

“But for”, “Could” and “Would”: The Patent Damages Approach to Non-infringing Alternatives

The Supreme Court of Canada, by denying leave to appeal on April 14, 2016 from the Federal Court of Appeal decision in *Apotex et al. v. Merck et al.* 2015 FCA 171, has clarified the role of non-infringing alternatives in patent damages' calculations. By choosing not to hear the case, the decision of the Canadian Federal Court of Appeal provides the current approach to non-infringing alternatives.

The patent damages issue arose from a decision finding that Apotex infringed Merck's Canadian Patent No. 1,161,380 for the anti-cholesterol drug lovastatin. The '380 Patent claimed lovastatin by a product-by-process, called the AFI-1 process. Apotex obtained a notice of compliance (NOC) to market a generic version of lovastatin by asserting that the process used to produce lovastatin would not fall within the scope of the patent, i.e., by using a different process, called the AFI-4 process.

Despite Apotex's assertion, the trial judge found that batches of lovastatin were produced using the AFI-1 process and held that the patentee was entitled to compensatory damages, amounting to over \$119 million dollars. In coming to this amount, the trial judge rejected Apotex's argument that a non-infringing alternative (i.e., use of the AFI-4 process) should be taken into account in the assessment of damages.

The issue for the Federal Court of Appeal was whether non-infringing alternatives should properly be considered: “whether the requirement that damages be sustained ‘by reason of infringement’ is, as the judge found, in some way restricted so that a court is required to disregard legitimate competition from an infringer? In the alternative, is potential legitimate competition from the infringer a legally relevant consideration?”

The Federal Court of Appeal discussed the policy reasons for providing compensatory damages, noting that under-compensation discourages research and development, as well as disclosure of useful inventions and over-compensation chills potential competition. From this starting point, the Federal Court of Appeal delved into what factors are relevant for the determination of “perfect compensation”, recognizing that damages must arise ‘by reason of infringement’.

At the trial, the trial judge had refused to apply principles of causation to the actions of Apotex, dismissing “a fiction that the defendant could have used a non-infringing alternative (but did not)’ and finding

it not to be ‘punitive to compensate Merck for lost profits where the Defendants could have (but did not) use the non-infringing alternative’.

The Federal Court of Appeal found difficulty with the trial judge's approach, explaining that “if damages for lost profits are calculated never having regard to an available non-infringing alternative, the patentee will sometimes be better off than it would have been in the absence of infringement”, i.e., it will be over-compensated.

Accordingly, the Federal Court of Appeal acknowledged that non-infringing alternatives are a relevant factor for consideration when assessing damages, providing this test:

When considering the effect of legitimate competition from a defendant marketing a non-infringing alternative, a court is required to consider at least the following questions of fact:

- i) *Is the alleged non-infringing alternative a true substitute and thus a real alternative?*
- ii) *Is the alleged non-infringing alternative a true alternative in the sense of being economically viable?*
- iii) *At the time of infringement, does the infringer have a sufficient supply of the non-infringing alternative to replace the non-infringing sales? Another way of framing this inquiry is could the infringer have sold the non-infringing alternative?*
- iv) *Would the infringer actually have sold the non-infringing alternative? (emphasis in original)*

The “but for” test for non-infringing alternatives is a “could” and “would” test. It is not enough to show that Apotex could have used a non-infringing alternative, the evidence needs to show that in the “but for” world, Apotex “would” have used it. The burden is on the defendant – in this case, Apotex – to prove that it “could” and “would” on a balance of probabilities. On the evidence adduced at trial, Apotex failed to meet its burden, despite having manufacturing capacity; while recognizing that Apotex had manufacturing capacity, there was uncertainty as to whether Apotex would have been able to meet market demand with non-infringing product. In finding that Apotex did not meet its burden, the Federal Court of Appeal agreed with Merck that the “alleged alternative must have been actually available” to meet the “could” and “would” test.

Although the Federal Court of Appeal has recognized that non-infringing alternatives are relevant in the assessment of patent damages, the “could” and “would” test for such alternatives will no doubt prove to be a difficult test for defendants to satisfy in evidence. With the Supreme Court of Canada having denied leave, the “could” and “would” test, and the evidentiary burden, is the approach to be used for non-infringing alternatives, however, it remains to be seen what evidence will be sufficient to prove, on a balance of probabilities, that the defendant not only could have used it, but would have in this fictional “but for” damages calculation world. ■

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