NOTICE OF COMPLIANCE: WORKING WITH THE NEW CANADIAN PATENTED MEDICINES REGULATIONS

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This presentation concerns the new Canadian Patented Medicines (Notice of Compliance) Regulations introduced in Canada in 1993. A detailed analysis of the Regulations will be provided and relevant case law evolution will be discussed.

LEGISLATIVE VALIDITY

Under the Canadian constitution, the Federal government has exclusive jurisdiction to legislate with respect to patents of invention (Patent Act R.S.C. 1985 ch. P-4). Pursuant to the Patent Act Amendment Act (1992 S.C. 1993 c. 2) which received Royal Assent on February 4, 1995, the compulsory licencing provisions were repealed in their entirety and compulsory licences issued on/or after December 20, 1991 were extinguished. With the abolition of compulsory licences for patented medicines, it is now possible for a medical patentee to sue infringers of its patent and obtain usual relief including interlocutory injunction, pending trial[1]. Additionally, section 55.1 was added, creating a presumption that, in an action for infringement of a patent granted for a process for obtaining a new product, any product that is the same as the new product shall, in the absence of proof to the contrary, be considered to have been produced by the patented process. Section 55.2

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[1]Merck Frosst Canada Inc. et al -vs- Minister of National Health and Welfare (1994), 55 C.P.R. (3d), 302

was also added, essentially creating two exceptions with respect to infringement: It is not considered 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 law of Canada regulating the manufacture, construction, use or sale of any product or for purposes of stock piling, six months before the expiry of the patent. New section 55.2(4) gives the Governors in Council powerA to make regulations to prevent infringement by any person who makes, constructs, uses or sells a patented invention.

The Patented Medicines (Notice of Compliance) Regulations proclaimed March 12, 1993, allow a patent holder to obtain an order prohibiting the Minister from issuing a Notice of CAompliance until after the expiration of the patent in issue, when a second person wishes to obtain a Notice of Compliance for the same medicine, unless the second person shows that no claim for the medicine itself and no claim for the use of the medicine, found in said patent, would be infringed.

LEGISLATIVE FRAMEWORK

In accordance with the Canadian Food and Drugs Act[2] and regulations adopted thereunder, a manufacturer wishing to sell a new drug, as defined in the Regulations, must obtain from the Ministry of Health and Welfare a Notice of Compliance (NOC). A NOC is obtained by the filing of a new drug submission (NDS) or an abbreviated new drug submission (ANDS) with the Minister, so as to enable the Minister to assess the safety and effectiveness of the new drug. Details of the manufacture of a pharmaceutical product and the controls to be used in the manufacture, preparation and packaging of the new drug must be provided by the person filing the NDS/ANDS.

The Regulations, adopted in 1993, provide to medical patentees an additional means, direct and easy, to prevent possible infringement: by seeking an order of prohibition against the Minister preventing him from allowing another alleged user of the patented medicine to market the allegedly infringing product. In effect, patentees can now prevent, or delay for up to 30 months, the issuance of a NOC. In discussing the regulations, the Federal Court of Appeal wrote in February 1997 "*Thus, the Minister's authority to refuse a Notice of Compliance, originally designed to protect the personal health of Canadians, has been harnessed to protect the financial health of drug patentees*"[3]. The same Court[4] had earlier commented on the difficult

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[2]R.S.C. 1985, ch. F 27

[3]Apotex Inc. -vs- Merck Frosst Canada Inc., an unreported decision of the Federal Court of Appeal dated February 10, 1997 (A-843-96)

task of interpreting the regulations: "*In large measure, the difficulty is due to the fact that those regulations, whose clear intention is to facilitate the protection of private commercial patent rights, have been grafted onto a regulatory scheme, the Food and Drug Regulations C.R.C. 1978 c. 870, as amended, whose sole purpose is the protection of public health and safety. The union is not a happy one! "*

PATENT LIST

Pursuant to Section 4 of the Regulations, a person who files a submission for a Notice of Compliance in respect of a drug that contains a medicine may submit to the Minister a patent list setting out any Canadian patent the person owns or in respect of which he has obtained an exclusive licence, that contains a claim for the medicine itself or a claim for the use of the medicine. "*Claim for the medicine itself*" is defined in Section 2 of the Regulations as including a claim for the medicine itself when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

The term "*claim for the medicine itself*" is not restricted to a claim for a simple substance as the active ingredient to the exclusion of a claim for a composition which includes the active ingredient. Such a claim comes within the ambit of the Regulations whether it is in the form of a single active ingredient or in that of a composition.[5]

In Canada, until very recently, a medicine itself could not be patented except when prepared by a specific process, even if the medicine was new. If the medicine was known, but a novel process to produce it was discovered, only the process could be claimed. Medicines themselves can now be patented. Accordingly, there are three types of claims that can be made in a medicine patent: a claim for the medicine itself, known as a product claim, a claim for the medicine when prepared by a particular process, known as a process-dependent product claim and a claim for the particular process that produces a medicine, known as a process claim.

It has been decided that the phrase "*claim for the medicine itself*" in the Regulations means a claim for the medicine itself in the ordinary and natural sense of the words and a claim for the medicine when prepared by a particular process, in the ordinary and natural sense of the words used in section 2. There is nothing in the language of the legislation which suggests

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[4]See note 1 above

[5]Hoffmann-La Roche Ltd. et al -vs- Minister of National Health and Welfare (1995), 62 C.P.R. (3d), 58 (confirmed 1996, 67 C.P.R. (3d), 25)

the phrase also covers a claim for a particular process used to produce a medicine[6].

"*Claim for the use of the medicine*" is defined as a claim for the use of the medicine for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof.

It has also been argued that claims for intermediates used to manufacture medicines were included in the definition of "*claims for the medicine itself*". The Federal Court of Appeal has held that such claims were not covered by the Regulations[7].

FILING OF A NEW DRUG SUBMISSION AND SERVICE OF THE NOTICE OF ALLEGATION BY A SECOND PERSON.

Where a person files a submission for Notice of Compliance in respect of a drug and wishes to compare that drug with, or make reference to, a drug that has been marketed in Canada pursuant to a Notice of Compliance issued to the first person in respect of which a patent list has been submitted, the second person shall, in its submission with respect to each patent on the patent list, either state that the second person accepts that the Notice of Compliance will not issue until the patent expires or alleges that the patent has expired, is not valid or that no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the Notice of Compliance is filed (Section 5 of the Regulations).

Section 5(3)(a) of the Regulations requires that the applicant for the Notice of Compliance provide a detailed statement of the basis in fact and in law for his allegation. It is intended that the patentee be fully made aware of the grounds on which the applicant says issuance of a Notice of Compliance will not lead to an infringement of the patent, before the patentee decides whether or not to apply to a court for determination. Such disclosure defines the issues at an early stage[8]. The Court will start from the proposition that the allegations of fact in the Notice of Allegation are true, unless the contrary is shown by the applicant. In determining whether or not the allegations are "justified", the Court will decide on the basis of the assumed or proven fact, if

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[6]Deprenyl Research Ltd. et al -vs- Apotex Inc. (1994) 55 C.P.R. (3d), 171 (confirmed 1995, 60 C.P.R. (3d), 501)

[7]Eli Lilly and Co. et al -vs- Apotex Inc. (1996), 68 C.P.R. (3d), 126

[8]Bayer AG et al -vs- Minister of National Health and Welfare (1993), 51 C.P.R. (3d), 329

the allegations would give rise in law to the conclusion that the patent would not be infringed by the respondent[9].

The Notice of Allegation is initially outside of the reach of the Court since it is not a document submitted to the Court[10]. Consequently, it cannot be stricken by the Court, amended pursuant to an order of the Court and particulars cannot be requested by the applicant.

A Notice of Allegation must be carefully drafted. There is no requirement under the rules of the Court that the Notice of Allegation be supported by affidavit evidence. It has been noted by the Court that once a second person product reaches the market, the first person is in a position to test the accuracy of the detailed statement; if it were shown to be inaccurate, the consequences for a second person "*... could well be very grave indeed*"[11].

When the allegation is the absence of infringement, the second person is not expected to make a full disclosure of its process without a protective order duly in place, which cannot be obtained until there is a proceeding in Court[12]. In practice, the statements supporting the allegation will initially be vague and include an undertaking to fully disclose the facts, once the protective order is in place.

CHALLENGING THE NOTICE OF ALLEGATION

Within 45 days after being served with a Notice of Allegation, the first person may apply for an order prohibiting the Minister from issuing a Notice of Compliance until after the expiration of one or more of the patents that are subject of an allegation. The Court will issue the writ of prohibition if it finds that the allegations are not justified[13]. The order of the Court applies only to the specific Notice of Allegation that triggered the motion for the issuance of a writ of prohibition. The second person may serve a second Notice of Allegation (for example alleging a different process in cases of process dependent product claims). The court focus in dealing with the regulations is the Notice of Allegation and whether the issuance of a NOC should be prohibited. The Court's task is to determine whether the allegation is justified. Thus, the scope of any prohibition order issued in proceedings brought under subsection 6(1) must be confined to the specific allegation advanced in

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[9]See note 1 above

[10]Pharmacia Inc. -vs- Minister of National Health and Welfare (1994) 58 C.P.R. (3d), 209

[11]Hoffmann-La Roche Ltd. -vs- Minister of Natioan Health and Welfare (1996), 70 C.P.R. (3d) 206

[12]See note 8, above

[13]Regulations, Section 6

those proceedings[14]. However, a subsequent Notice of Allegation must not be essentially the same as one previously filed.

When the first person is not the patentee (an exclusive licensee) the owner shall be made a party to the application[15]. Even though the writ is addressed to the Minister, the second person shall also be made a party[16].

NATURE OF THE PROCEEDINGS

Litigants have tried to have these cases heard as full-fledged patent infringement actions. In October 1993, early after the regulations were adopted, it was decided by the Federal Court of Appeal[17] that proceedings under the regulations should be governed by part V.1 of the Federal Court Rules[18] (applications for judicial review, rules 1600 - 1619). Part V.1 of the Federal Court Rules dictates a timetable for the expeditious conduct of proceedings "*... alien to the court and practitioners in this field of the law*".

Therefore, the proceeding initiated under the Regulations is not an action in infringement and its object is solely to prohibit the issuance of a Notice of Compliance. The sole issue is whether the allegations of the second person are sufficient to allow the Minister to issue a Notice of Compliance.

BURDEN OF PROOF

It has been decided[19] that the moving party under Section 6 of the Regulations (the first person) has the carriage of the litigation and bears the initial burden of proof. That burden has been qualified as difficult since the first person must disprove the allegations in the Notice of Allegation which, if left unchallenged, would allow the Minister to issue a Notice of Compliance.

Where the notice alleged non-infringement, the Court will start from the proposition that the allegations of fact in the Notice of Allegation are true except to the extent that the contrary has been shown by the applicant. The Court must decide whether, on the basis of the facts assumed or proved,

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[14]Apotex inc -vs- Minister of National Health and Welfare , an unreported decision of the Trial Division of the Federal (Mr. Justice Jerome), dated April 25, 1997 (T-1237-95)

[15]Regulations, Section (4)

[16]See note 1 above

[17]See note 8, above

[18]C.R.C. 1978 c. 663

[19]See note 1 above

the allegations would give rise in law to the conclusion that the patent would not be infringed by the respondent.

The first person bears the legal burden. The second person bears the evidential burden. The Federal Court of Appeal conveniently summarized the case law as follows with regards to the burden of proof [20]:

- *The initial burden of proof is known, in a civil case, as the persuasive burden or the legal burden and it is the burden of establishing a case to the civil standard of proof. By contrast, the evidential burden consists of a burden of putting an issue in play and means that a party has the responsibility to ensure that there is sufficient evidence of the existence or non-existence of a fact or an issue on the record to pass the threshold for that particular fact or issue.*

- *Consequently, where second persons fail to file Notices of Allegation or adequate Notices of Allegation, they must assume their own risk when it comes to attacks on the adequacy of such allegations once prohibition proceedings are commenced.*

  A bald statement of non-infringement in a detailed statement without any factual assertion in support thereof does not meet the requirements of the Regulations.

- *A common law presumption that a second person's process would infringe the patent applies where that person has asserted no facts to support his allegation of non-infringement, the evidence of non-infringement lay particularly within his knowledge, no evidence of non-infringement has been presented by that person and the first person has no other available means of assessing such evidence.*

RULES OF THE FEDERAL COURT

Under the rules of the Federal Court, an application for judicial review is made by an originating notice of motion, identifying the precise relief sought and setting out the grounds intended to be argued[21]. All parties adverse in

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[20] See note 11 above

[21] Rule 1602, Rules of the Federal Court

interest to the applicant must be named as respondent[22]. The facts relied on by the applicants must be verified by one or more affidavits. Any adverse party may file affidavits in reply within thirty days after service of the notice of motion[23]. The rules do not specifically allow reply affidavits. In practice, since the first substantive evidence is filed by the respondent, leave is granted to the applicant by the Court to file reply evidence.

The applicant must file its motion record within sixty days after the filing of the originating notice of motion. The respondent must file its motion record thirty days later[24]. In theory, the file must be ready for hearing within four months, clear evidence that the proceedings are summary in nature.

Without leave of the court, a deponent of any affidavit may be cross-examined by an adverse party[25].

DECISION OF THE COURT

As mentioned before, the decision will apply only to the particular allegation made by the second person. An appeal is possible against the decision and must be filed within thirty days of the judgment[26]. The filing of the notice of appeal does not stay the effect of the decision below. If the motion for the issuance of a writ is dismissed, the NOC will issue.

TIME LIMIT TO COMPLETE THE PROCEEDINGS

The regulations provide that the Minister shall not issue a Notice of Compliance to a second person before <u>at the latest</u> 30 months after the filing of an application for the issuance of a writ of prohibition, unless the patent has expired or the court has dismissed the application[27]. By merely commencing the proceedings, the first person obtains the equivalent of an interlocutory injunction for up to 30 months, without having to satisfy the criteria any court in the world would require before granting such an extraordinary remedy (serious question to be tried - prima facie rights - irreparable harm - balance of convenience between the parties - urgency).

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[22]Rule 1602(3), Rules of the Federal Court

[23]Rule 160(3), Rules of the Federal Court

[24]Rules 1606 and 1607, Rules of the Federal Court

[25]Rule 332.1, Rules of the Federal Court

[26]Rule 1201, Rules of the Federal Court

[27]Regulations, Section 7

The thirty month bar to marketing (No NOC - no marketing) by competitors triggered by the patentee filing an application for prohibition was qualified by the Court as a legislative stay, subject to the terms imposed by the regulations, not a judicial injunction[28].

Where the Court finds that a party to the application failed to reasonably cooperate in expediting the application, it may alter the legislative duration of the thirty-month period and extend or shorten it[29]. The legislative stay is an extraordinary sanction distracting from the normal rights of a defendant under ordinary patent law. It was intended to focus the minds of the parties and the Court as to the need of an expeditious prosecution of the application for prohibition. The regulations disclose an intention that the proceedings should be conducted expeditiously and are not meant to become a patent action[30]. Commenting on the importance for the parties to meet the thirty-month delay, the Federal Court of Appeal recently said:

> *A time limit for the legislative stay was fixed at thirty months, not just as one of many options for the parties but as a time limit which was to be respected unless altered by the Court for the sole reason authorized in section 7(5). The message for the parties is clear: They must either so conduct themselves that they cannot be found to have failed to cooperate reasonably to expedite the proceedings or they may face an alteration of the thirty-month stay, either a shortening or lengthening depending on which party is at fault. Agreement by the parties to delay will not avail to protract the legislative stay. Unwarranted refusals to make witnesses available, the failure to respect undertakings or to answer questions, or extravagant demands for information on cross-examinations, and requests for wasteful adjournments for flimsy reasons, must be viewed as failures to cooperate reasonably. Parties who are the victims of such tactics must not assume the thirty-month period will be altered unless they are prepared to document through these tactics a failure by their opponent to cooperate reasonably in the expedition of the application. A party will consent to adjournments at the cost of not being able to blame the other for delay on a subsection 7(5) application. Interlocutory motions indulged in by a party will be assessed by their outcome, to determine whether they were brought or opposed unreasonably. There are also implications for the Court: that it must control or suppress unnecessary interlocutory proceedings and the conduct that gives rise to*

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[28]See note 3 above

[29]Regulations, Section 7(5)

[30]See note 10 above

them; limit the length and frequency of adjournments; insist that matters proceed at a pace likely to allow a hearing of the application before the expiration of the (not unreasonable) period of thirty months; and finally, refuse extensions unless the criteria of subsection 7(5) are strictly met after a careful assessment of the conduct of the parties".[31]

CONCLUSION

The Regulations were proclaimed four years ago. Their adoption created a substantial amount of litigation. Motions for the issuance of writs of prohibition are filed by medical patentees routinely as soon as Notices of Allegation are served. Cases having doubtful merits or no merits at all drag through the court system. It is my view that the Regulations have not reached the objective contemplated by their enactment. Both sides are responsible for this situation. For example, patentees are still filing motions raising patents with process claim only. Generics are serving Notices of Allegation before even filing their NDS or ANDS and are thereafter process shopping, leaving patentees in the dark as to their true intentions.

Fortunately, many important issues have been decided by the Court of Appeal having the effect of unfeathering the litigious process. Many more are still outstanding and must be clarified.

Pressure has been put on the government by both sides to substantially overhaul the Regulations. The government's true intention is unknown.

[31] See note 3 above