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PHARMACEUTICAL RELATED PATENT EXAMINATION CHANGES THE DECISION TO "CREATE AN UNHEALTHY PATENT"?

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The IPO COMMITTEE NEWSLETTER edition of April 2012 addressed the BR Federal Attorney General's epoch-making legal opinion by which ANVISA (the Brazilian Health Regulatory Agency) is precluded from acting as a second and final "patent examination division" its role being restricted to solely assess public health risks of the pharmaceutical product.

More specifically, an excerpt of said decision of January 7, 2011 reads as follows: *"having regard to the current legal frame, it is solely up to INPI, (the Brazilian PTO), to whether consider or not, the aids to examination submitted by ANVISA and in turn to definitively assess the fulfillment of patentability criteria when deciding to grant or to deny the patent"* (ipsis litteris).

The well documented decision of January 2011 was presented during the 2011 Annual AIPLA Meeting as the most relevant change to the IP law in the last 12 months if not in the last 10 years considering that ANVISA was introduced in 1999 by a "Provisional Measure" (Provisional Presidential Decree) and after several reissues it became in 2001 a new article of the Brazilian IP Law without representation of the members of the society (!).

The captioned legal opinion stemming from the Attorney General Office (AGU = Advocacia Geral da Uniao) deciding against the appeal filed by ANVISA was expected to put an end to the "reexamination" by ANVISA which purpose is to stop the grant of patents of commercial drugs for which the Brazilian Unified National Health System "SUS" otherwise would have to pay royalties to the patentee for its respective licenses and to return control to the BPTO.

Nevertheless ANVISA continues to meddle in patent examination. Despite the aforesaid legal opinion indicated in *italic,* a so called "Interministerial Ordinance" No. 1065 of May 24, 2012 stemming from a later on created Interministerial Working Group (GTI) which includes ANVISA, the Brazilian Ministry of Health and the Brazilian PTO ruled that ANVISA shall now examine all pharmaceutical patent applications before the BPTO examiners take up the file for examination.

As a reaction to the aforesaid AGU decision indicated in italics, it appears that any objection raised by ANVISA alleging insufficient disclosure, lack of novelty in the very unique opinion of ANVISA is "transubstantiated" into a risk or danger to public health. Taking by way of example a recent application that had passed to allowance by the BPTO, ANVISA's Examiner concluded: *"….Therefore, the application is contrary to public health since it hinders the access to information about technological innovation, which should help third parties in developing new inventions and contribute to technological improvements and thereby the application restricts people's access to medicaments, especially in the area of the Unified National Health System - SUS."* Not a single word about clinical tests ANVISA's report would rely upon (!!!).

Similar reasoning can be found in other deeply flawed reports against selection inventions related applications and that have passed to allowance by the examiners of the Brazilian PTO. It is the case when assessing the allowability of limitations in claims applied to general concepts as addressed by the well-known G 1/03 decision of the EPO Boards of Appeal referring to novelty.

The axiom confirmed by said G 1/03 is that the description of a general concept does not disclose specific embodiments falling within

the generally described area. This principle is derived from the premise that a specific teaching is not directly and unambiguously derivable from a general teaching. It applies to chemical formulae and the individual compounds comprised therein as well as to ranges of values and individual values between the defined limits which is of common occurrence in inventions relating to metallic alloys also.

Of normal acceptance by the examiners of the Brazilian PTO because it allows the protection of an "invention by selection" based on valuable technical contributions within a known area the axiom is ignored by ANVISA.

Conclusion:

For the time being it looks as if ANVISA has arm-twisted the Brazilian PTO unduly restricting claims, forcing applicants to give up some protection to obtain a patent on pain of having the grant of the corresponding patent denied.

Nevertheless, the aforesaid AGU decision in italics remains the main issue in patent matters in Brazil and it is a cornerstone for the Courts reverting ANVISA's denial to the grant of patent to applications that had previously passed to allowance by the Brazilian PTO and ruling that ANVISA should follow said legal opinion by AGU.

On the other hand, the PTO is a government agency and as such it might not have too much autonomy. However the goal of any national patent system is to promote long term investments in production, technological progress. To rest short of this aspiration by denying patents on false premises is not wise whatever the level of "contribution of" or "cooperation with" ANVISA moreover having regard to the recent Court decisions restricting ANVISA's range.

Perhaps the only "contribution" that ANVISA should be aware of it will provide is a larger pendency of the examination of patent applications with the result of a 10 year protection term after grant as provided by law.

COMPARING GRACE PERIODS: CANADIAN VS THE AMERICA INVENTS ACT

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Under the *America Invents Act*[1] (AIA) the US patent system will be converted from a first-to-invent to a first-inventor-to-file scheme effective March 16, 2013. The new scheme will also provide a grace period allowing the inventor to file for a patent after disclosing the subject matter of the invention. This paper will discuss the similarities and differences between the grace periods provided under the AIA and under the Canadian *Patent Act*.[2]

The Canadian and the AIA grace periods are similar in that they are both a maximum of one year in duration. In addition, for both grace periods the triggering disclosure can be in any form and can take place anywhere in the world.[3]

There are, however, important differences between the AIA and the Canadian grace periods regarding the start date of the period, the nature of the disclosure, and the scope of protection offered to inventors.

The Canadian grace period runs one year back from the Canadian filing date.[4] The AIA grace period, however, is calculated from the "effective filing date"[5], which is the earlier of the U.S. filing date and the priority date.[6] This

[1] *Leahy-Smith America Invents Act*, Public Law 112-29, 125 Stat. 284 (Sept. 16, 2011) [AIA].
[2] *Patent Act*, R.S.C., 1985, c. P-4 [CPA].
[3] For an example of a discussion on geographical limits of disclosure see Jeff Leuschner, "The one-year grace period for patent filing in Canada: An overview for U.S. practitioners" *IP Perspectives* (25 June 2012), online: *IP Perspectives* < http://www.smart-biggar.ca/en/articles_detail.cfm?news_id=625>.
[4] CPA, *supra* note 2, s. 28.2(1)(a).
[5] AIA, *supra* note 1, s. 102(b)(1).
[6] *Ibid*., s. 100(i)(1).

may present the possibility of obtaining an effective US grace period that is longer than one year by disclosing the subject matter, then filing in Canada within the one year grace period, and sometime later filing in the US claiming priority to the Canadian application.

Another potential difference is the nature of disclosure that would trigger the grace period. In Canada there is no strict on-sale bar to novelty: disclosure must be public and enabling.[7] In contrast, under the AIA being "on sale" is explicitly mentioned as being novelty-destroying.[8] However, it is uncertain whether a non-public, *i.e.* secret, sale or commercial exploitation would be novelty destroying and/or would trigger the grace period.[9] Under the current US patent legislation[10] and the jurisprudence that has developed around it, certain secret sales or commercial exploitations are considered novelty-destroying and trigger a one-year grace period.[11] It is unclear whether under the AIA the US courts would change their approach to secret sales.

A further important difference between the Canadian and the AIA grace periods is that the AIA offers much broader protection for inventors' right to obtain a patent once they disclose the subject matter of their invention. Under the AIA, a disclosure by the inventor effectively precludes any subsequent disclosure from being cited as prior art against the inventor's patent application during the grace period.

Figure 1 shows the differences between the Canadian and the AIA scope of protection during the grace period for four different disclosure/filing scenarios. In scenario 1, the Canadian and the AIA protections are similar; however, in scenarios 2, 3, and 4 the AIA preserves the inventor's post-disclosure right to potential patent protection while the Canadian *Patent Act* does not.

[7] See for example *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2008 SCC 61 at para 26.
[8] AIA, *supra* note 1, s. 102(a)(1).
[9] See for example Kevin Noonan, "Interpreting 35 U.S.C. § 102 under the America Invents Act" *Patent Docs* (31 January 2012), online: < http://www.patentdocs.org/2012/01/interpreting-35-usc-102-under-the-america-invents-act.html>.
[10] *U.S. Patent Law*, 35 U.S.C. § 102(b).
[11] See for example MPEP, s. 2133.03 citing *Hobbs v. United States*, 451 F.2d 849 at 859-60 (5th Cir. 1971).

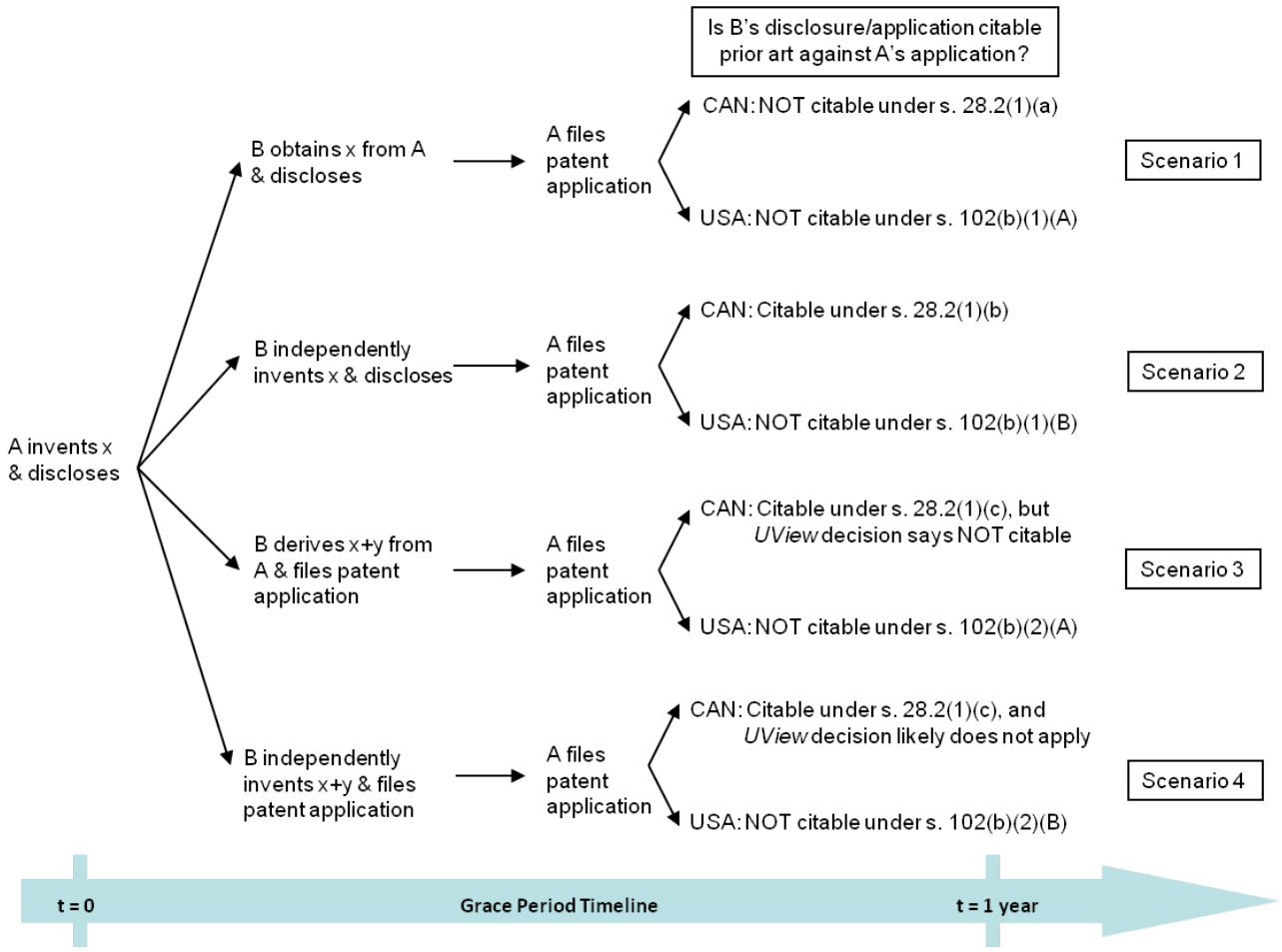

Figure 1: Differences between the Canadian and the AIA scope of protection during the grace period.

In all of these scenarios, determinations need to be made as to the fact, timing, and substance of A's initial disclosure and whether B's subsequent disclosure/application was obtained/derived from A. In the case of scenarios 3 and 4, the AIA provides for formal Derivation Proceedings.[1] If A provides a sufficient evidentiary basis, Derivation Proceedings are commenced and are then decided by the Patent Trial and Appeal Board.[2] These formalized proceedings provide a convenient administrative means for deciding issues of disclosure and derivation.

Canada has no equivalent derivation proceedings. One reason may be that under s. 28.2(1)(c) of the Canadian *Patent Act* B's application is always citable as prior art against A's application, regardless of whether B's application was derived from A's earlier disclosure.[3] However, in at least one decision, *UView Ultraviolet Systems v. Brasscorp,*[4] the Federal Court carried out a derivation determination[5] and decided in favour of A.[6]

In *UView* the Court recognized the inconsistency between the s. 28.2(1)(a) grace period and ss. 28.2(1)(c) and (1)(d). The evidence in *UView* showed that B was aware of A's disclosed invention and considered it relevant prior art to B's invention. Based on this finding the Court stated:

Section 28.2 allows the disclosure of the subject matter defined by a claim within a period of one year before the applicant's filing date.…[I]t would not make any sense to allow the subject matter of a claim to be disclosed in the period of one year prior to the filing date and still be patentable if someone else could use the disclosed subject matter as prior art to defeat the applicant's application for a patent.[7]

In light of *UView*, in scenario 3 B's application is likely not citable prior art against A's application during the one-year grace period despite s. 28.2(1)(c) of the *Patent Act*. Considering the lack of formalized derivation proceedings in Canada, should a dispute arise in a scenario 3 situation, A may consider filing affidavit evidence before the Commissioner of Patents to establish the fact and substance of his/her initial disclosure and to prove that B has derived his/her invention from A. If administrative means are exhausted, Courts can also be called upon to resolve disclosure and derivation issues.

The AIA converts the US to a first-inventor-to-file jurisdiction while providing grace periods for inventors who disclose their inventions. The AIA grace period is similar to the Canadian grace periods in some respects; however, there are important differences in the start date of the grace period and in the level of protection granted to inventors. Under the AIA, disclosing an invention protects the inventor during the grace period from having any subsequent disclosure or patent application cited as prior art against his/her patent application. This effectively creates a first-to-disclose scheme.

This scheme is in keeping with the patent bargain in that it preserves the possibility of obtaining a patent monopoly for an additional one-year grace period in return for the inventors' disclosing their invention earlier. The grace period also provides added incentive for innovation by protecting naïve inventors who disclose inadvertently and academics who face pressure to publish. Considering the significant rewards under the AIA for disclosing, it remains to be seen whether the US courts adopt a higher standard for disclosure, for example by requiring it to be public and enabling, as is the case in Canada.

[1] AIA, *supra* note 1, s. 135.
[2] The Patent Trial and Appeal Board is the successor under the AIA to the Board of Patent Appeals and Interferences.
[3] In this situation there are additional issues regarding whether B should be able to obtain a patent. A can protest against a patent being granted to B by filing prior art under s. 34.1(1) of the *Patent Act* and by filing a protest under chapter 18 of MOPOP.
[4] *UView Ultraviolet Systems Inc. v. Brasscorp Ltd.*, 2009 FC 58 at paras 220-26 [*UView*].
[5] Facts of *UView* fall under s. 28.2(1)(d); however, the *ratio* of the decision appears to encompass s. 28.2(1)(c) as well as (1)(d). See *UView*, *ibid*., at para 224.
[6] *UView* has been discussed in the derivation context in *supra* note 3.
[7] *UView*, *supra* note 15, at para 224.

RAISING THE BAR- CHANGES TO THE AUSTRALIAN PATENTS ACT

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Introduction

The *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* received Royal Assent on 15 April 2012 and represents the most significant set of reforms to intellectual property laws in Australia in the last 20 years. The reach of the legislation is broad and touches upon almost every piece of intellectual property legislation in Australia, however, it has its most significant impact on patent law and trade mark law. The focus on the present article is the impact of the changes on patent law and practice in Australia and provides recommendations for users of the patent system to enable them to pro-actively manage their portfolio to take advantage of the timing provisions of the commencement of the Act.

Objectives of the Act

There were a number of different objectives to be realised by the changes to the patent law including:

Raising the quality of granted patents;
Providing access to patented inventions for research and regulatory activities;
Reducing delays in resolving patent application proceedings.

As such many of the changes in relation to patent law were directed towards changing provisions that had an impact on the prosecution of patents and making changes to restrict the ability of patent applicants to delay proceedings during prosecution and contentious matters. As one of the stated aims was to improve patent quality it is speculated that many of the changes will make it more difficult to obtain broad patent protection in Australia although exactly how the changes will play out in practice remains to be seen.

Major Changes

The purpose of this article is not to provide a comprehensive listing of all the changes but rather to highlight the most important changes that will have a direct impact on patent prosecution practice in Australia. If any reader requires a comprehensive list of changes please contact the author and I will be more than happy to provide a full listing. The major changes are as follows:

Inventive Step

In order for an invention to be protected as a standard patent in Australia it is required to have an inventive step. An invention will be seen as possessing an inventive step if a person skilled in the art would not consider the invention to be obvious in light of the common general knowledge in the art when taken either alone or together with the publicly available information contained in prior art base.

At the present point in time the “common general knowledge” used in assessing this test is limited to that which is commonly known in Australia. In addition, in order for information to be considered to be publicly available it has to satisfy 3 criteria, namely the information is restricted to information that can be (1) ascertained, (2) understood and (3) regarded as relevant by a person skilled in the art.

Under the new laws the above limitations will be removed significantly broadening the material that an examiner can use to sustain an inventive step objection. Thus, the common general knowledge applicable as of 15 April 2013 will be that of a person skilled in the art as it existed before the priority date of the relevant claim, without geographical limitations.

In addition under the new act the prior art base for assessing inventive step will be any information made publicly available before

the relevant priority date. As such it is anticipated that at least in the short term examiners may cite non analogous prior art for the purposes of inventive step whereas under the current act documents of this type could be discounted as being non-admissible prior art.

Sufficiency

The law of sufficiency in Australia requires that a patent specification "*describe the invention fully including the best method known of performing the invention"*. Case law in relation to the law of sufficiency has established that a specification is sufficient if it allows a person skilled in the art to produce something (or carry out something in relation to a process or method patent) falling within the scope of every claim.

Under the amended legislation a complete patent specification must disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art. In addition the legislation sets out that there is a requirement for full enablement across the scope of the claims. The effect of this is that sufficient information must be provided to enable the whole breadth of the claimed invention to be performed by the skilled person without undue burden, or the need for further invention. The explanatory memorandum to the bill explains that this provision is intended to be interpreted in the same way as similar provisions in the UK and EU. As such it is anticipated that following the passage of the legislation it is likely to be more difficult to obtain broad patent protection without sufficient worked examples and/or disclosure in the specification.

Utility

Under the current act inventions only failed the test for utility where it could be shown that the invention either did not work or failed to meet one or more promises of the invention, Under the new act a requirement has been introduced requiring the specification to disclose "*a specific, substantial and credible use*" for the invention. The disclosure "*must be sufficient for that specific, substantial and credible use to be appreciated by a person skilled in the relevant art*". The Explanatory Memorandum associated with the Bill indicates that the intent is that the language "*specific, substantial and credible*" be given the same meaning as is currently given by the US courts and the USPTO. '*Specific*' means a use specific to the subject matter claimed and can "*provide a well-defined and particular benefit to the public*". '*Substantia*l' means the claimed invention does not require further research to identify or reasonably confirm a 'real world use'. "*An application must show that an invention is useful to the public as disclosed in its current form, not that it prove useful at some future date after further research*".

Fair Basis

Current Australian patent law requires the claims to be fairly based on the disclosure in the specification. This has generally been seen to be satisfied where the scope of the claims was consistent with the breadth of disclosure in the specification.

Under the amended act section 40(3) no longer includes the requirement that the claims must be "*fairly based on the matter described"*. Instead this section now requires that the claims must be "*supported by matter disclosed*". The amended language is intended to align the Australian requirement with those of overseas jurisdictions (such as the UK). In such jurisdictions, language such as 'supported by' or 'fully supported by' the description is used. The terms 'support' and 'full support' pick up two important concepts. There must be a basis in the description for each claim and the scope of the claims must not be broader than is justified by the extent of the description, drawings and contribution to the art. There must also be consistency, or basis, for each claim in the description.

Divisional Patent Applications

Under the current law there are two deadlines for filing divisional patent applications. The

first deadline allows for the filing of a divisional application for an invention disclosed in the parent standard patent specification as originally filed. Such a divisional patent application must be filed within 3 months of the date of advertisement of acceptance of the parent application. The second deadline allows for the filing of a divisional application for an invention falling within the scope of the accepted claims of the parent standard application. Such a divisional patent application must be filed before grant of a patent on the parent application.

Under the current arrangements, it is also possible for an applicant to file a divisional application (with restricted claims scope) during opposition proceedings. A standard patent application can also be converted to a divisional patent application of an earlier application as long as it was filed while the parent was still pending. As a result, divisional patent applications are used tactically to maintain pending patent protection for an invention that is the subject of an opposition proceeding.

The amended provisions will maintain the deadline for filing a divisional application to within 3 months from the date of advertisement of acceptance of the parent standard application. However, it will no longer be possible to file a divisional patent application (with restricted claim scope) after this initial date. The amended divisional filing deadline means that an applicant will be unable to file a divisional patent application or convert an existing patent application to a divisional application beyond the deadline for commencing opposition proceedings. As such the flexibility provided to patent applicants both during opposition proceedings and in the prosecution of closely related subject matter has been significantly reduced by these changes.

Examination Standard

Under the current examination standards in Australia the applicant is provided with the benefit of the doubt during prosecution of the application. As such under the current act an examiner is required to accept a patent application "*unless it appears practically certain*" or "*clear*" that it would be invalid if granted. As such it has generally been possible to argue during prosecution in problematic cases that the benefit of the doubt should favour the applicant.

Under the new patentability requirements, Australian Patent Examiners will apply a different test to applicable applications when determining whether to accept them for patent grant. This new test will require the examiners to be satisfied "*on the balance of probabilities*" that a patent granted on the application will be valid. Similarly, the Patent Office will only be required to certify an applicable innovation patent when satisfied, on the balance of probabilities, that the innovation patent is valid. When the Patent Office is not so satisfied, then the innovation patent can be revoked.

It is difficult to know the exact impact of this change although it is anticipated by the author that the change will embolden examiners to maintain objections leading to an increase in the number of divisional applications being filed to maintain the pendency of cases. It is also anticipated that the number of oral hearings before the patent office will increase.

Impact on changes to Prosecution practice

As will be apparent from a reading of the above the changes will almost certainly make it harder to obtain patent protection in Australia and are also more likely to lead to patents being granted that are narrower in scope than those that are able to be obtained under the present act. In addition to arguing for the maintenance of patent scope it is also likely that patent prosecution costs will increase until examiners and practitioners alike become acquainted with the new standards.

Application of the New Act – the Transitional provisions

Most of the provisions of the new act do not come into force until 15 April 2013 although they could potentially impact on pending Australian applications and pending PCT applications. The provisions of the act state that the new act will apply to both (1) all patent applications with an Australian filing date after 15 April 2013 and (2) all applications for which examination has not been requested by that date. For practical purposes, therefore the act applies to all cases for which examination has not been requested by 15 April 2013.

Recommended Actions - things to consider doing before 15 April 2013:

It is noted that the standard of prosecution that applies to a patent application will continue to apply to that case through its entire lifespan. As such there are a number of things that patent owners should consider if they wish any of their applications to enjoy the more lenient standards of patentability provided by the current act.

Request examination or modified examination of any pending Australian patent applications prior to 15 April 2013;

Request deferment of acceptance of any pending complete applications prior to 15 April 2013;

Enter the National phase in Australia and request examination prior to 15 April 2013 for all pending PCT applications that you know will ultimately enter national phase in Australia;

Consider Filing a Convention application and an examination request prior to 15 April 2013 where a PCT application has not been filed;

File any required divisional applications with an examination request prior to 15 April 2013;

Convert pending applications which are intended to claim divisional status prior to 15 April 2013 if the deadline for filing a new divisional application has already passed;

If it is intended to withdraw an opposed application, file any required divisional applications (with an examination request) and withdraw the opposed application prior to 15 April 2013; and

Consider amending the specifications of pending applications prior to commencement to clearly describe the utility of the invention and to provide the necessary level of "support" for the claims.

Conclusion

In conclusion the amendments made to the patents act will have a significant impact on the prosecution of applications in Australia and it is highly recommended, where possible, that intellectual property owners give serious consideration to ensuring that their applications are treated under the more generous provisions that currently apply instead of the more onerous provisions that will apply once the new act commences.

Please contact the author at attorney@pof.com.au if you need further assistance in determining what action you should take in relation to any pending or proposed new Australian patent applications.

ARGENTINA—NEW GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL-CHEMICAL APPLICATIONS (*)

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On May 2, 2012 the Argentine Patent Office (National Institute of Industrial Property, or INPI), together with the Ministries of Industry and of Health, issued Joint Regulation Nos. 118/2012, 546/2012 and 107/2012 with new guidelines for examining pharmaceutical-chemical patent applications.

This Regulation, which was published in the Official Gazette on May 8, 2012, severely restricts the patentability of several categories of invention in the pharmaceutical field. Pursuant to Article 2 of the Regulation, it became effective on the day following its publication (i.e., on May 9, 2012), and will be applied to pending applications immediately.

Background of the new guidelines

Ever since the TRIPs Agreement gradually came into force, complaints arose in several developing countries that patent enforcement was essentially incompatible with a sound public health policy. Rather than an all-out attack against pharmaceutical patents, this stance espoused the view that they were being granted for innovations that were not really patentable, and to keep within the bounds of TRIPs it was argued that the Agreement allowed flexibilities to raise the threshold for granting patents and thus conversely lower the level of protection afforded to these inventions.

This position was reflected in a statement issued in the Meeting of Health Ministers of the Mercosur Countries (Argentina, Brazil, Paraguay and Uruguay) held in Montevideo, Uruguay, on December 4, 2009, which expressed the Member Countries' concern with "the proliferation of patent applications for matters which are not properly an invention or are marginal developments". This statement also pointed out that "the importance and difficulties caused by pharmaceutical patents has been acknowledged and developed in various regional and international agreements and particularly with regard to the access to medicines". As a result, the Health Ministers agreed "to promote the adoption of criteria to protect public health in the guidelines for patentability".

Consistent with this approach, Brazil has a system where pharmaceutical applications are studied not only by the Patent Office but also by the health authority. In turn, Paraguay adopted a Brazilian-type system and recently issued restrictive guidelines for pharmaceutical applications of its own.

Lately a Latin American initiative, the "Prosur", appears to follow this line of thought. "Prosur" is an abbreviation which stands for "Proyecto Sur" ("Southern Project", or "Project of the South"), whose more formal name is "Sistema de Cooperación Regional en Propiedad Industrial" ("Industrial Property Regional Cooperation System"). It is a loose organization formed by the patent offices of Argentina, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Surinam and Uruguay to provide a common platform for carrying out novelty searches and patentability examinations, in order to avoid duplicating efforts.

It is against this backdrop that the Joint Regulation must be analyzed.

Purpose of the new guidelines

The preparatory documents produced by the Health Ministry as a basis for the Joint Regulation reveal the philosophy behind it. They state that "intellectual property, and particularly the patent system, are the cornerstone for designing a health policy", and as "the patent system ensures that the first person to meet the legal requirements for a patent shall obtain a legal monopoly in the patent invention (…) the system generates additional social costs derived from the owner's right to bar the unauthorized manufacture, commercialization and sale of his or her invention". "The mere existence of monopolies", the documents goes on, "causes the supply of a good to fall and therefore for its price to rise".

In turn, the recitals of this Regulation quote extensively from the above statement of the Health Ministers' Meeting. The same recitals, moreover, point out that TRIPs allows member countries to determine in their national laws the standards of novelty and non-obviousness required for patentability.

The new guidelines

As indicated above, in essence the Joint Regulation restricts severely the patentability of several categories of inventions in the pharmaceutical field. Its main points can be summarized as follows:

Polymorphs, hydrates and solvates: Claims directed to polymorphs, hydrates and solvates of known compounds will not be allowed, as they are considered to be an intrinsic property of matter in its solid state and therefore is not considered to be an invention. Processes for obtaining them constitute routine experimentation and therefore will not be considered patentable.
Single enantiomers: They will not be patentable subject matter when the racemic mixture is already known. However, novel and inventive processes for obtaining enantiomers may be patentable if they are clearly disclosed and the resulting compound is fully characterized by spectroscopic data.

Markush-type claims: Compounds represented by Markush structures will be accepted if the specification includes examples which are representative of all the claimed compounds. These examples must include physicochemical data for each compound obtained.

Selection patents: They will not be allowed as novelty will not be recognized for the selection of one or more elements which were already generically disclosed in the art (such as in a Markush claim), even if these elements show different or improved properties.

Salts, esters and other derivatives (such as amides and complexes): They will not be patentable since they are considered to be the same substance as the basic compound.

Active metabolites: They will not be considered as inventions since they are derivatives from the active ingredients that are produced in the body. Metabolites will not be patentable as an independent object from the active compound.

Prodrugs: The new guidelines require the claimed prodrug to be specifically disclosed and to be inactive or less active than the active compound.

New formulations and compositions as well as the processes for preparing them: They shall generally be deemed obvious over the prior art. Exceptionally, claims directed to formulations will be acceptable when a long-felt need is solved in a non-obvious manner.

Combinations: Claims directed to combinations of known active compounds, second medical uses or dosage regimes will be considered as methods of treatment, which are excluded from patent protection.

Dosage regimes: They will be considered to be equivalent to methods of treatment, and therefore not patentable.

Second medical uses: They continue not being patentable subject matter.

Processes: Synthesis and manufacturing processes which are not novel and inventive per se, regardless of whether the starting materials, intermediate compounds or the end product are novel and inventive, will not be considered to be patentable. An example provided by the guidelines is the production of a new salt of a known product.

The new guidelines also provide that any additional example or information filed during the prosecution of an application will be accepted as long as it does not broaden the original disclosure.

Furthermore, manufacture methods must produce an industrial result. Therefore, processes for the manufacture of active compounds disclosed in a specification must be reproducible and applicable on an industrial scale.

Finally, the new guidelines end on a rather cryptic note, stating that “[w]hether to extend these Guidelines to pharmaceutical

biotechnological inventions will have to be analyzed for the specific case".

Practical overview

While in some cases the Joint Regulation puts into writing what the Argentine PTO has been doing hitherto, it also introduces new restrictions on patentable subject matter. Indeed, some of the claim categories listed in the new guidelines were already considered to be non-patentable subject matter by the PTO. This is the case of second medical uses, dosage regimes, and combinations, which were considered to be directed to methods of treatment, expressly excluded from patentable subject matter by the Argentine Patent Law.

On the other hand, for some other categories the Regulation makes the PTO's practice official. This is the case of Markush claims, where the PTO has been applying lately a restrictive criterion allowing only a limited generalization of the examples. Similarly, the PTO was applying the criteria now outlined in the new guidelines regarding active metabolites and prodrugs.

However, for some other categories of inventions the new guidelines severely restrict patentability. This is the case of polymorphs, hydrates and solvates, single enantiomers, salts, esters and other derivatives, as well as compositions. For these inventions, although the PTO used to apply high standards for evaluating inventiveness, it was still possible to obtain patent protection.

In the case of compositions, the new guidelines state that they shall generally be deemed obvious over the prior art and they will be acceptable only exceptionally, when a long-felt need is solved in a non-obvious manner. It is not clear why only solving a long-felt need was included, as this is not the only secondary consideration of non-obviousness that can be taken into account.

The following table makes a before-and-after comparison between the prior practice of the Argentine PTO and the new guidelines:

Chemical entity	Prior practice	Criteria set forth in the new guidelines
Polymorphs	Polymorphs were patentable if, in addition to being novel, they had improved or unexpected characteristics over previously known forms. Usually, extensive additional information (Rx diffraction, Tm, IR, Raman, NMR, etc.) was requested, so as to prove novelty and inventiveness. Processes for obtaining polymorphs were acceptable if they were novel, inventive and industrially applicable.	Claims directed to polymorphs of known compounds shall not be allowed, as polymorphism is considered to be an intrinsic property of matter in its solid state and therefore it is not an invention. Processes to obtain polymorphs constitute routine experimentation and therefore are not patentable.
Solvates and Hydrates	Solvates were patentable if they had improved or unexpected characteristics over previously known forms. Usually, extensive additional information (Rx diffraction, Tm, IR, Raman, NMR, etc) was requested, so as to prove novelty and inventiveness. Processes to obtain solvates were acceptable if they were novel, inventive and industrially applicable.	Claims directed to solvates of known compounds will not be allowed. Even though it is recognized that they have a different chemical composition, they form upon exposure of the compound to a particular set of conditions, and cannot be considered as an invention. Processes to obtain solvates constitute routine experimentation and therefore are not patentable.
Enantiomers	Prior disclosure of a racemate did not affect novelty of a particular enantiomer. The claimed enantiomer had to show improved and unexpected features. Processes for preparing enantiomers were patentable.	Single enantiomers are not patentable when the racemic mixture was known. Nevertheless, novel and inventive processes for obtaining enantiomers may be patentable if they are clearly disclosed and the resulting compound is fully characterized by spectroscopic data
Markush structures	Compounds represented by Markush structures were accepted if the specification included examples which were representative of all the compounds claimed.	Compounds represented by Markush structures will be accepted if the specification includes examples which are representative of all the compounds claimed. These examples must include physicochemical data for each compound obtained.
Selection Patents	Selection patents were accepted. Novelty was recognized as long as the specific compound or composition was not expressly disclosed or claimed in the prior art, and the selected object showed improved or unexpected features.	Selection patents shall not be allowed as novelty will not be recognized for the selection of one or more elements which were already generically disclosed in the art (such as in a Markush claim), even if these elements show different or improved properties. Under the new guidelines, pharmaceutical compositions, the processes for preparing them and the resulting medicines are deemed to be selection of compound patents, and therefore not patentable due to lack of novelty.

Chemical entity	Prior practice	Criteria set forth in the new guidelines
Salts, esters and other derivatives of known substances	Patents directed to salts, esters and other derivatives were accepted. Novelty was recognized as long as the specific compound was not expressly disclosed or claimed in the prior art, and the selected compound was adequately supported and showed improved or unexpected features.	Salts, esters and other derivatives (such as amides and complexes) of known substances are considered as the same substance and are not patentable for lack of novelty.
Active metabolites	Metabolites were considered as a discovery, and hence not patentable.	Active metabolites are derivatives from the active ingredients that are produced in the body, and cannot be considered as "created" or "invented". Metabolites are not patentable as an independent object from the active compound.
Prodrugs	A claim directed to prodrugs in a general manner was not accepted as it was considered unclear and unsupported. Only those specific prodrugs that were disclosed and exemplified in the specification were accepted.	Prodrugs must be supported by the specification, which must include the best method for obtaining them and their characterization. The specification must also demonstrate that the prodrug is inactive or less active than the active compound
Formulations and compositions	Formulations and compositions were patentable subject matter if the applicant could show that they were novel and non-obvious. The Patent Office had raised their standards regarding inventiveness in the last years. Usually, comparative data showing improved/unexpected results over the prior art were requested by examiners.	New formulations and compositions as well as the processes for preparing them should generally be deemed obvious over the prior art. Exceptionally, claims directed to formulations will be acceptable when a long-felt need is solved in a non-obvious manner.
Combinations	Claims directed to combinations of known active compounds were considered as equivalent to methods of treatment, since the Patent Office understands that the scope of a claim to a combination includes separate administration of two or more known compounds. Methods of treatment are excluded from patent protection. Occasionally the application might be studied as a composition if the specification supported this interpretation and the claims were amended accordingly.	Claims directed to combinations of known active compounds shall be considered as equivalent to methods of treatment, since the Patent Office understands that the scope of a claim to a combination includes separate administration of two or more known compounds. Methods of treatment are excluded from patent protection.
Dosage	Claims directed to dosage regimes were considered as equivalent to methods of treatment, which are excluded from patent protection by the Statute.	Claims directed to dosage regimes shall be considered as equivalent to methods of treatment, and therefore excluded from patent protection.

Chemical entity	Prior practice	Criteria set forth in the new guidelines
Second Medical Uses	Claims directed to the new use of a known compound were considered as equivalent to a methods of treatment, which are excluded from patent protection by the Statute.	Claims directed to the new use of a known compound shall be considered as equivalent to a methods of treatment, and therefore excluded from patent protection.
Analogy processes	They were granted, as the PTO considered them new if the steps or reagents were different and non-obvious if performance was improved, a higher purity was obtained or a problem was solved.	These processes shall not be patentable because they are considered to be neither new nor inventive.
Disclosure and scope	Additional examples or information filed during prosecution of an application were accepted as far as they did not broaden the original disclosure. The Patent Law includes best mode provisions.	Any additional example or information filed during prosecution of an application shall be accepted as far as it does not broaden the original disclosure. Manufacturing methods must produce an industrial result. Therefore, processes for the manufacture of active compounds disclosed in a specification must be reproducible and applicable on an industrial scale.

According to the Regulation, these guidelines are conceived as general instructions addressed to the patent examiners. The experience with the existing general guidelines for patent examination has shown, however, that in practice such guidelines operate as very specific legal provisions which must be adhered to. What is more, the Regulation expressly states that any exceptions to the guidelines must be duly justified.

At this early stage it is impossible to anticipate exactly how the new guidelines will be applied by the Argentine PTO. Will the PTO issue blanket refusals at top speed, or will it issue office actions as heretofore, albeit with the new criteria? Will it allow the objected subject matter in secondary claims, or will it require that such claims be deleted always? One thing is certain: the new guidelines will be applied, no matter what, regardless of speed, and a safe assumption is that the PTO will proceed slowly but surely. Moreover, as we pointed out above, the new guidelines will be applied immediately to pending applications.

Legal analysis

The only chance to overcome the new guidelines will be on appeal before the courts. According to the Argentine legal procedure, a rejection must first be appealed to the President of the National Institute of Industrial Property, who as a rule rubber-stamps the rejection, and thereafter to the courts. The significance of this legal analysis lies in that it may provide the grounds for such an appeal.

In our opinion the new guidelines are contrary to the Argentine Constitution, the TRIPS Agreement and the Argentine Patent Law.

First, although these guidelines purport to be only instructions addressed to the examiners, in fact the Government, through the PTO and the Ministries of Industry and of Health, is legislating as if it were Congress (here, on patentable subject matter and on the requirements for patentability), something which it is expressly barred from doing by Article 99.3 of the Argentine Constitution ("In no case, under penalty of absolute and incurable nullity, may the Executive issue provisions of legislative nature").

Furthermore, insofar as the guidelines exclude patentable subject matter from patent protection, they are in violation of Article 17 of the Argentine Constitution. This provision, drafted after the Patent and Copyright Clause of the U.S. Constitution, provides that "[a]ny author or inventor is the exclusive owner of his work, invention or discovery for the term granted by law".

Moreover, the new guidelines are inconsistent with the TRIPS Agreement. First, they redefine terms such as "invention", "novelty" and "non-obviousness" with a meaning that is different from the meaning they were given in said treaty, and thus, to all practical purposes, rewrite the treaty. Secondly, they discriminate between technologies, as they impose restriction on pharmaceutical inventions which are not extended to other technologies of similar nature. Thirdly, the new guidelines extend well beyond the flexibilities authorized by article 31 of the TRIPs Agreement and new art. 31 bis introduced pursuant to the 2003 Doha Declaration.

Finally, the guidelines run counter to the pertinent provisions of the Argentine Patent Law on requirements for patentability and patentable subject matter.

Suggested strategies

What is to be done with this somewhat unfavorable scenario (to put it mildly) for pharmaceutical patent applications? At this point in time, the following general strategy appears to be advisable:

Continue filing the applications for the categories of inventions comprised by the guidelines, at least for the most likely

candidates, as otherwise they will be permanently and irrevocably forfeited even if the new rules are repealed or amended by the Government or overruled by the Courts; such decisions will take years, but for the applications to be alive they must first have been filed.

Delay filing the request for substantive examination, in the event the guidelines may be repealed in the meantime.

File divisional applications in those cases where the original application includes both subject matter that is and is not objectionable under the new guidelines.

Appeal to the Courts the refusal of patent applications issued pursuant to the new guidelines. These arguments must be set forth briefly when responding to office actions that cite the new guidelines and in the appeal to the president of the National Institute of Industrial Property, and must be fully developed when appealing before the Courts.

Final remarks

As has been seen, the new guidelines go beyond the objections made by even the most vocal critics of these types of invention, who, regardless of their skepticism, did acknowledge that these innovations could be patented as long as they met the general definitions or requirements of invention, novelty, non-obviousness and industrial applicability.

The new guidelines, on the contrary, in several instances have introduced absolute *per se* bars to patentability, as in the case of polymorphs, solvates, hydrates, selection patents, salts, esters, combinations and dosages; and patentability has only exceptionally been allowed for prodrugs, formulations and compositions. Needless to say, these guidelines also depart from the standard practice in the USPTO, EPO and other highly qualified patent offices.

The path to overcome them will be neither easy nor fast. The strategies set out above will probably have to be adapted to a legal scenario which will evolve in accordance with the decisions which will be coming gradually from the Argentine PTO and the Argentine courts.

SUPREME COURT OF CANADA UPHOLDS STANDARDS OF DISCLOSURE

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The Supreme Court of Canada, in *Teva Canada v. Pfizer Canada* held Pfizer's patent for the use of sildenafil, commercially known as Viagra®, void, thereby allowing Teva to market a generic version of the drug prior to expiry of the patent in 2014. In overturning the lower court decisions, the Supreme Court unanimously held that the patent failed to adequately disclose sildenafil's efficacy in treating erectile dysfunction (ED).

In interpreting the requirements under Canadian law for sufficiently disclosing a claimed invention, the Supreme Court's decision provides valuable guidance on how such requirements must be met when preparing a patent application.

The issue before the Court was Teva's application for a Notice of Compliance (NOC) from Health Canada to produce a generic version of sildenafil. In its decision, rather than disposing of this single issue, the Supreme Court arguably overextended its jurisdictional reach in holding the patent to be void. Pfizer has responded by moving to have the Supreme Court's decision amended to address only the NOC application or, alternatively, to have a re-hearing on the remedy awarded.

In a separate action, *Apotex v. Pfizer Ireland,* another major generic drug company, Apotex, sought impeachment of the patent. Following the Supreme Court's decision, and several days before a hearing in this case, Apotex successfully moved for summary judgment on its impeachment action. The Federal Court held the patent invalid and void.

Background

Pfizer obtained the patent, which is directed to a known genus of compounds having formula (I) claimed to have utility as an orally administered medication for the treatment of ED. The genus was found to encompass approximately 260 quintillion compounds. The patent generally discloses a genus of compounds and a number of "especially preferred" members of the genus for use in treating ED. The patent briefly refers to a study that was conducted on one of the compounds, which was found to have the desired activity. This compound was not specifically identified in the disclosure but was later shown to be sildenafil. No further data were presented in the patent indicating the effectiveness or lack of effectiveness of other compounds of the genus.

The Supreme Court noted that the patent includes "cascading claims", starting with a claim to the use of a genus of pyrazolopyrimidinones followed by subsequent claims of narrowing scope. Claims 6 and 7 are directed to the use of individual compounds of the genus, with claim 7 being directed to use of sildenafil.

Teva Canada sought an NOC to market a generic version of sildenafil, alleging that the patent was invalid on various grounds, namely, obviousness, lack of utility and insufficiency of disclosure. These allegations were successfully denied by Pfizer before the Federal Court, in a decision that was upheld by the Federal Court of Appeal. Teva then appealed to the Supreme Court.

The Decision

The Supreme Court focussed on two issues: lack of utility and sufficiency of disclosure. The obviousness argument was not asserted by Teva on appeal.

Lack of Utility

The Supreme Court readily dealt with the lack of utility allegation by acknowledging that the utility of one compound, sildenafil, was demonstrated by the patentee as of the filing date of the application. The Court also confirmed that there exists no requirement under Canadian law that the utility of an invention must be disclosed in the patent. The Supreme Court further indicated that, even if such a disclosure requirement existed, it was met by the reference to the study that was conducted by Pfizer, even though the identity of the effective compound was not mentioned.

Sufficiency of Disclosure

The Supreme Court, however, found that the patent failed to sufficiently disclose the subject invention. In allowing Teva's appeal, the Court stated that "*sufficiency of disclosure lies at the very heart of the patent system*" and that a sufficient disclosure, as required under the *Patent Act,* is a precondition for the grant of a patent.

The Supreme Court began its analysis by identifying the "nature of the invention". In the lower court decisions, each claim of the patent was found to comprise a separate invention and the sufficiency of disclosure assessment was therefore made on a claim-by-claim basis. In so doing, the lower courts found the use of sildenafil, covered by claim 7, was adequately disclosed. Specifically, the lower courts found that the disclosure of one compound at the narrow end of cascading claims of the genus having the required utility was sufficient to allow a person skilled in the art to conclude, without undue

experimentation, that the one compound effective for treating ED was sildenafil.

The Supreme Court rejected the lower courts' approach and stated that a patent must be directed to a single inventive concept, the nature of which must be determined based on a review of the whole specification, including the disclosure and the claims. The Court found that the inventive concept covered by the patent is the use of a genus of compounds that is effective in treating ED. However, the Supreme Court went on further to state that, since Pfizer's study identified only sildenafil as being effective in treating ED, the use of sildenafil in the treatment of ED was in fact the "true" invention that must be disclosed in the patent to satisfy the disclosure requirements of the Act.

While the Supreme Court agreed that the specification disclosed one compound having the desired utility, such teaching was found to be insufficient to enable a skilled reader to conclude that the identity of that one compound was sildenafil. The Supreme Court said: "More importantly, what must be considered is whether a skilled reader having only the specification would have been able to put the invention into practice."

While willful intent to mislead was not alleged in this case, the Supreme Court was critical of the lack of detail provided in the specification, particularly in view of the fact that Pfizer had obtained data on sildenafil as of the filing date of the application but failed to include such data in the patent specification. The Supreme Court said: "The disclosure failed to state in clear terms what the invention was. Pfizer gained a benefit from the Act – exclusive monopoly – while withholding disclosure in spite of its disclosure obligations under the Act. As a matter of policy and sound statutory interpretation, *patentees cannot be allowed to "game" the system in this way."* (emphasis added)

Commentary

The Supreme Court's decision provides a roadmap for both applicants and patentees.

First, the decision serves to emphasize the importance of including in a patent specification a clear and unambiguous definition of the "inventive concept" underlying the invention. The Supreme Court's decision adds to the body of law developing in Canada that the applicant for a patent should clearly indicate the "inventive concept", or "promise of the patent", so as to avoid the adoption of an unintended interpretation later. An incorrect interpretation of the inventive concept may result in unforeseen utility or disclosure requirements.

Second, once the inventive concept has been identified, the specification should provide a clear and enabling disclosure of the claimed invention. As the Supreme Court's decision highlights, a patentee cannot rely solely on the claims for disclosure of specific embodiments of the invention or Third, a patent specification should include sufficient and specific data to support all claimed embodiments and, in particular, each working embodiment. The inclusion of all test data, both positive and negative, and identification of the tested species may prove to be crucial for supporting claims to such embodiments. In the case of sildenafil, while the testing conducted by Pfizer was found sufficient to establish the utility of sildenafil, the failure to specifically identify sildenafil as the effective compound resulted in a finding that the sufficiency of disclosure requirements were not met. Arguably, had Pfizer's test data been included in the specification, a different conclusion may have been reached. In particular, if test data are available for only a certain subset of claimed compounds, such data should be clearly associated with the relevant compounds. As noted by the Supreme Court, the patent disclosed only one compound to be effective while the patent "ended with two individually claimed

compounds, thereby obscuring the true invention".

Fourth, the Supreme Court has reiterated that there is no requirement to disclose demonstrated utility in a specification. It is sufficient for the patentee to have conducted the required investigation as of the filing date of the application. As stated by the Court: "The fact that Pfizer did not disclose that the tested compound was sildenafil goes to the issue of disclosure of the invention, not to that of disclosure of the invention's utility."

Fifth, for patent applications that are currently pending, applicants may be advised to review the pending claims and to amend the claims or disclosure accordingly to address any deficiencies in the specification. For example, where needed, suitable claim amendments may be considered so as to limit specifically claimed compounds to those that are explicitly described in the specification.

Finally, for issued patents, patentees may consider assessing their Canadian patents to determine whether disclaimers may avoid any unsupported claims from jeopardizing other claims.