IT TAKES TWO TO TANGO: LESSONS LEARNED FOR BOTH INNOVATOR AND GENERIC DRUG MANUFACTURERS

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In an administrative proceeding before the Federal Court of Canada for an application to prohibit the Minister of Health from issuing a market approval (Notice of Compliance) to Cobalt Pharmaceuticals Company for a generic version of the contraceptive drug "YAZ", known in Canada as a PM(NOC) proceeding, the Federal Court studied the applicability and validity of two of Bayer Pharma Aktiengesellschaft's patents, CA2,382,426 and 2,179,728, relating to a drospirenone + ethinylestradiol combination birth control product. This decision confirmed two important principles relevant to both innovator and generic patent practice in Canada [*Bayer Inc. v. Cobalt Pharmaceuticals Company,* 2013 FC 1061, October 22, 2013, Hughes].

NOC Proceedings

In Canada, the owner of a patent relating to a drug product can request that said patent be listed on a register managed by the Minister of Health, in association with a medicinal ingredient already approved for sale in Canada. A generic drug manufacturer who wishes to manufacture and sell a drug product containing this medicinal ingredient would then have to address the validity and/or applicability of any such listed patent, in what is referred to as a Notice of Allegation (NOA). This step needs to be completed before the Minister of Health can issue a marketing authorization for said generic drug, by way of a Notice of Compliance (NOC).

When served with an NOA, an innovator drug company then has the opportunity to file for an application before the Courts, seeking to prohibit the Minister of Health from issuing an NOC to a generic drug company for the remainder of the life of any such listed patents.

Accordingly, such an application was brought by Bayer Pharma Aktiengesellschaft (hereinafter "Bayer") in response to an NOA that was filed by Cobalt Pharmaceuticals

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Company (hereinafter “Cobalt”), with respect to Bayer’s CA 2,382,426 (‘426) and 2,179,728 (‘728) patents. On December 8th 2011, Cobalt served Bayer its NOA, stating that it has applied for market approval to distribute generic versions of Bayer’s brand name “YAZ” birth control tablets, comprising of 3mg drospirenone + 20mg ethinylestradiol in tablet form, for oral administration. In such a proceeding, the fundamental issue to be tried is whether the allegations of non-infringement and invalidity made by the generic manufacturer in its NOA are justified. Cobalt alleged that its product will not infringe either of the ‘426 or ‘728 patents and that the claims are invalid. The Court allowed the application with respect to the ‘426 patent, but dismissed it as it concerns patent ‘728.

The ‘426 patent

The burden to prove that Cobalt’s allegations of invalidity and non-infringement are not justified vests with Bayer. The added layer of difficulty in this reversal of the onus is that it is up to the Plaintiff, Bayer, to prove infringement with respect to a drug that has either not been manufactured yet, or has not been distributed for sale. As such, despite a motion it brought to compel Cobalt to produce samples, which Cobalt refused and the Court did not compel it do to so, Cobalt had adduced only a limited amount of evidence with respect to its product: that it will contain 3mg of drospirenone and that it was formulated with a “spray on” technique. The Court had to address Cobalt’s non-infringement and invalidity allegations with the evidence that was on record.

Amongst other arguments, Cobalt argued that the claims at issue are directed to a contraceptive product where the drospirenone is “micronized”. Bayer argued that the patent was not restricted in this way and applied to any form of drospirenone having rapid dissolution characteristics. The Court studied the description of the patent, as well as the submissions from the parties, to construe the claims. The Court found that the claims were not to be restricted to a “micronized” tablet, but were restricted in respect to certain dissolution parameters. This is why it is important to always put your best foot forward. Since Cobalt refused to provide sample tablets and did not provide any information as it concerns the dissolution parameters of its product, the Court concluded that Cobalt’s NOA was insufficient and the allegations of non-infringement were therefore not justified.

The Court then studied the validity of the patent with respect to obviousness, *inutility*, over breadth, ambiguity and lack of sound prediction. The inventive concept was determined to be “an oral contraceptive comprised of a combination of drospirenone and ethinylestradiol, the drospirenone may be provided in micronized or other rapidly dissolving form without an enteric coat”. None of Cobalt allegations as to invalidity were found to be justified.

Therefore, a prohibition order was issued against Cobalt for the ‘426 patent.

The '728 patent

As it concerns the '728 patent, Cobalt argued non-infringement, claiming a method of medical treatment (prohibited in Canada), double patenting, obviousness, dose equivalency (a non-infringement argument), as well as *inutility* and sound prediction. The claims related to a dosage of drospirenone, the highest dosage being a "dose equivalent of 0.075mg (75µg) of gestodene". Cobalt argued that the "dose equivalent" cannot be calculated accurately, or more precisely, if it could be calculated, it would result in approximately 2mg of drospirenone, and therefore Cobalt's product would not infringe because it contains around 3mg drospirenone. The Court construed the claims and found that since Cobalt's product will contain 3 mg of drospirenone, and the claims relate to a "maximum or only" dosage (either 2 mg of drospirenone or an indeterminate amount of drospirenone), Cobalt's product would therefore not infringe any claims at issue.

Notwithstanding Cobalt's arguments relating to double patenting, obviousness, *inutility* and sound prediction, an interesting debate arose with respect to the claiming of a method for medical treatment, since "claims 1, 2, 6, 7 and 8, are all directed to the use, in oral dosage form, for contraception for a female of a certain age, of a composition drug with two active components; an estrogen and a gestagen."

In its study of the claims, the Court determined that all claims are clearly expressed in terms of "use for a contraceptive". All claims except claim 8 provide for a range of dosages for one or both of the estrogen and gestagen components. Submissions were made with respect to the fact that commercially speaking, the "products are sold in the form of a kit containing tablets of fixed dosages to be used in a daily regimen".

The Court reiterated however that it is not important how the product is sold, but what the claims say. All claims at issue are "use claims" and were not product claims. Aside from claim 8, all other claims that were studied related to the use as a "contraceptive of a two-component drug with each component to be selected from a choice of components, and with each component to be furnished at a dosage within a range of dosages". As such, these claims were not: "proper subject matter for a Canadian patent, as they do not claim a vendible product; they provide for a choice to be made by those prescribing or providing contraceptive drugs to choose between a variety of components and a variety of dosage ranges". Only Claim 8 survived for being directed to a single dosage of each of two compounds.

Cobalt's allegations of invalidity and non-infringement were therefore found to be justified.

Since half the battle was won, Bayer was entitled to recover one-half of its costs from Cobalt.

Conclusion

In its decision, the Court reiterated two important principles relevant to Canadian NOC practice. The first revolves around putting your best foot forward in your NOA. With respect the '426 patent, Cobalt did not provide product samples, nor did it provide any evidence as to the dissolution parameters of its tablets. As such, an unsubstantiated allegation of non-infringement, without anything more, is insufficient to support an assertion of non-infringement. A party making such an allegation should advance sufficient evidence in support of its NOA. While it is correct that the burden of proving that a generic manufacturer's allegations of non-infringement are not justified vests with the Innovator, this determination is contingent upon whether or not the allegations made by the generic manufacturer were sufficiently substantiated to begin with.

Secondly, as it concerns the Innovator, how you commercialize a product will not be taken into account when a Court is construing the claims of your patent. In other words, "what do the claims say"? If the claims at issue are directed to the "use", the fact that your product is sold as a kit cannot then be relied on to escape a rejection for claiming a method of medical treatment.

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