A PROTOCOL FOR TRADEMARK PROTECTION:

The Madrid Protocol offers companies another option for trademark registration on a global scale.

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For pharmaceutical and biopharmaceutical companies, a patent may be the most important intellectual property tool for protecting innovations, but it's not the only one. Patents protect the formulation and manufacturing process of drugs, but they eventually expire. Trademarks, however, protect names and brands. And, they can "live" as long as the owner uses the mark. Therefore, while a competitor may start producing the same biologic, a trademark can ensure brand recognition – and confer a sales advantage worth perhaps millions of dollars – for the innovator company.

Many countries have laws affording trademark rights based on a "first-to-register" system (the US recognizes rights based on a "first-to-use" system). Even if a company has been using its trademark extensively in one of the many first-to-register countries, halting an infringer may not be possible until the company obtains a trademark registration in that country. What's more, if an infringer is the first to register the trademark in that country, then infringer may be permitted to continue using the trademark and prevent the other company from using it there.

With the Madrid Protocol, trademark owners in the United States have a new option for obtaining and maintaining foreign trademark protection that is designed to make filing and post-registration procedures easier and more cost efficient. While applicable to trademark owners in all industries, the Madrid Protocol offers benefits of particular interest to pharmaceutical and biopharmaceutical companies – especially since counterfeiting and foreign competition continue to concern many in the industry. In fact, three of the top five users of the Madrid Protocol and the related Madrid Agreement in 2003 were pharmaceutical companies: Novartis of Switzerland (#2), France-based Sanofi-Synthelabo (#3), and Janssen Pharmaceutica in Belgium (#5).

The National Approach

Traditionally, trademark protection is sought through national trademark applications on a country-by-country basis with obstacles and costs encountered each step of the way.

First, the trademark owner must employ a trademark attorney in each country of interest because trademark offices usually correspond only with local attorneys. Then the owner must correspond with each attorney to provide information, such as filing instructions, for each trademark. Normally there is correspondence confirming details, such as the specific goods or services that will be protected.

This process is plagued with communication and translation problems, significant backlogs at trademark offices, and foreign exchange difficulties arising from the onslaught of invoices in

various currencies. Furthermore, to maintain, renew, or record a change in ownership, name, or address for each trademark registration, the whole process must be repeated for each trademark in each country.

Despite its problems, this national approach is still commonly used by trademark owners to obtain foreign protection. In some countries, it may be the *only* option.

International Registration

Due to the many hurdles of the national approach and the increasing importance of registering trademarks abroad, the international community developed several registration alternatives: the Madrid Agreement, the Madrid Protocol, and the Community Trademark system.

The Madrid Agreement was designed to make it easier for trademark owners to file foreign trademark applications and maintain foreign trademark registrations worldwide. More than 50 countries use the Madrid Agreement, an international trademark system launched in 1891 and overseen by the World Intellectual Property Organization (WIPO) in Geneva. If a trademark owner belongs to a country that is a member of the Madrid Agreement, the owner can file a single application to seek protection of a trademark in other Madrid Agreement countries and renew and maintain the resulting registrations through WIPO.

The Madrid Agreement has its quirks though, and consequently, many countries (including the US) have refused to join. In an effort to attract those reluctant countries — without disturbing the practices of those using the Madrid Agreement for more than a hundred years — the international community developed the Madrid Protocol of 1996. The Protocol functions much like the Agreement: trademark owners from a Madrid Protocol member country can file a single application for trademark protection in other Madrid Protocol countries and renew and maintain resulting registrations through WIPO. On November 2, 2003, the United States became the fifty-ninth country to begin using the Madrid Protocol.

The principal goals of the Madrid Agreement and Madrid Protocol are to facilitate filing and maintenance. However, filing does not equal registration. That step remains subject to the same hurdles as registration using the more cumbersome and time-consuming national approach. After an owner files an application, WIPO forwards the information to the designated countries. The countries then decide whether to permit registration using the same procedures and criteria normally employed for an application not submitted via the Madrid Agreement or Protocol. Although both the Madrid Agreement and Protocol impose time restrictions to expedite the examination process, neither make it significantly more likely that a trademark will become registered in the desired countries.

The Community Trademark system allows trademark owners to file a single application to afford protection throughout the entire European Union. The application is reviewed by the Office for Harmonization in the Internal Market (OHIM); trademark offices in the individual EU countries are not involved in the examination or registration process.

Interestingly, OHIM will register a trademark without evaluating whether the trademark is likely to conflict with other Community Trademarks or those registered in European Union countries; instead, owners are encouraged to monitor Community Trademark applications and to submit an opposition if they object to registration.

The EU has taken steps toward joining the Madrid Protocol, and many believe that by the end of 2004, trademark owners will have the option of obtaining a Community Trademark through the Madrid Protocol or the option to use the Madrid Protocol based on a Community Trademark application or registration.

Madrid Protocol Registration

Step 1. You must own an active application or registration for the trademark in a Madrid Protocol member country. This country must also qualify as the owner's "country of origin" (where the owner is domiciled, is a national, or has a real and effective commercial establishment). This initial filing is referred to as the "basic application" or "basic registration."

It is important to note that the Madrid Protocol permits the owner to obtain protection solely for the identical trademark and for the same or narrower goods or services as covered by the basic application or registration. For example, a US-based company may use the Madrid Protocol if it owns a US application or registration for the same trademark it wants to protect abroad.

Step 2. No matter how old the basic application or registration is (as long as it is still active), the owner may apply to protect that trademark abroad by submitting a Madrid Protocol "International Application" in English, French or Spanish through the trademark office in its country of origin. The International Application must include the details of the basic application or registration, and it must specify the member countries where it desires protection.

For example, a US company that owns a US trademark registration may submit an International Application based on it. The company can complete the application in English, check the boxes corresponding to the countries where protection is sought, file the application with the US Patent and Trademark Office (USPTO) and send payment for the USPTO and WIPO fees. Because the USPTO has postponed the launch of its Madrid Protocol-related electronic forms until November 2, 2004, US companies must download the International Application form from WIPO's website.

If the owner previously has registered the trademark via the Madrid Protocol and now wants to expand its registration to cover additional member countries, the company can file a Request for Subsequent Designation form (similar to the International Application) with WIPO.

Step 3. Upon receipt of the International Application, the trademark office in the country of origin checks that it was completed properly. If no irregularities are found, the trademark office forwards the application to WIPO.

If anything is missing, the trademark office will notify the owner that the form has been rejected and refiling may be required.

- **Step 4.** Once WIPO receives the International Application or a Request for Subsequent Designation, it performs a review to ensure the owner has complied with all formalities, including payment of WIPO's official fees. If WIPO detects any irregularities, it notifies the owner, who usually is given three months to respond.
- **Step 5.** Once WIPO is satisfied that there are no irregularities in an International Application, it will promptly issue a registration date and number. Although the registration is not yet in effect in any country, the owner is said to own an International Registration. The International Registration date and number is published in WIPO's official gazette. Generally, this

registration date is backdated to the day of filing of the International Application — unless the originating trademark office took more than two months to forward the International Application to WIPO. Trademark rights also can be backdated under a "priority claim." This may be possible if the basic application was filed within the six months prior to the filing of the International Application.

If the owner files a Request for Subsequent Designation, then an International Registration date and number already exist, so WIPO does not issue new ones. The Request potentially entitles the trademark owner to rights in the countries designated in that Request dating back to when WIPO received the Request.

Step 6. WIPO then forwards a Request for Extension of Protection to the trademark office in each country designated by the owner in the International Application or Request for Subsequent Designation.

Step 7. Once each designated trademark office receives the Request for Extension of Protection from WIPO, it is given the chance to examine the Request in accordance with that country's usual procedures and decide whether to permit the International Registration to take effect there. The Request is treated just like a regular, non-Protocol application in that country and is subject to that country's usual trademark prosecution process, including publication and opposition by others.

If a trademark office does not issue a refusal within a certain period of time (either 12 or 18 months, depending on the country, and unless the trademark office notifies WIPO that more time is needed because of another party's potential opposition to the mark), then the International Registration is automatically deemed to have effect in that country. If the Request is refused or opposed, then the owner must employ a local attorney to respond.

Step 8. To update an International Registration to reflect transfers of ownership or changes in owner name or address, the trademark owner can file a simple form with WIPO. This is a significant advantage of the Madrid system, saving the trademark owner the task of recording the change in each country (sometimes with special proof of the change).

The trademark owner must file a single renewal form with WIPO every ten years from the International Registration date to maintain an International Registration. This presents an enormous advantage over national registrations because the trademark owner does not have to file a renewal in each country. As long as the International Registration is maintained, the trademark owner can expand the International Registration's geographic scope of protection at any time by filing a Request for Subsequent Designation.

Some countries – such as the US – complicate matters by imposing their own maintenance requirements. For example, if a Norwegian company owns an International Registration that has been extended to the US, then in addition to renewing the International Registration on every tenth anniversary, the company must then also file a Declaration of Use with the USPTO by the sixth anniversary – *and* on every tenth anniversary – of the USPTO's acceptance of the International Registration.

Dependency and Central Attack Principles

The International Application and resulting International Registration are dependent upon the basic application or registration until the fifth anniversary of the International Registration date.

If anything changes the basic application or registration during the five-year dependency period, then the same modifications affect the International Application or Registration. If such change occurs, the trademark office in the country of origin will notify WIPO, and the change will be incorporated in the International Application or Registration and all related Requests for Extension of Protection.

Sometimes the change may be severe, such as the termination or cancellation of the basic application or registration. If either of these "dies," then the International Application or Registration and related Requests for Extension of Protection die too.

This presents a unique opportunity for parties to challenge the owner's registrations. By successfully attacking the basic application or registration before the fifth anniversary of the International Registration date (a strategy referred to as a central attack), a party simultaneously and automatically cancels the entire International Application or Registration.

Although the Madrid Protocol (but not the Madrid Agreement) permits the trademark owner to convert a terminated International Application or Registration into national applications, the trademark owner must pay more filing fees for the new national applications and return to the beginning of the national trademark prosecution process

Strategy Considerations

The dependency period and potential for central attack lead many owners to question whether the Madrid Protocol is preferable to other methods of trademark registration. Indeed, the decision to use the Madrid Protocol requires consideration of complex legal and business issues and strategies.

In order to use the Madrid Agreement, the trademark owner's country of origin must be a member of the Madrid Agreement, and the country in which protection is sought also must be a member. To use the Madrid Protocol, similar membership rules apply. The Community Trademark, however, can be utilized by owners who are not EU members, but it is not an option if protection is desired in a country outside of the EU.

Because the US is not a member of the Madrid Agreement, most US companies cannot seek protection using the Madrid Agreement (unless they have a qualified foreign office). Furthermore, although the US is a member of the Madrid Protocol, a US company cannot use it to seek protection in Canada, for example, because Canada is not a Protocol member country.

While the list of members continues to grow, many countries (notably Canada, Mexico, and all Central and South American countries) are not yet members of the Madrid Protocol. Canada may have difficulty joining because it does not classify goods and services using the widely adopted Nice International Classification scheme. Many have speculated that Mexico and the countries in Central and South America were reluctant to join because Spanish was not an official language of the Protocol. Since Spanish became an official Protocol language in April, it will be interesting to see whether these countries join.

Transferability Issues

In order to assume ownership of an existing International Registration (or part thereof) that is governed by the Madrid Protocol or Madrid Agreement, one's country of origin must be a member of the Madrid Protocol or Madrid Agreement. This restriction affects the transferability

of trademarks, thus consideration should be given to whether the owner's trademarks may be transferred in the future. The potential problem is illustrated by the following example.

A US company is under a license agreement for a biologic therapy with a Canadian company, and the US company owns the trademark for that therapy. The US company obtains a US registration for the trademark and then wants to seek foreign protection. The US company can obtain protection in certain foreign countries by obtaining an International Registration through the Madrid Protocol, but the US company must file a national Canadian trademark application to obtain protection in Canada (because Canada is not a Madrid Protocol member). Furthermore, if the partnership changes so that the Canadian company wants to assume ownership of the trademark, the US and Canadian registrations can be assigned to the Canadian company, but the International Registration cannot (because Canada is not a member of the Madrid Protocol).

Trademark Permanence

When contemplating using the Madrid Agreement or the Madrid Protocol, one should consider the length of time the mark will be used, the potential for changes to the mark, the likelihood of ownership information changes, and how the mark will be used in other countries.

By filing for protection using the Madrid Protocol and Agreement systems, the trademark owner typically enjoys some up-front cost savings in contrast to national filings (with the amount saved increasing with the number of countries in which protection is sought). However, the most significant cost savings will arrive ten years later — when the trademark owner renews the International Registration instead of renewing registrations in individual countries. Therefore, substantial cost savings may be realized only if the trademark owner is going to be interested in the trademark for more than ten years.

Similarly, the Madrid Protocol and Agreement systems provide cost-effective ways to update changes to ownership information (through WIPO rather than having to record the update with each country). Accordingly, if the trademark owner is likely to be moving, changing its name, or transferring ownership of its trademarks, then the Madrid Protocol or Agreement systems may be preferable to national filings (unless transfers are likely to be made to companies in countries that are not members of the Madrid Protocol or the Agreement).

Trademark owners should also consider whether they are likely to make any alterations to the trademark and whether it will be used identically in foreign countries. While many countries permit owners to amend a registered trademark if the change is not material, trademark owners are not allowed to make any amendments (no matter how minor) to their trademarks under the Madrid Protocol and Agreement. Consequently, if the trademark owner expects that the trademark may change slightly over time, national filings may be preferable.

In addition, national filings may be preferable if the trademark will appear differently in some countries. For example, some companies may present their trademarks in English in the US while presenting the marks in Katakana in Japan. Such differences in the appearance of a trademark cannot be incorporated in a single International Application.

Impact on the Industry

It is clear that the US's accession to the Madrid Protocol will impact trademark owners in the biopharmaceutical industry. Some may be affected by the ease with which US companies now can seek protection abroad, while others may be affected by the influx of Requests for Extension

of Protection to the US. The WIPO and USPTO online databases indicate there have been more than 1800 in-bound Requests and more than 280 out-bound International Registrations since November 2, 2003, and the numbers continue to rise.

Whether the primary concern is the ability to cover many foreign countries with a single application and registration, the need to combat counterfeiting and infringement, or the desire to obtain European protection while avoiding an obstacle in an individual European country, the Madrid Protocol constitutes an exciting new option for trademark owners. While it should not be used to entirely replace traditional foreign trademark protection approaches, it should be employed in concert with them and as a means to diversify one's trademark holdings. Indeed, if used appropriately as part of a carefully planned legal strategy, the Madrid Protocol can reward the owner with extensive trademark protection and noticeable time and cost savings.

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If you have any questions or would like further information, please feel free to contact the author and/or visit the following Madrid Protocol online resources:

Pillsbury Winthrop's Madrid Protocol Resource Center:
<a href="http://www.pillsburywinthrop.com/spotlight/madrid/mad

Madrid Protocol Fee Calculator:

http://www.wipo.int/madrid/feecalc/firststep

• WIPO's Searchable Database of International Applications/Registrations:

http://www.wipo.int/madrid/en/madrid express.htm

• OHIM's Community Trademark website (with searchable database):

http://oami.eu.int/en/default.htm

• WIPO's Madrid Protocol website:

http://www.wipo.int/madrid/en/index.html

USPTO's Madrid Protocol website:

http://www.uspto.gov/web/trademarks/madrid/madridindex.htm

• Text of the Madrid Protocol:

http://www.wipo.int/madrid/en/legal texts/madrid protocol.htm

• Text of the U.S. Madrid Protocol Implementation Act:

http://www.uspto.gov/web/trademarks/PL107 273.htm#D

• Text of the Madrid Agreement:

http://www.wipo.int/madrid/en/legal texts/madrid agreement.htm