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Report Q202

in the name of the Canadian Group
by France CÔTÉ and Bill MAYO

The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

1) Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?

The courts in Canada have recognized an experimental use exception to patent infringement. Experimentation for the purpose of establishing a person's ability to use the invention will not constitute infringement provided there is no commercial use.

There is some uncertainty as to what will constitute an experimental use within this common law exception. In a recent decision of the Federal Court of Canada, the experimental use exception, also referred to as "fair dealing", was described as follows[1]:

The Supreme Court in *Micro Chemicals*, supra, at pages 518 to 520 affirmed a decision of the English Court of Appeal in *Frearson v. Loe* (1878), 9 Ch. D. 48, which states that there is a doctrine of "fair dealing" in respect of patent infringement:

Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not to be considered within the prohibition and, if it were, it is certainly not the subject for an injunction.

The Supreme Court in *Micro Chemicals* held it to be significant that the Trial Judge had found that small amounts of the patented compound had been produced, put in bottles, kept by Micro and never entered into commerce and no damage was suffered by the patentee and no profits made by Micro. They held that the Trial Judge was in error in finding that such activity constituted infringement. They found that an experimental user, without a license, in the course of *bona fide* experiments with a patented article was not an infringement. The use of the product, not for profit, but to establish the fact that a person could manufacture a product in accordance with the patent, was not an infringement.

2) Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law

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[1] Merck v. Apotex [2006] FCJ No. 671, 53 CPR (4th)1 at paras 160-161, affd. [2006] FCJ No. 1490, 55 CPR (4th) 1 at paras 105-113. In this case, it was found that the use of lisinopril in ongoing research and development of alternate formulations, alternate techniques for tablet making and the like was within the experimental use exception.

does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?

Canada does have a Bolar-type exception, which is provided under section 55.2 of the *Patent Act SC* 1993, c.2:

Exception
55.2 (1) **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.
[…]

For greater certainty
(6) For greater certainty, **subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose** or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.

This provision, also referred to as the "early working exception", was added to the *Act* in 1993 and while it is primarily directed to the food and pharmaceutical industries, it specifically states that it applies to "any product".[2] However, the policy objective in adding this exception was to "balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors".

More specifically, the early-working exception was intended to encourage timely generic competition by allowing generic drug companies to develop a drug and take the necessary steps to obtain regulatory approval while the equivalent brand-name drug is still under patent. This enables generic drug companies to enter the market as soon as the patents for the brand-name drug expire.

Section 55.2 also allows the government to "make such regulations as the Governor in Counsel considers necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection 1….". Regulations enacted under that provision, the *Patented Medicines (Notice of Compliance) Regulations (the "PM(NOC) Regulations"*), were intended to provide a patent enforcement mechanism to ensure that the early working exception is not abused and that generic drugs are not sold before relevant patent expiry.

Under the *PM(NOC) Regulations*, a pharmaceutical manufacturer (typically a brand or innovative manufacturer) can list patents that are relevant to its product on a Patent Register maintained by Health Canada[3]. A subsequent manufacturer (typically a generic manufacturer)

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2 When the "Bolar"-type exception to infringement was added to the Patent Act in 1993, a further exception was also added to allow the production and stockpiling of an otherwise infringing product for a prescribed period of time prior to patent expiry (Section 55.2(2)). However, this exception, along with the early working exception, was challenged by the European Union under the WTO dispute settlement mechanism. The WTO panel decision confirmed that an early working exception is consistent with the TRIPs Agreement, even in the absence of an extended period of protection for the patent, but considered that the right to manufacture and stockpile before the expiration of the patent was not consistent with the TRIPs Agreement (see WT/DS114/R, 17 March, 2.000).

3 Pursuant to sections 3 and 4 of the PM(NOC) Regulations, Health Canada is required to maintain a public register of patents and other information submitted by first persons. The requirements that must be met before a patent can be listed on the Patent Register are provided by section 4 of the PM(NOC) Regulations. Section 4 describes (i) the timing of filing of patent lists; (ii) the information that must be provided on a patent list; (iii) the type of drug submissions for which a patent list may be filed; and (iv) more substantive eligibility requirements relating to the claims of the patent.

seeking to copy a patented innovative drug is required to address the patents listed on the Patent Register against that innovative drug. The subsequent manufacturer may either agree to wait for expiry of the patent before receiving regulatory approval (i.e. issuance of a compliance or "NOC") or challenge the patent by making an allegation of non-infringement or invalidity that would justify the issuance of the NOC. The allegation may be accepted by the innovator or challenged by way of an application to the Federal Court. If the allegation is challenged, an automatic stay is triggered which bars the issuance of a NOC to the generic company for 24 months or until the litigation is resolved in its favour, whichever comes first.

It is important to note that a court proceeding under the *PM(NOC) Regulations* does not result in a declaration of invalidity or non-infringement. It is intended to be a summary proceeding simply to determine whether the generic manufacturer should receive its NOC. Accordingly, if a generic company is successful in litigation under the PM(NOC) Regulations, the innovator company can still bring an action for patent infringement in the normal course.

The *PM(NOC) Regulations* were created in 1993, along with the "early-working exception" through amendments to the Patent Act brought into force by Bill C-91. Both instruments are an integral part of the government's drug patent policy, which seeks to strike an appropriate balance between encouraging continued innovation in new drugs and promoting timely generic competition.

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Not applicable.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

Not applicable.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Methods of medical treatment per se are not permitted. Swiss style and "use" claims, however, are permissible and can be used in Canada to provide patent protection for medical treatment to some extent.

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

The Canadian *Patent Act* used to have broad compulsory licensing provisions relating to medicines and food, but they were repealed in 1993. Compulsory licences granted under those provisions before December 20, 1991, and which had not been terminated before February 15, 1993 continue to be enforced. Any compulsory licences granted on or after December 20, 1991, ceased to have effect as of February 14, 1993.

In 2004, the *Patent Act* was amended to allow the Commissioner of Patents to grant compulsory licences to facilitate access to pharmaceutical products to address public health problems in developing and least developed countries. This is discussed further in the response to question 7 below.

There are also general provisions under the *Patent Act* that allow the Commissioner of Patents to grant a compulsory licence where a patent is "deemed to be abused" pursuant to s. 65(2) of the Patent Act:

2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:

a) and b) [Repealed, 1993, c. 44, s. 196]

c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;

d) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;

e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or

f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

3) and 4) [Repealed, 1993, c. 44, s. 196].

In an application under s. 65(2)(c), the party seeking a licence must demonstrate that "demand for the patented article in Canada" is not being met "to an adequate extent and on reasonable terms". The party seeking a licence must show that the demand in Canada is a general one in the sense that there is a market in Canada that demands the patented article and that this demand is not being met. A demand created by the party seeking the licence is considered an artificial demand. The party seeking a licence must also show that the group of consumers to whom they expect to sell their product do not have access to presently available products (*Brantford Chemicals Inc. v. Canada (Commissioner of Patents*), [2006] F.C.J. No. 1712; aff'd [2006] F.C.J. No. 1712).

In an application under s. 65(2)(d), the party seeking a licence must first ask the patentee for a licence or, if the patentee is making the product, for the product, giving adequate opportunity for response. Three elements must be satisfied to establish abuse: a refusal to grant a licence on reasonable terms; prejudice to a trade or industry and not merely to an individual party seeking to get into the business; and that the public interest is served by granting the licence (*Brantford Chemicals Inc. v. Canada (Commissioner of Patents*), [2006] F.C.J. No. 1712). Where the patentee acknowledged that it had been unable to meet the demand, a compulsory licence was granted by the Commissioner at the rate offered by the applicant to manufacture and sell in Canada, with the requirement to provide quarterly statements and payments (*Puckhandler Inc. v. BADS Industries Inc.* (1998), 81 C.P.R. (3d) 261).

Mere neglect to answer a request for a licence does not constitute a refusal to license (*Sarco Co. Inc. v. Sarco Canada Ltd.*, [1969] 2 Ex. C.R. 190 at 207-208; *LPA Plastics (1976) Ltd. V. Windsurfing Int'l Inc.* (1981) 59 C.P.R. (2d) 188 at 199), ample time for response must be provided (*Torpharm Inc. v. Merck & Co.* (2000), 9 C.P.R. (4th) 520 at 530-533). The trade or industry of the applicant, while considered broadly, must mean in general terms the existing trade or industry of the applicant (*Sarco, supra*).

If the patent is deemed to be abused, the Commissioner of Patent may order any of the following (s. 66):

66. (1) On being satisfied that a case of abuse of the exclusive rights under a patent has been established, the Commissioner may exercise any of the following powers as he may deem expedient in the circumstances:

a) he may order the grant to the applicant of a licence on such terms as the Commissioner may think expedient, including a term precluding the licensee from importing into Canada any goods the importation of which, if made by persons other than the patentee or persons claiming under him, would be an infringement of the patent, and in that case the patentee and all licensees for the time being shall be deemed to have mutually covenanted against that importation;

b) [Repealed, 1993, c. 44, s. 197]

c) if the Commissioner is satisfied that the exclusive rights have been abused in the circumstances specified in paragraph 65(2)(f), he may order the grant of licences to the applicant and to such of his customers, and containing such terms, as the Commissioner may think expedient;

d) if the Commissioner is satisfied that the objects of this section and section 65 cannot be attained by the exercise of any of the foregoing powers, the Commissioner shall order the patent to be revoked, either forthwith or after such reasonable interval as may be specified in the order, unless in the meantime such conditions as may be specified in the order with a view to attaining the objects of this section and section 65 are fulfilled, and the Commissioner may, on reasonable cause shown in any case, by subsequent order extend the interval so specified, but the Commissioner shall not make an order for revocation which is at variance with any treaty, convention, arrangement, or engagement with any other country to which Canada is a party; or

e) if the Commissioner is of opinion that the objects of this section and section 65 will be best attained by not making an order under the provisions of this section, he may make an order refusing the application and dispose of any question as to costs thereon as he thinks just.

A licence when granted operates as if by way of deed executed by the patentee and all other necessary parties.

Since the provisions relating to compulsory licences were repealed there have been no compulsory licences granted in Canada for domestic manufacture and supply of pharmaceutical products.

More generally, there are not many cases interpreting the compulsory licence provisions relating to patent abuse. The only case in which the Commissioner granted a compulsory licence under these provisions is *Puckhandler Inc. v. BADS Industries, Inc.* (1998), 81 C.P.R. (3d) 261 (Comm'r). In this case the Commissioner granted the applicant a non-exclusive compulsory licence under s. 65(2)(c), after the patentee acknowledged that there had been a failure to fulfill the demand for the patented article. The patent in this case related to a hockey training device, not a pharmaceutical product.

There are two cases where an applicant seeking a compulsory licence with respect to a pharmaceutical. In both cases, the applicant was unsuccessful. In *Brantford Chemicals Inc. v. Merck & Co.* (2005), 29 C.P.R. (4th) 380, Brantford Chemicals brought an application for a licence under s. 65(2)(c) and (d) of the *Patent Act* alleging that there had been abuse of exclusive rights with respect to Merck's patent for enalapril and its acid addition salts for use in the treatment of hypertension. The Commissioner refused the application under s. 65(2)(c), finding that there was no unmet demand in Canada for the patented article. The

Commissioner refused the application under s. 65(2)(d) on the basis that he was not satisfied that the patentee, Merck, had refused to grant Brantford a licence on reasonable terms, that Merck had not been provided with sufficient time to consider its position prior to Brantford commencing its application and that there was no prejudice. The decision was upheld on appeal to the Federal Court. The Federal Court decision has not been appealed to the Federal Court of Appeal.

In *Torpharm Inc. v. Merck & Co.* (2000), 9 C.P.R. (4th) 520 (Comm'r), Torpharm sought a compulsory licence to allow it to acquire bulk enalapril maleate to manufacture tablets containing enalapril maleate for sale in the United States and elsewhere. Torpharm alleged abuse on the basis of s. 65(2)(c), (d) and 65(1) of the Patent Act. The application was dismissed. Under the s. 65(2)(c) application the Commissioner found that the only demand that the applicant alleged was not being met was its own demand for bulk enalapril maleate. There was no assertion that the patentee refused to supply bulk enalapril or that Torpharm had ever made a request for bulk enalapril from Merck. Also, a demand for an article in Canada solely for the purpose of exporting the article was not within the scope of the section. Under the s. 65(2)(d) application, the Commissioner found that the patentee had insufficient time to consider the licence request and that a refusal would not cause prejudice to Torpharm's trade. The Commissioner found that the public interest would not be served by the issue of a compulsory licence. Torpharm's third allegation of abuse, under s. 65(1), was also dismissed. Torpharm argued that even if it was unsuccessful under the s. 65(2) application, the Commissioner could find that the patentee had abused its patent under s. 65(1). The Commissioner found that s. 65(2) was exhaustive in delineating the instances in which abuse might be found to exist. The appeal of this decision is pending before the Federal Court. The hearing in this case was scheduled for May 20, 2003 but was adjourned *sine die* on May 15, 2003.

7) Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

Article 31bis has not been ratified in Canada. Canada has, however, implemented the August 30, 2003 WTO decision in its national law with the enactment of Bill C-9 (*An Act to Amend Patent Act and Food and Drugs Act*) in May 2005. There has been one licence issued under these provisions of the Patent Act. In September of 2007 the Commissioner of Patents issued a compulsory licence allowing Apotex to manufacture and export ApoTriavir, a triple combination AIDS therapy. The licensors were Glaxo Smith Kline, Shire and Boehringer Ingelheim. Rwanda has indicated that it will import ApoTriavir.

8) Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?

The government is allowed to make use of a patented invention pursuant to sections 19, 19.1 and 65 of the Patent Act. Section 65 is discussed above under the Question 6. Sections 19 and 19.1 are set out below.

USE OF PATENTS BY GOVERNMENT

Government may apply to use patented invention

19. (1) Subject to section 19.1, the Commissioner may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government.

Terms of use
2) Subject to section 19.1, the use of the patented invention may be authorized for such purpose, for such period and on such other terms as the Commissioner considers expedient but the Commissioner shall settle those terms in accordance with the following principles:

a) the scope and duration of the use shall be limited to the purpose for which the use is authorized;

b) the use authorized shall be non-exclusive; and

c) any use shall be authorized predominantly to supply the domestic market.

Notice
3) The Commissioner shall notify the patentee of any use of the patented invention that is authorized under this section.

Payment of remuneration
4) Where the use of the patented invention is authorized, the authorized user shall pay to the patentee such amount as the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization.

Termination of authorization
5) The Commissioner may, on application by the patentee and after giving all concerned parties an opportunity to be heard, terminate the authorization if the Commissioner is satisfied that the circumstances that led to the granting of the authorization have ceased to exist and are unlikely to recur, subject to such conditions as the Commissioner deems appropriate to protect the legitimate interests of the authorized user.

Authorization not transferable
6) An authorization granted under this section is not transferable.

Conditions for authorizing use
19.1 (1) The Commissioner may not authorize the use of a patented invention under section 19 unless the applicant establishes that:

a) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention; and

b) its efforts have not been successful within a reasonable period.

Exception
2) Subsection 1) does not apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

Prescribed uses
3) The Commissioner may not, under section 19, authorize any use that is a prescribed use unless the proposed user complies with the prescribed conditions.

Limitation on use of semi-conductor technology
(4) The Commissioner may not, under section 19, authorize any use of semi-conductor technology other than a public non-commercial use.

9) Is the government allowed to expropriate a patent and, if so, under which conditions?

There is no specific section in the Patent Act conferring rights of expropriation to the government.

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

Not applicable.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  We support such an exception of the type currently recognized under Canadian law (see Question 1 above).
- *Bolar exception;*
  We support a Bolar-type exception similar in substance to that provided by s. 55.2 of the Canadian Patent Act.
- *parallel import of patented medicines;*
  Parallel importation of patented medicines is not currently provided for under Canadian law and we take no position at this time.
- *individual prescriptions exception;*
  We support such an exception.
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

If so, under what circumstances? If not, why not?

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

Summary

The courts in Canada have recognized an experimental use exception to patent infringement provided there is no commercial use. Canada does have a Bolar-type exception (section 55.2 of the Patent Act SC 1993, c.2). Parallel imports of patented medicines and medical devices along with individual prescriptions exception are not provided to under Canadian law.

Résumé

Les courts au Canada ont reconnu une exception à la contrefaçon en brevet pour l'usage expérimental à condition que celui-ci soit sans but commercial. Le Canada prévoit une exception de type Bolar (article 55.2 de la Loi sur les brevets SC 1993, c.2). Les importations parallèles de médicaments et d'appareils médicaux ainsi que l'exception de prescriptions individuelles ne sont pas prévus selon la Loi Canadienne.