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Biotech & Pharma: Divisional Practices and New Prosecution Opportunities

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Evolving and increasingly more costly patent practices in Patent Offices around the world are challenging patentees with global filing aspirations to come up with filing and prosecution strategies that allow them to seek expeditious, cost effective and most importantly, meaningful patent protection in jurisdictions of interest.

In the past and still today, one common approach to address one's Canadian patent aspirations was to take claims allowed in the US or Europe and essentially place these claims on file in a related Canadian application. Canada's deferred examination request system and the fact that Canadian Examiners routinely consider aspects of related US and European prosecution histories helped make this strategy commonplace.

To default to this strategy however, in the absence of considering how Canadian patent practice has evolved relative to other jurisdictions and without considering more broadly what it has to offer, may be unnecessarily leading some applicants to limit their strategic prosecution options.

Canada, as a member of the G8, is still one of the most inexpensive jurisdictions for obtaining patents. Business in Canada is also uniquely positioned to participate in the most open movement of trade with the US. Fortunately, Canadian patent laws also correspond closely with US patent laws and therefore opportunities exist for consistent patent protection to be obtained in both countries. Moreover, it may be anticipated that with the operation of the Canadian based International (PCT) Examination Authority and the continuation of programs like the Patent Prosecution Highway, the review work of Canadian Examiners will either by necessity, practice, or reputation carry more and more weight with Examiners in other jurisdictions considering related applications.

It is important, however, to keep in mind differences between Canadian and US Patent Office practice. Restriction practice is one notable aspect of Canadian Patent Office practice that has evolved differently from the practice of the US Patent and Trademark Office. Simply stated, in the US applicants have come to expect it and in Canada applicants do not.

In the US, this has had the consequence of turning applicants' attention more towards continuing prosecution options as the path of least resistance in order to expeditiously secure some initial scope of patent protection, while still prosecuting for the full scope of protection desired. By contrast, Canadian patent practice does not provide for the filing

of continuation applications and terminal disclaimers which, in effect, allows applicants in the US to obtain patents with claims that may not be patentably distinct, so long as such patents remain commonly owned.

Applicants in Canada only have the option of filing a divisional application for a patentably distinct invention described in an original application. The guiding principle is that there can be only one invention claimed per patent. The option to file a divisional application when more than one invention may be described in the original application may arise as a result of an Examiner's restriction (if more than one invention appears to be claimed), or may be done voluntarily by an applicant.

This difference between Canadian and US practice can give rise to a dilemma for applicants seeking to align their Canadian and US claims. The dilemma is whether to: (1) accept claiming less if it is not an option to devote more resources and time to the prosecution of Canadian claims, (2) try and claim all subject matter of interest based on one or more US claim sets in a single Canadian application, or (3) consider alternative prosecution strategies based on a different claim structure than what may have been pursued in the US.

This dilemma, however, might also be appreciated as an opportunity for applicants to position their claims, both within and outside of the Canadian legal framework, in order to maximize the options for the future exercise of rights as patentees.

For example, it is commonplace in the biotechnological and pharmaceutical arts for applicants in Canada and the US to have patent claims pending in a genus/species relationship. In the US, depending on the circumstances, one may first seek to expeditiously obtain claims for a commercially "preferred" species (or sub-genus), irrespective of whether it may in fact represent an unobvious improvement over a genus. The option then remains to pursue claims to the genus or other species in a continuation or divisional application.

Under Canadian practice, similar circumstances would instead lead one to consider either pursuing a complete genus/species claim set in one Canadian application, or a different claim structure in two or more applications, as may be dictated by the inventive aspects embodied in one or more species. In other words, claims to an unobvious species may be allowable even when a genus encompassing that species has been previously disclosed or filed for in an application.

When species claims are examined in an application filed at a later date, or in an application filed by a different applicant, examination generally proceeds with more confidence that a faithful application of the tests for novelty and obviousness will naturally not result in any double patenting. In the context of a voluntary divisional filing, however, the inquiry immediately takes on a heightened anxiety to ensure that two patents are not granted for the same invention to the same applicant, which may, or may not translate into more conservative applications of the tests for novelty and obviousness. Therefore, if a division in subject matter is to be contemplated and be broken down along the lines of a genus/species relationship, the species chosen for a divisional application should be described in the specification in such a way as to make it apparent to one skilled in the art, that the species has some additional inventive advantage not possessed as a whole by the genus claimed in the original (parent) application.

Whether or not consistency in claim structure in the US and Canada is of paramount importance, the differences in Patent Office practice may be overcome by opting to leverage the processes available for expedited examination in Canada, particularly given the relatively inexpensive costs of prosecuting patent applications in Canada. Notably, upon the payment of a modest government fee, applicants in Canada may request that the Commissioner advance an application in the examination queue. There is no need as part of this process to provide anything in the way of a brief or search to assist the Examiner with the review of the application. In addition, the Canadian Patent Office has implemented a Patent Prosecution Highway (PPH) Pilot Project with the US which under defined conditions may allow applicants to align their US and Canadian claims more readily if claims have been found allowable in either jurisdiction.¹

Accordingly, genus/species claims found to be allowable in Canada using procedures available for expedited examination, can then be used to help achieve consistent claim language in the US. Whether or not it is an objective to maintain Canadian patent rights in the long run because of regulatory considerations, the economics of such an approach may well play out in favor of taking the time to prosecute Canadian claims to allowance, if the overall costs with regard to the prosecution of US and European claims are thereby reduced.

For example, a search done by a Canadian Examiner giving rise to an art objection that is successfully overcome by the applicant with regard to a Canadian application, may provide the threshold information necessary to support a request for expedited examination in the US. If a divisional strategy has also been successfully applied in Canada, then the options for continued prosecution in the US become more numerous and may even allow one to avoid having to rely on terminal disclaimers as part of a US prosecution strategy.

Finally, it is also important to keep in mind that the more minimalist Canadian practice that exists with regard to the division of subject matter may in fact be very well aligned with the legal framework governing the exercise of patent rights in Canada. Potential patentees are faced with new strategic considerations today in view of: (1) the continued oversight of the pricing of patented medicines by the Patented Medicines Prices Review Board (PMPRB), (2) the 2006 regulatory amendments improving the availability of data protection in Canada and (3) the 2006 regulatory amendments impacting access to the injunctive-like relief available under the *Patented Medicines (Notice of Compliance) Regulations* (PM(NOC) Regulations) against potentially infringing generic manufacturers.

In this greater context, some layering of patent protection may be needed to leave all options open while market assessments can be made of the impact of the PMPRB on innovator drug sales. By not committing, however, to the filing of numerous applications, innovators are less likely to find themselves dealing with potential inefficiencies under the new regulatory framework of the PM(NOC) Regulations, and costs can be more effectively managed until decisions on the long term course of patent rights in Canada can be made for innovative drug products.

¹ Roch, Jonathan. (2008, March). Canada Joins the Patent Prosecution Highway. *Canadian IP Law News from MBM Intellectual Property Law*, electronic newsletter (<http://www.mbm.com/news/index.html>).