FCA provides much needed clarification on obviousness and anticipation

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In *Apotex v. Shire*, the Federal Court of Appeal (FCA) dismissed Apotex' appeal and affirmed the decision of the Trial Judge holding that the patent relating to lisdexamfetamine (LDX) is valid and infringed. In so doing, the FCA provided much needed clarification on the law related to obviousness and anticipation.

The underlying court proceeding concerned both an application pursuant to the pre-2017 *Patented Medicines (Notice of Compliance) Regulations*, and a patent impeachment proceeding, which were consolidated prior to trial. The claims of the patent at issue were described by the FCA as relating to a bare chemical formula, a reduced potential for abuse, pharmacokinetic properties, use, and dosing amounts. LDX is a prodrug that reduces amphetamine's pharmacological activity when it is taken in doses above those considered therapeutic, or using methods other than those prescribed.

Apotex argued that sections 28.2 and 28.3 of the *Patent Act* mandate that the focus is on the individual claims, and their precise language, and the Trial Judge erred by examining the patent as a whole and considering the notion of "inventive concept". Apotex argued that only with selection patents should the advantageous qualities of a compound be considered in the validity assessment.

Selection Patents

In dismissing Apotex' appeal, the FCA held that there "is no magic to the term 'selection patent'." (para 31) Selection patents are not referred to in the *Patent Act*, and the case law is clear that they do not differ from other patents in substance or in form. Thus, they are subject to the same requirements as other patents. They are also vulnerable to the same attacks. The FCA confirmed that a consideration of whether the characteristics of a selection patent have been met cannot found an independent validity attack.

Classes of patents, such as selection or process patents, make it easier to compare the facts of the case at hand to those in previous jurisprudence. The focus of a validity analysis with respect to anticipation or obviousness "is, as always, on what the patent actually claims in comparison to what is disclosed in the prior art." (para 34) One needs to apply the specific facts of the case against the relevant test.

Anticipation

The FCA stated that, for anticipation, the law is clear: the prior art reference needs to both disclose and enable the essential elements of the claim. The FCA also cited *General Tire*,[1] restating that for disclosure, performing the prior art must necessarily infringe the patent claim, and a signpost on the road to the invention is not enough. To be enabled, the prior art needs to be detailed enough to enable a person of ordinary skill in the art (POSITA) to perform the claimed invention without needing to exercise inventive ingenuity or conduct undue experimentation.

Apotex argued that this means that genus patents necessarily anticipate selection patents. The FCA disagreed, holding that it is not sufficient for the prior art to encompass or include the claimed invention. The flag must be planted at the precise point (para 45). In this case, while the genus patent referred to a class of compounds, the specific compound claimed in the patent at issue was not disclosed. There were numerous ways to perform the prior art without necessarily infringing the claims at issue. Thus, the compound claims were not anticipated. The Court analyzed each asserted claim, and concluded none were anticipated.

The Court also held that as Apotex had not contested the validity of certain claims, it bore the onus of showing that claims dependent on the uncontested claims were invalid, despite the presumed validity of the unasserted claims (para 52).

Obviousness

The FCA noted that obviousness is also determined on a claim-by-claim basis. Apotex argued that the Trial Judge erred by not focusing the second point in the obviousness analysis solely on the subject matter of the claim without recourse to the specification or disclosure. The FCA disagreed, holding:

> Section 28.3 of the Patent Act does not displace the common law test for obviousness. The inventive concept, properly construed and applied, remains the end point for the obviousness inquiry. Second, I do not see an error in the judge's analysis of the inventive concept, nor in its application. (para 65)

The FCA confirmed that the Trial Judge can look to the specification for insight into the inventive concept when it is not possible to fully grasp its nature solely from the claims. The inventive concept must be of the claim in question, not a generalized concept from the specification as a whole. Furthermore, determining the inventive concept is a distinct, separate exercise from claims construction. The purpose of claims construction is to determine the scope of the claim. It does not determine validity. While s. 28.3 codified the common law requirement that inventions be inventive, it does not displace the jurisprudence explaining how to make that determination.

In this case, the essential element of claims 1-5 was the bare chemical compound. As this says nothing about the inventiveness of the claims, it is *necessary* to turn to the specification for amplification. The Court specifically held that s. 28.3 of the *Patent Act* does not narrow the inventive concept to the essential elements of the claim itself. The FCA reaffirmed that the term 'inventive concept' is not materially different to the 'solution taught by the patent'.

The FCA also dismissed Apotex' argument that incorporating elements into the inventive concept made some of the claims redundant. The Court held that "a single inventive concept must flow through a patent, but each claim's specific inventive concept may be different." (para 77) Thus, the overarching inventive concept connects all of the claims. However, individual claims can have different inventive concepts that are stitched onto the common, overarching concept. "Practically speaking, however, so long as the single common inventive concept is found to be non-obvious, the Court will typically not need to explicitly consider any amendments to it made by later claims." (para 87) Thus, the potential for redundancy is inherent in the inventive concept exercise.

However, the FCA cautioned against reading a narrow limitation from one claim into another. Redundancy should only be permitted where a purposive analysis shows effective duplication of the claims. The purposive analysis as to inventive concept is different from the purpose behind a claims construction.

The FCA also confirmed that the legal principles surrounding obviousness apply to all types of patents. Similarly, the Supreme Court of Canada's statements in *Sanofi* are not only to be used for selection patents or bare chemical formula claims.

The FCA considered Apotex' other alleged errors, including in respect of step four of the test, and concluded that there was no reviewable error in either the legal framework or its application to the facts.

The FCA issued a separate decision with respect to Apotex' appeal of the costs award.

[1] *General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited*, [1972] RPC 457

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