NON-INFRINGING ALTERNATIVES, NOT AN ALTERNATIVE TO DAMAGES: CANADIAN FEDERAL COURT OF APPEAL RECOGNIZES "NON-INFRINGING ALTERNATIVE" DEFENSE IN LANDMARK PATENT INFRINGEMENT CASE.

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On July 23rd, 2015, the Canadian Federal Court of Appeal found that, when assessing damages in a patent infringement case, it is relevant to consider the availability of non-infringing alternatives at the time the infringement took place. The case in question relates to APOTEX Inc's ("Apotex") manufacturing and sale of a generic version of lovastatin, a medication used to mitigate cholesterol. This drug was the subject matter of certain "product by process" claims found in Canadian patent No. 1,161,380 ("380 Patent"), owned by MERCK & Co., Inc ("Merck"). Apotex infringed the 380 patent and was ordered to pay over C$ 120 Million, plus pre-judgement and post-judgement interest; an unprecedented amount. Apotex appealed this decision, alleging that the Federal Court erred by not considering the availability of non-infringing alternatives that it could and would have used. [Apotex Inc. v. Merck & Co., Inc., 2015 FCA 171]

Background and Trial Decision

Merck sells lovastatin in Canada under the trademark MEVACOR®. The 380 Patent was issued in 1984 and expired in 2001.

In 1993, Apotex sought market approval for a generic version of lovastatin and filed an application to the Minister of Health for a Notice of Compliance (« NOC »). At the time, Apotex represented that its own lovastatin product did not infringe on Merck`s 380 patent, since it used a process that was outside the scope of this patent. The NOC was issued in 1997, at which point Merck took an action against Apotex for patent infringement.

After a lengthy trial on the issue of liability, and after many appeals, Apotex was ultimately found to have infringed by selling batches of lovastatin manufactured by a process that read into the 380 patent.

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On the issue of damages, Merck claimed a loss of profits with regards to the tablets it "would have sold prior to the patent's expiry, but for the infringement". Apotex submitted that Merck should only be entitled to a reasonable royalty, for not having been able to show that it had sustained damages "by reason of the infringement", as required under subsection 55(1) of the Patent Act[1] (``ACT``).

Apotex argued that the Court should consider the fact that it had also manufactured the drug by other non-infringing processes. This premise was based on the allegation that Apotex had a non-infringing alternative that it could and would have used. Therefore, Apotex's argument was that any "but for" causation analysis should also account for the fact that, as of the time it received regulatory approval, it had the capability to produce any and all pre-expiry tablets that were sold in Canada, so as long as they were not covered by the patented process. Apotex also submitted that Merck did not demonstrate that its losses were caused by the use of the infringing process. Merck's loss should therefore only be a reasonable royalty on pre-expiration date sales. Merck maintained that there was no legal basis for the recognition of "non-infringing alternatives" in Canada.

The Trial judge rejected Apotex's submissions. The Trial judge was of the view that, had Apotex not infringed the patent, Merck would have made the sales, mainly for reasons of causation, as well as a matter of public policy: since, "acknowledging the relevance of non-infringing alternatives would create an incentive to infringe"[2].

The Appeal

On appeal, Apotex asserted that the Trial judge erred by not considering the relevance of a non-infringing alternative when assessing damages, and the damages awarded needed to be reviewed in that context.

As such, the main issues before the Court of Appeal were 1) to establish if the Trial judge erred in rejecting the legal relevance of non-infringing lovastatin, 2) to decide if Apotex had factually established the relevance of a non-infringing alternative, based on the existence of non-infringing lovastatin, and 3) to determine if this had an effect on the quantum of damages awarded.

On the first issue, the Court of Appeal referred to subsection 55(1) of the Act: "A person who infringes a patent is liable […] for all damages sustained […]by reason of the infringement."

[1] R.S.C. 1985, c. P-4
[2] *Apotex Inc. v. Merck & Co., Inc.,* 2015 FCA 171, par. 29

Therefore, the first issue relates to the legal requirement that the damages have to be sustained "by reason of the infringement" and if this requirement is restricted so as to disregard competition from an infringer. Or, otherwise said, is it relevant to consider competition from the infringer?

The Court of Appeal considered the intent behind the Act, as well as the purpose of the award of damages. It found that it all boils down the question of causation which, in patent infringement matters, is established by the "but for" test: "but for the defendant's infringement, the plaintiff would not have suffered loss".

On the question of causation, the Court of Appeal found that the Trial judge erred by associating "the relevance of the non-infringing alternative" defense, with the applicability of this defense to Apotex, from a factual perspective. In so doing, if damages do not take into account available non-infringing alternatives, this can create a situation where the patentee could be better off than it would have been without the infringement. Therefore, if a defendant manufactures and sells a non-infringing alternative, the patentee would have less of a complete monopoly and more of a market share. As such, a defendant`s "lawful competition in the "but for" world may have deprived the patentee of some sales"[3]. The Court of Appeal recognized the relevance of a "non-infringing alternative" defense.

The Court then had to establish if this defense was applicable to Apotex, and if this had an effect on the damages that were awarded. It was Apotex`s burden to prove that it would have, factually speaking, used the non-infringing alternative.

The Court of Appeal set out a four part test to study the effect of legitimate non-infringing competition from a defendant:

i) Is the non-infringing alternative a real alternative?
ii) Is the non-infringing alternative economically viable?
iii) At the time of infringement, did the infringer have sufficient supply? (could it have sold the non-infringing alternative?)
iv) Would the infringer actually have sold this alternative?

When applied to Apotex, at the time it had obtained its NOC, it had the ability to manufacture a non-infringing alternative. However, from a factual perspective, Apotex had failed to show that, its ability to manufacture notwithstanding, it "could and would have sold non-infringing lovastatin" instead of the infringing lovastatin.

On the issue of whether or not Apotex could have sold the non-infringing lovastatin, Merck alleged that the alternative must have been available to replace the infringing sales "as they were being made". The Court agreed with this submission both in fact and in law, despite Apotex`s representations that it had non-infringing batches of

[3] *Ibid* par. 48

lovastatin that it sold in 1998, and that this lovastatin was available to replace the infringing product.

For reasons that are specific to the facts surrounding this case (such as supply chain and manufacturing partners), the Court found that Apotex failed to establish that it could have replaced all of the infringing sales with a non-infringing product, which disposed of the issue regarding the review of the quantum of damages.

Conclusion

This decision by the Canadian Federal Court of Appeal confirms the relevance of the non-infringing alternative defense with regards matters involving the award of damages following a finding of patent infringement. However, the relevance of this defense needs to be separated from the availability of this defense to a defendant, from a factual perspective. It is not sufficient to simply allege that one "could and would have used" a non-infringing alternative. It needs to be shown that, in line with the four part test established by the court, the Defendant had the capacity to use, and would have used, the non-infringing alternative for the Defense to apply.

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