

Compulsory Licensing in Canada

There are few legislative restrictions regarding technology transfer, but working of patents is encouraged

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By way of comparison with many countries, there are relatively few legislative restrictions on the licensing of technology under Canadian patent laws. The major feature of the Canadian patent system, as it relates to the transfer of technology, is the compulsory licensing scheme, which has as its purpose the encouragement of the working of a patented invention in Canada.

It must be remembered that a license agreement is a contract. A license is a permission given by the owner of a right in property, such as a patent, to another to invade the right free from legal recourse. The permission may be oral or written. The permission may be a mere dispensation that is revocable. It may alternatively be found in a contract that defines the respective rights and obligations of the licensor and the licensee. A license does not set up rights as between the licensee and the public, but only permits the licensee to do acts that the licensee would otherwise be prohibited from doing. It does not create a property right in the licensed property.

Because the license agreement is a contract, it is subject to the same rules that relate to contracts in general. A license agreement is construed under its applicable law. Parties may choose an applicable law or may be governed by the principles of private international law.

By entering into a license agreement, both the patentee and a licensee create mutual rights and obligations that are independent and distinct from the patent. Therefore, these rights can subsist whether the patent subsists or not. I will not say any more with respect to "voluntary," as opposed to "compulsory," licenses, except to mention several statutes pertaining to the transfer of technology. The discussion will then proceed to the compulsory licensing provisions.

CANADIAN GOVERNMENT CONTROLS

The Export and Import Permits Act places certain restrictions on the export of certain technical devices and technical documentation to certain designated nations. Permits are required to ship such devices or documentation. The list of countries and types of

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devices and documentation is extensive and beyond the scope of this paper. In practice, documents pertaining to the filing of foreign patent applications are not included within the scope of the restrictions. However, the legislation is broad enough to cover such applications. The Patent and Trademark Institute of Canada is lobbying to have patent applications expressly exempted from the scope of the legislation. A clause should be inserted in any license to make the license conditional on obtaining a permit, if necessary.

Reporting Requirements

The Corporations and Labour Unions Returns Act, known as "CALURA," applies to all corporations that conduct business in Canada, unless specifically exempted, which have together with all affiliated corporations, as defined, gross revenues for the reporting period, exceeding \$15 million or assets exceeding \$10 million. Such corporations must file detailed corporate and financial information annually. In certain circumstances, information relating to transactions involving the transfer of technology must also be filed.

Annual returns concerning the amounts of royalties paid to persons outside Canada for patents, copyrights, industrial designs, trademarks and tradename rights must be filed. New provisions require additional information relating to transfers of technology from abroad.

Tax Considerations

Under the Canadian Income Tax Act, there is a 25% withholding tax on amounts paid or credited by a resident of Canada to a nonresident as a rent, royalty or similar payment, including any payment for the use of or the right to use in Canada any property, invention, patent, design or model, plan, secret formula, process or other thing. This withholding tax may be reduced or eliminated under one of Canada's international tax conventions. For example, under the Canada-U.S. Income Tax Convention, the rate of withholding tax on royalties, as defined in the Convention, is generally reduced to 10%.

Competition Law

In assessing the validity and enforceability of patent licensing agreements, consideration must be given to those sections of the Patent Act and the Competition Act that are intended to guard against the abuse of exclusive rights under patents. The insertion of any restrictive term in a patent license agreement, even if it constitutes an abuse of exclusive rights, does not avail the defendant as a defense in an action for infringement of the patent concerned. Such abuse can only be established and remedied by the compulsory licensing pro-

cedure provided by the Patent Act or by invoking the powers of the Competition Act.

Recordal

Every grant of any exclusive right to make and use and to grant to others the right to make and use a patented invention, within and throughout Canada or any part thereof, must be registered in the Patent Office. While it is only necessary to register an exclusive license, it is advisable to record even a nonexclusive license. However, because a license often contains terms, such as royalties, which the parties wish to keep confidential, a short-form license agreement should be registered.

The Canadian Government has recently revealed its plans to make amendments to the Canadian Patent Act. One aspect of the proposal relates to voluntary licenses.

Although assignments of patents will still have to be recorded, the proposed legislation removes the requirement that exclusive licenses be recorded in the Patent Office. However, within a prescribed period, a patentee will have to provide to the Commissioner prescribed information concerning licenses granted after the amendments are enacted. At present, it is not known what information will be required.

COMPULSORY LICENSES

A patent is not an unfettered right in Canada. It is subject to the rights of others to have or acquire a license under the patent in certain situations. These situations include use by the government and compulsory licensing in the case of an abuse of the patent rights or in respect of patents for foods and medicines. The right to deal with a patent is also restricted by competition law.

Use by Government

The Canadian Federal Government may, at any time, use any patented invention, although it must pay to the patentee a sum that the Commissioner decides to be reasonable compensation for such use. The preferred position of the government extends only to its servants and agents and not to independent contractors or suppliers. It is unlikely that the Provincial Governments are entitled to this advantage.

Compulsory Licenses for Abuse

There is an old tale that an inventor developed and patented an improved carburetor which enables an automobile to travel 200 kilometers per litre of gasoline and that an oil company purchased the patent to ensure that the invention could never be commercially exploited in Canada. In fact, this could not be done for any length of time because the Patent Act provides that, after three years from the grant of a patent, in the case of certain enumerated "abuses," which include the failure to commercially "work" an invention in Canada, an interested person may apply for a "compulsory license," which is imposed on the patentee by the Commission if a license is deemed appropriate in the circumstances.

Patents for new inventions are granted not only to encourage invention, but also, so far as possible, to secure that new inventions are worked on a commercial

scale in Canada without undue delay. "Work on a commercial scale" means the manufacture of the article, or the carrying out of the process, claimed in the patent in or by means of a definite and substantial establishment or organization and on a scale that is adequate and reasonable under the circumstances.

The exclusive rights under a patent are deemed to be abused in a number of enumerated circumstances. However, these circumstances are not exhaustive and, although unlikely, it may be possible to establish an abuse which does not fall within the enumerated list. In the following discussion of the abuses, wherever reference is made to a "patented article," this term also includes articles made by a patented process.

Non-Working.

The exclusive rights in a patent may be abused if the patented invention which is capable of being worked in Canada is not being worked within Canada on a commercial scale and no satisfactory reason can be given for such non-working. This is the most common ground of abuse alleged and proved. It is the patented invention as defined by the claim which must be worked. Whether an invention is being worked in Canada may be a difficult question to answer. For example, advance engineering work, the appointment of selling agents or licensing does not constitute working of an invention on a commercial scale. Nor does the separation and packing of bulk product into individual packages. On the other hand, the assembly in Canada of parts made outside of Canada may constitute working in Canada, depending on the nature of the invention.

If working is not carried out in Canada, the onus is on the patentee to give a satisfactory reason why it is not carried on. The absence of domestic demand may be a satisfactory reason. But if there is a demand abroad where the patentee works the invention, the absence of demand in Canada may not be a sufficient reason. That an industry based on the patented invention cannot be pursued as profitably as abroad because of labor or material costs is not a satisfactory reason. That the demand for the invention is too limited to warrant domestic manufacture is not sufficient either.

Importation

An abuse exists if the working of the invention within Canada on a commercial scale is being prevented or hindered by the importation from abroad of patented articles. Such importation may be by the patentee or persons claiming under the patentee, by persons directly or indirectly purchasing from the patentee, or by other persons against whom the patentee is not taking any proceedings for infringement. It must be noted that mere importation by itself does not constitute an abuse. It must be shown that the working in Canada of the invention on a commercial scale is being prevented or hindered.

Insufficient Supply

An abuse of the exclusive rights in a patent may exist if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms. This may occur if the patentee is restricting the

supply to keep prices high.

Refusal to License

The exclusive rights in a patent may be abused if, by reason of the refusal of the patentee to grant a license upon reasonable terms, the trade or industry of Canada, 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 license be granted. In order for this abuse to exist, the patentee must refuse a license entirely or attach unreasonable conditions to it. The mere refusal of a license, though, is not sufficient. It must also be shown that the trade as a whole or the trade of the applicant is being prejudiced. Further, the public interest must be served and the abuse must be curable by the grant of a license.

Onerous Conditions

The exclusive rights in a patent may be abused 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 to the purchase, hire, license or use of the patented article, or to the using or working of the patented process.

Working of Unpatented Materials

The exclusive rights in a patent may be abused if a patent for 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 to unfairly prejudice in Canada the manufacture, use or sale of any such materials.

Application

After the expiration of three years from the date of the grant of a patent, the Attorney General of Canada or any interested person may apply to the Commissioner alleging that there has been an abuse of the exclusive rights under that patent and asking for relief from such abuse.

No Order

If the Commissioner is of the opinion that the objects of the Patent Act will be best attained by making no order, the Commissioner may make an order refusing the application and dispose of any question as to costs of the proceedings as the Commissioner thinks just. The application may be dismissed even if an abuse is established. Unlike the compulsory license provisions for inventions relating to foods and medicines, the grant of relief is entirely discretionary and dependent on furthering the stated aim of the act. For example, if at the time of the application based on non-working or the determination, the patentee is taking active steps to pursue domestic working, a compulsory license may be refused.

Revocation

If the Commissioner is satisfied that the objects of the act cannot be attained by the exercise of any grant of a license, the Commissioner can order the patent to be revoked, either immediately or after such reasonable interval as may be specified in the order, unless, in the meantime, such conditions as may be prescribed in the

order with a view to attaining the aim of the act are fulfilled. The Commissioner may, on reasonable cause shown in any case, by subsequent order, extend the specified interval. Revocation is an extreme remedy and has never been ordered in Canada.

Nonexclusive License

The most common order made by the Commissioner upon finding that a case of abuse of the exclusive rights under a patent has been established is the grant to the applicant of a license on such terms as the Commissioner thinks appropriate. In settling the terms of such a license, the Commissioner must be guided by the following considerations:

1. The Commissioner must, on the one hand, endeavor to secure the widest possible use of the invention in Canada consistent with the patentee deriving a reasonable advantage from the patent rights.
2. The Commissioner must, on the other hand, endeavor to secure to the patentee the maximum advantage consistent with the invention being worked by the licensee at a reasonable profit in Canada.
3. The Commissioner must also endeavor to secure equality of advantage among the several licensees. For this purpose, the Commissioner, on due cause being shown, may reduce the royalties or other payments accruing to the patentee under any license previously granted by the Commissioner. In considering the question of equality of advantage, the Commissioner must take into account any work done or outlay incurred by any previous licensee with a view to testing the commercial value of the invention or to securing its working on a commercial scale in Canada.

Among the terms that may be included in the license is one 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 the patentee, would be an infringement of the patent. In such case, the patentee and all licensees are deemed to have mutually covenanted against such importation. The reason for this term should be obvious as the goal of the compulsory license is to encourage working of the invention on a commercial scale in Canada. Any order for the grant of a compulsory license operates as if it were embodied in a deed granting a license executed by the patentee and all other necessary parties.

License for Customers

If the Commissioner is satisfied that there has been an abuse of the exclusive rights in a patent for a process such that the manufacture, use or sale of materials used in the process is prejudiced, the Commissioner may order the grant of licenses to the applicant and to such of the applicant's customers, and containing such terms, as the Commissioner thinks appropriate.

Excusive License

If the Commissioner is satisfied that the invention is not being worked on a commercial scale in Canada, and is such that it cannot be worked on a commercial scale in Canada without the expenditure of capital for the raising of which it will be necessary to rely on the exclusive rights under the patent, unless the patentee or those claiming under the patentee will undertake to find

such capital, the Commissioner may order the grant, to the applicant or to another person who is able and willing to provide such capital, of an exclusive license on such terms as the Commissioner may think just. In deciding to whom such an exclusive license is to be granted, the Commissioner must, unless good reason is shown to the contrary, prefer an existing licensee to a person having no registered interest in the patent.

In settling the terms of any such exclusive license, the Commissioner must have regard to the risks undertaken by the licensee in providing the capital and working the invention. The Commissioner must also be guided by the following factors:

1. The maximum royalty should be secured to the patentee compatible with the licensee working the invention within Canada on a commercial scale and at a reasonable profit.

2. A minimum yearly sum by way of royalty should be guaranteed to the patentee, if and so far as is reasonable to do so, having regard to the capital requisite for the proper working of the invention and all the circumstances of the case.

In addition to any other powers expressed in the license or order, the license and the order granting the license is made revocable at the discretion of the Commissioner if the licensee fails to expend the amount specified in the license as being the amount that the licensee is able and willing to provide for the purpose of working the invention on a commercial scale within Canada, or if the licensee fails to work the invention on a commercial scale within Canada within the time specified in the order.

The order granting an exclusive license operates to take away from the patentee any right that the patentee may have as patentee to exploit the invention and operates to revoke all existing licenses, unless otherwise provided in the order. However, on granting an exclusive license, the Commissioner may, if the Commissioner thinks it fair and equitable, make it a condition that the exclusive licensee give proper compensation to be fixed by the Commissioner for any money or labor expended by the patentee or any existing licensee in developing or exploiting the invention.

COMPULSORY LICENSES FOR FOODS AND MEDICINES

It is the stated intention of the Patent Act to make foods and medicines available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention. For this reason, unless the Commissioner sees good reason to the contrary, any person may obtain a license from the Commissioner under a patent for an invention intended or capable of being used for the preparation or production of food or under a patent for an invention intended or capable of being used for the preparation or production of a medicine. Although such licenses are compulsory licenses, they differ from compulsory licenses in relation to other inventions in a number of important aspects.

First, a license under a patent relating to a food or medicine is available to any person, rather than only to an "interested person."

Second, a license under a patent relating to a food or

medicine must be granted unless there is good reason not to grant such a license. There is no need to establish an abuse of the exclusive rights under a patent, as is the case for other patented inventions, and no need to establish that the grant of a license will cure the abuse.

A third major difference is that a license under a patent relating to a food or medicine is available as soon as the patent is granted. There is no need, at least at the present time, to wait three years from the date of grant of the patent, as in the case of patents for other inventions.

A fourth distinguishing factor is that a compulsory license under a patent relating to an invention intended or capable of being used for a medicine or for its production or preparation may include the right to import the patented substance or a substance made by the patented process.

License for Food

In the case of a patent for an invention intended or capable of being used for the preparation or production of food, the Commissioner must, unless there is good reason to the contrary, grant to any applicant a license limited to the use of the invention for the purposes of the preparation or production of food. However, if the invention can be used for other purposes, the license cannot extend to those other purposes.

A "food" is considered to be a substance that enables the metabolic process of the living cellular system to replace those constituents that are constantly being used as a source of heat and energy, or for the growth, upkeep and normal function of the living cellular system of the body. Food is not limited to human food, but also includes food for animals. An example illustrating what constitutes a food lies in the field of sweeteners. While sugar is a food, saccharin, aspartame and similar artificial sweeteners do not participate in the metabolic processes of the body and are not considered to be foods. Similarly, condiments, artificial colorings, food preservatives, flavoring agents and the like are not foods.

Proteins, carbohydrates, fats, lipids, vitamins and substances which contribute to the synthesis of such substances by the human body are foods. Some materials may be a food or a medicine; these include modified proteins, specific amino acids and the like for use as food supplements.

License for Medicine

In the case of a patent for an invention intended or capable of being used for medicine or for the preparation or production of medicine, the Commissioner must grant a license to practice the invention to any applicant unless there is good reason to not grant a license or to limit the things that may be done under the license.

A "medicine" is considered to be any drug, therapeutic agent, biological agent or pharmaceutical specialty. These include antihistamines, anti-infectives, autonomic drugs, cardiovascular drugs, anti-anemia agents, hemostatics, diagnostic agents, expectorant and cough preparations, gastro-intestinal drugs, hormones, oxythotics, vitamins, anaesthetics, spasmolytic agents and the like intended for use in the treatment of living humans, animals, birds or fish for the cure, alleviation and prevention of ailments, the restoration and preser-

vation of health, the regulation of diet and the like.

Other examples of substances considered to be medicines include glandular extracts such as insulin, sex hormones and thyroid, liver and adrenal cortical extracts. Similarly, toxins, anti-toxins, vaccines, and virus concentrates produced from natural sources may not have been chemically changed from the form produced in nature, but are considered as medicines produced by chemical techniques. Modified proteins, specific amino acids and the like for use as medicines are also included.

What is not considered a medicine is a substance used in diagnostic or testing procedures. An example is an electrode cream for use in taking an electrocardiogram. Similarly, a composition having nonmedicinal utility comprising a medicinally active substance in combination with other ingredients is not considered a medicine. On the other hand, a compound having both medicinal and nonmedicinal uses is considered a medicine, whether the medicinal use is disclosed in the specification or elsewhere. A compound used as an intermediate in the production of medicine is considered as a medicine even if the intermediate is itself not a medicine and has other nonmedicinal uses.

Where the invention is a process, the license may include the right to use the invention for the preparation or production of medicine, to import any medicine in the preparation or production of which the invention has been used or to sell any medicine in the preparation or production of which the invention has been used. Where the invention is other than a process, the license may include the right to import, make, use or sell the invention for medicine or for the preparation of medicine. The application involves a sometimes complex procedure which generally results in the grant of a license to a qualified applicant.

Determination

The Commissioner must dispose of an application by granting or refusing a license not later than 18 months after the day on which a copy of the application is served on the patentee. The Commissioner must grant to the applicant a license to do the things specified in the application and permitted by the Patent Act, except such, if any, of those things in respect of which the Commissioner sees good reason not to grant such a license. There have been only a very few cases where the Commissioner has seen good reason not to grant a license. In setting the terms of the license and fixing the amount of royalty or other consideration payable, the Commissioner must have regard to the desirability of making the medicine available to the public at the lowest possible price, consistent with giving to the patentee due reward for the research leading to the invention and other relevant factors. In fact, most licenses have a royalty fixed at 4% of the net selling price of the drug in final dosage form in respect of arms'-length transactions. Where a license involves more than one patent, the royalty is equally divided among those patents. The licensee never pays more than 4% for the rights to manufacture and import any drug.

PROPOSED AMENDMENTS

Such compulsory licenses, enabling persons other than the patentee to manufacture patented medicines

in Canada have been in existence since 1923. They were seldom used prior to 1969, when the compulsory license provisions were amended, making such licenses much easier to obtain. They may, for example, enable licensees to manufacture medicines in Canada from raw materials or imported intermediates, or to import actual medicines in bulk for encapsulation in Canada.

It is generally considered that the majority of the compulsory licensees import bulk medicines from countries where patent protection for medicines is limited and blend those medicines with suitable carriers to make the final dosage form of the medicine.

Most generic drug manufacturers have chosen to limit their activities to those drugs that have proven to be commercially successful and have obtained compulsory licenses to import, produce and sell them. They do not incur the risks and expenses associated with pharmaceutical research and are often able to take advantage of the clinical work of the patentee to obtain government approval for the sale of the generic product.

Many pharmaceutical companies have complained that the compulsory licensing system results in entirely inadequate compensation to the patentee for the risk and magnitude of his investment in research, and have expressed the view that the system discourages pharmaceutical research in Canada.

Over the last few years, there has been much discussion with respect to changes to the compulsory licensing system. In May 1985, the report of the Eastman Commission of Inquiry recommended a guaranteed period of exclusivity to innovative companies and an increased royalty rate for those licenses that were granted.

Conditional Exclusivity for 10 Years

The proposed amendments to what is now Section 41 of the Patent Act provide for a 10-year period of exclusivity against compulsory licenses commencing from the date that the patentee receives approval to market the medicine in Canada provided that the patentee commences manufacture of the medicine in Canada within two years of receipt of the Notice of Compliance from Health and Welfare Canada. If manufacture in Canada does not commence within this two-year period, compulsory licenses to manufacture the medicine in Canada will be available.

Transitional Provisions

The proposed amendments provide that medicines patented as of June 27, 1986, will receive a phased-in period of market exclusivity, depending on whether they are currently on the market (an existing medicine) or not yet on the market (a new medicine). Most of the proposed amendments dealing with medicine patents would take effect as of June 27, 1986, so that compulsory license applications filed after that date, but before the new legislation takes effect, will be governed by the amended legislation. The proposed legislation provides for the following:

1. All medicines that are the subject of a compulsory license and for which a Notice of Compliance from Health and Welfare Canada has been received will be unaffected by the new legislation.

2. A seven-year period of market exclusivity from the date of the Notice of Compliance will be granted to a

patentee for any medicine for which a compulsory license has been granted, but for which the licensee has not received a Notice of Compliance in Canada.

3. An eight-year period of market exclusivity will be granted to a patentee for any existing medicine if neither a compulsory license nor a Notice of Compliance has been granted to a prospective licensee.

4. A ten-year period of market exclusivity will be granted to a patentee for a new medicine for which a Notice of Compliance is issued after June 27, 1986.

Patents for Products

The proposed legislation will permit patents to be issued for medicines, which can now be patented only in association with the process or processes by which they are made, as well as for processes of making them.

Patented Medicine Prices Review Board

In order to protect Canadian consumers from excessive medicine prices, an independent Patent Medicine Prices Review Board will be established. The Board will be able to establish price ceilings if it is shown that prices for any particular medicines are too high. The failure of a patentee to roll back prices to this set ceiling will result in the revocation of the period of market exclusivity. The Board will be required to assess medicine prices in relation to specific factors, such as the Consumer Price Index, the actual production cost of the medicine and the prevailing price levels in other countries for medicines in the same therapeutic class. The Board will have the mandate to review all prescription patented medicine prices to determine the fairness of the price charged to consumers.

The Board is required to work in close cooperation with the provincial governments, which have a signifi-

cant interest in medicine prices, because of the many provincial medicine subsidy plans. The Federal Government estimates that the total cost to provincial treasuries resulting from the delay in the availability of compulsory licenses will not exceed \$100 million by 1990. In order to ensure that those consumers most in need do not bear this cost, the Federal Government will provide transitional financial assistance to the provinces totalling \$100 million over the four-year period.

Generic Farm Chemicals

The proposed amendments make the fate of current Bill C-274, introduced on March 6, 1986, to amend the Patent Act, uncertain. This private member's bill, directed to generic farm chemicals, proposed to extend the compulsory licensing provisions of existing Section 41 of the Patent Act to "pest" "control products," as defined. Private members' bills are rarely passed.

The legislation provides that in the case of any patent for an invention intended or capable of being used for the preparation or production of a pest control product, the Commissioner shall, unless he sees good reason to the contrary, or the pest control product was registered within the immediately preceding four years under the Pest Control Products Act, grant to any person applying for the same a license limited to the use of the invention for the purposes of the preparation or production of the control product. In settling the term of such a license and fixing the amounts of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the control product available to farmers in Canada at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.