Medical Design

International patents pose challenges

Editor's note: The following is the second part of a two-part series on patents. This month, the authors discuss the ins and outs of US foreign patents. The first part on US patents appeared in the May issue, and this second part will address foreign patents.

Few modern businesses design, manufacture, and sell their product only within the borders of a single country. For many companies, the development of an innovative product may originate in the US, but the product may be refined and manufactured in China, for sale ultimately in Europe or South America. It is thus imperative to recognize that modern business is international and that imitations of innovative products may surface in any part of the world.

Unfortunately, the patents protecting innovative products are far more provincial. A US patent cannot be used to stop production of an imitation in China, or sales in Europe or South America. The protection afforded by a US patent generally ends at the US border. If you wish to stop an imitator operating in China, Germany, or Brazil, you need a patent issued by the government of that particular country.

Similarities and differences

The fundamental nature of a patent is relatively constant throughout the world. It provides the patent holder with the right to seek legal intervention against another party to stop them from using, manufacturing, or selling a patented product or practicing a patented method. The intervention might also result in the infringer having to pay the patent holder monetary damages for their activity.

Written by: Patrick D. Ertel and Paul C. Craane,
Partners
Marshall, Gerstein & Borun LLP, Chicago
marshallip.com

Edited by: Joe Jancsurak
joe.jancsurak@penton.com

ARTICLE FOCUS:

- Similarities and differences
- Applying for protection
- Disparate treatment

Similarly, all countries will perform some review of the patent application to ensure that it meets certain formality requirements imposed by that country's laws prior to issuing a patent. Most countries will require that the patent application, and in particular the claims of the application, meet a fundamental threshold of novelty and inventiveness. Certain countries, most notably South Africa, will issue a patent without an examination as to novelty and inventiveness, but these countries are in the minority.

Of course, specific legal standards vary. For example, the US permits a one-year grace period for seeking patent protection following certain actions taken by the applicant or by others. However, many countries have no such grace period. Others have a grace period that applies only to the applicant's actions, and/or only to actions taken within a shorter time period (e.g., six months). In fact, the US may soon join those countries permitting a grace period only for the applicant's actions. There are also considerable differences in the threshold for inventiveness among the various countries of the world.

The availability and speed of enforcement may also differ on a country-by-country basis. A patent is not a self-executing form of protection; rather, enforcement must be sought through the appropriate legal authorities. In this regard, Germany has a remarkably swift and efficient mechanism for resolving patent disputes. On the other hand, many foreign companies continue to find China a difficult country in which to enforce patent rights, although this situation is changing. In extreme cases, Brazil has been known to suspend patent enforcement rights altogether for matters of public health and safety.

Another way in which patent systems differ is with regard to the availability of options for protecting a product beyond the traditional patent. These legal alternatives may be issued for meeting a lesser threshold than required for the traditional patent or without any examination at all, but may have a shorter life or other limitations that must be considered in deciding whether the protection will be adequate in a particular circumstance. Whether referred to as a utility model or an innovation patent, these mechanisms may provide patent strategies not available under US law.

Applying for patent protection abroad

It is not a requirement to have a foreign commercial presence or foreign inventors to apply for a patent outside the US. In fact, international treaties and conventions have been established to level the playing field for domestic and foreign applicants. For instance, there are conventions and bilateral

agreements that permit a US applicant to rely upon its US filing date when determining the novelty and inventiveness of the innovation, if a foreign application is filed within one year of the US filing date. The availability of the US filing date can be important. As noted above, different countries have different approaches as to whether a grace period will be permitted as to actions taken by the applicant.

Typically, applying for foreign patent protection is a focused, targeted undertaking for all but the most unique and valuable products because of the costs involved. While it is not necessary to prepare the patent documents from scratch for each new foreign filing, there still will be fees due to the local government and to local legal professionals who will handle the filing. Moreover, many countries will require that the patent application be translated into the local language, and that correspondence with the patent office be conducted in that language.

One mechanism used to control the costs of the application process is the international, or Patent Cooperation Treaty (PCT) application. The international application permits an applicant to keep the door open in almost all countries for up to 30 or 31 months from the effective filing date, which may be the earlier US filing date mentioned above. The additional time may be significant in permitting the applicant to determine whether the innovative product or method will be commercially viable, or in which countries the product will be manufactured and sold or the method practiced.

On the downside, the international application cannot mature into an international patent. At some point, the international application must be converted into national or regional patent applications to secure patents in selected countries. Moreover, while some of the costs of the PCT process will be recovered when filing those national or regional applications, other costs cannot be recovered.

Another mechanism used to control costs is the regional patent application, of which the most well-known is the European patent (EP) application. Like the international application, the EP application will not result in a patent that is automatically enforceable in all member nations. Thus, while an EP patent can be obtained through examination carried out by a single authority, the European Patent Office (EPO) the patent must be validated or nationalized in each member country in which the applicant wishes to have protection.

The examination of the EP application can be carried out entirely in English, however, which has many benefits in keeping the costs of the examination process down for US applicants. As a rule of thumb, if protection is desired in three or more European countries, the cost of filing and prosecuting an EP application followed by national validation may be less than the costs of filing and prosecuting national applications directly in those countries.

Disparate treatment impacting devices and methods

Medical treatments, like computer software, is a topic on which countries of the world have agreed to disagree. As a consequence, what may be patentable in the US may not be patentable in Europe. Even when a country might permit a patent to be issued, the patent may not be enforceable against all parties.

For instance, if protection is sought not on a medical device, but on the method of carrying out a procedure using the medical device, protection may be difficult or impossible to obtain in Europe because methods of medical treatment are generally considered to be unpatentable. By contrast, methods of medical treatment are generally patentable in the US, but enforcement against an individual medical practitioner may not be possible. To illustrate why such limitations might be important, consider a medical device that is well-known and in the public domain, but for which a new method of use has been discovered. Under European law, this method may well be unpatentable; under US law, the method may be patentable, but enforcement may be complex.

Similarly, consider a situation, not uncommon to many medical devices, where the basic structure and operation of the device are known early on, but the exact details of the commercial device may not be known for some time. Caution may suggest filing early even though the exact details of the commercial device are not yet known so as to prevent applicant's own activity from becoming a problem relative to the validity of any patent to issue from the application.

In the US, it may be possible to change or adapt the language of the claims later in the process to attempt to cover the basic device disclosed and the later-developed commercial device. By contrast, European laws (as presently applied) may make later alteration of the claim language difficult, if not impossible. Moreover, because of recent changes to the European application process, it may be more difficult to maintain a European application pending to address later developments than is possible under US practice. Consequently, differences in US and European practice may lead to different levels of patent protection being available for the same product in different countries.

Patrick D. Ertel
Partner

Paul C. Craane
Partner

MARSHALL GERSTEIN BORUN LLP