Intellectual Property

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MARKETING INNOVATIVE DRUGS IN CANADA: REGULATORY AND IP CONSIDERATIONS

For an innovator, successful management of a drug's life cycle will involve consideration of: (i) the *Patent Act*, (ii) the *Patented Medicines (Notice of Compliance) Regulations* ("*NOC Regulations*"), and (iii) data protection under the *Food and Drug Regulations* (*FDR*). In Canada, the same regulatory and legislative framework governs the approval process for traditional drugs as for biotech drugs.

PATENTS: Discovery of a promising lead should trigger the filing of patent applications for the specific substance and related compounds. The innovator should file additional patent applications for new formulations, dosage forms and therapeutic uses that are discovered during drug development.

NOC REGULATIONS: The *NOC Regulations* link generic drug regulatory approval to an innovator's patent rights. Before a generic drug manufacturer receives approval (i.e., a notice of compliance or "NOC") to sell its generic drug in Canada, the generic must first address patents listed on the Patent Register in relation to the innovator's drug. This may involve the generic alleging that its product does not infringe the listed patents or that the patents are invalid, with the innovator having the option of commencing a Court proceeding in response. A proceeding under the *NOC Regulations* prohibits Health Canada from issuing an NOC to the generic for up to 24 months while the proceeding is ongoing, and potentially for the unexpired term of listed patents if the Court finds that none of the allegations made by the generic are justified. The *NOC Regulations* effectively result in an interlocutory injunction, which would otherwise be very difficult to obtain in Canada.

The *NOC Regulations* have strict timing requirements that must be considered when prosecuting Canadian patent applications. In order to be eligible for listing, a "patent list" including the patent must be submitted to Health Canada together with the related regulatory submission or within thirty days of patent grant if a

related drug submission has already been filed at the time of grant. A patent is eligible for listing only if its filing date (Canadian or PCT) is before the filing date of the related regulatory submission in Canada.

There is also a specific relevance requirement for patent listing that must be considered when prosecuting Canadian patent applications. In order to be eligible for listing in relation to a regulatory submission, a patent must include at least one claim for the medicinal ingredient, formulation, dosage form or use, or change in formulation, dosage form or use, for which an NOC is granted from the related submission. Therefore, to the extent possible, the patent should contain claims that are specific to the medicinal ingredient, formulation, dosage form and use for which regulatory approval has been or will be sought.

The timing and relevance requirements for patent listing mean that the patent and regulatory submission processes must be closely coordinated. For example, it is important to ensure that all relevant patent applications have been filed in Canada (or PCT) before the regulatory submission is filed; otherwise, the resulting patents will not be eligible for listing in relation to the submission.

A generic is required to address only those patents that were added to the Patent Register before it files its regulatory submission. Therefore, it may be necessary for innovator applicants to accelerate prosecution in Canada in order to timely list relevant patents on the Register.

DATA PROTECTION: Canada's *FDR* were amended on October 5, 2006, to include more robust data protection provisions for innovative drugs that receive an NOC on or after June 17, 2006. An innovative drug is defined as a drug that contains a medicinal ingredient not previously approved in a drug and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. The provisions prohibit a generic from obtaining an NOC for a generic version of a drug for a period of eight years from the innovator's first NOC for the drug (8½ if there is a pediatric extension). Also, a generic cannot file its regulatory submission within six years of the date of the innovator's first NOC for the drug. Note that data protection may be lost if the innovative drug is not being marketed in Canada.

SUBSEQUENT ENTRY BIOLOGICS (SEBs): Health Canada recently released a revised draft Guidance Document on SEBs. The period for public comment expires on May 26, 2009. In the revised draft Guidance, the term SEB is defined as a biologic product that would enter the market subsequent to, and "similar" to, an innovator product authorized for sale in Canada, the SEB submission relying in part on safety and efficacy information in respect of the reference biologic. See the full Document at http://www.hc-sc.gc.ca/dhp-mps/consultation/biolog/2009-03-seb-pbu-eng.php. Although the revised draft Guidance is still open to public comment, Health Canada has indicated that this will not delay its review or approval of SEBs in Canada.