NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Federal Court allows prohibition application due to insufficient notice of allegation

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Case: *Bayer Inc. v Fresenius Kabi Canada Ltd.*, 2016 FC 581 (Court File No. T-1440-14)
Drug: AVELOX I.V.™ (moxifloxacin)
Nature of case: Prohibition application pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the ***Regulations***)
Successful party: Bayer Inc. and Bayer Intellectual Property GmbH
Date of decision: July 5, 2016

Summary

Bayer Inc. markets moxifloxacin in Canada under the name AVELOX I.V.™ for use in the treatment of bacterial infection. Fresenius Kabi Canada Ltd. sought approval to market a generic version of moxifloxacin and was required to address Bayer's Canadian Patent No. 2,192,418 (the **'418 Patent**) under the *Regulations*. Fresenius alleged that it does not infringe the '418 Patent in a notice of allegation (**NOA**); Bayer responded with an application for a prohibition order.

Fresenius also addressed two other patents in its NOA, and Bayer's application initially addressed all three patents. However, Bayer's application for one of the patents was struck on the grounds that Bayer's evidence could not support a conclusion of infringement (reported here). The other patent expired before the hearing.

The Court allowed Bayer's application and issued a prohibition order. It held that Fresenius's NOA did not adequately detail the factual and legal bases for its non-infringement allegation. This was fatal to its case, even though Bayer failed to show that the non-infringement allegation itself was not justified.

Background

The '418 Patent claims the monohydrate form of moxifloxacin hydrochloride (the **Monohydrate**) according to a chemical formula and certain characterization data (XRPD and ^{13}C-NMR data). As construed in a previous moxifloxacin case (reported here), each of these features was construed to be an essential element of the claims, all of which were required to prove infringement.

Fresenius makes Fresenius-moxifloxacin overseas and then imports it into Canada. The parties agreed that the finished product does not infringe the '418 Patent. However, Bayer argued that Fresenius infringed the '418 Patent by the making of the Monohydrate as an intermediate in the manufacture of the finished product. In its NOA, Fresenius alleged that it did not use the Monohydrate and, in any event, the solid form used to make Fresenius-moxifloxacin was "trivial and merely incidental" to the finished product.

Failed NOA: Fresenius was required to disclose foreign manufacture and importation

The sufficiency of Fresenius's NOA was called into question because Fresenius did not allege non-infringement by importation or disclose that its product is manufactured outside of Canada. The legal test for infringement by importation of a non-infringing article made overseas using an infringing process (were it done in Canada), known as the *Saccharin Doctrine*, is different than the test for direct infringement in Canada. Justice Brown held that while Fresenius was not required to anticipate every theory of infringement in its NOA, omission of these details deprived Bayer of sufficiently complete information to enable it to assess its course of action and chances of success or failure as required by the *Regulations*.

Fresenius made numerous arguments in support of its NOA, all of which were rejected by the Court. Justice Brown held that Fresenius's use of "code words" in its NOA (i.e., "trivial and merely incidental," which appear in *Saccharin Doctrine* cases) was perhaps a clue to Fresenius' basis for non-infringement, but not a detailed statement. Justice Brown also held that Bayer was not required to guess what the NOA meant, commence an application, and then bring a motion to determine the sufficiency and meaning of the NOA. Likewise, the NOA was not saved by the subsequent disclosure of offshore manufacture pursuant to a confidentiality agreement, which effectively turned the NOA into a "Trojan horse" for unalleged arguments. Post-NOA disclosure can be used to elaborate upon an allegation, but not to disclose a new basis of non-infringement.

In addition, Brown J held that Bayer's subjective opinion was irrelevant to the legal question of whether Fresenius's NOA was sufficient; thus, affidavit evidence of surprise was not required. Justice Brown also rejected Fresenius's arguments that it was not required to raise infringement by importation and that the fact of importation was confidential, both of which were inconsistent with its argument that the use of "code words" put Bayer on notice.

As a result of the foregoing, the Court held that Fresenius's NOA was not a detailed statement as required under the Regulations and allowed the application.

Obiter dictum on the merits: no infringement under the *Saccharin Doctrine*

Notwithstanding its finding with respect to the sufficiency of Fresenius's NOA, the Court went on to consider the merits of its non-infringement allegation in a detailed *obiter dictum*. Bayer attempted to show infringement by conducting reduced-scale experiments intended to replicate the process used by Fresenius to manufacture Fresenius-moxifloxacin. However, the Court was not persuaded that Fresenius infringed any of the elements of the claim.

Justice Brown held that Bayer had not shown the presence of the Monohydrate or either characteristic peaks (XRPD and ^{13}C-NMR) claimed in the '418 Patent. In any event, even if the Monohydrate were used in Fresenius's manufacturing process, Brown J found that the use would be merely incidental to the finished product and would not meet the test for infringement under the *Saccharin Doctrine*.

The Court noted that had it not decided the NOA issue in Bayer's favour, it would have dismissed the application.

Reconsideration and appeal

Fresenius moved in the Federal Court for reconsideration of its judgment. In addition, Fresenius has appealed the judgment to the Federal Court of Appeal (Court File No. A-236-16).

Links:

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