PRODUCT-BY-PROCESS CLAIMS IN CANADA: USEFUL OR USELESS?

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What happens when a drug manufacturer attempts to claim a known medicinal drug made according to a new and non-obvious process? Should such a claim be interpreted as covering the known drug itself, irrespective of how it's produced? Or, should the claim instead be interpreted as covering the known drug, provided that it is made according to the process? These were the main questions the Federal Court had to grapple with in *Bayer Inc. v. Cobalt Pharmaceuticals Company*2013 FC 573, which was rendered on May 29, 2013.

This decision is important to both generic and innovative pharmaceutical drug manufacturers because it provides guidance on how these types of claims, known as "product-by-process" claims, are to be interpreted in Canada. The decision may also serve as a cautionary tale to those patent agents who draft patent applications in this field. Remember to include or describe variants of an element of the claims if you want the Court to construe the element as non-essential.

Facts

In the pharmaceutical industry, Cobalt 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 Bayer. The development of these innovative or "brand name" drugs by companies like Bayer often involves years of research and clinical trials. When an innovative drug finally enters the market, its chemical composition is usually already patented.

In its landmark decision [*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61], the Supreme Court of Canada explained as follows the procedure by which a manufacturer of generic drugs may place its product in the Canadian marketplace:

> [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 notice of compliance is well known. A manufacturer, usually a generic manufacturer, wishes to compare its drug with that of a patent holder

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> […]. 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, Cobalt filed for a notice of compliance (NOC) to sell its version of the oral contraceptive commercialized by Bayer under the name YASMIN®. The drug contains drospirenone as the active medicinal ingredient. Bayer applied for a patent claiming a process for producing drospirenone, and the patent was granted in 2005 as Canadian patent 2,261,137 (137 patent). The patent is set to expire in April, 2017.

In the present case, Cobalt alleged that it was entitled to a NOC on the grounds that its product did not infringe claim 13 of the 137 patent (the only claim in issue), and because the 137 patent was invalid because the claimed process was obvious.

Claim 13 of the 137 is a "product-by-process" claim (i.e. a claim for a product which is produced according to a process). It relates to "A product prepared according to the process of claim 12", where the product contains drospirenone without a certain percentage of contaminants.

Bayer argued that claim 13 is a pure product claim, and that it should be read as if the words "prepared according to the process of claim 12" were not written. In other words, Bayer argued that claim 13 covers any product containing the recited

percentage of drospirenone without the contaminants, regardless of the process by which such a product was manufactured. Bayer further argued that the process of claim 13 does not require the presence of a particular salt during the oxidation stage. Bayer plead such an argument in an attempt to cover Cobalt's process for making its version of the drug, which does not employ the salt as an oxidizing agent.

Judgement

In PM(NOC) proceedings, Cobalt needed to only present sufficient evidence to give its allegations of non-infringement "an air of reality". Once it satisfied this onus, the burden shifted to Bayer to prove that Cobalt's allegations of non-infringement are unjustified. Justice O'Reilly of the Federal Court therefore dealt first with Bayer's submissions.

With respect to claim construction (i.e. how claim 13 should be interpreted), Bayer argued that claim 13 is really a product claim. It relied on a decision of the Supreme Court of Canada from the 1950s for this interpretation. Justice O'Reilly did not agree with their understanding of that case:

> [18] *Hoffman-LaRoche* (the Supreme Court decision) tells us that a new patent cannot be obtained for a known compound even if a new process has been discovered for making it. Accordingly, claims for a product made by a particular process should be assessed as if they were claims for the product alone and should be upheld only if the product is new. In other words, a new process for making an old compound does not justify a new patent for that same compound.

Therefore, the Court did not accept Bayer's argument that claim 13 should be interpreted to cover any product containing drospirenone without the contaminants. It held that claim 13 clearly and expressly incorporates the process described in claim 12.

With respect to Bayer's argument that the process of claim 13 could be practiced without the recited salt as an oxidizing agent, the Court disagreed and found that this element was essential to the process. In finding the salt to be an essential element, the Court was stating that any competitor's process would need to have this element in order to infringe claim 13. Here, the Court provided guidance to patent agents as to how specifications should be drafted so as to specifically list or describe variants of elements:

> [33] The only metal salts mentioned in the patent as being suitable alternatives to chromium are ruthenium salts. As mentioned, ruthenium salts are specifically included in Claims 1, 5, 6 and 11. No alternatives are cited, and there is no reference to the possibility that other metal salts might work. The patent's disclosure also contains numerous references to ruthenium. There is only one passage that could be read as admitting of an alternative to ruthenium.

Finally, Bayer had the burden of showing that Cobalt's allegation of non-infringement was unjustified. The evidence showed that the process used by Cobalt to make its version of drospirenone did not employ the recited salt of claim 13 of the 137 patent. Since the process used by Cobalt did not include an essential element of claim 13, the Court found that Cobalt's process is non-infringing and that Bayer failed to discharge its burden.

The Court therefore dismissed Bayer's application for an order prohibiting the issuance of a NOC, with costs.

Conclusion

This case illustrates that product-by-process claims are not always easy to enforce. This case shows that such claims are usually found to be invalid unless they relate to a product which is itself new.

This may be surprising to many drug manufacturers, which often include these types of claims in their process patents as an afterthought, and think that these claims will protect against a competitor making the same product. It may thus be prudent for these manufacturers to verify whether their Canadian process patents actually protect the product being produced.

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