

**Council for Trade-Related Aspects
of Intellectual Property Rights**

Original: English

REVIEW OF LEGISLATION IN THE FIELDS OF PATENTS, LAYOUT-DESIGNS
(TOPOGRAPHIES) OF INTEGRATED CIRCUITS, PROTECTION OF
UNDISCLOSED INFORMATION AND CONTROL OF
ANTI-COMPETITIVE PRACTICES IN
CONTRACTUAL LICENCES

Canada¹

The present document reproduces the questions put to the delegation of Canada and the responses given in the review of legislation on patents, layout-designs (topographies) of integrated circuits, protection of undisclosed information and control of anti-competitive practices in contractual licences at the Council's meeting of 26-30 May 1997.²

I. REPLY TO THE GENERAL QUESTION ON PRIORITY RIGHTS³

Does your country recognize a right of priority on the basis of an earlier patent application filed in any other WTO Member by a national of a WTO Member?

Yes, Canada recognizes a right of priority on the basis of an earlier patent application filed in any other WTO Member by a national of a WTO Member.

II. REPLIES TO QUESTIONS POSED BY THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES

1. In the circumstances where the Commissioner of Patents exercises the power to authorize use of the subject matter of a patent by third parties without the authorization of the right holder, are there any conditions applicable to the exercise of that discretion which meet the terms of Article 31 of the TRIPS Agreement, especially paragraphs (b), (c) first half sentence, (d) and (e)?

¹As regards laws and regulations relevant to the areas under review and notified by Canada under Article 63.2, reference is made to documents IP/N/1/CAN/1, IP/N/1/P/1-4, IP/N/1/CAN/O/1, IP/N/1/CAN/L/1-2, IP/N/1/CAN/U/1-3. Subsequent to the meeting of the TRIPS Council of 26-30 May, a supplementary notification was received from the delegation of Canada and distributed as reflected in document IP/N/1/CAN/1/Add.1.

²The minutes of the meeting have been circulated in document IP/C/M/13.

³At the meeting of the TRIPS Council of 27 February 1997, Members agreed to respond to this question in the context of the present review (document IP/C/M/12, paragraph 18).

In Canada, Section 65 of the Patent Act allows for an application to the Commissioner of Patents where there has allegedly been an abuse of the exclusive rights contained in a patent. The Commissioner may grant licences for the purpose of remedying such abuses upon "such terms as the Commissioner may think expedient" (Section 66). By administrative practice, the requirements of the above Article would be taken into account by the Commissioner in settling such terms. Section 19 of the Patent Act allows for the Government of Canada or of a province to apply to the Commissioner for authorization to use a patented invention, upon terms to be settled by the Commissioner of Patents, in accordance with Sections 19, and 19.1 to 19.3 of the Act. The principles and conditions contained in those sections are consistent with Article 31 of the TRIPS Agreement.

[Follow-up question from the EC]

In its answer Canada explains that the decisions of the Commissioner of Patents in cases of authorization to use a patented invention would follow Sections 19, 19.1 to 19.3 of the Patent Act. However, these Sections do not seem to contain the principles as set out in Article 31 of the TRIPS Agreement. Therefore, could the Government of Canada clarify how these Sections comply with Article 31(b), (c) first half of the sentence, (d) and (e) of the TRIPS Agreement?

Sections 19 and 19.1 comply with Article 31 of the TRIPS Agreement. For compliance with Article 31(b), see Section 19.1 of the Patent Act, which reads as follows:

"19.1(1) The Commission 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;
- (b) its efforts have not been successful within a reasonable period.

19.1(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."

For compliance with Article 31(c) and (d), see subsection 19(2) of the Patent Act, which reads as follows:

"19(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 Commission 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."

For compliance with Article 31(e), see subsection 19(6) of the Patent Act, which reads as follows:

"19(6) An authorization granted under this section is not transferable."

[Follow-up question from the US]

Section 65 of Canada's Patent Act allows the Commissioner of Patents to grant licences under patents to remedy abuses of exclusive rights. Must the determination that patent rights are being abused be made by a court or may such determination be made by the Commissioner? If the latter is the case, please describe the procedure followed in reaching such determination.

Under sections 65 and 66 of the Patent Act, the Commissioner has the authority to make a determination of whether there has been an abuse of patent rights. This decision is subject to appeal to the Federal Court pursuant to section 71 of the Patent Act. A number of circumstances are set out in subsection 65(2), which are deemed to be abuses of patent rights.

2. Does the Patent Act, R.S.C. 1985, as amended, contain any provision to ensure that in the case of the Commissioner of Patents exercising the power to authorize any public, non-commercial use of a patent by a government without the authorization of the right holder, the right holder shall be informed promptly where the government without making a patent search knows or has demonstrable grounds to know that a patent is or will be used by or for the government (Article 31(b) of the TRIPS Agreement)?

Subsection 19(3) of the Patent Act requires the Commissioner to notify the patentee of any use of the patented invention that is authorized under that section.

[Follow-up question from the EC]

Could the Government of Canada clarify whether prompt notice will be given by the Commissioner?

In situations where the Government of Canada must provide notice to a party, it will, as a matter of practice, provide such notice in a timely manner.

3. Does the Plant Breeders' Rights Act, S.C. 1990, c. 20 extend to all Members of the WTO as required by the TRIPS Agreement? Please explain.

Article 3.1 of the TRIPS Agreement requires national treatment for nationals of other WTO Members with regard to the protection of intellectual property. Article 1.2 of the TRIPS Agreement provides that "[f]or the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Section 1 through 7 of Part II". Plant breeders rights is not a category of intellectual property listed in the TRIPS Agreement.

[Follow-up question from the US]

Canada states, in its answer to question 3 from the European Communities, that its laws do not provide national treatment for plant breeders' rights because Article 3.1 of the TRIPS Agreement requires national treatment only with regard to protection of "intellectual property", defined in Article 1.2 as categories of intellectual property that are the subject of Sections 1 through 7 of Part II. On this basis, Canada states that it does not have obligations with regard to providing plant breeders' rights to nationals of non-WTO Member nationals. Canada, however, has indicated that it does not make patent protection available for plants or plant varieties. Please explain how Canada fulfils its obligations of Article 27.3(b) to provide protection for plant varieties either through an effective *sui generis* system, or through patents, or both.

Canada provides an effective *sui generis* system, for the protection of plant varieties, as set out in the Plant Breeders' Rights Act. Furthermore, patent protection is available for plant and animal genes, cell lines, etc.

4. Could the Government of Canada clarify whether and how micro-organisms are patented (Article 27.3(b) of the TRIPS Agreement)?

Living matter or lower life forms which are essentially unicellular in composition (e.g. bacteria, many fungi (including yeasts), cells in culture, transformed cell lines and hybridomas) are patentable in Canada provided that they are new, useful and inventive. A process to produce or which utilizes these organisms may also be patentable.

[Follow-up question from the EC]

Could the Government of Canada clarify how micro-organisms are defined under Canadian legislation and could Canada give examples of protection granted pursuant to relevant case law?

There is no definition of "micro-organism" contained in the Patent Act. Relevant case law through which micro-organisms were found to be patentable are as follows: *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81.

5. Does the Patent Act, R.S.C. 1985, as amended, expressly confer the rights to offer for sale or import a product, based on either product- or process-based patents, pursuant to Article 28.1 of the TRIPS Agreement?

Under the inherent equitable jurisdiction of Canada's superior courts, there is a remedy available for offering for sale without the authorization of the patent holder. Under Canadian case law, importation of a patented article for infringing purposes has itself been held to be an infringement.

[Follow-up question from the EC]

What is the legal basis on which "a remedy" would be available for offering for sale without the authorization of the right holder?

Could Canada give examples of such case law where "the importation of a patented article for infringing purposes has itself been held to be an infringement"?

Please also confirm whether the remedy is available in respect of the product obtained directly by a patented process.

Canadian superior courts have inherent equitable jurisdiction to issue injunctions to prevent the offering for sale of patented articles, on a *quia timet* basis.

Importation of patented articles has been held to be an infringement under Canada's Patent Act (*Société des Usines Chimiques Rhône-Poulenc v. Jules r. Gilbert Ltd.* (1967); *Farbwerke Hoechst Aktiengesellschaft v. Halocarbon* (1979), 42 C.P.R. (2d) 145 (S.C.C.); *Hoffman-LaRoche Ltd. v. Apotex Inc.* (1983), 171 C.P.R. (2d) 20 (Ont. H.C.J.); *Wellcome Foundation v. Apotex Inc.* (1990) 3 F.C. 528 (Fed. Ct. Trial Division)).

It is infringement of a process claim to import into Canada a product manufactured elsewhere in accordance with the process defined in the claim (see cases cited above).

6. Section 55.2(2) of Canada's C-91 Bill appears to permit, in certain circumstances, a third party to make and stockpile an unlimited supply of a patented product without the consent of the patent holder during the life of a patent. If this is the case, could Canada please explain how this is consistent with the rights, including the right to prevent unauthorized making of a patented product, conferred on the patent holder by Article 28 of the TRIPS Agreement?

The Manufacturing and Storage of Patented Medicines Regulations, of 1993, provide that "[t]he applicable period referred to in subsection 55.5(2) of the Patent Act is the six month period immediately preceding the date on which the term of the patent expires".

This provision, in conjunction with Section 55.2(2) of the Patent Act, allows the manufacturing and storage of medicines under patent by someone else than the patent holder during the last six months of the life of the patent.

The exception to the rights of the patent holder are limited exceptions to the rights of the patent holder that are permitted by Article 30 of the TRIPS Agreement.

[Follow-up question from the EC]

Article 28(a) of the TRIPS Agreement confers on the patent holder, *inter alia*, the exclusive right to prevent third parties not having the owner's consent from the act of making a patented product. Furthermore, Article 33 provides that the term of patent protection shall not end before the expiration of a period of twenty years counted from the filing date.

In light of the above, please explain how provisions permitting the unauthorized manufacture of an unlimited quantity of a patented product during the last six months of the patent does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent holder, even taking in account the limited interest of third parties.

Could the Government of Canada explain in more detail how the "limited exception" described in the answer to question No. 6 with Article 30 of the TRIPS Agreement?

Subsection 55.2(2) of the Patent Act is permitted by Article 30 of the TRIPS Agreement.

7. How does the Patent Act, R.S.C. 1985, as amended, in reversing the burden of proof for an action for infringement of a patented process for obtaining a new product, take into account the legitimate interests of defendants in protecting their manufacturing and business secrets pursuant to Article 34.3 of the TRIPS Agreement)?

The superior courts have inherent jurisdiction to make protective orders for confidential information.

[Follow-up question from the EC]

What would be the criteria and legal basis for the superior courts to issue protective orders to protect confidential information?

What competences have lower courts to issue such orders?

Canada's superior courts are courts of first instance (subject to certain limitations regarding the Federal Court) of general jurisdiction.

8. Does the ICTA (Integrated Circuits Topography Act S.C. 1990) fully implement Canada's obligations under Article 37.2 of the TRIPS Agreement (which incorporates by reference sub-paragraphs (a) through (k) of Article 31 of the TRIPS Agreement) with respect to the conditions for the authorization of a compulsory licence for use by or for the government of an integrated circuit topography?

Sections 7.1, 7.2, 7.3 and 7.4 of the Integrated Circuit Topography Act reflect Canada's obligations under Article 37.2 of the TRIPS Agreement.

[Follow-up question from the EC]

Could Canada more specifically explain how the ICTA implements Article 37.2 of the TRIPS Agreement in conjunction with Article 31(b) of the TRIPS Agreement?

Article 31(b) of the TRIPS Agreement allows WTO Members to waive this provision in cases of public non-commercial use. Section 7.1 of the Integrated Circuit Topography Act makes it clear that this and the following provisions (sections 7.2 and 7.3) deal with public non-commercial use.

9. What does Canada understand by reference to "any private and non-commercial purpose" in sub-paragraph 6(2)(d) of the ICTA, and does this provide the same scope of protection for topographies as required by Article 35 of the TRIPS Agreement?

Paragraph 6(2) (d) of the Integrated Circuit Topography Act reflects the exception contained in Article 6(2) of the Treaty on Intellectual Property in Respect of Integrated Circuits, i.e., acts performed by a third party for private purposes or for the sole purpose of evaluation, analysis, research or teaching.

[Follow-up question from the EC]

In its answer Canada explains that Section 6(2)(d) of the ICTA reflects the exceptions contained in Article 6(2) of the Treaty on Intellectual Property in Respect of Integrated Circuits, i.e. acts performed by a third party for private purposes or for the sole purpose of evaluation, analysis, research or teaching. However, the wording of Section 6(2)(d) of the ICTA refers to acts "done for a private and non-commercial use". Please explain.

Paragraph 6(2)(a) of the Integrated Circuit Topography Act provides an exception for acts that are "for the sole purpose of analysis or evaluation or of research or teaching". Paragraph 6(2)(d), by contrast, deals with acts for private purposes. In Canada's assessment, acts for private purposes must inevitably be of a non-commercial nature and this is reflected in paragraph 6(2)(d). Thus subsection 6(2) is fully consistent with Article 6(2) of the Treaty on Intellectual Property in Respect of Integrated Circuits.

10. Does Article 1472 of the new Quebec Civil Code in respect of disclosure of trade secrets for considerations of general interest permit undisclosed information to be disclosed by a person contrary to Article 39.2 of the TRIPS Agreement even if that information is secret, has commercial value because it is secret, and has been subject to reasonable steps to keep it secret?

Article 1472 of the Civil Code of Quebec (CcQ) reads as follows:

"A person may free himself from his liability for injury caused to another as a result of the disclosure of a trade secret by proving that considerations of general interest

prevailed over keeping the secret and, particularly, that its disclosure was justified for reasons of public health or safety."

This provision forms part of Chapter III (of Title 7) -- Civil Liability and, in particular, falls within Section II -- Certain Cases of Exemption From Liability. From that context, it is clear that the above Article does not create a rule of general application but is, instead, an exception to the general rule which would impose civil liability for any breach of confidence. Furthermore, this exception confirms the existence of the general rule that there is protection for trade secrets.

Other provisions of the CcQ (and the *doctrine* of Quebec) clarify that there is a firm rule against breaching obligations of confidentiality. In the context of contracts, Article 1458 provides as follows:

"Every person has a duty to honour his contractual undertakings.

Where he fails in this duty, he is liable for any bodily, moral or material injury he causes to the other contracting party and is liable to reparation for the injury; neither he nor the other party may in such a case avoid the rules governing contractual liability by opting for rules that would be more favourable to them."

The above Article must be read in conjunction with CcQ, Article 1434, which reads as follows:

"A contract validly formed binds the parties who have entered into it not only as to what they have expressed in it but also as to what is incident to it according to its nature and in conformity with usage, equity or law."

Outside the contractual context, breaches of confidentiality would be covered by CcQ, Article 1457. The latter states that:

"Every person has a duty to abide by the rules of conduct which lie upon him, according to the circumstances, usage or law, so as not to cause injury to another.

Where he is endowed with reason and fails in this duty, he is responsible for any injury he causes to another person and is liable to reparation for the injury, whether it be bodily, moral or material in nature....".

Thus, it is well settled in the law of Quebec that breaches of confidence are unlawful. As mentioned above, CcQ Article 1472 is a narrow exception which allows exoneration from civil liability. Note that liability may only be avoided in certain circumstances -- the proof of which would be upon the disclosing party -- i.e., that the disclosure was justified for reasons of public health or safety.

11. To what extent does Canadian legislation (on a federal and sub-federal level) protect undisclosed information obtained by an employee during his/her employment in the case where this person's term of employment ends, even if that information meets the requirements of Article 39.2(a), (b) and (c) of the TRIPS Agreement? Please explain.

There is no requirement in Article 39.2 of the TRIPS Agreement that such undisclosed information be protected by legislation. Under Canadian case law, where information is given under circumstances where a reasonable person would realize, upon reasonable grounds, that that information was being given in confidence, the equitable obligation of confidence attaches. That rule has been applied in numerous cases to employees who obtain access to confidential information in the course of their employment. Similarly, Article 2088 of the Civil Code of Quebec provides that "The

employee is bound...not to use any confidential information he may obtain in carrying on or in the course of his work".

[Follow-up questions from the US]

Please indicate whether Article 2088 of the Civil Code of Quebec prohibits disclosure as well as use of confidential information obtained by an employee in the course of his work. Please provide a copy of the text of Article 2088.

The Article concerned states as follows: "Le salarié, outre qu'il est tenu d'exécuter son travail avec prudence et diligence, doit agir avec loyauté et ne pas faire usage de l'information à caractère confidentiel qu'il obtient dans l'exécution ou à l'occasion de son travail".

"The employee is bound not only to carry on his work with prudence and diligence, but also to act faithfully and honestly and not to use any confidential information he may obtain in carrying on or in the course of his work."

Under Article 2088, an employee has an obligation not to use confidential information received during the employment relationship. This obligation includes a duty not to disclose the information concerned.

Please explain in detail how the equitable obligation of confidence is defined by Canadian courts; in other words, indicate what acts are prohibited as a result of the obligation.

A person who is party to a relationship to which a confidence obligation attaches will be held liable for a breach of confidence. Where a person receives information in circumstances where it is clear or implicit that the information is confidential, that person is under a duty not to disclose it without the consent of the provider of that information (*Lac Minerals v. International Corona Resources Ltd.* [1989] 2 S.C.R. 574).

12. What legislation or regulations exist to fulfil Canada's obligations under Article 39.3 of the TRIPS Agreement? Please explain.

There is no requirement that Article 39.3 of the TRIPS Agreement be implemented by legislation or regulations. By administrative practice reflecting common law principles and consistent with Section 20 of the Access to Information Act, test or other data which are submitted to the Government of Canada, as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities, are not disclosed to third parties.

[Follow-up question from the EC]

Could Canada confirm that no legislation or regulation exist to ensure Canada's compliance with Article 39.3 of the TRIPS Agreement and that compliance is effected only through administrative practices?

Canada's compliance with Article 39(3) of the TRIPS Agreement is ensured by a combination of common law case law, administrative practice and legislation, e.g., subsection 20(1) of the Access to Information Act. As well, a public servant must, upon taking office, swear an oath, not to "without due authority in that behalf, disclose or make known any matter" that comes to his or her knowledge by reason of such employment.

III. REPLIES TO QUESTIONS POSED BY JAPAN

1. In your country, are the following subject matters protectable by patent: (1) plants and animals, and (2) plant and animal varieties?

- (i) In Canada, it is not possible to obtain a patent containing claims to plants or animals *per se*. However, patents may be obtained for claims covering plant and animal genes and cell lines.
- (ii) In Canada, it is not possible to obtain a patent containing claims to plant and animal varieties *per se*. However, patents may be obtained for claims covering plant and animal genes and cell lines.

2. In your country, is the act of offering for sale included in the exclusive rights of patent?

Under the inherent equitable jurisdiction of Canada's superior courts, there is a remedy available for offering for sale without the authorization of the patent holder. Under Canadian case law, importation of a patented article for infringing purposes has itself been held to be an infringement.

3. In your country, what kinds of acts are recognized as exceptions to the exclusive rights conferred by a patent right?

The Patent Act contains the following exceptions:

- (a) section 23 - use, other than manufacturing, of a patented invention is allowed on visiting ships, aircraft and vehicles;
- (b) subsection 55.2(1) - uses related to the development and submission of information for regulatory approval of a product;
- (c) subsection 55.2(2) - manufacturing and storage of patented articles (so far, only patented medicines) during the six months period prior to patent expiry;
- (d) (as referred to subsection 55.2(6)) - non-commercial uses, such as experimentation; and
- (e) section 56 - using a patented article which was purchased prior to the patent filing or priority date.

4. In your country, in which case is use without the authorization of the right holder permitted, including use by the government or by third parties authorized by the government?

In Canada, Section 65 of the Patent Act allows for an application to the Commissioner of Patents where there has allegedly been an abuse of the exclusive rights contained in a patent. The Commissioner may grant licences for the purpose of remedying such abuses upon "such terms as the Commissioner may think expedient" (Section 66). By administrative practice, the requirements of the above Article would be taken into account by the Commissioner in settling such terms. Section 19 of the Patent Act allows for the Government of Canada or of a province to apply to the Commissioner for authorization to use a patented invention, upon terms to be settled by the Commissioner of Patents in accordance with Sections 19 and 19.1 to 19.3 of the Act. In addition, the Minister of Public Works and Government Services of the Government of Canada may relieve a defence contractor from liability for royalties, upon compensation agreed to by the patentee or fixed by the Commissioner of

Patents, in accordance with Section 21 of the Defence Production Act. Under Section 32 of the Competition Act, where patent rights are exercised to restrain competition, the Federal Court may, on information by the Attorney General, make an order directing the grant of a licence, provided that that order complies with Canada's international agreements.

5. In your country, how is the obligation under Articles 34.1 and 34.2 of the TRIPS Agreement regarding the shift of the burden of proof in civil proceedings for patent infringement related to a process patent implemented?

Under Article 34.2 of the TRIPS Agreement, Member States are allowed to implement the obligation in paragraph (1) either in respect of sub-paragraphs (a) or (b). Canada gives patent protection in accordance with sub-paragraph (a), for new products, as contained in Section 55.1 of the Patent Act.

6. Article 20(1) of the Canadian Patent Law states that any public officer who, acting within the scope of his duties and employment, invents any invention in instruments or munitions of war shall, if so required by the Minister of National Defence, assign to that Minister on behalf of Her Majesty all the benefits of the invention and of any patent obtained or to be obtained for the invention. Please explain how Article 31(b) and (h) of the TRIPS Agreement is secured when the above provision is applied.

This provision is justified by Article 73(b) of the TRIPS Agreement.

7. Does a foreign applicant for patent in Canada enjoy a priority right based on the prior application filed in a WTO Member country which does not satisfy the description requirement as is prescribed in Article 34(1)(c) of the Canadian Patent Law? If not, please explain the consistency with the Article 4 of the Paris Convention applied by Article 2.1 of the TRIPS Agreement.

Yes.

It should be noted that the relevant provision is now paragraph 27(3)(c) of the Patent Act, which provides as follows: "(3) The specification of an invention must...(c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle;..."

8. Please explain the consistency between Article 4 of the Paris Convention applied by Article 2.1 of the TRIPS Agreement and Article 28(1) of the Canadian Patent Law, which prescribes that a priority right is enjoyable in Canada provided that the priority claim is based on an application filed in a country which affords a priority right to Canadian citizens.

Paragraph 28.1(1)(a) (replacing subsection 28(1)) requires that a prior application has been filed in a country that affords similar protection to that provided by Canada. Canada assumes that all WTO Members, or all Members of the Paris Union for that matter, provide such similar protection.

9. Are the acts of offering for sale or importing included in the exclusive rights mentioned in Article 42 of the Canadian Patent Law which prescribes that patent rights shall cover making, constructing, using and selling? Furthermore, regarding the provision of the said Article which sets out that "subject to adjudication in respect thereof before any court of competent jurisdiction", what specific cases, if any, exist? If there are any exceptions to patent rights regarding the above-mentioned points, please explain the consistency with Article 28 of the TRIPS Agreement.

Under the inherent equitable jurisdiction of Canada's superior courts, there is a remedy available for offering for sale without the authorization of the patent holder. Under Canadian case law, importation of a patented article for infringing purposes has itself been held to be an infringement.

10. Article 55.2(1) of the Canadian Patent Law prescribes that it is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses related to the development and submission of information provided under any law of Canada, a state thereof or a country other than Canada, and paragraph 2(2) of the said Article prescribes that it is not an infringement of a patent for any person to make, construct, use or sell a patented invention, during the applicable period provided for by the regulations, for the purpose of manufacturing and storing articles intended for sale after the expiration date of the patent. Please explain the specific cases envisaged for the above provisions and consistency with Articles 28 and 30 of the TRIPS Agreement.

Subsection 55.2(1) is of general application. It permits applicants for regulatory approval in Canada and elsewhere to engage in acts that would otherwise constitute violations of the rights of a patent owner in Canada.

Subsection 55.2(2) has been made operational through the adoption of the Manufacturing and Storage of Patented Medicines Regulations, of 1993, which provide that "[t]he applicable period referred to in subsection 55.5(2) of the Patent Act is the six month period immediately preceding the date on which the term of the patent expires."

Both subsection 55.2(1) and 55.2(2) are justified by Article 30 of the TRIPS Agreement as constituting limited exceptions to the rights of the patent holder.

11. Article 55.2(6) of the Canadian Patent Law prescribes that any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject matter of the invention are exceptions to the exclusive right of patent. Please explain whether the above-mentioned sale falls under the exceptions to the patent right allowed by TRIPS Article 30 of the TRIPS Agreement.

Subsection 55.2(6) of the Patent Act interprets subsection 55.2(1). This is indicated by the words "For greater certainty". The effect of this provision is that the exception of subsection 55.2(1) will not be interpreted as narrowing or abolishing any of the exceptions described in subsection 55.2(6) that existed in the case law prior to the enactment of subsection 55.2(1), e.g., experimental use. Such limited exceptions are expressly permitted by Article 30 of the TRIPS Agreement.

IV. REPLIES TO QUESTIONS POSED BY THE UNITED STATES

1. Article 55.2(1) of the Canadian Patent Act permits a third party, without the consent of the patent owner (i.e., "[i]t is not an infringement to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any ... [Canadian law] .. that regulates the manufacture, construction, use or sale of any product"). Article 55.2(2) appears to enable a third party to manufacture and store articles subject to a patent without the consent of the patent owner for a defined period of time prior to the expiration of a patent. In relation to these provisions, please:

- (a) identify the categories of products whose manufacture, construction use or sale are regulated in Canada, and thus subject to the scope of this provision;**

- (b) **explain whether this authority would permit a third party to manufacture and sell commercially significant amounts of a patented pharmaceutical product without the consent of the patent owner;**
 - (c) **explain whether a third party is entitled to manufacture and store any product that is regulated in Canada, and if so, whether any limits apply as to the scale of this manufacturing and storage activity;**
 - (d) **identify the time limits that have been set in regulations in relation to the right of a third party to manufacture and store products in anticipation of the expiration of the term of patent, as contemplated in Article 55.2(3); and**
 - (e) **explain how these provisions comply with the requirements of the TRIPS Agreement:**
 - (i) **not to discriminate in the enjoyment of patent rights based on the field of technology, or as to whether patented products are produced locally or imported [Article 27];**
 - (ii) **concerning the exclusive rights to be accorded to the patent owner [Article 28]; and**
 - (iii) **concerning the restrictions that must be present in national law concerning third party use of an invention without consent of the patent owner found [Articles 30 and 31].**
- (a) Subsection 55.2(1) applies generally. Examples of the categories of products are: medicines and fertilizers.
- (b) Any commercial sale under subsection 55.2(1) would have to be solely for uses reasonably related to the development and submission of information required by law.
- (c) By virtue of the Manufacturing and Storage of Patented Medicines Regulations, subsection 55.2(2) applies to the manufacturing and storing of medicines and is limited to the last six months of the life of the patent concerned.
- (d) See answer to question 1(c) above.
- (e) (i) Both subsections 55.2(1) and (2) are neutral as to the fields of technology to which they may be applied.
- (ii) These provisions establish limited exceptions to the rights of the patent owners within the meaning of Article 30 of the TRIPS Agreement.
- (iii) These provisions meet the conditions of Article 30 of the TRIPS Agreement. Article 31 of the TRIPS Agreement does not apply.

2. Article 2 of the Patent Act defines as an "invention" "any new and useful art, process, machine, manufacture or composition, or any new and useful improvement ... [to such inventions]". This definition apparently serves to define the scope of subject matter that can be patented in Canada. Please explain whether, under this definition, any of the following

inventions are considered ineligible to be patented notwithstanding the fact that the invention is new, useful and involves an inventive step:

- (a) process inventions which, in whole or in part, consist of steps that are performed by a computer and are directed by a computer program;**
 - (b) product inventions consisting of elements of a computer-implemented invention, including in particular:**
 - (i) machine-readable computer program code stored on a tangible medium such as a floppy disk, computer hard drive or computer memory; and**
 - (ii) a general purpose computer whose novelty over the prior art arises primarily due to its combination with a specific computer program.**
 - (c) non-naturally occurring microorganisms, plants or animals that have been developed through human intervention.**
- (a) Process inventions may be patentable even if they consist of steps that are performed by a computer and are directed by a computer program.
- (b) (i) A computer-readable memory for storing the instructions or statements for use in the execution of a patentable process on a computer would not be ineligible under the category of manufacture under the definition of "invention" in Section 2 of the Patent Act.
- (ii) The presence of a general purpose computer in combination with a specific computer program is patentable if the computer-related matter has been integrated with another practical system that falls within an area which is traditionally patentable.
- (c) Lower life forms which are new, useful and inventive are patentable. Claims to a higher life form, *per se*, are not patentable subject matter. However, patents may be obtained for claims covering plant and animal genes and cell lines.

[Follow-up question from the US]

In its answer to question No. 2(c) from the US, Canada has stated that higher life forms, *per se*, are not patentable subject matter under its law. Article 27.3 of the Canadian Patent Act appears to be the only provision of Canadian law that specifically addresses the issue of non-patentable subject matter. Article 27.3, however, does not explicitly exclude plants or animals. Please clarify whether Article 27.3 is the basis upon which plants and animals are excluded from patent eligibility under Canadian law, and if so, whether the exclusion stems from an interpretation of the law by a Canadian judicial authority or a decision taken by the Canadian Government.

Section 27(3) of the Patent Act (now section 27(8)) is not a basis for excluding plants and animals from patent eligibility. There is no express exclusion from patentability for higher life forms contained in the Canada's Patent Act. However, the Commissioner of Patents determined in the *Harvard Mouse* decision (unreported; August 4, 1995) that a non-human animal like a mouse did not fall within the meaning of "invention" in s.2 of the Patent Act.

3. Article 42 of the Canadian Patent Act specifies that the grant of a patent grants to the patentee the exclusive right of "making, constructing and using the invention and selling it to others to be used." This provision does not bestow on the patent owner the exclusive right to prevent others from importing or offering for sale the patented invention. Please explain how Article 42 complies with Article 28.1 of the TRIPS Agreement, which requires that the patent bestow on the patent holder the exclusive right of making, using, selling, offering for sale or importing the patented invention.

Under the inherent equitable jurisdiction of Canada's superior courts, there is a remedy available for offering for sale without the authorization of the patent holder. Under Canadian case law, importation of a patented article for infringing purposes has itself been held to be an infringement.

[Follow-up question from the US]

Please confirm that the mere offering for sale of a product that is subject to a patent in Canada and that has been imported into Canada through any means would be held to be an infringement of the patent right under the "equitable jurisdiction" of Canada's Superior Courts.

Canadian superior courts have inherent equitable jurisdiction to issue injunctions to prevent the offering for sale of patented articles, on a *quia timet* basis. Importation of patented articles has been held to be an infringement under Canada's Patent Act. (*Société des Usines Chimiques Rhône-Poulenc v. Jules r. Gilbert Ltd.* (1967); *Farbwerke Hoechst Aktiengesellschaft v. Halocarbon* (1979), 42 C.P.R. (2d) 145 (S.C.C.); *Hoffman-LaRoche Ltd. v. Apotex Inc.* (1983), 171 C.P.R. (2d) 20 (Ont. H.C.J.); *Wellcome Foundation v. Apotex Inc.* (1990) 3 F.C. 528 (Fed. Ct. Trial Division)).

4. In the notifications made by the Government of Canada, a number of laws concerning regulation of products have been provided. A common clause concerning the handling of test data is in these laws states regulations shall be promulgated that are deemed necessary for the purpose of complying with Canada's obligations under the NAFTA (Article 1711) and under the WTO Agreement (Article 39.3). Please explain how these clauses have been implemented by the various Canadian regulatory agencies. Please also explain how the practices dictated by these regulations relate to and are consistent with the requirements of Article 39.3 of the TRIPS Agreement with respect to steps that must be taken to prevent disclosure of confidential information provided to a regulatory agency by private parties seeking marketing approval.

Although a regulation-making authority was added to the Fertilizers Act (subsection 5(2) and (3)), the Food and Drugs Act (subsections 30(3) and (4)), and the Pest Control Products Act (subsections 6(2) and (3)), for purposes of Article 39.3 of the TRIPS Agreement, those provisions are strictly suppletive to existing measures for protection. So far, no regulations have been promulgated, as there has been no need. By administrative practice reflecting common law principles and consistent with Section 20 of the Access to Information Act, test or other data which are submitted to the Government of Canada, as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities, are not disclosed to third parties.

[Follow-up question from the US]

In its answer to question No. 4 from the United States, the Canadian Government has indicated that test data provided to a Canadian regulatory authority is not disclosed to third parties under administrative practice reflecting common law principles and consistent with Article 20 of the Access to Information Act. Please explain how the government of Canada ensures that test data is also protected against "unfair commercial use" as required by Article 39.3 of the TRIPS Agreement.

Confidential test data are not disclosed to third parties. At no time can a third party obtain access to the data. A relevant legislative provision, which protects information from disclosure, is section 20 of the Access to Information Act, which provides as follows:

"(1) [...] the head of a government institution shall refuse to disclose any record requested under this Act that contains:

- (a) trade secrets of a third party;
- (b) financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party;
- (c) information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or
- (d) information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of a third party."

5. Canadian law [Food and Drug Regulation C.08.004.1] appears to enable third parties to obtain access to test data provided by a party to the regulatory authorities in Canada under certain conditions. Please explain:

- (a) **the conditions under which a third party can gain access to confidential information provided to a Canadian regulatory agency for purposes of obtaining marketing approval; and**
- (b) **how this regime complies with the requirements of Article 39.3, which require WTO Members to take steps to protect parties that have provided such data against unfair competition.**

By administrative practice reflecting common law principles and consistent with Section 20 of the Access to Information Act, third parties are not given access to confidential information provided in another manufacturer's new drug submission.

[Follow-up question from the US]

In answer to a number of questions, Canada has stated that it has implemented its obligations under the TRIPS Agreement through recognition of common law (i.e., judicial decisions). Please provide citations to and the contents of judicial decisions relied upon to establish compliance of Canadian law with the following obligations of the TRIPS Agreement:

- (a) **importation/offering for sale as among the exclusive rights of patents owners;**
 - (b) **protection of undisclosed information against disclosure and use;**
 - (c) **administrative practice for implementation of Article 39.3.**
- (a) *Société des Usines Chimiques Rhône-Poulenc v. Jules r. Gilbert Ltd.* (1967); *Farbwerke Hoechst Aktiengesellschaft v. Halocarbon* (1979), 42 C.P.R. (2d) 145

(S.C.C.); *Hoffman-LaRoche Ltd. v. Apotex Inc.* (1983), 171 C.P.R. (2d) 20 (Ont. H.C.J.); *Wellcome Foundation v. Apotex Inc.* (1990) 3 F.C. 528 (Fed. Ct. Trial Division).

- (b) *Lac Minerals v. International Corona Resources Ltd.* [1989] 2 S.C.R. 574.
 - (c) Canada's compliance with Article 39(3) of the TRIPS Agreement is ensured by a combination of common law, case law, administrative practice and legislation, e.g., subsection 20(1) of the Access to Information Act. As well, a public servant must, upon taking office, swear an oath, not to "without due authority in that behalf, disclose or make known any matter" that comes to his or her knowledge by reason of such employment.
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