlier decisions by Chinese courts may not be seen as binding on subsequent court cases. Brazil only implemented *stare decisis* in 2004, through a constitutional change. Russia now follows *stare decisis*, at least since 1994. Therefore, these countries do not have the same long history of case law that can guide patent owners as to the likelihood of success for patent enforcement.

Another concern of many patent owners is whether extraneous factors may affect court decisions in the BRIC countries. On the one hand, the BRIC countries have acceded to—or indicated their desire to accede to—international trade standards such as the TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement, which places significant requirements for IP enforcement on member countries. On the other hand, laws or actual court practice in these countries are viewed with concern by foreign patent holders.

Brazil, for example, provides for various exemptions to patent grant and enforcement for pharmaceutical patents. The International Chamber of Commerce (ICC)

conducted a survey in 2007, which found that China and Russia were perceived to have the least fair enforcement systems.¹ In India, Roche received a patent for its anticancer drug, Tarceva, and attempted to obtain a preliminary injunction against Cipla in 2009. This was denied on the basis of apparent invalidity of the patent protecting Tarceva (even though Cipla had lost in opposition proceedings in an attempt to invalidate this patent).

Patent enforcement in the BRICs can only improve

Overall, however, perhaps the most important point to consider is that the owner of an invention has no protection in the BRIC countries if a patent application is not filed and prosecuted to grant. Furthermore, the law in these countries is evolving under the influence of local companies attempting to protect their innovations (most patent disputes currently in litigation in China involve Chinese companies, for example) and international pressure from TRIPS and other international standards. Since the life of a patent extends for 20 years from the date of filing, the ability to enforce a patent in the BRIC countries may actually increase over the patent's lifetime.

Patents are a powerful tool for protecting a business from competitors and carving out a global market, including in the BRIC countries. A proper understanding of the process will help companies save money while obtaining the coverage that suits individual business needs and capabilities.

1. A. Bhalla, P. Jha and J. Lampel, “Global Survey on Counterfeiting and Piracy,” ICC (International Chamber of Commerce) Business Action to Stop Counterfeiting and Piracy (2007), published in conjunction with the Cass Business School of the City University of London online at www.iccwbo.org/bascap/id892/index.html.



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