Non-Infringing Alternatives in Patent Remedies

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NIA is Relevant

- I have concluded that, as a matter of law, the availability of a non-infringing alternative is a relevant consideration.
  - *Lovastatin FCA* 2015 FCA 171

Rationale

- [42] The Act as a whole is intended to advance research and development, and to encourage broader economic activity.
- [56] Second, only by comparing the patented invention to non-infringing alternatives can a court discern the market value of the patent owner's exclusive right, and therefore his expected profit or reward.
  - *Lovastatin FCA* 2015 FCA 171

"COULD" BRANCH & AVAILABILITY OF NIA

Instantaneously Available

- [79] In *Advanced Building Systems* . . . the Federal Court of Australia rejected the relevance of a non-infringing alternative, but held that if it was legally relevant, it could only apply "if at the moment of infringement […] there is available on the market instantaneously the appropriate substitute" in the reconstituted market. I agree.
  - *Lovastatin FCA*
- It would have taken three weeks to ramp up production: [82]
- Therefore NIA not "available": [92]

Grain Processing

- Grain Processing had patent for maltodextrins with "descriptive ratio" (DR) > 2
  - Buyers did not care about DR
- Defendant American Maize was "determined to avoid shipping a single bag of Lo-Dex 10 with a D.R. exceeding 1.9."
- AM developed Process III with DR < 1.9

Grain Processing

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- AM developed Process III with DR < 1.9
  - … measured by "Lane-Eynon" test

Grain Processing

- Claim construction decision held "Schoorl" test should be used
- Two weeks later, AM developed non-infringing Process IV
- AM could have developed Process IV at any time
  - Did not because it thought Process III was non-infringing

Grain Processing

- Can NIA be "a noninfringing substitute that did not exist during, and was not developed until after, the period of infringement"?
  - Yes – *Grain Processing VI* Judge Easterbrook
  - No – *Grain Processing VII* Federal Circuit
  - Yes – *Grain Processing VIII* Judge Easterbrook
    - I do not wish to be presumptuous, but it seems to me that my opinion did what the court of appeals believes ought to have been done.
  - Yes – *Grain Processing* Federal Circuit

Grain Processing

- Lost-profits damages are designed to give the patent holder the economic benefits it would have enjoyed had its intellectual property been respected. . . . A product that is within a firm's existing production abilities but not on the market-in this case, Lo-Dex 10 made by Process IV effectively constrains the patent holder's profits. Potential competition can be as powerful as actual competition in constraining price.
  - *Grain Processing VIII*

Grain Processing

- To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture.
  - *Grain Processing*

Grain Processing

- Process IV was 2.3% more expensive than Process III
  - Reasonable royalty awarded on that basis
- Value of the invention
  - Is not the value of maltodrextrin
  - It is the production cost difference (2.3%)
  - If cost difference had been 0, royalty would have been zero
- A minor invention should receive a commensurate reward

"WOULD" BRANCH & BURDEN OF PROOF

Initial Burden on Plaintiff

- Burden is on plaintiff to prove its case
  - [45] The legal test for establishing causation is the "but for" test. A plaintiff must show on a balance of probabilities that "but for" the defendant's wrongful conduct, the plaintiff would not have suffered loss.
    - *Lovastatin* FCA

Shifting Burden

- But burden is on defendant to prove relevance of NIA
  - [74] As a matter of principle, the burden lies on the defendant to establish the factual relevance of a non-infringing alternative on a balance of probabilities.
    - *Lovastatin* FCA, citing *Rainbow Caterers* [1991] 3 SCR 3

"Would" Branch

- [94] Even accepting that the parties agreed in the Streamlining Agreement that Apotex had capacity to make the non-infringing lovastatin and that Apotex would have made an accounting profit by producing the non-infringing tablets, Apotex has not established that it would have pursued that alternative in the "but for" world.
  - *Lovastatin* FCA

"Would" Branch

- [94] Specifically, Apotex did not point to evidence that demonstrated the profits that it would have made through the non-infringing alternative would have been greater than value lost in any of the identified scenarios (for example, the research and development activities foregone by repurposing the Winnipeg facility). As such, notwithstanding whether it had the capacity to produce the non-infringing alternative, Apotex has not satisfied its persuasive burden to demonstrate on the facts that it would have produced the non-infringing lovastatin.
  - *Lovastatin FCA*

"Would" Branch

- Apotex established NIA was profitable
- But did not establish it was more profitable than any outside option
  - Therefore NIA was not established

Venlafaxine

- S 8 NOC
  - Teva is Plaintiff, Pfizer is Defendant
- Would Teva have been able to supply the market from its supplier Alembic?
  - Teva argued Pfizer had the burden of proving otherwise
  - Rejected by the FCA
- Burden of proof principles are the same in s 8 NOC and damages: [57]

Initial Burden

- P bears burden of proving its case
- [54] In [*Lovastatin*], this Court held that the plaintiffs bear the burden of proving the hypothetical world on the balance of probabilities as part of their damages claim (at para. 45).
  - *Venlafaxine FCA* 2016 FCA 161

Initial Burden

- Teva set up "but for" world (1) in which it buys from Alembic
  - Pfizer disputed that Alembic could have supplied in that "but for" world
- Burden is on Teva to prove "but for" world (1)
  - Just as in *Lovastatin*, burden is on Merck to prove its loss

Shifting Burden

- What if instead of disputing "but for" world (1), Pfizer instead set up a different "but for" world (2) in which Teva withdrew from the market entirely?
- The burden shifts to Pfizer, as the party setting up a "new issue"

Burden on New Issue

- Burden shifts to D who raises a "new issue"
- [63] In the Supreme Court's view [in *Rainbow Caterers*], a defendant that sets up a new issue bears the burden of proving it. The plaintiff, having proved its version of the hypothetical world, does not have to disprove other speculative hypotheses.
  - *Venlafaxine FCA*
  - As in *Lovastatin* shifting burden to Apotex to prove NIA

Burden on New Issue

- [65] Suppose Pfizer [Defendant] took the position that Ratiopharm (Teva) would not have tried to obtain venlafaxine from Alembic but instead would have given up and pursued another business objective, such as getting another generic drug to market. *Rainbow Industrial Caterers* instructs us that Pfizer, setting up a different hypothetical, would have borne the burden of proof on that point. Put a different way, Teva would not have borne the burden of proving that it would not have pursued a different business objective.
  - *Venlafaxine FCA*

Summary

- *Venlafaxine FCA*
- P has to prove its "but for" world (1)
  - Does not have to disprove alternative "but for" world
- D has to prove alternative "but for" world (2)
- *Lovastatin FCA*
- P has to prove "but for" world (1)
- D has to prove "but for" world (2) with NIA
- But D must also disprove alternative NIA world (3)
- Is alternative NIA world (3) a "new issue" shifting burden back to P?

Compare

- Apotex did not point to evidence that demonstrated the profits that it would have made through the non-infringing alternative would have been greater than value lost in any of the identified scenarios
  - *Lovastatin FCA*
- Put a different way, Teva would not have borne the burden of proving that it would not have pursued a different business objective.
  - *Venlafaxine FCA*

Should the Outside Option Matter?

- Regardless of who bears burden
- Suppose return from NIA is 10%
  - If return from D's outside option is 11%, P recovers its entire lost profits
  - If return from D's outside option is 9%, P recovery is limited by NIA
- Whether outside option is worth 9% o 11% is irrelevant to the value of the invention

Balance of Probabilities. . .

- But burden is on defendant to prove relevance of NIA
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    - *Lovastatin* FCA, citing *Rainbow Caterers* [1991] 3 SCR 3
  - What that position would have been is a matter that the plaintiff must establish on a balance of probabilities.
    - *Rainbow Caterers*

Or Relative Likelihood?

- Hypothetical events (such as how the plaintiff's life would have proceeded without the tortious injury) or future events need not be proven on a balance of probabilities. Instead, they are simply given weight according to their relative likelihood. For example, if there is a 30 percent chance that the plaintiff's injuries will worsen, then the damage award may be increased by 30 percent of the anticipated extra damages to reflect that risk. A future or hypothetical possibility will be taken into consideration as long as it is a real and substantial possibility and not mere speculation.
  - *Athey v. Leonati*, [1996] 3 SCR 458, [27]

Patentee's Response

- Should we consider how patentee would have responded in the but for world?
- A defendant who alleges that a plaintiff would have entered into a transaction on different terms sets up a new issue. It is an issue that requires the court to speculate as to what would have happened in a hypothetical situation.
  - *Rainbow Caterers*