

## IP and Regulatory Issues for Biotechnology Companies in Canada

**Gene Patents Remain Patentable.** Although a New York court recently ruled that isolated genes cannot be patented under U.S. law, the Canadian Intellectual Property Office continues to issue patents on genes.

**Listable Patents.** A recent court decision makes it more difficult for companies to obtain patents directed to dosing regimens. The court ruled that such regimens are methods of medical treatment, which are not patentable subject matter in Canada. Health Canada's Office of Patented Medicines, which determines the eligibility of patents for listing in Canada's version of the US Orange Book, has also indicated that patents on dosing regimens are presumptively not listable.

**Test for Sufficiency.** With leave granted in *Teva Canada Limited v. Pfizer Canada Inc.*, the Supreme Court of Canada will revisit a 30-year old law on what constitutes sufficient disclosure for the purposes of supporting a patent claim. The Court is also expected to comment on the level of demonstrated utility that must be included in a patent specification.

The recent federal election in Canada resulted in the Conservative Party forming a majority government. The Conservative government is perceived as "business friendly" and supportive of the innovator pharmaceutical and biopharmaceutical sectors.

The Conservative government has committed to finalize a Comprehensive Economic and Trade Agreement (CETA) with the European Union by 2012. Key provisions in a draft CETA include a right of appeal for an innovator company under the *Patented Medicines (Notice of Compliance) Regulations* (Canada's version of Hatch-Waxman); an extension of data protection to 10 years, from the current 8 years; and the introduction of patent term extension to compensate for delays in obtaining regulatory approval. These proposals would require significant reforms to current Canadian legislation.

**International Pharmaceutical Transfer Pricing.** The existence of a licence agreement, even between non-arm's-length parties, can be an important factor in determining international transfer pricing of cross-border supplies of pharmaceutical ingredients. The tax court is encouraged to take into account the full extent of the business and market realities in a supply arrangement in order to properly assess transfer pricing.

**Subsequent Entry Biologics.** The first Subsequent Entry Biologic (SEB) received marketing approval in Canada in April 2009. SEBs are approved by the existing New Drug Submission pathway since there are no regulations specific to SEBs; there is, however, a Health Canada guidance document outlining the requirements for SEB approval. Eligibility for the SEB pathway hinges on the ability to demonstrate similarity to a suitable reference biologic product through comparative studies.



**Scope of Data Protection.** The current definition of an “innovative drug” for the purposes of data protection may be judicially considered in the coming months. The Canadian Generic Pharmaceutical Association has challenged the listing of a drug on Health Canada’s Register of Innovative Drugs on the basis that it does not meet the requirement of being “a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that *is not a variation* of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.” The drug in question and a previously approved drug are both esters of the same base.

**Special Access Programme.** Drugs available through the Special Access Programme (SAP) are eligible for data protection once full marketing authorization is granted. Sales of drugs (as opposed to those offered as free goods) through SAP may affect price determination by the Patent Medicine Pricing Review Board.

**Extraordinary Use New Drugs.** Extraordinary Use New Drugs (EUNDS), for situations of extreme emergency, can now receive limited marketing authorization without a demonstration of safety and efficacy to the standard required for other new drugs. Approval of an EUND submission authorizes the sale of the drug only to governments.

**Drug Pricing Reform in Ontario.** The Ontario government has revised drug-pricing regulations by reducing caps on the price of generic drugs and phasing out professional allowances paid to pharmacies in relation to the sale of drugs. Rebates from drug manufacturers to wholesalers and pharmacies continue to be prohibited, but the regulations carve out certain permissible benefits that may be offered in accordance with ordinary commercial terms (e.g., a customary prompt-payment discount). The regulation of private label drug products remains in flux, pending a decision to address whether such products are eligible for reimbursement by the public system and for interchangeability status in the private sector.

**For more information on any of these issues, please contact one of the following lawyers from Torys LLP:**

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