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Comparative study of Patent laws In United States, Canada and Patent infringement Litigation in Japan

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ABSTRACT
A fundamental purpose of patent law is to encourage the development of new inventions by granting to the inventor exclusivity in the market place for a limited period of time. Patent law in the area of pharmaceuticals is complicated by the responsibility of governments not only to encourage research and development of new drugs, but also to assure that new drugs are widely available and affordable, as well as safe and effective. Government influenced by market and political philosophies, design patent laws and drug.Regulatory schemes to meet this requirement. The United States has well developed pharmaceutical industries and thus has strong patent protection for pharmaceuticals. In past few years ago in Japan, particularly from 1999, the practice before the Japanese courts in patent infringement litigation has gone through various suitable changes. Be In this paper, discussions on patent infringement litigation from the standpoint of the defense and primarily for the initial phase of arguments and process of various aspects of infringement and litigation in innovated molecule of moiety of drug by the patentee.
In Japan protect the innovated patent from the infringement, and study both cases from two applicants.
Keywords: Patent protection, encourage research and development, affordable, safe and effective, infringement.

INTRODUCTION
Canada and the united states jointly a common border and as well as have a common law legal heritage. However they have differing political system and market strategies have led to significant difference in protection for every pharmaceutical. The main objective is to encourage invention and discover new innovative things by granting to the innovators exclusivity in the market place for a limited period of time.

Patent protection for new inventions in the pharmaceuticals industry is complicated by competing public interest the public always been interested to encourage researchers and development of new medicines to increase longevity and quality of life however keeping then price of new medicine low to maximize the number of person who have access to the drug furthermore the public has an interest in ensuring that new medicines entering in to the market are both safe and effective do not harm to the public health.

Government policy in the area of pharmaceutical thus has three main objectives

1. To protect the intellectual property rights and encourages the research and development

2. Promote the growth of strong generic drug industry to contain the cost of new drugs
3. To design a regulatory an elaborate and systematic plan of action that balance the interest of pharmaceutical companies and generic drug companies, while ensuring the safety and efficacy of drug in the market place.

Canadian and United States government have designed their patent law and regulatory process to fulfill their obligation.

METHODOLOGY

THE LAW IN UNITED STATES

The United States[2] has a very strong domestic pharmaceutical industry .Pharmaceutical companies in ("R&D") of new drugs worldwide. United States government has an interest in maintaining a healthy pharmaceutical industry, the government is also concerned with providing the public with affordable drugs. The United States has at its core a free market economy[3].

Patent protection for pharmaceuticals- The Patent Act

The patent Act[4] governs the granting of patents in the United States: every patent shall grant to the patentee the right to the invention throughout the united states or importing the invention into the united states whoever, without authority makes, uses, offers to sell, or sells any patented invention, within the united states or imports in to the united states any patented invention during the term of the patent therefore, infringes the patent.

Regulation of safety and efficacy of pharmaceutical prior to 1984

Patent protection for the pharmaceuticals is complicated by requirements bring down under the federal regulatory process to ensure the safety and efficacy of drugs.

The federal food, drug, and cosmetic act[5]

In 1962, congress enacted major changes to the federal food, drug and cosmetic act, requiring drug manufacturers to submit "substantial evidence" that their drugs were both safe and effective. To implement this requirement, the Food and drug administration (FDA) set up a lengthy approval process for new drugs patent term for innovator drugs because the drugs are not in the commercial market during the regulatory process.

Infringement by generic companies during the regulatory process[6]

FDA regulations also required generic manufacturers to comply with its regulatory process without relying on data submitted by the innovator drug manufacturer to prove safety and efficacy. Generic manufacturers thus had to perform many of their own tests. Because it is an act of infringement to manufacturers or use a patented product during the term of the patent, generic manufacturers could not begin testing until after the patent term expired. As a result, the entry of generic drugs into the market was often delayed for several years after the brand-name drugs patent expired. These regulations gave pioneer drugs patent term extension.

The court of appeals for the federal circuit affirmed that a generic drug manufacturer commits infringement by using the active ingredient of a patented drug to perform pre-market entry tests mandated by the FDA before the patent term of the innovator drug expires.

The Roche patent had expired. Bolar had begun the regulatory process during the patent term in preparation for market entry when Roche patent expired.

The drug price competition and patent term restoration ("Waxman-Hatch") Act of 1984[7]

In 1984 congress attempted to resolve the conflict between the patent act the food, drug, and cosmetic with passage of the drug price competition and term restoration ("Waxman-Hatch") Act. The Act was a compromise between the interest of generic manufacturers obtaining faster entry into the market and the interest of brand-name pharmaceutical companies in regaining patent term lost during the regulatory process. Title 1 of the act established an abbreviated new drug application ("ANDA") approval process for generic drugs, eliminating the requirement for independent proof that the generic version of a pioneer drug is safe and effective. Under the ANDA, the safety and efficacy of the generic drug is accepted if the manufacturer certifies generally that the generic drug has the same active

ingredients as the pioneer drugs that the route of administration the dosage form and the strength of the generic drug is the same as the pioneer drug; and that the generic drugs is the bioequivalent of the pioneer drug.

Title-II of the act also provide some relief for the manufacturers of brand names pharmaceuticals by restoring a portion the patent term lost while pioneer drug is in the regulatory process. It also requires the generic manufacturer to certify that no patent exists on the pioneer drugs. or if a there a patent ,that the patent has expired or that patent invalided.Will not be infringed by the actions.

THE LAW IN THE CANADA[8]

Canada has a system of within the country medicine in which the government is directly involved in providing health care for all its citizens. The government thus has a vested interest in keeping drug price low .therefore, although Canada provide patent protection for pharmaceuticals, the government weakened the rights of the patentee[9] by instituting a compulsory licensing system .when the government eventually abolished licensing, it instituted price control

Patent protection of pharmaceuticals

The patent act[10]

Patent protection in Canada is governed by the patent act, which provides that every patent granted by under this Act shall grant to the patentee the exclusive right, privilege and liberty of making, constructing and using the inventions and selling it to other to be used.

Compulsory licensing[11]

Compulsory licensing the united states of did not limit the rights of pharmaceuticals patent holders until the Waxman hatch Act of 1984 Canada began limiting the exclusive rights of pharmaceuticals patentees as early as 1923, when parliament amended the patent act to provide for compulsory licensing of pharmaceuticals .under the amendment, a party Act to the commissioner of patents for a license to manufacture and market patented drug before the term of the patent expired.

The compulsory nature of the license meant that the patent owner could not prevent the commissioner from granting the license .in exchange for giving up the exclusivity of the patent the patent owner received a small royalty fee. The idea behind amendment was to contain the cost of drugs through competitive market forces by providing multiple sources for the patented drug.

Twenty two (22) licenses were granted in-between 1923 and 1969 the main reason policy was that the amendment required generic version of a patented drug to be manufactured in Canada, and there were very few manufacturing facilities in Canada .in 1969, the government eliminated this requirement and permitted drug import licensing. This policy leads to development of strong generic industry in Canada pharmaceuticals.

Parliament passed the Bill C-22, amending the compulsory licensing regime.Under Bill C-22.

Compulsory licensing was still mandated, but only after the first seven years of the patent protection had expired. This encouraged the research and development by pharmaceuticals' companies a period of exclusivity granted to the pharmaceutical companies, another provision of Bill C-22 established the patented the Patented Medicine Price Review Board (PMBR) to monitor and control patented drug price. In 1993, in response to the North America free trade agreement between Canada, the United States, and Mexico, parliament passed Bill C-91 eliminating compulsory licensing.

Regulations of the safety and efficacy of pharmaceuticals the food and drug Act [12]

In 1963, Canada enacted major changes in the Canada Food and Drug Act. The changes, using language very similar to the 1962 amendments to the united states of "federal food and drug cosmetic Act ,required manufacturer to sunlit substantial evidence that a new drug was both safe and effective before market entry would be allow. Canada's administrative body, the therapeutic products directorate (counter part of united states FDA), employed a regulatory process for market entry of new drugs very similar to that used by the FDA.

The Canadian drug approval process had similar implications for patent protection as in the United States. Pioneer drug lost effective patent term while in the regulatory a process, but had de facto patent term extension because the generic drug company

could not begin the regulatory process until patent term expired.

Litigation of the notice of compliance regulation[13]

While there has been litigation in the United States regarding what activities are entitled to the

Benefits of the safe harbor provision, there have been little if any litigation in Canada over this issue .this is in spite of the fact that both status use almost identical language. It is not infringement to make use or sell patent inventions solely for uses reasonably related to the development and submission of information to a regulatory body.

The litigation in Canada instead has centered on the issuance of the notice of compliance and has been further complicated by compulsory licenses that are in still in effect under regulations "when a party applies for a notice of compliance, they must allege that the patent has expired.

When a party makes an allegation of non infringement, the party should provide a detailed statement of the legal and factual basis for the allegation. The patent owner then may within 45 days after being served with a notice of an allegation apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of allegation. Subjected to some conditions the minister shall not issue a notice of compliance before the court has declared that the patent is not valid or not that no claim for the medicine itself and no claim for the use of the medicine would be infringement

Canada Law, Though Still Favoring the Generic Manufacturer, Has Become More Balanced[14]

Early Canada patent law governing pharmaceuticals with its compulsory license system, clearly favored generic manufacturer. Abolished of the compulsory license system provided a huge benefit to the brand name pharmaceuticals industry. However, as a trade off the government established the patented Medicine price review Board to control the price of patented drugs. Furthermore, Canada unlike the United States has no provision for restoring patent term lost by the pioneer drug company while its product is in the regulatory process.

Although compulsory licensing has been abolished, there are still provisions in the law to support the generic drug industry. For instance, there is no counterpart agency to the PMPRB to monitor and control the price of generic drugs. In addition, the generic manufacturer can use the data of the pioneer drug manufacturer to hasten entry in to the market and is also protected from infringement actions during the regulatory process by the safe harbor provision. Although law remain tilted in favor of the generic manufacturer.

INTERNATIONAL AGREEMENTS

The North America free Trade Agreement (NAFTA)

In 1922 the United States, Canada and Mexico entered into the north America Free Trade Agreement (NAFTA).NAFTA requires a minimum patent term of "at least 20 years from the date of filing or 17 years from the date of grant.NAFTA also allow, but does not require, the restoration of the patent term lost during a regulatory process .NAFTA require patent protection for pharmaceuticals, requires the same term of protection for all patented inventions, and severely restrict compulsory license.

Effect of NAFTA in the United States

NAFTA has had little impact on patent protection for pharmaceuticals in the United States .the united states at the same time of the signing of NAFTA had seventeen years date of issue patent term also had provision for restoration of patent term due to regulatory process and furthermore united states had a compulsory licensing, regime.

Effect of NAFTA in Canada

NAFTA had a much greater strong effect on the pharmaceuticals industry in Canada. in anticipation of the signing of NAFTA, parliament passed Bill c-91 in 1993. Bill C-91 abolished the compulsory licensing system and extended the patent term for pharmaceuticals from seventeen years from the date of issue to twenty years from date of filing .However, to balance the added protection given to pharmaceuticals, the Bill strengthened the patented medicines, prices review board. as could be expected the end of compulsory licensing engendered much litigation while no new license were issued licenses

in effect at the time of the legislation where allowed to continue .the Canadian supreme court addressed some of the issue surrounding residual compulsory.

Canada (Ministry of Health and Welfare)

The cases involved an agreement made between Apotex and novo pharma, two major generic drug companies in Canada. Apotex and novo each held compulsory licenses issued to them before the passage of the BIllC-9 in anticipation of the passage of the Bill, they entered into an agreement to " share their rights under license for any product for which only one of the parties may hold useable license .the agreement further provided that the licensed party shall supply material to the unlicensed party from the licensed party 's source at a price equal to the fair market price of the material together with such royalties as shall be payable under the terms of license. This agreement was the subject at issue in these both cases.

PATENT INFRINGEMENT LITIGATION IN JAPAN

How to face warning letters[15]

In Japan, as in many other countries, in the world two different qualifications are important
In relation with the patent litigation:
One is follows
1. The attorney at law and the other one is
2. The patent attorney

The attorney at law is a litigator who is qualified to represent Clients prior the court and conduct legal work in general. In order to become an Attorney at law, a candidate has to pass the national entry of examination.

From the old system in which no certain or specific legal educational requirements were existed, all candidates will soon has to have graduate school of education from an American law school in order to take this entry examination. After passing the entry of examination, which is also a required path to become judges and public prosecutors?

There is a one-year period of practical training under the supervision of the Supreme
Court. Attorneys at law can stand before all courts in Japan representing clients in all Types of litigation and also exclusively deal with many legal services for fees.

Disputes often begin with an unexpected warning letter from a known or unknown party. They may also arise from broken licensing agreements and happen failed negotiations. In Japan, warning letter is not required to begin litigation. The patentee is allowed to Take to be the cases that a third party has infringed its patent negligently with a showing of Infringing acts, while under the civil law willfulness or negligence has to be proven to Obtain damages as a matter of general principle. The alleged infringer has the burden Of proof and has to break the presumption by proving that he used due care not to Infringe the patent, for example, by having carried out a comprehensive patent search.

Despite such provisions, the patentee normally sends a letter to a potential Infringer because it is considered prudent to have negotiations before going to the court.

Aim of the Patentee

Upon the determination of patent infringement, the main aim of the patentee is too actions taken by the patentee will depend on his overall business goals. He has have right to ask you to enter into licensing. Negotiations, and to pay money for preinfringement which is happened by the previous. You should asked to stop the infringement so that he can enjoy the exclusiveness throughout until patent expiration of the patent and regulate the miss- use , sale, use, without knowledge of the patentee give them complete exclusiveness and in the market.

First Actions to Take in Response to the Warning Letter

Verify the Patent (step 1)

Warning latter is to verify the present the validity of the patent the patent validity may be some times lapse prior the patent end of the patent term which is date of twenty years from the date of filing of the patent in terms some cases them unable to pay the fee payment. At the same time patent related to pharmaceuticals and agriculture or any like chemicals could be extended patent terms.

Read the history of the patent files[16]. (Step 2)

Take the one copy of the patent file thought-out history for the purpose of analysis. This is helpful to both persons 1.examiner 2. Applicant, provide all

valuable information to determine the scope of the patent and provide the protection.

Search the patent history family. (Step 3)

It is very use full to every patent files or history to determine which has have to be if the related to which applicant or patentee in Japanese patent system and gather or collect the as much as copies of the patents for the purposes of references .the Japanese examiner grant the patent simply because of they did not have the overall very any references for the verification purposes then they could be grant the patent therefore as much as references and information of the prior patents.

Over all conduct the search Art. From starting to end what could happened till now

To respond the Warning letters fast three steps are important factors for these in case of the existence of more related to the prior Art references is suspected and it is must and should conduct the threw out the verify the past files all among utility model and patents publications in the Japan and other countries also search academic and non academic journals, news papers and magazines there are various data available from different authors and it an important for us and in some circumstances it necessary to visit some places which will give complete view on our mind and its give the practical knowledge.

Review analyze

According to the previous study prosecution history and the overall results of your validity of the patent claim should be sought out investigation, suppose newly discovered prior art reference anticipator destroy the novelty of the patented invention it may be patent invalid.

If another reference found which does not eliminate the novelty of the patented claims totally?

But clearly covers according to the happened infringing product or process to is likely that the court adopt a narrow interpretation of the patented claims to reject the allegation of the patent infringement. For the purpose of invalidity a patent it is possible to go to the patent office in Japan as opposed to a court as in many countries. Study the all matter related to the both sides and decide the correct judgment based on the previous cases history.

CONCLUSION

Canada and United States encourage research and development to access new drugs and to ensure the safety and efficacy, provide all pre- requisite facilities to invent new drug molecule. Provide protection for new innovations to the patentee. The Canadian government abolished the compulsory license there are two reasons.

- To develop well generic companies.
- And invest more expenditure on research and development.

In1999 adopted various changes in Japan to protect the patent from infringement and give the exclusive right to the owner

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