"OBJECT CLAUSE" UNDER THE MICROSCOPE: THE FEDERAL COURT OF APPEAL INTERPRETS A COMMON PATENT EXPRESSION

A. SASHA MANDY*
ROBIC, LLP
LAWYERS, PATENT AND TRADE-MARK AGENTS

What meaning should be given to paragraphs or sentences in a patent specification that describe the "object of the invention"? Does such a statement have any bearing on the utility of an invention? These were among some of the questions the Federal Court of Appeal of Canada had to grapple with in *Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*[1], which was rendered on April 11, 2012.

This case is important to patent practitioners and agents because it provides guidance on how these common statements may be interpreted by the courts, and thus indirectly guides practitioners on how they should be drafted to begin with. The case may also interest those patent litigators who may wish to scrutinize such statements in future cases in light of the Court's reasons.

Facts

In the pharmaceutical industry, Mylan Pharmaceuticals is what is known as a "generic" because it manufactures generic drugs. Very often, these generic drugs are replicas of popular, patented drugs made by "innovators", such as pharmaceutical companies like AstraZeneca. The development of these innovative or "brand name" drugs by companies like AstraZeneca often involves years of research, experimentation, and clinical trials. When an innovative drug finally enters the market, its chemical composition is usually already patented.

In its landmark decision[2], the Supreme Court of Canada explained as follows the procedure by which a manufacturer of generic drugs may place its product in the market:

> [13] The procedure under the [*Patented Medicines Notice of Compliance Regulations*, or "NOC Regulations"] pursuant to which a manufacturer of drugs may apply to the Minister of Health for a

* Lawyer and Junior Engineer, A. Sasha Mandy is a member of ROBIC, LLP, a firm of lawyers, and patent and trademark agents. Published in the June 2012 issue of the *World Intellectual Property Report*. Publication 142.265.

[1] 2012 FCA 109.

[2] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, [2008] 3 S.C.R. 265, 2008 SCC 61.

> notice of compliance is well known. A manufacturer, usually a generic manufacturer, wishes to compare its drug with that of a patent holder […]. The generic manufacturer's purpose is to establish the safety and efficacy of its drug for the purposes of securing marketing approval from the Minister. The process of comparison saves the generic competitor time and resources. However, the Minister will not issue a notice of compliance unless the patent on the comparator drug has expired, is invalid, or the generic's product will not otherwise infringe the patent. Thus the NOC Regulations create a connection between government approval to market a generic drug and the issue of patent validity and infringement.
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> [14] Section 5(1)(b) of the NOC Regulations states that the generic manufacturer, in its submission for a notice of compliance, may allege that the patent has expired, is not valid or will not be infringed. The patent holder may then apply to the Federal Court for an order prohibiting the Minister from issuing a notice of compliance to the generic manufacturer until after expiration of the patent that is the subject of the notice of allegation. The court will grant the prohibition order if it finds that the allegation of invalidity, expiry or non-infringement is not justified. If it finds the allegation justified, it will dismiss the application for prohibition and the Minister may then issue a notice of compliance to the generic manufacturer if all other requirements are met.
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> [15] The NOC Regulations do not provide guidance about how an allegation of "not valid" as stated in s. 5(1)(b)(iii) is to be considered and determined by the court. For this purpose, reference must be made to the relevant version of the Patent Act.

In the present case, Mylan filed for a notice of compliance to sell its version of the medicine anastrozole in Canada. AstraZeneca owns Canadian patent 1,337,420 (420 patent) relating to the compound anastrozole, which expires in October, 2012. One effective use of anastrozole can be as an inhibitor of the enzyme aromatase. As explained by the Court, "an aromatase inhibitor blocks the conversion of androgens to estrogens, which reduces the availability of circulating estrogens in the body. The reduction of estrogens has particular significance for the treatment of forms of breast cancer that depend on estrogen for their growth."

In its submission, Mylan alleged that is version of anastrozole would not infringe the 420 patent because the patent was invalid for, *inter alia*, lacking utility. At trial, Justice Rennie of the Federal Court disagreed, and granted an order prohibiting the Minister of Health from issuing a Notice of Compliance to Mylan to sell its version of anastrozole until after the 420 patent expires. Mylan appealed this decision to the Federal Court of Appeal, arguing that one sentence in the specification of the patent

constitutes a promise that was not demonstrated at the time of the invention, and the invention therefore lacked utility.

Judgement

The specification of the 420 patent contains the following paragraph:

> A variety of compounds possessing aromatase inhibitory activity is known, of which the most important clinically is aminogluthethimide [AG]. [AG], however, has the drawback that it affects other aspects of steroid metabolism, with the consequence that its use is often associated with undesirable side-effects. *It is a particular object of the present invention to provide aromatase inhibitory compounds with fewer undesirable side effects than [AG].* (Emphasis from the decision)

Mylan focused its utility argument on the underlined "object" clause. Drafters of patents will often use expressions such as "an object of the present invention is …" to express a goal or an objective of the solution provided by the invention. The risk, of course, is that a court might interpret such a clause as a specific promise of the invention, which must be demonstrated or at least be soundly predicted at the time of filing of the patent application.

Indeed, Mylan argued exactly that. For Mylan, the clause "constitutes a promise that anastrozole has fewer undesirable side effects than AG, the first aromatase inhibitor to be used in the treatment of breast cancer." Since the inventors could not demonstrate at the time the patent application was filed that anastrozole produced fewer side effects than AG, and since this utility was not disclosed in the specification, the invention lacks utility.

AstraZeneca countered that the object of the invention refers to "the forward-looking or aspirational aim of the invention." The disputed sentence "merely looks to the future attainment" of the goal of reducing undesirable side effects. Alternatively, AstraZeneca argues that the patent did meet the alleged promise. Anastrozole is a selective enzyme inhibitor, and thus produces fewer undesirable side effects that AG.

The Federal Court of Appeal framed the issue before it as thus:

> It will be recalled that the question is whether the words "object of the present invention" mean that anastrozole produces fewer effects than AG, as Mylan argues, or whether, as AstraZeneca says, it means that this is what the invention aims to do, without promising that it has succeeded.

The Court first addressed Mylan's objection that Justice Rennie relied too heavily on a particular dictionary definition of the word "object", when it should have interpreted

the word in the context of patent law. Mylan cited other authorities[3] where, according to Mylan, the court had relied on the "object" clauses to define the scope of the invention. The Court found that Justice Rennie properly construed the term "object" in light of the patent as a whole, and in view of the evidence before him.

Secondly, Mylan argued that the word "provide" in the disputed sentence should, in light of the patent as a whole and the use of "provide" in other areas of the patent, be interpreted as a promise. Again, the Court disagreed.

Thirdly, Mylan plead that a person of ordinary skill in the art (a POSITA) would understand the object clause to be a promise that anastrozole is an aromatase enzyme inhibitor that causes fewer side effects. Mylan argued that Justice Rennie overlooked crucial expert testimony in this regard. Once more, the Court did not agree, holding that Justice Rennie committed no reversible error in coming to his conclusions regarding the expert testimony on file.

The Court therefore rejected Mylan's appeal, with costs.

Conclusion

This case should help patent drafters to better understand and use "object clauses". Generally, such clauses will not be interpreted by the court as a particular promise that must be met for the patent to be considered useful. Still, it should be noted that the object clause may have some bearing on how the courts assess issues other than utility, such as determining the scope of the invention. Patent practitioners would also do well to heed this warning from the Court:

> Patents are not required to contain a clause describing the object of the invention. When they do, the meaning of the object clause depends on the specific context, including the wording of the particular clause in question and its relationship to the rest of the patent.

Thus, the Court leaves open the possibility that an object clause can be interpreted as a promise. In such a situation, the patentee would be wise to give this promise the support required to demonstrate its utility.

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[3] *Amfac Foods Inc. v. Irving Pulp & Paper, Ltd.* (1986), 12 C.P.R. (3d) 193 (F.C.A.) at 199.

ROBIC, LLP
www.robic.ca
info@robic.com

MONTREAL
1001 Square-Victoria - Bloc E - 8th Floor
Montreal, Quebec, Canada H2Z 2B7
Tel.: +1 514 987-6242 Fax: +1 514 845-7874

QUEBEC
2828 Laurier Boulevard, Tower 1, Suite 925
Quebec, Quebec, Canada G1V 0B9
Tel.: +1 418 653-1888 Fax.: +1 418 653-0006