Federal Court  Cour fédérale

Date: 20130529

Docket: T-1044-11

Citation: 2013 FC 573

Ottawa, Ontario, May 29, 2013

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

BAYER INC AND BAYER PHARMA AKTIENGESELLSCHAFT

Applicants

and

COBALT PHARMACEUTICALS COMPANY COBALT PHARMACEUTICALS INC AND THE MINISTER OF HEALTH

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

I. Overview

[1] The applicants, Bayer, seek an order prohibiting the Minister of Health from issuing a Notice of Compliance [NOC] to the respondents, Cobalt, in respect of a generic version of Bayer's product, an oral contraceptive marketed as YASMIN®. The NOC would permit Cobalt to market tablets containing drospirenone, a compound claimed in Bayer's Canadian Patent No 2,261,137 [the

‘137 patent], which does not expire until August 11, 2017. Bayer contends that Cobalt’s product would infringe the ‘137 patent, while Cobalt alleges that it would not. In addition, Cobalt alleges that the ‘137 patent is invalid for obviousness.

[2] I am satisfied, based on my reading of the ‘137 patent, that Cobalt’s allegation that its product would not infringe the ‘137 patent is justified. Therefore, I must dismiss Bayer’s application. It is unnecessary to consider the issue of whether the patent is invalid.

[3] The issues are:

1. What is the proper construction of the ‘137 patent?
2. Are Cobalt’s allegations of non-infringement justified?

II. The ‘137 Patent

[4] The ‘137 patent is entitled “Process for Producing Drospirenone”. It states that the invention relates to a process for producing drospirenone, as well as two intermediate compounds referred to as ZK 92836 and ZK 90965. The patent describes the process for producing drospirenone in the prior art and characterizes the invention as being a “new production process for drospirenone, which is more selective and simpler in execution than that from the prior art and, in addition, is ecological (savings of a chromium trioxide oxidation).”

[5] The patent then sets out the new process showing three steps: (1) hydrogenation to make ZK 92836; (2) oxidation through the use of ruthenium salts (such as $RuCl_3$, RuO_2, $KRuO_4$, K_2RuO_4, but "preferably" a catalytic amount of $RuCl_3$) to make ZK 90965; and then (3) dehydration to make drospirenone. The patent describes the second step, oxidation, as "a key reaction". The patent includes an example of the three-stage process in which a catalytic amount of the ruthenium salt $RuCl_3$ is used at the oxidation stage.

[6] Claim 1 of the patent addresses the three-step process (using ruthenium salt at the oxidation stage) for producing drospirenone. Claims 2 to 11 address variations on the process, although none suggests any alternative to the use of a ruthenium salt at the oxidation stage. Indeed, Claim 5 specifically mentions the four ruthenium salts referred to in the patent's disclosure ($RuCl_3$, RuO_2, $KRuO_4$, K_2RuO_4), while Claims 6 and 11 cover the preferred oxidizing agent, a catalytic amount of the ruthenium salt $RuCl_3$.

[7] Claim 12 claims all of the processes in Claims 1 to 11 which yield two named contaminants in a concentration of less than 0.2%.

[8] Claim 13 is the only claim in issue here. It claims a product "prepared according to the process of claim 12, wherein the product comprises drospirenone and less than 0.2%" of the two contaminants identified in Claim 12.

[9] The remaining claims address the intermediate ZK 90965 (Claim 14), and processes for making it (Claims 15 and 16).

III. Issue One – What is the proper construction of the '137 patent?

[10] As mentioned, the only claim in issue is Claim 13, which addresses a "product prepared according to the process of Claim 12". Bayer maintains that Claim 13 is a pure product claim. It contends that the claim should be read as if the words "prepared according to the process of Claim 12" were not there.

[11] Bayer presents two reasons for its construction of Claim 13. First, it says that its construction is required as a matter of law according to *Hoffman-LaRoche & Co v Commissioner of Patents*, [1955] SCR 414. Second, Bayer submits that its construction conforms with the interpretation that a skilled person would give to Claim 13.

[12] I am not persuaded that Bayer's construction is correct in law or consistent with how a skilled person would read Claim 13. In my view, Claim 13 incorporates the patented process for making drospirenone.

[13] In the alternative, Bayer argues that the process referred to in Claim 13 does not require the presence of a ruthenium salt at the oxidation stage; any appropriate metal salt could be substituted at the oxidation stage and still fall within the claims of the patent.

[14] Again, based on my reading of the '137 patent, I cannot accept Bayer's construction. In my view, the presence of a ruthenium salt at the oxidation stage is an essential element of the invention described in the '137 patent.

(1) Bayer's construction of Claim 13 is not required by law

[15] Bayer relies on *Hoffman-LaRoche*, above, for the following propositions: (i) product-by-process claims should be read as hypothetical claims for the product alone. If the product is not new, then the claims are invalid, even if the process is new. Therefore, any reference to a process within a claim for a product made according to that process should be disregarded; (ii) claims must be given the same construction for all purposes, including invalidity and infringement. Since *Hoffman-LaRoche* requires product-by-process claims to be read as claims for the product alone for the purposes of an invalidity challenge, I must also consider Cobalt's allegations of non-infringement as against Claim 13 as if that claim were for the product alone. According to that construction, Cobalt's allegation of non-infringement would not be justified because Cobalt's product is essentially the same as Bayer's.

[16] I disagree with Bayer's legal arguments. In particular, I do not read in *Hoffman-LaRoche* a requirement to construe product-by-process claims in the manner Bayer puts forward. In my view, product-by-process claims should not always be read without reference to the specified process. Therefore, Bayer's Claim 13 must be construed as including the patented process.

[17] When Bayer obtained the '137 patent in 1996, drospirenone was a known, and already patented, compound. As described above, the '137 patent is directed at an improved process for making drospirenone and the allegedly purer form described in Claim 13.

[18] *Hoffman-LaRoche* tells us that a new patent cannot be obtained for a known compound even if a new process has been discovered for making it. Accordingly, claims for a product made by a particular process should be assessed as if they were claims for the product alone and should be upheld only if the product is new. In other words, a new process for making an old compound does not justify a new patent for that same compound.

[19] Assuming that the compound in Claim 13 is new (ie, a form of drospirenone with a particular purity), an issue I need not decide here, the issue in *Hoffman-LaRoche* simply does not arise.

[20] In that case, Hoffman-LaRoche had invented a new process for manufacturing aldehyde, a known substance. It sought a patent for the product made according to that process. The Supreme Court of Canada held that Hoffman-LaRoche could not obtain a new patent for the old compound, even though a new process for making it had been invented. In that sense, the patent's claims had to be read as if they were claims for the compound alone, and only if the compound was new could the claims be valid.

[21] Accordingly, in considering whether Bayer would be entitled to a patent for the drospirenone product made by its new process, I would have to consider whether that product,

regardless of how it was made, was new. That is an issue of invalidity, not claims construction. *Hoffman-LaRoche* does not establish a rule of claims construction requiring that all product-by-process claims be read as if there were no reference to the process within the claims. It merely provides that claims for a product (even a product made by a new process) must meet the definition of an invention.

[22] Therefore, as a matter of law, I cannot accept Bayer's assertion that Claim 13 should be construed as if the words "[a] product prepared according to the process of claim 12" did not exist.

(2) A skilled person would not construe Claim 13 as a product claim

[23] The parties agree that a skilled person for present purposes would be a chemist with 1 to 5 years of experience.

[24] Bayer argues that a skilled person would read Claim 13 as a claim for the purer form of drospirenone, regardless of how it was made. Bayer's expert, Dr Mark Lautens (Professor of Organic Chemistry, University of Toronto) read Claim 13 that way. Indeed, according to Bayer, a skilled person would not read Claim 13 as including the patented process because that would render redundant the other claims in the patent specifically addressing that process.

[25] Dr Lautens' view is that the '137 patent discloses the highly pure form of drospirenone, as well as the form of drospirenone prepared according to the process set out in the patent (avoiding

toxic chromium), and the simplified process for making drospirenone. His opinion is that Claim 13 claims the product alone.

[26] In contrast, Cobalt's expert, Dr Lakshmi Kotra (Professor, Faculty of Pharmacy, University of Toronto), read Claim 13 as covering drospirenone, prepared according to the process in Claim 12, and having the specified purity profile.

[27] I cannot accept Dr Lautens' construction of Claim 13. Claim 13 clearly makes reference to certain impurities but nothing in the disclosure suggests that this purity profile was an object of the invention. Nor is there any evidence that the previously known drospirenone product was impure. Most importantly, Claim 13 clearly and expressly incorporates the process described in Claim 12.

[28] Nor do I accept that construing Claim 13 as including the patented process would render the other claims to that process redundant. Those other claims, described above, stand on their own. The fact that Claim 13 incorporates Claim 12 (and, in turn, Claims 1 to 11) does not render those other claims superfluous. Claim 13 addresses a product made by a specified process. The process itself is patentable and can, as the '137 patent does, be claimed independently.

[29] In short, Claim 13 relates to a drospirenone product made according to the three-step process described in the patent and claimed in Claim 12, with a particular level of purity.

(3) The presence of a ruthenium salt is an essential element

[30] Bayer contends that if Claim 13 is construed as containing the process of Claim 12, then the process of Claim 12 should not be read as including oxidation in the presence of a ruthenium salt as an essential element. The patent, Bayer says, only requires oxidation in the presence of an appropriate metal salt, not necessarily ruthenium.

[31] I cannot agree with Bayer's interpretation of the '137 patent.

[32] The patent describes a three-step process for making drospirenone. The first step, hydrogenation, and the third step, dehydration, are both routine and well-understood operations that are relatively insignificant aspects of the inventive process. The "key reaction" of the invention is the second step, oxidation in the absence of chromium trioxide. This step achieves the ecological objective of the patent by avoiding the prior art's use of toxic chromium.

[33] The only metal salts mentioned in the patent as being suitable alternatives to chromium are ruthenium salts. As mentioned, ruthenium salts are specifically included in Claims 1, 5, 6 and 11. No alternatives are cited, and there is no reference to the possibility that other metal salts might work. The patent's disclosure also contains numerous references to ruthenium. There is only one passage that could be read as admitting of an alternative to ruthenium:

> Another very basic advantage of the process according to the invention compared to the prior art lies in the range of ecology. It has been possible to replace the previously used toxic chromium compounds, which so far have been used in the form of pyridinium dichromate salts for oxidation and must subsequently be disposed of in the form of their solutions, by catalytic amounts of a metal.

[34] This general statement, in the context of the patent as a whole, cannot expand the breadth of the patent's invention. The invention is set out unambiguously in the claims and the only compounds mentioned as being suitable candidates for the key reaction of the invention are ruthenium salts. The clear language of the claims limits the scope of the invention (*Free World Trust v Électro Santé Inc*., 2000 SCC 66, at para 51). Here, the invention is a process for making drospirenone that uses ruthenium salts as an alternative oxidizing agent to chromium trioxide.

[35] I note that Dr Lautens' opinion is that ruthenium salts are simply mentioned as examples for appropriate metal salts. He maintains that a skilled reader would have realized that other metal salts would work.

[36] However, Dr Lautens does not mention any potential alternatives to ruthenium that would be appropriate, nor does he make reference to the patent's claims where only ruthenium salts are identified as oxidizing agents.

IV. Issue Two – Are Cobalt's allegations of non-infringement justified?

(1) Burden of Proof

[37] It is well-accepted that, once a second person has presented sufficient evidence to give the allegations in its NOA an air of reality, the burden falls on the first person to show on a balance of probabilities that the second person's allegations are unjustified (*Pfizer Canada Inc v*

Apotex Inc, 2007 FC 26, at paras 9-12). (A recent decision of this Court seems to suggest that the burden of proof falls on the second person, but that appears to be the result of a typographical error: see *Pfizer Canada Inc v Pharmascience Inc*, 2013 FC 120, at para 27). In this case, in keeping with the prevailing case law, the parties agree that the burden falls on Bayer to show that Cobalt's allegations of non-infringement are unjustified.

(2) Cobalt's allegation of non-infringement is justified

[38] Cobalt's Notice of Allegation [NOA] contended that its product would not infringe Claim 13 because it would not use the process for making drospirenone that is described in the '137 patent. In particular, Cobalt's process would not yield the intermediate compounds that form part of the invention set out in the '137 patent. Further, Cobalt would not use the three-step process identified in Claim 1 of the patent and, in particular, would not employ a ruthenium salt as an oxidizing agent. For present purposes, I need not describe Cobalt's process in any further detail.

[39] As discussed above, Bayer contends that the process described and claimed in the '137 patent includes some inessential elements and, therefore, even though Cobalt would use a different process to produce drospirenone, its claim of non-infringement is not justified. Cobalt's process would still come within the scope of the process claims of the '137 patent, even though its process differs from Bayer's in certain respects.

[40] However, in light of my conclusion that Claim 13 incorporates the process for making drospirenone set out in the '137 patent, which includes the key oxidation reaction with a ruthenium

salt, I cannot agree with Bayer's submission. In short, Cobalt relies on a non-infringing process to make drospirenone. Accordingly, Bayer has failed to show that Cobalt's allegation of non-infringement is unjustified.

V. Conclusion and Disposition

[41] Bayer's burden was to show that Cobalt's allegation of non-infringement was unjustified. Claim 13 of the '137 patent addresses a product made by the three-step process set out in the patent, an essential element of which is oxidation in the presence of a ruthenium salt. As this essential operation is not part of Cobalt's process, I find that Bayer has failed to discharge its burden. I must, therefore, dismiss Bayer's application for an order prohibiting the Minister of Health from issuing a NOC to Cobalt, with costs.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application for an order prohibiting the Minister of Health from issuing a Notice of Compliance to the respondents is dismissed, with costs.

"James W. O'Reilly"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1044-11
STYLE OF CAUSE:	BAYER INC ET AL v COBALT PHARMACEUTICALS COMPANY, ET AL
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	March 18-19, 2013
REASONS FOR JUDGMENT AND JUDGMENT:	O'REILLY J.
DATED:	May 29, 2013

APPEARANCES:

Christopher C Van Barr Kiernan A Murphy	FOR THE APPLICANTS
Douglas N Deeth Heather E A Watts	FOR THE RESPONDENTS COBALT PHARMACEUTICALS COMPANY AND COBALT PHARMACEUTICALS INC

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANT
Deeth Williams Wall LLP Barristers and Solicitors Toronto, Ontario	THE RESPONDENTS COBALT PHARMACEUTICALS COMPANY AND COBALT PHARMACEUTICALS INC