



IPO COMMITTEE NEWSLETTER

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Written by Members of the IPO Patent Law and Practice (International) Committee

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This paper was created by the authors for the Intellectual Property Owners Association all of whom are members of the Patent Law and Practice (International) Committee to provide background to IPO members. It should not be construed as providing legal advice or as representing the views of IPO.

AN UPDATE ON THE COMMUNITY PATENT PROJECT

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Following the publication by the Commission of a “non-white paper” on “solutions for a unified patent litigation system” it seems almost certain that the troubled history of the Community patent may be coming to an end.

In December 2009 the Council reaffirmed that enhancing the patent system in Europe was a necessary prerequisite for boosting growth through innovation and for helping European business face the economic crisis and international competition.

They concluded that this enhanced patent system should be based on two pillars:

the creation of a Community patent;
and

the setting up of an integrated specialised and unified jurisdiction for patent related disputes to improve the enforcement of patents and enhance legal certainty across Europe.

The European Patent with Unitary Effect

In March 2011, 25 Member States (Italy and Spain opted out on the basis of their objections to the translation regime) were authorised by the Council to establish enhanced cooperation in the area of the creation of unitary patent protection. This was closely followed, in April 2011, by the publication of two proposed

Regulations for implementing this enhanced cooperation:

Proposal for a Council Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection (COM (2011) 215/3);
and

Proposal for a Council Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (COM (2011) 216/3).

The first proposal builds on the existing system of European patents and relies to a large extent on the existing framework of the EPC. Unitary patent protection may be given to European patents granted for the territories of the participating Member States. Unitary patent protection will be optional and will co-exist with national and European patents and with national utility models.

The proposal states that the proprietors of European patents granted by the EPO may submit a request to the EPO within one month after the publication of the mention of the grant of the European patent, asking for the patent to have unitary effect. This will mean that the patent will attract uniform protection and equal effect throughout all participating Member States, and that it may only be limited, licensed, transferred, revoked or allowed to lapse in respect of all of them (Article 3). There is an exception for revocation on the ground of novelty where there is a prior but unpublished conflicting national right, which has only national effect (Article 5).

There is no provision in the proposal for European patents which have been

granted prior to the coming into force of unitary patent protection. Such European patents will remain subject to the EPC and their proprietors will not be able to request that they have unitary effect.

The proposed regulation makes provision as to the substantive law on infringement (Articles 6 and 7) and the defences to it (Articles 8 and 9). Where provision is not made in the proposed regulation the EPC or national law and its rules of private international law will apply (Article 10).

For a European patent to be validated in a Member State, national law may require that the patent proprietor files a translation of the European patent into the official language of that Member State. As a result, the current patent system in the EU involves very high costs and complexity.

The second proposed regulation maintains Article 14(6) of the EPC governing the languages of the EPO. Hence, where the specification of a European patent with unitary effect is published in one of the official languages of the EPO (English, French and German) and includes a translation of the claims into the other two official languages of the EPO, further translations are only required in the case of a dispute (Article 3 of the proposed regulation). The transitional provisions of the proposed regulation (Article 6) envisage only one full translation being filed when the unitary option is taken: one into English if the language of the EPO proceedings is French or German, and one in French or German if the language of the proceedings is English. There will always be a full English version.

In the case of a dispute, a translation into the official language of the

Member State in which the alleged infringement took place or in which the alleged infringer is domiciled must be provided. The alleged infringer would be able to rely, as a defence to a claim for damages, that, before having been provided with a translation in its own language, it acted in good faith and may not have known or had reasonable grounds to know that it was infringing the patent (Article 4).

The drafts were discussed in detail by a working group (known as a 'Mertens group'); issues where there was not agreement on the original draft were mainly related to the distribution of renewal fees for unitary patents between the EPO and the national patent offices of the participating states. As a result of these discussions, a revised draft of the first proposed regulation was issued on 21 June 2011 and both proposed regulations were approved by a meeting of the Competitiveness Council on 27 June 2011. They now go to the European Parliament, which is likely to approve them.

The two Member States which have not joined this enhanced cooperation, Italy and Spain, have already complained to the ECJ that the proposal is against the spirit of the single market. The Council and the Commission have stated that this complaint need not delay the introduction of the unitary patent, but Italy has already said that, if Parliament passes the regulations, it will file another action attacking them.

The European and EU Patents Court

The real issue that remains in establishing a unified patent system is therefore the establishment of a unified litigation regime.

A draft agreement on the European and EU Patents Court (EEUPC) was published by the Council in March 2003. The agreement provided for the establishment of a unified patent court, the EEUPC, consisting of a Court of First Instance (with central, regional and local divisions) and a Court of Appeal. These courts would have exclusive jurisdiction in relation to European patents and European patents with unitary effect. The draft agreement was designed to be concluded by the Union, the Member States and certain third states party to the European Patent Convention (e.g. Switzerland).

The Council requested the Court of Justice of the European Union (CJEU) to give an opinion on whether the draft agreement was compatible with the Treaties. The CJEU's Opinion, delivered on 8 March 2011, held that the agreement was, in its current state, incompatible with the Treaties.

Essentially, the CJEU was concerned that the proposed court would be interpreting and applying EU law despite being outside the EU framework. Further it was concerned that the setting up of the EEUPC would deprive national courts of their powers and obligations to refer questions to the CJEU on the interpretation of EU law in the field of patents, and thus in turn would impinge on the CJEU's own powers (for example bringing infringement proceedings against the Member States would be impossible if the EEUPC were to breach Union law).

As a result of the CJEU's Opinion, it is clear that the participation of third countries must be excluded from any agreement relating to the EEUPC.

In May 2001 the Commission circulated a "non-paper" to Member States to examine and outline a possible solution in the light of the Opinion of the CJEU. The Commission proposed three possible solutions:

conferral of exclusive jurisdiction on patent litigation upon the CJEU;

conferral of jurisdiction on the national courts which could deliver judgments for the whole territory of the participating Member States, as for the Community trade mark; or

conferral of exclusive jurisdiction upon an independent court to be established by the Member States.

It is generally accepted by interested parties that a litigation regime that makes use of national courts, as applies to the Community trade mark and the Community design, would be unsuitable as few courts in the EU have much experience of patent litigation. In addition, with no common appeal court, uniformity of judgments for the whole territory would not be achievable. Further, as highlighted in the Commission's 2006 consultation on future patent policy, it is clear that Member States and users of the patent system are opposed to the first option.

In the light of the above, the Commission concludes in its 2011 "non-paper" that the "only possible solution ... is the conclusion of an international agreement between the Member States to set up a unified patent court with jurisdiction for the Member states only".

It is likely that, given the work already invested in it, any agreement would be based on the draft agreement on the EEUPC. Considering that, in the

CJEU's Opinion, the draft is incompatible with the Treaties, it would need to be modified at least to exclude the non-EU aspects of it and the participation of third party states. This should ensure the respect of Union law by the EEUPC and allow the Commission to start infringement proceedings against all Member States jointly in cases where the EEUPC has violated Union law.

An Update On The Community Patent

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POST-FILED DATA IN EUROPEAN PATENT PROSECUTION

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If a European patent application does not contain enough data in the view of the examiner, an objection may be raised under the grounds of sufficiency (Article 83 EPC), or inventive step (Article 56 EPC). This article considers the situations in which it may be beneficial to provide data generated post filing.

Supplementary data that has been published after the filing date of a patent application may be supplied to the European Patent Office to correct certain deficiencies in the application or patent. However, post-filed data does not provide a remedy in all situations.

Inventive Step - Article 56 EPC

One of the most cited cases that has been decided by the EPO in recent years is T1329/04. The patent application concerned the identification of a polypeptide sequence that was found to have homology to the GDF growth factor genes. Several speculative uses for the polypeptide had been listed in the specification. Some of these uses were later shown to be correct, demonstrated by post-published documents.

The Technical Board of Appeal (TBA) decided that the data presented in post-published documents did indeed

confirm the invention. However, the TBA considered that these data were the first disclosure that went beyond speculation. Therefore, since the TBA considered that the disclosure in the application as filed was mainly speculative, the post-published evidence was not considered to be relevant and was not taken into account during the assessment of the content of the application. The TBA held that even if supplementary post-published evidence can be taken into consideration, it may not serve as a *sole basis* that an application actually solves the problem it purports to solve. The invention must at least be made plausible by the disclosure in the application.

In other instances, supplementary post-published data has proved useful. In T0433/05, the TBA, taking into account the finding of T1329/04, considered that the quality of evidence provided in the patent was such that the claimed invention was considered to be a *bona fide* solution to the problem to be solved, which was further supported by the post-published document. In this case the patent itself contained some evidence showing that the problem had been solved and therefore the post-published document was not the sole disclosure that went beyond speculation.

Sufficiency of disclosure - Article 83 EPC

It is a requirement for the application/patent to describe the invention in a manner sufficiently clearly and concisely for the skilled person to carry out the claimed invention. The skilled person must be given sufficient guidance for performing the invention across the whole range claimed without undue burden using common general

knowledge. This requirement is usually met by providing at least one working example and a description of how this may be performed.

In T0609/02 the TBA stated that the description of a patent specification provided no more than a vague indication of possible medical use for a chemical compound yet to be identified. In this case, later, more detailed evidence could not be used to remedy the fundamental insufficiency of disclosure of such subject matter. The case in question related to a compound as identified by a previously claimed method for the preparation of a pharmaceutical against over expression of steroid hormone responsive genes. However, the patent specification provided no evidence that the claimed steroid hormone was identified as binding to the hormone receptor in such a way that the complex may disrupt steroid hormone regulated transcription, again as alleged. Therefore, the TBA held that the medical use that was claimed was merely speculative and would place an undue burden on the skilled person to repeat this aspect of the invention. Post-published evidence showed that the steroid hormones as claimed were later structurally identified and they did indeed have an effect on steroid hormone regulated transcription. However, since Article 83 EPC requires that the description of *the application or the patent* should teach the skilled person sufficiently clearly and completely how to carry out the invention, the post-published evidence of this instance could not remedy the shortcomings of the patent.

In T1262/04 the technical teaching in the application as filed was considered as credible enough to meet the requirements of Article 83 even though there were no working examples.

Post-published evidence was considered to be acceptable in this case as it was to merely confirm the teaching of the application as filed and was not providing any additional information that was lacking in the application.

How many data should be provided in the application as filed?

It is not necessarily a requirement that clinical trials or *in vivo* data are supplied, merely that an appropriate *in vitro* model is used to show that the claimed invention is plausible. It must not be mere speculation that a certain molecule can be used to treat a certain disease; there must be some evidence present in the application *as filed* showing that the disease claimed is not merely picked from a “laundry list” and there are clear reasons as to why the claimed molecule is able to be used in the treatment of a particular disease. Evidence or teaching in the application must make it at least plausible that the solution will work, which can be further supplemented by post-published data in the case of inventive step.

When should post-published data be allowed?

Regarding the scope of the claim, it may be necessary to provide post-filed data in order to support a breadth of claim or to show that additional uses may even be considered based on the original disclosure. However, post-filed data cannot remedy Article 83 deficiencies.

Therefore, it is important to note that it is clearly set out in the description of the original application that the invention has been made and to ensure that the teaching enables the skilled person to carry out the invention. For

inventive step it must be made plausible that the invention solves the problem and provided the plausibility is present in the application as filed it appears, for the time being, that post-published data can be used to supplement the inventive step position at a later date.

PATENT BARRIERS TO BIOSIMILARS IN CANADA

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Introduction

Canada has a specialized litigation option available to protect certain patented drugs on the market. The process may block a second-entry drug that is referencing a patent owner’s clinical trial data.

This unique system is informally called the “NOC Regulations.”¹ It requires generic and biosimilar drug companies to establish freedom-to-operate with respect to key patents as a *precondition* to market authorization. This is in sharp contrast to conventional Canadian patent enforcement litigation that typically begins only *after* marketing authorization is granted.

This article will review the NOC Regulations as well as conventional patent litigation options that apply to biosimilars.

Biosimilars

A biosimilar is a second-entry biologic drug, such as a protein, that takes a

¹ *Patented Medicines (Notice of Compliance) Regulations*, SOR 93-133.

regulatory shortcut to market, saving time and money². The biosimilar drug submission relies in part on a pioneer biologic's clinical data in order to get its own marketing authorization. It is not considered a "generic" drug, like a conventional, small molecule pharmaceutical. The biosimilar is a complex chemical that can be chemically similar, but not bioequivalent, to the pioneer biologic drug. Until recently, Canadian regulators, like those in the US and Canada, were hesitant to allow biosimilars to reference biologic drugs in the regulatory approval process.

Health Canada Opens the Door to Biosimilars

Health Canada is the Canadian counterpart of the U.S. F.D.A. Health Canada approves drugs for marketing by issuing a marketing authorization, called a Notice of Compliance ("NOC"). An NOC is issued when a drug manufacturer's new drug submission ("NDS") or a supplemental new drug submission ("SNDS") has met Health Canada's regulatory requirements for safety, efficacy and quality. Omnitrope (somatotropin; human growth hormone) is an example of a biosimilar that has been approved in Canada³. Health Canada also recently issued guidance on the regulatory pathway for

biosimilar approval in Canada⁴. Now that the regulatory pathway is clearly open, innovator companies are reviewing and improving their patent barriers. Biosimilar manufacturers are trying to find a safe pathway for Canadian freedom to operate.

The Health Canada Patent Register

Health Canada maintains its own Patent Register of patents relating to medicines and their use. It is analogous to the U.S. Orange Book. The Register is independent from than the Canadian Intellectual Property Office. Health Canada does not have any involvement in examining or issuing patents.

The sole purpose of the Register is to prevent patent infringement. Only a company that applies for, or already has, an NOC for an approved, patented drug may be eligible to take advantage of this specialized process. The timelines to submit patents for the Register are strict and only certain types of patents qualify. Health Canada clearly stated that biologic patents are eligible for the Register⁵. To be eligible for listing, a patent must claim either an approved: medicinal ingredient; formulation that contains the medicinal ingredient; dosage form; or use of the medicinal ingredient.

² Noel Courage and Ainslie Parsons, *The Comparability Conundrum: Biosimilars in the United States, Europe and Canada*, Food and Drug Law Journal Volume 66, Issue 2 (2011).

³ Health Canada, Health Products and Food Branch, Summary Basis of Decision (SBD) ^{Pt}OmnitropeTM (Sep. 14, 2009), "Omnitrope Health Canada Approval".

⁴ Health Canada, Health Products and Food Branch, Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biology (SEBs), Mar. 5, 2010.

⁵ Health Canada Guidance Document, *Patented Medicines (Notice of Compliance) Regulations* (March 8, 2010), at page 8.

The Patent Register also has strict, non-extendable time limits. A patent can be listed at one of two times:

A patent that is issued at the time of filing an NDS or a SNDS must be listed at the time of filing the submission; or

A patent application that has a filing date before the filing of the NDS or SNDS, must be listed within 30 days after the issuance of the patent.

Health Canada vets all requests to list patents on the Register. If a patent is not listed, the patent owner can still rely on conventional patent litigation.

Patent Register Procedure

The biosimilar company must address freedom to operate with respect to patents on the Health Canada Patent Register or else it will not receive marketing authorization. Prior to the creation of the Patent Register, the patent owner often had to use conventional patent litigation to chase a competitor for patent infringement *after* the medicine was already on the market. Since interlocutory injunctions are difficult to obtain and it takes a long time to bring a patent infringement case to a trial, there are significant benefits to a patent owner in keeping a competitor from entering the market.

If the Patent Register procedure applies, the biosimilar company must allege that its product does not infringe any valid, non-expired claims of relevant patents on the Patent Register. This statement is made in a document called a notice of allegation and detailed statement ("NOA"). The NOA is served on the company that listed the patent of the Patent Register. The purpose of the NOA is to make the patentee fully aware of the grounds on

which the biosimilar company says that issuance of an NOC will not lead to patent infringement.

If the patentee does not challenge the NOA, the biosimilar company will receive its NOC upon satisfying Health Canada's efficacy, safety and other regulatory requirements.

If the patentee disagrees with the NOA and believes that a claim of a patent would be infringed, then it is entitled to bring an Application in Canadian Federal Court for a prohibition order. If granted, this order would prevent Health Canada from issuing an NOC to the biosimilar company because the biosimilar product may infringe the patent. This type of court proceeding is often called an "NOC Proceeding."

The NOC Proceeding is *not an action to decide infringement or validity*. It is a summary judicial review proceeding to determine *whether Health Canada will be prohibited from issuing an NOC*. The NOC Proceeding does not affect the right to sue the biosimilar drug company for patent infringement separate from an NOC Proceeding.

The court assumes that the facts in the NOA are true, except to the extent that the contrary is shown by the applicant. The patent owner has the burden of proof to establish on a balance of probabilities that the allegations of non-infringement and invalidity not justified. Affidavits are typically provided by expert witnesses, such as chemists and physicians.

After both parties have filed affidavit evidence, cross-examinations of affiants begin. There is no discovery or deposition in an NOC Proceeding. Each party receives the opportunity to cross-examine on the affidavits provided by the opposite party. Cross-

examination is limited to questions going to credibility and relevant matters arising from the affidavit.

The Application is a faster and cheaper way to keep a competitor off the market than a patent infringement trial. The filing of the Application starts an automatic 24-month stay of NOC issuance to the biosimilar company (it is, in effect, like an injunction). The NOC may only be issued when the patent expires or the biosimilar company wins the Application. In contrast, it is typically very difficult to obtain an interlocutory injunction in Canada in a patent infringement lawsuit.

A disadvantage of filing the Application is that the patent owner may be liable to the respondent for costs and damages for delaying biosimilar drug entry into the market.

The NOC Regulations have been extensively litigated in the context of conventional, small molecule pharmaceuticals. No NOC Proceeding has been completed for a biosimilar yet. However, the NOC Regulations will become an important patent protection tool as biosimilar development increases.

If the Patent Register procedure does not apply, a conventional patent infringement lawsuit may be brought by a patent owner.

Conventional Patent Infringement Lawsuit

The patent owner can commence a patent infringement lawsuit in Federal Court, irrespective of the outcome of the NOC Proceeding. This right is not diminished by the outcome of the NOC Proceeding. Likewise, the biosimilar company may lose in the NOC

Proceeding, but later establish at a trial that the patent is invalid or not infringed.

The patent owner would typically sue for patent infringement and request remedies such as damages or an accounting of profits. Accounting of profits is a remedy that is an alternative to damages - the plaintiff receives the defendant's profits from the infringement. An injunction and delivery up to the patent owner of the infringing drug may also be requested. An injunction may also be requested before trial, but is unlikely to be granted. It is very difficult for a patent owner to show irreparable harm not compensable by damages, which is a precondition for the interlocutory injunction. Discovery and trial testimony both occur in Canadian patent infringement litigation.

The validity of a patent may be challenged, for example, if the patent claims lack novelty, inventiveness or support. A patent is presumed valid during litigation and it is difficult to invalidate a patent. Evidence used to attack validity of a patent in another country may be useful in Canada, however, each country has different laws and standards on patent validity issues.

It would typically take at least a couple of years (often much longer) before a trial decision.

Conclusion

Conventional patent litigation in Canada is generally similar to other major jurisdictions. Patent owners and biosimilar manufacturers need to be prepared to engage the unique Canadian NOC Regulations. The protection for patent owners is a helpful supplement to conventional

patent infringement litigation. If Health Canada accepts the list for its Patent Register, the ball is then in the biosimilar manufacturer's court to address non-infringement and validity issues before receiving an NOC. There is no down side to listing on the Register.

Biosimilar manufacturers may have to prepare for a delay in market access regardless of the merits of the patent owner's case. Where there is a patent on the Register, the patent owner ultimately controls whether the parties go to court. The statutory stay in marketing authorization during the NOC Proceeding is automatic. This raises a significant barrier to freedom to operate in Canada.

**SOUTH AMERICAN IP
COLLABORATIVE PROJECT
"PROSUR" KEEPS MOVING
FORWARD**

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Introduction

Anybody familiarized with the work of any Patent and Trademark Office (PTO) worldwide knows that in recent year almost all of them have been receiving a steady growing number of new applications that in no case could be matched by only increasing local capabilities.

As a result, the backlogs of existing applications pending of examination, lodged oppositions pending of decision and other related procedures, continue to create more problems for the local PTOs and their users including individual inventors, universities as

well as small business and international companies.

Among the different measures that have been taken by PTOs worldwide and international organizations such as WIPO, the latest trend has been the implementation of collaborative procedures between local PTOs to achieve greater efficiency. This is mainly achieved by speeding up the examination processes without affecting the quality of the examinations, which, at least in theory, should be easy to achieve at the international level by avoiding the duplication of examinations and other redundant work.

These are the reasons that have been inspiring concrete projects among PTOs in different regions worldwide. The most important is the one entered in 2008 by (back then the three and now) the five PTOs handling the largest numbers of patent matters, which are the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO) and the United States Patent & Trademark Office (USPTO). They are known as "Five IP Offices" and have been developing different "foundation projects" that can be followed on its website.

Moreover, similar measures have been taken by other PTOs of industrialized and most developed countries such as the "Vancouver Group", which was set up in 2008 and is composed by the PTOs of Australia, Canada and U.K.

Last but not least, emerging markets and less developed regions are not exceptions to this trend, as was proved by South Asia where the Patent Examination Co-operation (ASPEC)

program was set in 2009 among different PTOs of that geographical region.

A similar project has been unfolding in South America, which may have operative results sooner than expected. The advantages for South American PTOs to adopt this trend are very clear but any step to have them materialized still must overcome multiple difficulties including political, economic and technical factors.

Relevant background regarding official IP collaboration in Latin America

As it is very well known, the participation of most South American PTOs in international treaties facilitating the filing and prosecution of IP rights⁶ had been kept at a minimum until the entrance in force of TRIPs in the middle of the 90's and,

⁶ For instance, there are still several countries that have not yet entered into the Patent Cooperation Treaty (PCT) including Argentina, Bolivia, Paraguay and Venezuela. Furthermore, the official activities and roles assumed by most Latin American PTOs had remained very small even in Brazil, which is a founding member of the PCT. Let us recall that it was only in August, 2009 that the Brazilian PTO started acting as an International Search Authority under the PCT System.

Regarding international systems for filing trademark application like the Madrid Protocol, so far only Cuba has become a member.

In the area of industrial models (known as patent designs in the U.S.) no single country has adopted the Hague System for the international registration of industrial designs established by the Hague Agreement.

more relevant, of certain bilateral Free Trade Agreements signed with the U.S. few years ago.

Likewise, minimal has been so far the participation of South American PTOs in ongoing specific patent bilateral agreements between global PTOs, which compose a system known as the "patent prosecution highway" that only Mexico has implemented through a bilateral agreement with Japan⁷.

Another reason for the low level of participation in international collaborative projects may be attributed to the fact that in Latin America there is no regional or sub-regional consolidated system for filing and prosecuting IP applications⁸, as it

⁷ According to WIPO, the bilateral agreements composing this system "enable patent applicants to request a fast-track examination procedure where patent examiners can make use of the work products from the other Office(s). These work products can include positive results of the written opinion of the International Searching Authority, the written opinion of the International Preliminary Examining Authority or the international preliminary examination report issued within the framework of the PCT", http://www.wipo.int/pct/en/filing/pct_pph.html

⁸ The closes formal system in place is the one enacted by the Andean Community of Nations (known in Spanish as CAN and encompassing Bolivia, Colombia, Ecuador and Peru), which is "Decision No. 486", a regional IP substantive legislation mandatory for all its members. However, all IP filings, examinations and administrative conflicts are handled by each local authority with the regional judicial authority (The Tribunal of the Andean Community

happens in Europe, where the European Patent Convention was established in 1977; in Africa, where two regional systems co-exist: one for English Speaking countries established in 1876 (ARIPO) and the other for the French Speaking Africa called the Industrial Property Convention ("OAPI") established in 1977; as well as in the territories of the former members of the Soviet Union that in 1993 established the Eurasian Patent Convention (EA).

Taking into account this particular background and the traditional difficulties that the region has had to align disperse interest, it is worth pointing out the commitment and efforts of many South American PTOs in pursuing the first collaborative system in the region, which may have important practical consequences in the future.

PROSUR pilot project

Few years ago, the PTOs of most South American countries started to work on a regional collaborative project named PROSUR that finally got the funding from the Inter-American Development Bank. The project is divided in different stages and keeps each country's sovereignty to regulate IP matters according to its own local law.

The first concrete step focuses on the non-binding exchange of patent examination results, which later may be extended to other intellectual property applications including trademarks.

of Nations) having the limited role of deciding matters that may conflict with the regional mandatory standards set forth in Decision 486.

Following a request made by the Argentinean PTOs on behalf of the counties participating in this project⁹, in early March of this year, WIPO issued a press brief¹⁰ stating that it was going to support the regional project PROSUR. According to its statement, the main role of WIPO will be acting as a "specialized cooperating agency of the project". Given that WIPO had developed a special platform for such purpose, called WIPO CASE, its primary technical assistance to the PROSUR project is focusing on developing the necessary infrastructure, training local patent examiners and other IP professionals "as well in strengthening ongoing horizontal cooperation efforts to support PROSUR".

The following concrete step was a training meeting held in Santiago de Chile in April, 2011, funded by WIPO, where patent examiners working on the areas of mechanicals and biotechnology from Argentina, Brazil, Colombia, Ecuador, Paraguay, Peru, Uruguay and Chile shared their particular experiences and familiarized with the WIPO CASE platform.

Then, in late June, the Directive Committee of PROSUR composed by representatives of some of the PTOs participating in the project (Argentina, Brazil, Chile, Ecuador, Paraguay, Peru, Uruguay) gathered in Rio de Janeiro, Brazil. Among other actions¹¹, they

⁹ Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Suriname and Uruguay

¹⁰ PR/2011/680 available at http://www.wipo.int/pressroom/en/articles/2011/article_0006.html

¹¹ A minute of the meeting is available on in (Portuguese and Spanish) the website of the Brazilian PTO at <http://www.inpi.gov.br/noticias/colab>

reviewed the results of the examiners' meeting finding relevant differences in the technological capabilities of the offices and concluding on the necessity to improve the access to the different databases of each PTO.

Moreover, they agreed on sending a request to WIPO asking to move forward with the implementation of the WIPO CASE platform and compiled a list of 300 pending patent applications to be uploaded thereon. A deadline for having these applications uploaded was agreed and set for early August, 2011, when a second pilot test, this time composed by patent application filed after January 2008, may be initiated. It was also mentioned that a regional evaluation over the exchange of patent examination results among the participating PTOs is expected to be completed by the end of August 2011.

The next meeting of the examiners was scheduled for November, 2011 and a proposal to start working on a similar cooperation project involving trademark applications was submitted by the Argentina delegation.

Overall, the rationales behind this project are worth pointing out so all those interested in these areas of international IP practice are encouraged to monitor the latest developments.

PATENT REFORM ACT PASSED

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Washington, DC

On June 23, 2011 the House of Representatives passed the America

Invents Act (304-117) (H.R. 1249), which will alter some central aspects of the current patent system. The Senate approved the America Invents Act, S. 23, by a vote of 95 to five on March 8, 2011. The final bill still needs to be reconciled with an earlier version passed by the Senate. President Obama has signaled he will sign the resulting bill into law.

Background

Over the last five years, various members of Congress have been seeking to reform the Patent Act (Title 35 of the United States Code), and several key reforms have gained both bipartisan and broad industry support, e.g., a first-inventor-to-file (FITF) regime and expanded reexamination proceedings. However, there are some issues that have divided supporters of patent reform. In particular, groups representing the electronics and software industries have disagreed with groups representing the pharmaceutical industry about the types of relief available for patent infringement, in particular the calculation of money damages.

H.R. 1249 adopts many of the key reforms that now have broad support. For example, this bill alters how the U.S. Patent and Trademark Office (USPTO) is funded. In addition, it calls for converting the patent system from the current first-to-invent system into a first-to-file system, creating a post-grant review system, establishing a pilot committee to review questionable business-method patents, and removing the qui tam provision from the false marking statute. The final vote (304-117) included 168 Republicans and 136 Democrats voting in favor of and 67 Republicans and 50 Democrats voting against the bill.

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U.S. Patent and Trademark Office Funding

The biggest point of contention raised by detractors from H.R. 1249 related to the provisions regarding the USPTO's funding. Currently, the USPTO collects various fees, but that money is not specifically allocated to the USPTO's budget. Instead, Congress can allocate those funds to any program, and it often does. As a result, the USPTO must rely on a separate appropriations process from Congress. Rep. Lamar Smith (R-TX), the House bill's chief sponsor, included a manager's amendment into H.R. 1249 that allows the USPTO to hold all fees in a dedicated account. The USPTO must then seek approval from Congress before spending those fees. The manager's amendment passed 283-140, and was included in the final bill.

The Senate version of patent reform, the Patent Reform Act of 2011 (S. 23), would also give the USPTO more control over the filing fees that it collects. S. 23 calls for the creation of a "USPTO Revolving Fund" for the sole purpose of collecting fees and funding the USPTO.

First-Inventor-to-File Regime

In addition to modifying the USPTO funding process, H.R. 1249 converts the current first-to-invent regime into the internationally adopted FITF regime. This change has been criticized by some as both unconstitutional and harmful to individual inventors and small businesses. Despite this opposition, however, the adoption of an FITF regime has gained broad support from various industry players over the last few years. Adaptation to the FITF regime will harmonize U.S. patent law with the patent laws of most

other countries whose patent laws are also based upon FITF.

Post-Grant Review

Another major change in H.R. 1249 requires the USPTO to create a new administrative procedure called the "post-grant review." This process is intended to resolve disputes involving patent quality and scope. The post-grant review process allows any person the right to file a petition to institute an inter partes review shortly after the patent issues. The patent owner may then file a preliminary response that sets forth reasons why no inter partes review should be instituted by the USPTO. The post-grant review process then requires the USPTO to grant or deny the inter partes review within one year from the date the patent was granted. This process appears similar to the post-grant opposition procedure available in the European Patent Office.

H.R. 1249 also establishes a post-grant procedure specifically for reviewing business-method patents. This inter partes review functions in the same manner outlined above for the "post-grant review." It also includes an automatic stay of any litigation pending the USPTO's final determination of the business method patent's validity and scope. This specific post-grant review procedure appears to be unique to the USPTO as it deals only with a subset of patents which are subject matter specific.

False Marking Statute

This bill also modifies the false marking statute, which has seen hundreds of qui tam relators institute lawsuits against companies for alleged false marking based on expired patent markings. H.R. 1249 removes the qui

tam provision and only allows the United States, via the U.S. Department of Justice, to institute a false marking lawsuit. This modification will presumably eliminate false marking litigations brought by uninterested parties attempting to collect damages on behalf of the government.

Anti-cloning Provision

Finally, H.R. 1249 includes a prohibition on patenting any invention directed to or encompassing a human organism. This is widely seen as an anti-cloning provision. This provision is similar to patent laws in many other countries which prohibit the patenting of cloned organisms.

Additional Amendments

In addition to the main aspects of this bill, H.R. 1249 also includes the following:

FITF

Not only does the bill convert the patent system into the internationally favored FITF regime, but it also includes Amendment No. 10, which establishes a procedure for the USPTO to determine the proper inventors through a process called “derivation.” This practice would replace the current interference practice and allow the USPTO to “prescribe a requirement that parties provide sufficient evidence to prove and rebut a claim of derivation.” This amendment was sponsored by Rep. Jackie Speier (D-CA).

Small business assistance

Amendment No. 5 and Amendment No. 7 were included in the bill to support small businesses. In particular, Amendment No. 7 requires the USPTO to conduct a study to determine what the USPTO, the Small Business

Administration, and other federal agencies “can do to help small businesses obtain, maintain, and enforce foreign patents.” Amendment No. 5 was sponsored by Rep. Sheila Jackson Lee (D-TX) and Amendment No. 7 was sponsored by Rep. Gary Peters (D-MI) and Rep. James B. Renacci (R-OH).

PTO satellite offices

Amendment No. 6 requires the USPTO to establish up to three satellite offices, in addition to the previously announced Detroit satellite office. The USPTO would be required to consult with local communities and analyze the cost of building the office, the cost of recruiting talent, and the impact the office would have on the community. Amendment No. 6 was sponsored by Rep. Ben Ray Lujan (D-NM).

Diversity study

Amendment No. 4 to the bill requires the USPTO to perform an analysis of the “diversity of patent applicants, including those applicants who are minorities, women, or veterans.” This amendment was sponsored by Rep. Gwen Moore (D-WI).

Patent term extension

H.R. 1249 initially included a section clarifying the method for calculating the 60-day period for patent owners to file for a patent term extension. This amendment removes this language and breathes new life into the patent at issue in the currently pending case *Medicines Co. v. Kappos*, No. 01:10-cv-286 (E.D. Va. Aug. 3, 2010). Amendment No. 9 was sponsored by Rep. John Conyers, Jr. (D-MI) and was ultimately adopted by a 223-198 vote.

Conference Committee

Finally, H.R. 1249 includes many of the same reforms included in S. 23. However, each of the differences

between these bills will now need to be reconciled. A conference committee will be established so members of the House and Senate can negotiate a compromise. To date, conferees have not been announced. If they succeed, they will issue a conference report, which will need to be approved by both the House and the Senate. If both the House and the Senate pass the conference report, the unified bill will be sent to the president for his review and signature. The primary sponsor of patent reform in the Senate is Patrick J. Leahy (D-VT). The primary sponsor of patent reform in the House is Lamar Smith.

The text of H.R. 1249 as reported by the Judiciary Committee is available at <http://pub.bna.com/ptcj/HR1249asreportedApr14.pdf>.

Lamar Smith's final manager's amendment, including the fee diversion compromise, is available at <http://pub.bna.com/ptcj/HR1249MgrAmendJun20.pdf>.

The House Judiciary Committee report on H.R. 1249 is available at <http://pub.bna.com/ptcj/HR1249ReportJun1.pdf>.

The text of S. 23 is available at <http://pub.bna.com/ptcj/S23aspassedMar8.pdf>.

H.R. 1249's digest is available at <http://www.gop.gov/bill/112/1/hr1249>

SUFFICIENCY OF DISCLOSURE AND SOUND PREDICTION REQUIREMENTS IN CANADA

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Recent case-law relating to the issues of sufficiency of disclosure and sound prediction of utility should be noted by practitioners drafting patents that are to be filed in Canada. The case-law appears to be developing to require additional information in the specification than might be included in a patent application drafted for other jurisdictions. As will be discussed more fully below, the Supreme Court of Canada (SCC) will soon consider a case requiring it to opine on the requirements for a finding that the disclosure of a patent is sufficient. This review focuses on cases relating to pharmaceutical products, but these principles may be broadly applicable.

Sufficiency of Disclosure

A number of proceedings under the *Patented Medicines (Notice of Compliance) Regulations*¹² (the *NOC Regulations*) and infringement actions have addressed the substantive requirements for sufficiency of disclosure under the *Patent Act*.¹³ Generally, the generic companies are attacking patents on the basis of a lack of disclosure. There was much turmoil in the law until several recent Federal Court of Appeal (FCA) decisions all appear to be following the same

¹² *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended.

¹³ *Patent Act*, R.S.C. 1985, c. P-4 as amended.

principles. However, the SCC recently granted Teva leave to appeal a decision where the primary issues relate to sufficiency.¹⁴

In Canada, sufficiency of a patent's disclosure is governed by the *Patent Act* which states:

27(3) Specification – The specification of an invention must

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;

(b) set out clearly the various steps in the process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;

(c) in the case of the machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and

(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.¹⁵

In *Consolboard*, in 1981, the SCC interpreted a previous version of this provision to require the inventor to explain: "What is your invention?"

¹⁴ *Teva Canada Limited v. Pfizer Canada Inc. et al.* (SCC docket 33951); Judgments in Appeal and Leave Applications: <http://scc.lexum.org/en/news_releases/2011/11-05-05.3/11-05-05.3.html>.

¹⁵ *Patent Act*, s. 27(3).

How does it work?"¹⁶ The SCC commented again on sufficiency, in 1989, in *Pioneer*, stating:

The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built. The applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency.¹⁷

The first statements that seemed to affect the sufficiency requirements stemmed from a 2007 Eli Lilly decision dealing with a selection patent claiming *inter alia*, the compound olanzapine. The Federal Court held that the patents at issue in *Consolboard* were not selection patents, and thus sufficiency in this context did not arise in *Consolboard*.¹⁸ The Court then examined the requirements for a proper selection patent and held that the "advantage" of the selection must be stated in the specification of the patent. The Court determined that the advantage in selecting olanzapine in comparison to other compounds from the previously disclosed genus was not supported by any comparative data in the patent and as such, the allegations that the patent was invalid for insufficiency of disclosure were

¹⁶ *Consolboard v. MacMilan Bloedel*, [1981] 1 S.C.R. 504 at 520 [hereinafter *Consolboard*].

¹⁷ *Pioneer Hi Bred v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at 1638 [citations omitted; hereinafter *Pioneer*].

¹⁸ *Eli Lilly v. Novopharm*, 2007 FC 596 at para 132 [hereinafter *olanzapine I*].

justified.¹⁹ Because Novopharm received its marketing approval shortly after the decision of the Federal Court, and before Lilly's appeal could be heard, the appeal was held to be moot,²⁰ preventing the FCA from addressing this apparent change to the law of sufficiency.²¹

However, shortly after dismissing the *olanzapine 1* appeal for mootness, the FCA issued its decision addressing sufficiency of disclosure in a Pfizer case involving, *inter alia*, claims to amlodipine besylate.²² This was also a selection patent case. The FCA held:

The Applications Judge was wrong in interpreting the disclosure requirement

¹⁹ *Ibid.* at para. 162-165.

²⁰ In Canada's two-tiered system dealing with pharmaceuticals, proceedings under the *NOC Regulations* are deemed administrative proceedings to determine whether a generic allegation as to invalidity or non-infringement is justified. Such proceedings are Applications for an Order Prohibiting the Minister of Health from issuing a NOC (marketing approval) to the generic company. Furthermore, there is no discovery and no live testimony in these cases. Evidence is adduced by way of affidavit and cross-examination out of Court. The Courts have held that such a determination is not binding on the validity or infringement of the patent *in rem*. Thus, once a generic company receives its marketing approval, any appeal is moot. At this point, the innovator is free to start a patent infringement proceeding.

²¹ *Eli Lilly v. Novopharm*, 2007 FCA 359.

²² *Pfizer Canada v. Ranbaxy*, 2008 FCA 108 [hereinafter *amlodipine*].

of subsection 27(3) of the Act as requiring that a patentee back up his invention by data. By so doing, he confused the requirements that an invention be new, useful and non-obvious with the requirement under subsection 27(3) that the specification disclose the "use" to which the inventor conceived the invention could be put: see *Consolboard*, supra, at 527. Whether or not a patentee has obtained enough data to substantiate its invention is, in my view, an irrelevant consideration with respect to the application of subsection 27(3). An analysis thereunder is concerned with the sufficiency of the disclosure, not the sufficiency of the data underlying the invention. Allowing Ranbaxy to attack the utility, novelty and/or obviousness of the 546 patent through the disclosure requirement unduly broadens the scope of an inventor's obligation under subsection 27(3) and disregards the purpose of this provision.²³

Thus, the FCA affirmed the concepts stated by the SCC in *Consolboard* and *Pioneer*, namely that selection patents do not have higher disclosure requirements than other patents, and that s. 27(3) does not require a patentee to support an invention with data.²⁴

The patent at issue in *olanzapine 1* was the subject of a full infringement trial, and again found invalid for insufficiency by the Trial Judge.²⁵ However, on appeal, the FCA held that the Trial Judge had misdirected himself as to the law of sufficiency by not following the directions in

²³ *Ibid.* at para. 56.

²⁴ *Ibid.* at paras 33-37, 42 and 56.

²⁵ *Eli Lilly v. Novopharm*, 2009 FC 1018.

amlodipine.²⁶ The FCA was also concerned with the Trial Judge's finding that the patent was an invalid selection patent, holding that this was not an independent basis upon which to attack the validity of a patent.²⁷ However, the FCA held that as part of the disclosure requirements for a selection patent, the patentee must set out in the disclosure a teaching of the selected compound and its advantages as well as a teaching of how it works.²⁸ The FCA ultimately held that there were insufficient factual determinations in the Trial Judge's decision to make a ruling on the issue of sufficiency, and sent the matter back to the Trial Judge for redetermination. That matter is still pending.

Shortly after sending *olanzapine 2* back to the Trial Judge, the FCA issued its decision in another Pfizer case dealing with sufficiency.²⁹ This is the case that the SCC will be considering in February 2012. This case was also decided pursuant to the *NOC Regulations*; however as Pfizer was successful before the Trial Judge, Teva's appeal was possible.

The patent at issue in *sildenafil* claimed, *inter alia*, the use of a genus of compounds to treat erectile dysfunction (ED), as well as the use of two specific compounds. These claims provided the chemical formulas for the compounds, one of which was sildenafil. Only the claim, claiming the use of sildenafil for the treatment of ED was at issue at the hearing (claim 7). At the FCA, Novopharm argued that Pfizer should be required to

disclose the best mode of practice of the invention; that claim 7 should not be read as an invention on its own for the purpose of disclosure requirements and that the test from *Consolboard* was misapplied.³⁰

The FCA held that the Judge was correct to limit the invention as described in claim 7. Claim 7 was construed to claim the compound sildenafil within a class of compounds used to treat ED. The Court of Appeal then held the claim 7 clearly states the formula for sildenafil and is thus clearly described. The Court of Appeal also held that Parliament chose to only require "best mode" to apply to mechanical inventions, as is clearly set out in s. 27(3)(c) of the *Patent Act*. Thus, the FCA upheld the Judge's decision that the allegations of insufficiency were not justified.

In its application for leave to appeal to the SCC, Teva argued that there is a discrepancy in the law whereby on one hand the disclosure lies at the heart of the patent system yet on the other hand an attack on insufficient disclosure is described as a mere "technical attack". Teva argued that Pfizer consciously drafted the patent with the intent of preventing a skilled reader from identifying the only compound with utility. Teva also argued that when a patentee is relying on a sound prediction of utility, the disclosure requirements for that test are also part of the sufficiency requirements under the *Act*. Teva is also making a "best mode" argument that Pfizer failed to disclose the essence of the invention. Finally, there appears to be an underlying theme attacking the cascading claims approach to patent drafting.

²⁶ *Eli Lilly v. Novopharm*, 2010 FCA 197 [hereinafter *olanzapine 2*].

²⁷ *Ibid.* at para. 39.

²⁸ *Ibid.* at para. 121.

²⁹ *Novopharm v. Pfizer*, 2010 FCA 242 [hereinafter *sildenafil*].

³⁰ *Ibid.* at paras. 37-40.

The SCC summarizes cases for information purposes. The summary touches on the “heart of the patent system” vs “technical attack” argument, best mode and the cascading claims issues.³¹ These arguments come from the Leave Application. The Facts on the appeal have yet to be filed. However, it is these arguments upon which the SCC decided to grant Teva leave to appeal.³² The decision, when it issues, is certain to impact many patents, both issued and pending.

Sound Prediction

Ancillary to a proper sufficiency attack are issues relating to sound prediction. The generic companies have tried to conflate the requirements for sufficiency of disclosure with the disclosure requirements for a sound prediction, but the FCA has held that the disclosure requirements are different.³³ However, as a practical matter, when drafting a patent application for filing in Canada, the sound prediction requirements are important to note.

The SCC held that there are three parts to the test in order to assess whether a prediction is sound:

The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In *Monsanto and Burton Parsons*, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may

suffice. Secondly, the inventor must have at the date of the patent application an articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis. In *Monsanto and Burton Parsons*, the line of reasoning was grounded in the known “architecture of chemical compounds”, but other lines of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure. Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised. It is generally not necessary for an inventor to provide a theory of *why* the invention works. Practical readers merely want to know that it does work and how to work it.³⁴

The SCC held that the soundness of the prediction is a question of fact and that in order to establish that fact, the parties must lead evidence about what was known and not known at the priority date. However, the SCC did not set out a particular threshold of what exactly must be present in order to establish a sound prediction. Indeed, the SCC stated that each case will turn on the particularities of the discipline to which it relates.³⁵

The FCA has ruled, on several occasions, that in order to rely on a sound prediction, there must be disclosure in the patent of both the factual basis of the prediction and the sound line of reasoning a person skilled in the art would use to make the prediction.³⁶ Similarly, the FCA has

³¹ <http://www.scc-csc.gc.ca/case-dossier/cms-sgd/sum-som-eng.aspx?cas=33951>

³² Generally leave to appeal to the SCC is only granted if the appeal will raise an issue of national importance which requires the SCC’s intervention.

³³ *olanzapine 2*, *supra* at para. 120.

³⁴ *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 [hereinafter *Wellcome*].

³⁵ *Ibid.* at para. 71.

³⁶ *Eli Lilly v. Apotex*, 2009 FCA 97 [hereinafter *raloxifene*]; *Eli Lilly v.*

rejected arguments that these disclosure requirements are inconsistent with the *Patent Cooperation Treaty (PCT)*, holding that the *PCT* permits countries to set rules for substantive conditions of patentability, and this is such a substantive condition.³⁷

In *raloxifene*, the FCA held that “when a patent is based on a sound prediction, the disclosure must include the prediction.”³⁸ In this case, the FCA held that disclosure in the patent application, of the results of a clinical study conducted in humans, was necessary to make the prediction sound.

In *olanzapine 2*, the FCA held that when dealing with “selection patents, the inventiveness lies in the making of the selected compound, coupled with its advantage or advantages, over the genus patent.”³⁹

Ultimately, for the purpose of utility regarding a selection patent, the question to be determined is whether, as of the date of filing, the patentee had sufficient information upon which to base the promise. In an infringement action, the patentee benefits from the presumption of validity (s. 43(2) of the Act) and the alleged infringer bears the onus of demonstrating that the patentee did not have sufficient information upon which to base the promise. If the alleged infringer is able to establish that there was insufficient information upon which to base the promise, the patentee may nevertheless

have had sufficient information upon which to make a sound prediction of the promise. The date for the soundness of the prediction is the date of the filing of the patent. However, by its nature, the doctrine of sound prediction presupposes that further work remains to be done: *Apotex v. Wellcome Foundation*, [2002] 4 S.C.R. 153 (AZT) at p. 190. Consequently, the promise need not have been met at the date of filing although it must ultimately be borne out.⁴⁰

In *olanzapine 2*, the FCA held that as the Trial Judge did not provide any foundation for the finding of the patent’s promise, it could not conduct a meaningful review and returned the issue of utility back to the Trial Judge for redetermination.⁴¹ As mentioned above, this case remains outstanding. However, the FCA did observe that the Trial Judge had summarized the various tests conducted by Lilly, and found that there was a factual basis for a sound prediction, and thus the relevant question for the Trial Judge was whether there was an articulable line of reasoning.⁴²

In *atomoxetine*, Lilly argued that it had evidence to establish the utility promised in the patent, and thus did not need to disclose that evidence in the patent specification. The Trial Judge held, and the FCA affirmed that this was not the case, as the patent was construed to be relying on a sound prediction of utility as opposed to actual utility. The patent was held to promise that atomoxetine would be “an effective treatment of ADHD, that is, it would alleviate manifestations of the disorder in some patients to such a degree that a doctor would consider

Teva Canada, 2011 FCA 220 [hereinafter *atomoxetine*]; *olanzapine 2*, *supra*.

³⁷ *raloxifene* at para 19; *atomoxetine* at paras. 48-50.

³⁸ *raloxifene* at para. 15.

³⁹ *olanzapine 2*, at para. 78.

⁴⁰ *olanzapine 2*, at paras. 81-82.

⁴¹ *olanzapine 2*, at para. 109.d

⁴² *olanzapine 2*, at paras. 110-112.

prescribing it.”⁴³ The clinical trial conducted by Lilly was held to have methodological limitations, and although the results were promising, its limited experimental data was not sufficient evidence of a clinically effective treatment. Furthermore, Lilly did not immediately proceed with the development of atomoxetine for ADHD after the study. Thus, the FCA held Lilly could not rely on actual utility, and must meet the test for a sound prediction of utility. As the clinical trial was not described in the patent, the FCA held that disclosure of the factual basis of the prediction was not present, and the patent was invalid for a lack of sound prediction:

Indeed, if disclosure in the patent of the factual basis of the prediction of utility was not required for sound prediction, it would be difficult to see what Lilly could be said to have given to the public, in exchange for the grant of the monopoly, that it did not already have. When utility is based on sound prediction, disclosure of its factual foundation goes to the essence of the bargain with the public underlying patentability.⁴⁴

Conclusions

Thus, when drafting a patent specification for filing in Canada, these recent decisions on sufficiency and sound prediction must be kept in mind in order to try to ensure that the patent will have a better chance of withstanding challenges to its validity.

⁴³ *atomoxetine*, at para. 36.

⁴⁴ *atomoxetine*, at para 51.

DESCRIPTION SUFFICIENCY IN BRAZIL

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As a general rule claims should be regarded as supported by the description. Article 24 of the Brazilian Industrial Property Law No. 9279/96, henceforth to be referred as BR Patent Law, is one of the three articles referring to written description sufficiency.

Article 24 refers to the enablement requirement stating that the specification must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry out the invention and to indicate, when applicable, the best mode of realization. It may look comprehensible to the general reader but it is still not specific enough to provide guidance for a written description that would secure the claims.

As is the case in many countries with substantive examination, in Brazil the threshold for written description sufficiency is prescribed in the Normative Act (BPTO rule)¹, the relevant Resolutions², and in the examination guidelines corresponding to the different technical areas.

Also, in virtue of a legal opinion issued by the Attorney-General³ one should be aware of the fact that, at present, once examination has been requested, the official filing of additional technical information related to the claims will not be accepted. Examiners might be reluctant also to accept its inclusion when replying to an office action or to an unfavorable examination report or even worse

during the prosecution with a divisional application. The examination procedures and examiners' decisions are bound to this legal opinion and the option to overcome this bar has not shown results so far.

The good news is that the controversial issues of the aforesaid legal provisions are being discussed and a draft is being prepared for submission to the Patent Office. In the meanwhile, the advice would read *“the enabling disclosure of the specification must be commensurate in scope with the claim under consideration.”*⁴

The common ground for a written description sufficiency for all the inventions that are allowed by the Brazilian Patent Law⁵ is that the initial disclosure must contain enough data, including examples and experimental results, to support the claims and this recommendation is not exhaustive.

Since the TRIPS agreement sets out that patent protection should be obtained for all fields of technology and on the other hand, Articles 10 and 18 of the BR Patent Law preclude plant varieties from obtaining a patent unlike the US protection system, In Brazil plants are protected by a *sui generis* protection system.

AN127/97 rules the filing of patent appl. The AN is being reviewed and modified for submission to the BPTO. Information will follow in a future newsletter.

Resolução No. 228/2009 related to sequence listing filings.
Parecer
/INPI/PROC/CJCON/no.012/2008
might be reviewed.

Understanding Intellectual Property Law, Chisum –Jacobs, page 2-132, ISBN:0-8205-0549-8).

Article 10 defines the subject matter that is not considered to be an invention. Article 18 defines what is not patentable.

The US has three legal systems to protect plant related inventions, i.e. the Utility Patent Act (1985), the Plant Patent Act (1930), and the Plant Variety Protection Act (1970). Each one protects a specific subject matter. A utility patent in the US may cover multiple varieties or an entire species that covers multiple plant parts, among other features, for which protection in Brazil Articles 10 and 18 constitute a bar.

As a matter of fact, BR Patent Law provides protection for transgenic microorganism related inventions only and plant varieties are protected in Brazil by the Plant Variety Protection Law No. 9.456/97 provisions. The description requirements of these systems are totally different and some inquiries coming from foreign associates about probable protection of a plant variety to be produced and sold in Brazil motivate to present some aspects of the pertinent description sufficiency requirements.

Plant protection is obtained with a respective protection certificate issued by the SNPC (Serviço Nacional de Proteção de Cultivares, the National Agency for the Protection of Plant Varieties)

Initially, morphological descriptors for the species for which protection is sought must have been issued otherwise the plant is not entitled to protection. This is the case when there

has not been any demand for the protection of the plant at issue.

However, if the plant has not been offered for sale in Brazil for more than 12 months or in other countries for more than 6 years prior to the filing date in Brazil, the SNPC would include the species to be protected in a corresponding table or list of morphological descriptors that will be issued.

The information further required to describe the plant variety shall include:

- the genetic origin;
- a statement assuring the existence of a live sample at the disposal of the SNPC and the localization thereof for eventual examination;
- name and address of the applicant and of the breeders;
- evidences of the DUS (distinctness, uniformity and stability) characteristics;
- report of other descriptors indicative of the distinctness, uniformity and stability thereof, or evidences regarding performance, by the applicant, or tests concerning the plant variety together with specific controls or those indicated by the competent agency; and
- an abstract allowing the identification of the plant variety.

DUS tests carried out by foreign governmental authorities are accepted in Brazil. The owner of the Plant Variety Protection Certificate has to keep, during the term of protection, a live sample of the protected plant variety at the disposal of the SNPC and convey two live samples of the

protected plant variety, one for handling and examination, the other to integrate into the germoplasm collection.

The above information does not exhaust the topic of description sufficiency. The agricultural field, mainly the part involving plant varieties related to commodities, is a sector in worldwide expansion. In view of the differences in national protection systems for plants it is hoped that the above information proves useful.