

Canada

Shedding light on selection patents: new business challenges

The landscape of pharmaceutical patents has recently changed in Canada. A Supreme Court battle pitched generic drug company Apotex against Sanofi-Aventis over the validity of Sanofi-Aventis's selection patent, which covers the anti-coagulating drug Plavix. The decision, in favour of Sanofi-Aventis, affirmed the patentability of Plavix even when one of Sanofi-Aventis's earlier patents claimed a mixture that contained the drug, but which the Sanofi-Aventis scientists had not identified as being valuable. Soon after the Supreme Court decision, the US Federal Court of Appeal reached a similar conclusion. The Supreme Court's decision addressed the broader issue of whether a generic patent claim should bar a future patentee from obtaining its own patent for an invention that lies hitherto undiscovered in the wide-ranging earlier patent. Clearly, the *Sanofi-Aventis* decision will affect the way in which pharmaceutical companies do business in Canada. This chapter explores the current landscape of selection patents in Canada in light of *Sanofi-Aventis* and its implication in drafting licence agreements.

Pharmaceutical selection patents

In their quest for new and more potent drugs, pharmaceutical companies look to their scientists for inspiration. Once a discovery is made, there is often a rush to patent as much of the discovery as it allows – and then some. Patent practitioners seek to protect new compounds by filing patent applications in which, once granted, broad genus claims protect not only the compounds actually made by the scientists, but also other compounds of similar chemical structure, which, if they are made, would be predicted to have similar properties. This type of broad claiming generally rewards the discovery of a hitherto unknown class of compounds identified by a common chemical structure and can protect many hundreds of thousands of compounds. However, available human and financial resources often limit the number of compounds claimed that can actually be made and tested. Given that the Patent

Act confers on an inventor the right to a monopoly for 20 years, where should the line be drawn in terms of extending claim protection beyond the initial discovery? Should there be a bar against 'new' discoveries that may be hiding somewhere in the broad genus claim, which the scientists may have overlooked in their initial discovery? The Patent Act and now the courts say no, if the discovery is new and provides unexpected advantages over the initial discovery.

Canadian pharmaceutical companies and those looking to protect their valuable pharmaceutical discoveries in Canada use so-called selection patents to protect their inventions when they discover a surprising and unexpected advantage of a selected compound, often a drug, over a claimed genus of compounds from which the selected compound was chosen. It is well-established law in Canada that if the selected compound is new and has properties of an unforeseen nature, then the inventive character is met. The Supreme Court has now confirmed that a selection patent does not differ in its nature from any other patent and that it is consequently compatible with the Patent Act.

The Supreme Court case centred on Sanofi-Aventis's earlier patent, which disclosed a genus covering more than 250,000 possible compounds that were useful for inhibiting platelet aggregation. One compound, a racemic mixture of two enantiomers, dextro-rotatory clopidriogel and levo-rotatory clopidriogel, was of particular interest to Sanofi-Aventis. Sanofi-Aventis discovered that when separated from the racemic mixture, the dextro-rotatory enantiomer had a higher therapeutic effect and lower toxicity when compared to the levo-rotatory enantiomer, and it was granted a later selection patent based on this discovery. Apotex attacked Sanofi-Aventis's selection patent on three fronts – anticipation, obviousness and double patenting (or 'evergreening') – but failed on all three.

Anticipation and obviousness

One of the fundamental canons of patent law is that

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prior public disclosure of an invention for which a patent is sought will effectively bar the patent applicant from obtaining a valid patent for the invention. The Supreme Court affirmed a two-step approach to establish whether a prior publication, such as a patent, patent application or scientific article, is so-called ‘prior art’, which destroys the newness or novelty of the invention. The approach requires separate consideration of ‘prior disclosure’ and ‘enablement’, both of which, if proven, establish that the prior art anticipates the invention. In the context of selection patents, if, when reading the genus claim in the prior patent, a person skilled in the art does not discover the special advantages of the selection, there is no anticipation by way of prior disclosure. No trial and error is allowed. Similarly, if the person skilled in the art must perform the invention with undue burden, then there is no anticipation by way of enablement. Skilled readers of the patent should be able to arrive at the invention the first time they try it and each time thereafter, with limited trial and error. In this case there was no anticipation because Sanofi-Aventis’s former patent did not reveal which enantiomer was more active, even if it was known that one enantiomer was often more active than another. Since anticipation requires both prior disclosure and enablement, it was unnecessary for the Supreme Court to consider the second issue of enablement. Even if the methods of separation of enantiomers were known, the Sanofi-Aventis inventors had to spend several months of research to identify the active enantiomer and its advantages. Therefore, the Supreme Court found that the prior disclosure was not enabling.

Historically, the Canadian courts have relied on rather strict language to decide the issue of obviousness

and whether a notional skilled person, in light of the state of the art and common general knowledge, would have been led directly and without difficulty to the solution taught by the patent. In addition, the courts have routinely rejected an ‘obvious to try’ criterion. Interestingly, the Supreme Court compared current Canadian attitudes towards the question of obviousness with those of the United Kingdom and the United States, where a stringent ‘obvious to try’ approach is the current state of the law. In addressing the obviousness issue in *Sanofi-Aventis*, the Supreme Court examined the circumstances under which it might be appropriate to use the ‘obvious to try’ criterion. The court concluded that for an invention to be obvious instead of it being merely obvious to try, it must also be “more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough”.

The Supreme Court found that Apotex failed to establish that the selected dextro-rotatory isomer was obvious to try from the 250,000 other possibilities in the earlier genus patent because it was not self-evident from the prior art and common general knowledge. In particular, there was no evidence that a person skilled in the art would have known which of the established separation techniques would work to separate the racemic mixture.

Double patenting

The Patent Act provides for “one invention per patent”. Apotex argued that selection patents extend the lifetime of the original genus patent by allowing so-called ‘evergreening’, or double patenting. The Supreme Court rejected this and pointed out that third parties can obtain selection patents, and that they encourage innovation by identifying hitherto unknown and useful

properties in the original genus. In a double-patenting challenge, the focus is on the claims of the two patents rather than on the disclosure, and because the claims of the genus patent are broader than those of the selection patent, there cannot be double patenting.

Licensing issues

A pharmaceutical company has many choices when establishing a research programme which aims to produce a drug. One is to carry out its own basic research and development, which can put an enormous strain on human and financial capital. Another is to in-license or out-license technologies which it can use to develop a drug. In fact, the content and the substance of the *Sanofi-Aventis* decision will have an impact on both these scenarios. From now on, and in view of the decision, rights owners of genus patents should carefully review their agreements to verify whether the possibility of a selection patent is covered by the terms and conditions contained therein. In doing so, they will have to judge if any action needs to be taken with respect to the existence, or possible existence, of a selection patent. Indeed, the *Sanofi-Aventis* decision will certainly affect the way in which genus patents are managed and licence agreements are drafted around them. From a business and licensing perspective, this decision raises many important questions related to the rights effectively granted or obtained under a research agreement related to a genus patent, under a licence agreement or even under the assignment of a genus patent. It also raises questions with respect to what constitutes an improvement and the issue of infringement. Therefore, anyone responsible for drafting, implementing or managing agreements dealing with the grant of rights on a genus patent should be conversant with the impact this decision may have on its business and projects. It is very important that all such agreements be reviewed to consider and address the impact that a selection may have in light of the rights granted on the genus patent. It should also be underlined that one of the main effects of this decision can be foreseen in situations where there is no contractual relationship between the owner of the genus patent and the inventor of the selection. In fact, the *Sanofi-Aventis* decision points out that no control can be exercised over any third party wishing to patent a selection, with the exception that in order for the third party to exploit the selection patent, it must enter into an agreement with the owner of the genus patent. The interested parties should evaluate whether it is advantageous either to negotiate with another party to reach an agreement for the exploitation of the selection

patent or to wait until the protection afforded by the genus patent has expired to be able to exploit its selection freely.

Moreover, important considerations should be taken into account upstream of any licensing activity – that is, at patent prosecution stage. The *Sanofi-Aventis* decision will affect how and when a patent related to a group of compounds should be prosecuted. Research and development departments must assess at an early stage whether they foresee a selection and whether such a selection is easy to achieve. This assessment will likely influence the scope of the claims and when a patent application is to be drafted and filed. Accordingly, this decision will add to the issues which need to be considered when a technology is to be developed and commercialised.

Conclusion

The pharmaceutical selection patent landscape has changed in Canada, most likely for the better. Provided that the drug selected from the previous broad patent satisfies the basic canons of patent law, the courts will look favourably on claims to such. Even before the *Sanofi-Aventis* decision, the lower courts in Canada heard a number of earlier selection patent cases and concluded that sufficient representative testing is required to establish a valid selection patent. Although it remains to be seen what exactly is meant by this term, clearly the more comparative data the patentee includes in an application for a selection patent and the more the patentee articulates the selection's advantages over the previous genus, the stronger the argument will be for a proper patentable selection. This requirement has obvious implications for research managers because in order to satisfy the valid claim to a selection, more bench work will be needed to produce the required representative testing for inclusion in an application for a selection patent. This additional work may delay filing a patent application and require the extension of internal timelines, but it is worth it, especially since the business goal is to discover an all-important blockbuster drug. The *Sanofi-Aventis* decision will no doubt pave the way for more selection patents in Canada. In the meantime, with the affirmation of the two-part test for anticipation, the apparent softening of the historically strict test for obviousness and the requirement for "sufficient representative testing", we can expect selection patents and applications for selection patents to be scrutinised for compliance with this decision. Finally, parties that deal with a selection patent will now have to consider which strategy they develop around prosecuting and exploiting genus and selection patents.

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