NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Federal Court addresses the relationship between prohibition applications and infringement/impeachment actions

Case:	*Bayer Inc. v Cobalt Pharmaceuticals Company*, 2016 FC 1013 (Court Files No. T-1379-13, T-1468-13, and T-1368-14)
Drug:	By Bayer Inc.: YAZ (3.0 mg drospirenone and 0.020 mg ethinyl estradiol tablets) and YASMIN (3.0 mg drospirenone and 0.030 mg ethinyl estradiol tablets) By Apotex Inc. (**Apotex**): MYA (3.0 mg drospirenone and 0.020 mg ethinyl estradiol tablets) and ZAMINE 21 & ZAMINE 28 (**ZAMINE**) (3.0 mg drospirenone and 0.030 mg ethinyl estradiol tablets) By Cobalt Pharmaceuticals Company (**Cobalt**): ZARAH 21 & ZARAH 28 (**ZARAH**) (3.0 mg drospirenone and 0.030 mg ethinyl estradiol tablets)
Nature of case:	Liability phase of bifurcated action for patent infringement and impeachment pursuant to the *Patent Act*, RSC 1985, c P-4
Successful party:	Bayer Inc. & Bayer Pharma Aktiengesellschaft (collectively **Bayer**)
Date of decision:	September 7, 2016

Summary

This action concerns Bayer's Canadian Patent No. 2,382,426 (the **'426 Patent**) and generic versions of two combination oral contraceptives marketed in Canada by Bayer: YAZ and YASMIN, both of which contain drospirenone and ethinyl estradiol.

The court found that the '426 Patent was valid, rejecting attacks on the bases of obviousness, anticipation, overbreadth, insufficiency, ambiguity, and inutility. The court also found that all of the alleged generic products infringed the asserted claims of the '426 Patent. Quantification will be determined in a subsequent proceeding.

Background

Both Apotex and Cobalt (now Actavis, itself recently acquired by Teva) market generic versions of YASMIN, known respectively as ZAMINE and ZARAH. Apotex also markets a generic version of YAZ, known as MYA. As we reported here and here, in proceedings under the *Patented Medicines (Notice of Compliance) Regulations* (the ***Regulations***), Bayer succeeded in preventing Cobalt from marketing a proposed generic version of YAZ. It failed to do so in respect of Apotex's generic YAZ product, which is marketed as MYA. Bayer sued Apotex and Cobalt for infringement; Apotex and Cobalt counterclaimed for a declaration of invalidity.

The '426 Patent is not listed against YASMIN; both Apotex and Cobalt were able to obtain NOCs for their generic versions of this product.

The court held that the claimed invention of asserted claims of the '426 Patent is rapidly dissolving oral formulations of drospirenone particles and ethinyl estradiol. These formulations exhibit surprisingly good bioavailability as a contraceptive despite being exposed directly to the gastric environment.

Preliminary issues: the precedential value of prohibition applications and expert blinding

Precedential value of prohibition applications in a subsequent action. Having twice litigated the construction and validity of the '426 Patent in prohibition applications, Bayer argued that the court should adopt the findings of the Federal Court of Appeal and Federal Court on these issues. Cobalt submitted that although the construction reached in the prohibition applications could be persuasive, the court was free to depart from findings made under the *Regulations* because of the broader evidentiary scope of an action. Apotex also acknowledged that the Court of Appeal's judgments on questions of law may be persuasive, but argued that findings made under the *Regulations* should have no bearing on this action.

The court held that as a question of law, the Court of Appeal's findings regarding claims construction — including determination of the inventive concept and promised utility — are *prima facie* binding but can be revisited if warranted by the evidence. Conversely, the court held that findings of fact, or mixed fact and law, are potentially persuasive but do not require judicial comity and must be approached with caution. This includes findings on obviousness, ambiguity, overbreadth, utility, and insufficiency.

Expert blinding. The court held that although "blinding" has recently found some favour, it is not a principle of law that applies in all cases. The main concern is the substance and reasoning of the expert's opinion. As a result, when issues of credibility arise, blinding may be persuasive, but is no guarantee of reliability. A well-supported but unblinded opinion needn't be given less weight. Blinding was not a significant factor in the court's decision in this case.

The asserted claims of the '426 Patent are valid

Obviousness. The court held that there was no good reason to depart from the construction of the inventive concept previously upheld by the Court of Appeal under the *Regulations*. Justice Fothergill was persuaded by the inventors' course of conduct, as well as the absence of any similar product prior to the '426 Patent, that while a skilled person may have been curious about whether such a formulation would work, the testing required to answer that question was "worth a try" — not obvious to try.

Anticipation. Apotex argued that the asserted claims were anticipated by Bayer's own clinical studies. Justice Fothergill agreed with Bayer that these trials were not disclosures: while there was a theoretical possibility that one or more tablets may have found their way into the hands of the skilled person, inventive insight would have been required to reverse-engineer the invention. The court also held that if disclosure has been made out, the claims would have nonetheless been saved under the experimental-use exception to anticipation.

Overbreadth. Apotex argued that the research conducted by the inventors of the '426 Patent was limited to only one method of obtaining a rapid drospirenone dissolution profile, whereas the asserted claims monopolized all manners of achieving that end. Apotex also argued that these claims are overbroad to the extent that they do not require exposure of the formulation to the gastric environment upon dissolution. Justice Fothergill adopted the reasons of the Court of Appeal on this issue, concluding that the patent teaches the solution to a problem and embraces all drospirenone particles that achieve that solution.

Insufficiency & ambiguity. Apotex's insufficiency and ambiguity arguments arose from the fact that the asserted claims specify a drospirenone dissolution profile described in the specification for a tablet dosage form containing 3 mg of drospirenone, yet the claims included any amount of drospirenone from about 2 to about 4 mg. Apotex asserted that a means of achieving the specified dissolution profile at strengths other than 3 mg was not provided. Justice Fothergill rejected Apotex's argument, holding that a skilled person could have scaled or otherwise adapted the instructions to obtain the desired dissolution profile without resort to inventive means.

Inutility. As a matter of judicial comity, the court adopted the promised utility found by Hughes J under the *Regulations* and was satisfied that this promise was demonstrated or soundly predicted by two examples in the specification of the '426 Patent.

The asserted claims of the '426 Patent are infringed

The court analyzed the infringement issues raised by Apotex and Cobalt separately.

Infringement by Apotex: ZAMINE and MYA. The sole issue regarding infringement by Apotex was whether ZAMINE and MYA tablets contain at least 2 mg of drospirenone particles. Apotex argued that these products contained a "molecular dispersion" of drospirenone, which is sufficiently dissolved that it no longer constitutes "particles." Bayer obtained samples of the Apotex tablets and used Raman spectroscopy to determine whether they contained drospirenone particles. Apotex countered this testing with infrared spectroscopy and replication of Bayer's testing.

The court found the testing evidence credible but was critical of experts for both sides regarding their difficulty explaining the results of some of their analytical techniques. Although Bayer abandoned part of its evidence for this reason and despite myriad attacks on the adequacy of its experiments, Bayer nonetheless succeeded in showing that Apotex's products infringe the asserted claims.

Infringement by Cobalt: ZARAH. Before trial, Cobalt unsuccessfully moved to amend its pleading to delete a reference to drospirenone particles in ZARAH and sought to plead instead that the product does not contain drospirenone particles. Justice Fothergill considered this pleading to be a formal admission that at least some of the drospirenone in ZARAH is in particle form, with the result that Cobalt was limited to disputing the proportion of particulate drospirenone present. Both Bayer and Cobalt used Raman spectroscopy to examine this issue.

Justice Fothergill accepted that Cobalt's manufacturing process necessarily produces drospirenone particles and that at least 90% of the drospirenone in its tablets was present in this form. As a result, Bayer's infringement argument was successful.

Relief & bifurcation. The court awarded Bayer a declaration of validity in respect of the asserted claims and injunctive relief against Apotex and Cobalt, as well as the delivery-up or destruction of infringing tablets. The parties were given 30 days to make submissions on Bayer's entitlement to claim its damages or an accounting of profits. The quantification of Bayer's monetary compensation for infringement is bifurcated and will be determined in a subsequent proceeding.

Appeal

Apotex and Cobalt have both appealed from the court's judgment (see Court Files No. A-314-16 and A-318-16, respectively).

Links:

This decision: *Bayer Inc. v Cobalt Pharmaceuticals Company*, 2016 FC 1013

Previous prohibition applications:

- *Bayer Inc. v Cobalt Pharmaceuticals Company*, 2013 FC 1061 (reported here), aff'd 2015 FCA 116 (reported here)
- *Bayer Inc. v Apotex Inc.*, 2014 FC 436

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