Exemptions to infringement for research under Canadian law

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Various jurisdictions provide exemptions to patent infringement based on research or non-commercial activities. Canada is no exception (pun intended) and provides both statutory and common law exemptions to patent infringement.

Statutory Exemption

The statutory exemption to infringement under Canadian law is based on section 55.2(1) of the *Patent Act*:

> *It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.*

This section generally concerns activities related to the development and submission of information required by a regulatory body. In the US, the corresponding provision is sometimes referred to as the “Hatch-Waxman exemption”, “271(e)(1) exemption”, “Bolar exemption” or the “FDA safe harbor”.

While the Canadian provision relates to regulatory approval for inventions in any area of technology (i.e., is not limited to medicines), the cases that have come before the Canadian Courts are primarily in the pharmaceutical area, most often in the context of a generic manufacturer performing tests in respect of a patented drug. Further, this provision relates to information that may be required by a regulatory body anywhere (i.e., not just in Canada).

Common Law Exemption

The common law exemption is in addition to the statutory exemption. The landmark case relating to the common law exemption is the Supreme Court decision in *Micro Chemicals* [1], where Micro Chemicals performed various experiments to establish that it was capable of producing a patented drug, for which they intended to obtain a compulsory license from the patentee. The Supreme Court found that Micro Chemicals' activities in this regard did not constitute infringement, based in particular on the following criteria:

> the compound was produced in small amounts;
> the compound was kept by Micro Chemicals and never entered into commerce;
> the patentee suffered no damage based on these activities;
> Micro Chemicals made no profits based on these activities; and
> the activities were considered *bona fide*

However, some passages of the *Micro Chemicals* decision suggested that the Court's reasoning may have been influenced by the fact that these research activities occurred in the context of Canada's earlier compulsory licensing regime for medicines, which has since been eliminated.

Both the statutory and common law exemptions were revisited by the Federal Court of Appeal in the *Merck v. Apotex*, 2006 [2] case.

Merck v. Apotex, 2006

Regarding the statutory exemption, the Court adopted a broad interpretation of section 55.2(1), considering the test samples in question to be "reasonably related" to regulatory submission:

> *Any samples which are reasonably related to the development and submission of information under legislation or regulations are exempt by the provision. It does not limit the exemption to information actually submitted.*

Regarding the common law exemption, the Court disagreed with the Patentee's arguments that the exemption defined in *Micro Chemicals* no longer applies in the absence of a compulsory licensing regime, commenting that:

> *I reject this assertion that the Micro Chemicals exception is limited and only applies as an adjunct to the grant of compulsory licences … In my analysis, all that is required is that the infringing product was made merely by way of bona fide experiment, and not with the intention of selling and making use of the product in the commercial market.*

The Court did note, however, that:

> *once the user had proceeded beyond the experimental and testing phase and has taken steps to manufacture, promote and sell the product, the fair dealing exception no longer applies.*

Thus it appears that activities which are limited to experimentation/testing, and do not advance to the stage of manufacture, promotion or sale, could fall under the common law exemption.

Maintain good records!

More recent decisions by the Courts have indicated that the use and status of such experimental samples should be carefully documented, in case it is necessary to establish that they were not destined for commerce. In *Apotex v. Sanofi-Aventis* [3], failure to produce records that certain lots

were destroyed led the Court to conclude that the experimental and regulatory use exemption did not apply to those lots. The importance of such record-keeping was confirmed in the *Teva and Apotex v. Novartis* [4] case, the Court noting that:

> *Apotex bears the burden of demonstrating that the imatinib inventory was used for experimental or regulatory uses and that no portion of the inventory was or will be used commercially.*

The Court did find the inventory to be exempt from infringement, since Apotex was able to account for the inventory, and further assured that the inventory would not be used commercially and would be destroyed once it expires.

Conclusions

In practice, exemption issues are fact-specific and need to be assessed on a case by case basis. It appears that research activities purely relating to experimentation, in respect of samples which are never commercialized (with supporting documentation), are considered exempt from infringement in Canada.

Please contact us should you require any information regarding Canadian intellectual property matters.

Kindly note that the above commentary is general in nature and cannot be considered to replace legal advice in relation to specific matters.

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1. *Micro Chemicals Ltd. V. Smith Kline & French Inter-American Corp*. (1971), 2 C.P.R. (2d) 193 (SCC).
2. *Merck & Co. v. Apotex Inc.*, 2006 FCA 323.
3. *Apotex Inc. v. Sanofi-Aventis*, 2013 FCA 141.
4. *Teva Canada Ltd. and Apotex Inc. v. Novartis AG*, 2013 FC 141.