Federal Court of Appeal  Cour d'appel fédérale

**Date: 20150504**

**Dockets: A-376-13**
**A-385-13**

**Citation: 2015 FCA 116**

**CORAM:** **PELLETIER J.A.**
**STRATAS J.A.**
**WEBB J.A.**

**Docket: A-376-13**

**BETWEEN:**

**COBALT PHARMACEUTICALS COMPANY**

**Appellant**

**and**

**BAYER INC. and BAYER PHARMA AKTIENGESELLSCHAFT and THE MINISTER OF HEALTH**

**Respondents**

**Docket: A-385-13**

**AND BETWEEN:**

**BAYER INC. and BAYER PHARMA AKTIENGESELLSCHAFT**

**Appellants**

**and**

**COBALT PHARMACEUTICALS COMPANY and THE MINISTER OF HEALTH**

**Respondents**

Heard at Toronto, Ontario, on September 11, 2014.

Judgment delivered at Ottawa, Ontario, on May 4, 2015.

| | |
|---|---|
| REASONS FOR JUDGMENT BY: | STRATAS J.A. |
| CONCURRED IN BY: | WEBB J.A. |
| CONCURRING REASONS BY: | PELLETIER J.A. |

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## REASONS FOR JUDGMENT

**STRATAS J.A.**

[1] Bayer Inc. and Bayer Pharma Aktiengesellschaft ("Bayer") and Cobalt Pharmaceuticals Company ("Cobalt") both appeal from the judgment dated October 22, 2013 of the Federal Court (*per* Justice Hughes): 2013 FC 1061. These are my reasons in both appeals.

[2] Bayer applied under the *Patented Medicines (Notice of Compliance) Regulations,* S.O.R./93-133 ("NOC Regulations"), to the Federal Court to prohibit the Minister of Health from issuing a notice of compliance to Cobalt concerning its proposed drospirenone and ethinylestradiol combination product until the expiry of each of Canadian Letters Patent Nos. 2,382,426 ('426 Patent) and 2,179,728 ('728 Patent).

[3] In its judgment, the Federal Court granted Bayer's application concerning the '426 Patent. Cobalt appeals from that (appeal A-376-13). The Federal Court dismissed Bayer's application concerning the '728 Patent. Bayer also appeals (appeal A-385-13).

[4] For the reasons below, I would dismiss both appeals with costs.

[5] These reasons are divided in two parts: Cobalt's appeal concerning the '426 patent and Bayer's appeal concerning the '728 Patent. First, however, I shall offer a few background facts relevant to both appeals.

[6] Bayer distributes in Canada birth control tablets under the brand name YAZ. The tablets include as active ingredients 3 mg drospirenone + 20 mg ethinylestradiol in tablet form for oral administration.

[7] Cobalt intends to distribute in Canada a generic version of YAZ. It has applied to the Minister of Health for a notice of compliance.

[8] Acting under the NOC Regulations, Cobalt issued a notice of allegation. In it, it alleged that it would not infringe the claims of the ’426 Patent and the ’728 Patent and that any relevant claims of the two Patents were invalid. In the notice of allegation concerning the ’426 Patent, it alleged invalidity on the basis of obviousness, lack of utility, overbreadth, insufficiency and ambiguity. In the notice of allegation concerning the ’728 Patent, it alleged that the claims were invalid on the basis of obviousness, double patenting, lack of utility and lack of sound prediction, and non-patentable subject-matter on the ground that it covers a method of medical treatment.

[9] In response to the notice of allegation, Bayer applied under the NOC Regulations for an order prohibiting the Minister of Health from issuing Cobalt a notice of compliance for its proposed drospirenone + ethinylestradiol combination product until after the expiry of the ’426 Patent and the ’728 Patent.

[10] As mentioned above, the Federal Court granted Bayer’s application concerning the ’426 Patent. It accepted Bayer’s construction of that Patent. As a result of that construction, it found that none of Cobalt’s allegations were justified.

[11] As also mentioned above, the Federal Court dismissed Bayer's application concerning the '728 Patent. It construed the Patent finding alternatively that it was invalid for ambiguity or that it claimed only, as a maximum or only dosage, 2 mg of drospirenone or an indeterminate amount of drospirenone: see the Federal Court's reasons at paragraphs 134-35. Cobalt's product contained 3 mg of drospirenone and so it did not infringe.

## A. Cobalt's appeal concerning the '426 Patent (A-376-13)

### (1) The construction of the patent

[12] The Federal Court's construction of the patent is to be reviewed on the basis of correctness: *Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109, 432 N.R. 292 at paragraph 20. As the Supreme Court has said, "claims construction is a matter of law for the judge": *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at paragraph 61.

[13] This view has been said to stem from the fact that issued letters patent are a "regulation" under subsection 2(1) of the *Interpretation Act*, R.S.C. 1985, c. I-21, and, thus, are laws whose interpretation should be reviewed on the basis of correctness: *Whirlpool*, above at paragraphs 49(e) and 61.

[14] However, in the process of interpretation, patents are to be read through the eyes of the skilled reader: *Whirlpool*, above at paragraph 45. The skilled reader approaches the patent with an appreciation of the common general knowledge in the art to which the patent relates. This is

not within the purview of a judge, so almost always the parties adduce expert evidence to explain how the skilled reader would read and understand the patent: *Whirlpool*, above at paragraphs 57-62; *Free World Trust v. Electro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at paragraph 51.

[15] The Federal Court's assessment of the expert evidence – for example, evidence concerning the state of scientific knowledge at the relevant time or how a reasonable person skilled in the art would understand the patent – is reviewable for palpable and overriding error: *Mylan Pharmaceuticals*, above at paragraph 20; *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.*, 2012 FCA 333, [2014] 2 F.C. 459 at paragraph 44; *Bell Helicopter Textron Canada Limitée v. Eurocopter*, 2013 FCA 219, 449 N.R. 111 at paragraphs 73-74; *Corlac Inc. v. Weatherford Canada Inc.*, 2011 FCA 228, 95 C.P.R. (4th) 101 at paragraph 24.

[16] That is the law I must apply in these appeals and I will do so. But, in the interests of the sound development of the law, I would like to offer certain observations for the Supreme Court of Canada to consider in a future case.

[17] Overall, a court nearly always reads a patent through goggles supplied by the experts whom the judge considers to be credible and accurate. Because of that, in practice, the standard of review of palpable and overriding error will often apply. This Court has acknowledged this practical reality for a while now:

> While the construction of a patent is for the court, it is not initially to be undertaken simply in the manner a court would construe an ordinary contract or a statute, for example, but with the knowledge of the skilled artisan to the extent that such knowledge is revealed by expert evidence accepted at trial. In short, construction turns heavily on the evidence of a person skilled in the art. [emphasis added]

(*Unilever PLC v. Procter & Gamble Inc.* (1995), 61 C.P.R. (3d) 499 at pages 506-07, 184 N.R. 378 (Fed. C.A.).)

[18] Often the experts' testimony stretches beyond opinion evidence and goes into factual matters within their knowledge that are relevant to the construction exercise:

> The problem with treating questions of construction as pure questions of law is that they frequently are not. Although direct evidence as to the meaning of non-technical terms is inadmissible, the court does not reach its conclusion as to the meaning of the claim in a factual vacuum. Evidence as to the common general knowledge can frequently have an important bearing, as part of the factual matrix against which construction is decided, as can factual evidence about the consequences of the teaching of passages in the specification.

(*Novartis AG v. Dexcel-Pharma Limited*, [2008] EWHC 1266 (Pat), [2008] All E.R. (D) 97 at paragraph 21.) And, as is well-known, appellate review of first instance judges' findings on factual matters is conducted on the basis of palpable and overriding error.

[19] Of course, I accept that in a formal sense a patent is a "law" under the *Interpretation Act*. And courts to date have simply assumed that the formal designation of letters patent as laws determines the standard of review issue. But I do not agree. That is to allow the form – a "law" in the formal sense – to dictate substance. The common law relating to the standard of review, a matter of substance, needs to be separately considered.

[20] The rationales supporting an appeal court adopting a deferential approach to the construction of patents where expert evidence has played a significant role seem overwhelming to me: *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R 235, at paragraphs 8-37. How are appellate judges supposed to cleave off those aspects of claim construction that flow from the

trial judge's appreciation of expert evidence from the words of the claim *per se*? Can appellate judges really second-guess the trial judge, who, often over many days, has been educated in the relevant art and has seen and evaluated the experts? Who are the appellate judges to review on the basis of correctness, stepping into the shoes of the trial judge and imposing their own views of the matter?

[21] I do not accept that correctness review is required for consistency and certainty in the interpretation of patents. The doctrine of comity among judges will ensure there is sufficient consistency and certainty in the meaning of patents, just as it ensures consistency and certainty under the current approach to the standard of review: *Apotex Inc. v. Allergan Inc.*, 2012 FCA 308, 105 C.P.R. (4th) 371.

[22] I also note that a recent decision of the Supreme Court of the United States signals a growing acceptance that, as a practical matter, deference should be accorded to the interpretations of patents reached by those who have seen the experts and have evaluated them: *Teva Pharmaceuticals USA, Inc. v. Sandoz*, Inc., No. 13-854, 574 U.S. __ (2015).

[23] In considering the standard of review, it seems to me there is much to be said for drawing a distinction between "letters patent" and patent specifications: William L. Hayhurst, "The Distinction Between 'Letters Patent' and Patent Specifications: How Did We Get Where We Are?" (2006), 57 C.P.R. (4th) 161. Under this approach, "letters patent" under the *Interpretation Act* include only the certificate bearing the seal of the Canadian Intellectual Property Office issued to an inventor upon approval of her application. The patent application – as it existed

immediately prior to approval – instead becomes the patent specification and is not to be considered "letters patent" under the *Interpretation Act*.

[24] This distinction has the practical effect that only the certificate – the "letters patent" – will necessarily be reviewed for correctness. Interpretations of the specification may be then be reviewed on the basis of palpable and overriding error when they are heavily dependent on expert testimony, as they usually are. The specification remains a legal document, but even legal documents may be subject to review on a deferential standard: *Sattva Capital Corp. v. Creston Moly Corp.*, 2014 SCC 53, [2014] 2 S.C.R. 633.

[25] As I have said, however, I shall apply the standard of review as it exists on the books at the present time. And under that law, I see no grounds to set aside the judgment of the Federal Court based on its construction of the '426 Patent.

[26] Before the Federal Court, Cobalt argued that Claim 31 is limited to micronized drospirenone particles. The Federal Court disagreed holding that Claim 31 was not so limited.

[27] Claim 31 of the '426 Patent reads as follows:

> 31. A pharmaceutical composition comprising:
>
> from about 2 mg to about 4 mg of drospirenone particles, wherein the drospirenone is in a form, which when provided in a tablet containing 3 mg of drospirenone, has a dissolution such that at least 70% of said drospirenone is dissolved in 900 ml of water at 37° C. (~0.5° C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles;
>
> about 0.01 mg to about 0.05 mg of 17.alpha.-ethinylestradiol; and

> one or more pharmaceutically acceptable carriers; the composition being in an oral dose form, and the composition being effective for oral contraception in a human female.

[28] In this Court, Cobalt argues that the Federal Court misinterpreted Claim 31. Cobalt says that, properly construed, Claim 31 claims only drospirenone particles in "micronized" form. Cobalt would read into Claim 31, as an essential element, the word "micronized" as follows: "from about 2 mg to about 4 mg of micronized drospirenone particles".

[29] Cobalt develops its submission by pointing to stray phrases in the patent description to argue that the "purpose and intent of the invention was to achieve rapid dissolution through micronizing drospirenone":

> To ensure good bioavailability of the compound, it is therefore advantageously provided in a form that promotes rapid dissolution thereof. It has surprisingly been found that when drospirenone is provided in micronized form (so that particles of the active substance have a surface area of more than 10,000 $cm^2/g$ and the following particle size distribution…) in a pharmaceutical composition, rapid dissolution of the active compound occurs in vitro ("rapid dissolution is defined as dissolution of at least 70% over about 30 minutes, in particular at least 80% over about 20 minutes…) [emphasis in original]

(Cobalt's Memorandum of Fact and Law at paragraph 51, citing the '426 Patent at page 4.)

[30] Cobalt additionally points to Claims 3 and 38, both of which specifically claim spraying onto inert carrier particles, to argue that had the inventors intended Claim 31 to capture sprayed drospirenone particles they would have so specified.

[31] I reject Cobalt's submission. In my view, Cobalt is cherry-picking particular portions of the patent to support the result it wishes to reach. Patents are not to be construed in a tendentious

way. Rather, we must examine the patent as a whole construing the language of the claims with due regard to the inventor's purpose through the eyes of the skilled reader: *Whirlpool*, above.

[32] Claim 31 embraces all drospirenone particles that rapidly dissolve in the manner described in the claim, whether micronized or not. The word "micronized" is absent from Claim 31. Claim 31 embraces all drospirenone particles that meet the remaining limitations of the claim: "when [the drospirenone particles are] provided in a tablet containing 3 mg of drospirenone, [the drospirenone] has a dissolution such that at least 70% of said drospirenone is dissolved in 900 ml of water at 37° C. (~0.5° C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles."

[33] Examining the '426 Patent as a whole, one must conclude, as the Federal Court did, that Claim 31 embraces all rapidly dissolving drospirenone particles.

[34] The purpose of the invention was to provide good bioavailability of drospirenone through rapid dissolution. The inventors are clear throughout the patent that the particular means by which rapid dissolution is achieved is not important. The inventors provide two examples of ways to achieve rapid dissolution, and throughout the claims they intermittently claim one, both, or any drospirenone particle that achieves rapid dissolution. A considered reading of the whole patent confirms that Claim 31 is not limited to micronized drospirenone particles.

[35] For example, around the excerpt at page 4 of the ’426 Patent that Cobalt cites (above), we see other passages that confirm the Federal Court’s reading of the patent. At page 4, the patent states that “[t]o ensure good bioavailability of the compound, it is therefore advantageously provided in a form that promotes rapid dissolution thereof,” and that:

> Instead of providing the drospirenone in micronized form, it is possible to dissolve it in a suitable solvent, e.g. methanol or ethyl acetate, and spray it onto the surface of inert carrier particles followed by incorporation of the particles containing drospirenone on their surface in the composition.
>
> Without wishing to be limited to any particular theory, it appears that the in vitro dissolution rate of drospirenone is connected to the dissolution rate in vivo resulting in rapid absorption of drospirenone in vivo on oral administration of the compound. This is an advantage because isomerization of the compound in the gastric environment and/or hydrolysis in the intestive is substantially reduced, leading to a high bioavailability of the compound. [emphasis added]

[36] Later, at page 9, the ’426 Patent states:

> The composition of the invention may be formulated in any manner known in the pharmaceutical art. In particular, as indicated above, the composition may be formulated by a method comprising providing drospirenone and, if desired, ethinylestradiol in micronized form in said unit dosage form, or sprayed from a solution onto particles of an inert carrier in admixture with one or more pharmaceutically acceptable excipients that promote dissolution of the drospirenone and ethinylestradiol so as to promote rapid dissolution of drospirenone and preferably enthinylestradiol on oral administration. [emphasis added]

[37] Claim 1 (and dependent claims) of the ’426 Patent claim compositions wherein the drospirenone particles are provided in “micronized” form. Claims 3 and 38 both claim spraying each onto an inert carrier particle. Claim 31, in contrast, specifies neither that drospirenone should be micronized, nor that it should be sprayed. Had the inventors intended to limit Claim 31 to one form of drospirenone or another, they would have specified the form, as they did in Claims 1, 3 and 38. The context of the claims evidences the contrary intention.

[38] Therefore, for the foregoing reasons, I agree with the Federal Court's conclusion that Claim 31 is not limited to micronized drospirenone particles.

**(2) The allegation of non-infringement**

[39] Any of the defendant's activities that interfere with the patentee's exclusive rights under section 42 of the *Patent Act* infringe the patent: *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 at paragraph 34, citing H. G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969) at page 349.

[40] Following claim construction, the question that must be asked is whether the defendant's proposed product embodies each of the essential elements of a patent claim. If so, the patent is infringed: *Monsanto*, above at paragraph 30; *Free World Trust*, above at paragraphs 68 and 75. According to the Supreme Court of Canada, the standard of review for infringement – a question of mixed fact and law – is palpable and overriding error: *Whirlpool*, above at paragraph 76.

[41] On appeal, Cobalt argued that it would not infringe the'426 Patent because, properly construed, Claim 31 of the '426 Patent was restricted to pharmaceutical compositions containing micronized hormone. Since Cobalt alleged that its product does not contain any micronized hormone, Cobalt argued it could not infringe.

[42] However, as the Federal Court held – a holding I have confirmed to be correct – Claim 31 is not restricted to compositions containing micronized hormone. Properly construed, Claim 31

claims all pharmaceutical compositions which embody the listed essential elements of Claim 31, irrespective of whether the hormone particles are micronized.

[43] Given that Cobalt's allegation of non-infringement depended on a construction of Claim 31 that captured only micronized hormone particles, and given that Cobalt's only allegation of non-infringement was that its product did not contain those particles, Cobalt's allegation of non-infringement is not justified. The Federal Court reached that conclusion, and there is no basis upon which it can be set aside.

**(3) The allegation of invalidity of the '426 Patent based on obviousness**

[44] On appeal, Cobalt argued that its allegation that the '426 Patent was invalid for obviousness was justified.

[45] In particular, Cobalt alleged that the Federal Court failed to compare the inventive concept of Claim 31 to what the skilled reader would have thought and known as of August 31, 1999. According to Cobalt, instead of the skilled reader, the Federal Court considered what two Bayer employees who were not named inventors did in 1983-1984 and failed to consider relevant prior art: Appellant's Memorandum, at paragraphs 69-74.

[46] Under s. 28.3 of the *Patent Act*, R.S.C. 1985, c. P-4, a patent may not issue for an obvious invention. In considering obviousness, Courts typically apply a four-step test:

(1) (a) Identify the notional "person skilled in the art";

(b) Identify the relevant common general knowledge of that person;

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

(3) Identify what, if any, difference exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

(*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at paragraph 67.)

[47] *Sanofi-Synthelabo* did not mandate the above test in every case, but held that it would be "useful in an obviousness inquiry". Strict rules are inappropriate, since obviousness is a factual determination: *Sanofi-Synthelabo* at paragraphs 63 and 67.

[48] Obviousness is a question of mixed fact and law. Unless the application judge committed an extricable legal error, his obviousness analysis is subject to review for palpable and overriding errors: *Wenzel Downhole Tools*, above at paragraph 44.

[49] The Federal Court's reasons for rejecting the obviousness claim are suffused by factual appreciation, including the assessment of expert witnesses and their testimony. It found that the prior art "taught away" from the solution of the '426 Patent.

[50] The Federal Court found that drospirenone is an acid-labile compound. In the stomach, it is subject to rapid degradation to an inactive form. The prior art method of overcoming acid-degradation was to provide the particles with an enteric coating, so that they would only release drospirenone in less acidic areas of the gastrointestinal tract. It was surprising that rapidly dissolving drospirenone particles solved this problem, and it was contrary to what had been observed *in vitro*. Therefore, Claim 31 of the '426 Patent was not obvious.

[51] In concluding as it did, the Federal Court considered the expert evidence as at the relevant date (August 31, 1999) and, for many reasons, preferred the evidence of Dr. Davies to that of Dr. Pramar:

> [78] In cross-examination, Dr. Pramar admitted that she was unaware of any literature that addressed the isomerization of spironolactone at a pH of 1 (Q 46). She could not tell whether spironolactone was an oral contraceptive because that was not her area of expertise (Q 196). She could not say whether she was aware of the Krause references before she was given them by Bayer's Counsel (Q 198).
>
> [79] On the other hand, Dr. Davies appeared to be quite comfortable in discussing the references. He states in answer to question 667 of his cross-examination that the information brought forward through Dr. Pramar would not help come to the invention.

> [80] I prefer the evidence of Dr. Davies in this respect. As of August 1999, it was known that a combination of drospirenone and ethinylestradiol in amounts falling within the range stipulated in the claims of the '426 patent could be used as an oral contraceptive. However, what was not known is that the dissolution of the drospirenone in the stomach could be enhanced by providing it, without enteric coating, in a form such as micronized, so that it would dissolve rapidly. Contrary to what in vitro testing might demonstrate, the in vivo administration of such a drug would not result in undue isomerization in the stomach.
>
> [81] The inventive concept is, as I have stated, that, in 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.
>
> [82] The difference between the prior art and the inventive concept is the provision of the drospirenone comprised in micronized or other rapidly dissolving form to provide a successful oral contraceptive.
>
> [83] I find that the difference was not more or less self-evident. The prior art pointed away from providing an acid-labile drug such as drospirenone, in a rapidly dissolving form. Previous attempts were tested in vitro; the breakthrough was to ignore the in vitro results and test in vivo with the unexpected result.
>
> [emphasis added]

[52] In this Court, Cobalt basically invites this Court to re-weigh the evidence already considered by the Federal Court. In its submissions, it parsed the Federal Court's reasons, attacking them by taking us to the *minutae* of the evidence.

[53] On appeal, that is not our job. The standard of review is palpable and overriding error. That is indeed a high standard:

> [46] Palpable and overriding error is a highly deferential standard of review: *H.L. v. Canada (Attorney General)*, 2005 SCC 25, [2005] 1 S.C.R. 401; *Peart v. Peel Regional Police Services* (2006), 217 O.A.C. 269 (C.A.) at paragraphs 158-59; *Waxman* [*v. Waxman* (2004), 186 O.A.C. 201]. "Palpable" means an error that is obvious. "Overriding" means an error that goes to the very core of the outcome of the case. When arguing palpable and overriding error, it is not enough to pull at leaves and branches and leave the tree standing. The entire tree must fall.

> [47] In applying the concept of palpable and overriding error, it is useful to keep front of mind the reasons why it is an appropriate standard in a complex case such as this.
>
> …
>
> [49] Immersed from day-to-day and week-to-week in a long and complex trial such as this, trial judges occupy a privileged and unique position. Armed with the tools of logic and reason, they study and observe all of the witnesses and the exhibits. Over time, factual assessments develop, evolve, and ultimately solidify into a factual narrative, full of complex interconnections, nuances and flavour.

(*Canada v. South Yukon Forest Corporation*, 2012 FCA 165, 431 N.R. 286.)

[54] The Federal Court's finding that Cobalt's obviousness allegation was not justified discloses no extricable legal error, nor any palpable and overriding errors of mixed fact and law. It cannot be disturbed on appeal.

**(4) The allegation of invalidity of the '426 Patent based on lack of sound prediction of utility**

[55] On appeal, unless there is an extricable legal error, the soundness of a prediction is a question of fact: *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paragraph 71; *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2011 FCA 300, 97 C.P.R. (4th) 415 at paragraph 5.

[56] A patented invention must be useful at the time of the patent's Canadian filing date. To establish utility, the inventor may rely on a demonstration or a sound prediction. "Sound prediction is not a free-standing statutory requirement [but rather] is a way of showing that an

invention is useful when the invention has not been directly demonstrated to work": *Teva Canada Limited v. Novartis AG*, 2013 FC 141, 109 C.P.R. (4th) 1 at paragraph 164.

[57] Sound prediction requires that the patentee provide "a solid teaching"; it does not protect "a lucky guess" or "mere speculation." An inventor need not explain exactly why or how the invention works, but must provide in the patent the underlying knowledge supporting that it does work. See generally *Apotex Inc. v. Wellcome Foundation Ltd*., above at paragraphs 69, 70 and 83.

[58] A sound prediction requires three things:

- a factual basis for the prediction;
- an articulable and sound line of reasoning connecting the desired result and the factual basis; and
- proper disclosure of the factual basis and line of reasoning in the patent.

(*Apotex Inc. v. Wellcome Foundation Ltd.*, above at paragraph 70.)

[59] On appeal, Cobalt submits in its memorandum (at paragraphs 93-95 and 99) that the utility of Claim 31 across its scope was not demonstrated because only micronized drospirenone was tested. Consequently, Cobalt says that Claim 31 is invalid because it depends on an unsound

prediction that pharmaceutical compositions containing rapidly dissolving drospirenone particles, however created, would work.

[60] However, in making this submission, Cobalt has strayed from its notice of allegation. In it, Cobalt only alleged that Claim 31 lacked utility because micronized drospirenone had *not* been demonstrated or soundly predicted to work:

> 346. As of August 31, 2000, the patentee had not demonstrated the utility of the subject matter claimed in the 426 Patent and could not have soundly predicted the utility of this subject matter…
>
> 350. …the studies conducted by the patentee and reported in the patent are not predictive of the utility of, nor do they support a sound prediction on the part of the patentee that tablets made according to Example 1 having the in vitro dissolution profile evidenced in Example 2, in fact, result in the rapid absorption of drospirenone in vivo on oral administration of the compound.
>
> 351. The study conducted by the patentee with respect to bioavailability in vivo, as reported in Example 4, did not use a pharmaceutical composition containing micronized drospirenone particles. Instead, this study investigated the relative bioavailability of a tablet formulation containing 3 mg of non-micronized drospirenone…

[61] It is not open to Cobalt in prohibition proceedings under the NOC Regulations or appeals therefrom to stray from its notice of allegation: *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, 2002 FCA 290, [2003] 1 F.C. 402 at paragraph 22. Therefore, Cobalt's submission must be rejected.

**(5) The allegation of invalidity of the ’426 Patent based on insufficiency of disclosure**

[62] The Federal Court held that it need not consider Cobalt’s sufficiency allegation, because it depended on a construction that limited Claim 31 to micronized drospirenone (at paragraphs 101-102).

[63] In my view, this was in error. When one examines Cobalt’s allegations as to insufficiency in its notice of allegation, one sees that they concern constructions of Claim 31 which are broader than micronized drospirenone particles:

> 344. The specification of the ’426 Patent is insufficient to support a claim to drospirenone other than micronized drospirenone with the specific features set out in the specification. To the extent that independent claims 30 to 35 and 44 to 46, dependent claims 36 to 42 and 47 to 51, are interpreted to include drospirenone particles that are not micronized (for example, drospirenone that has a surface area of more than 10,000 cm2/g, but no particular particle size distribution), then the specification is insufficient to support these claims. [my emphasis]

Cobalt’s allegation was that if Claim 31 claimed more than micronized drospirenone particles, then the ’426 Patent disclosure was insufficient. Since the Federal Court correctly construed Claim 31 to be broader than just micronized drospirenone, it was necessary for the Federal Court to consider Cobalt’s insufficiency allegation. Accordingly, this Court must consider Cobalt’s allegation of insufficiency.

[64] Disclosure lies at the heart of the patent system. The enabling description of an invention in the specification of a patent is the *quid pro quo* for the monopoly under the *Patent Act*: *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*, [1981] 1 S.C.R. 504 at page 517, 122 D.L.R.

(3d) 203. Paragraphs 27(3)(*a*) and (*b*) set out the requirements that an inventor describe and enable the invention:

| | |
|---|---|
| **27.** (3) The specification of an invention must | **27.** (3) Le mémoire descriptif doit : |
| (*a*) correctly and fully describe the invention and its operation or use as contemplated by the inventor; | *a*) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur; |
| (*b*) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;… | *b*) exposer clairement les diverses phases d'un procédé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner, construire, composer ou utiliser l'invention; |
| [emphasis added] | [j'ai souligné] |

[65] Basically, paragraphs 27(3)(*a*) and (*b*) require the inventor to answer two questions: What is your invention? How does it work, in the sense of how to put it into operation? See *Consolboard*, above at page 520. The purpose of these paragraphs is to ensure that when the monopoly ends, the skilled reader, armed only with the specification, can put the invention into practice: *Consolboard* at pages 520-21, citing *Minerals Separation North American Corporation v. Noranda Mines, Limited*, [1947] Ex. C.R. 306 at page 316, 12 C.P.R. 99.

[66] In *Pioneer Hi-Bred*, the Supreme Court put the test as follows:

> The applicant must define the nature of the invention [What is your invention?] and describe how it is put into operation [How does it work?]. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates for insufficiency. The description must be such as to enable a person skilled in the art of the field of the invention to produce it using only the instructions contained in the disclosure… and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application. [comments added]

(*Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at page 1638, 25 C.P.R. (3d) 257.)

[67] The question whether the patent specification sets out in sufficiently clear and exact terms how the invention may be deployed is one of fact: *Apotex Inc. v. Lundbeck Canada Inc.*, 2010 FCA 320, 88 C.P.R. (4th) 325 at paragraph 116. The disclosure must be sufficient as of the date of filing: *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paragraph 90.

[68] An inventor need not disclose all modes of the invention. Paragraphs 27(3)(*a*) and (*b*) are satisfied if the inventor sufficiently discloses one mode: *Abbvie Corporation v. Janssen Inc.*, 2014 FC 55, 116 C.P.R. (4th) 399 at paragraph 166, rev'd on other grounds 2014 FCA 242; *Patent Rules*, S.O.R./96-423, paragraph 80(1)(*f*). Were it otherwise, the requirement that an inventor of a mechanical invention must disclose only the "best mode" contemplated, as specified by paragraph 27(3)(*c*) of the *Patent Act*, would be purposeless.

[69] Applying these principles to the '426 Patent, I find that the disclosure is sufficient. The invention is that "an oral contraceptive comprised of a combination of drospirenone and ethinylestradiol, the drospirenone may be provided in… rapidly dissolving form without an

enteric coat": Federal Court's reasons at paragraph 81. The inventor teaches the skilled reader that the invention can be practiced by preparing a pharmaceutical composition using micronized drospirenone particles: '426 Patent at page 4. The inventor has both described the invention and taught the skilled reader how to practice it.

[70] Therefore, I conclude that while the Federal Court erred in failing to adjudicate Cobalt's insufficiency allegation, it would not have affected Bayer's entitlement to a prohibition order. Cobalt's allegation is not justified.

**(6) The allegation of invalidity of the '426 Patent based on overbreadth**

[71] The Federal Court also held that it need not consider Cobalt's overbreadth allegation, because that allegation depended on a construction of Claim 31 that was limited to micronized drospirenone (at paragraphs 101-102).

[72] This was the same error the Federal Court made when it considered Cobalt's insufficiency allegation. The relevant portion of Cobalt's notice of allegation is as follows:

> 341. The specification teaches only the use of drospirenone in micronized form and defines this as having both a surface area of more than 10,000 cm2/g and a particular particle size of distribution.
>
> 342. Thus, the patentee provides that the subject matter of the 426 Patent is limited to micronized drospirenone with certain characteristics. However, independent claims 30 to 35 and 44 to 46, dependent claims 36 to 42 and 47 to 51, are not so limited and, if they are interpreted to include drospirenone particles that are not micronized (which would be incorrect in our view), then these claims are overbroad.

[73] The essence of Cobalt's overbreadth allegation was that if Claim 31 claimed more than micronized drospirenone particles, then it was overbroad. As with Cobalt's insufficiency allegation, following its construction of Claim 31, the Federal Court should have considered Cobalt's overbreadth allegation. Accordingly, I must also decide whether this allegation is justified.

[74] One example of overbreadth is where a patent claims more than it sufficiently discloses. If it does, then the overbroad claims are invalid: *Leithiser v. Pengo Hydra-Pull of Canada Ltd.*, [1974] 2 F.C. 954, 6 N.R. 301 (C.A.); *Farbwerke Hoechst Akiengesellschaft Vormals Meister Lucius & Bruning v. Commissioner of Patents*, [1966] Ex. C.R. 91, 50 C.P.R. 220, aff'd [1966] S.C.R. 604.

[75] In my view, Claim 31 is not overbroad.

[76] As described above, Claim 31 embraces all drospirenone particles which, when formulated into a tablet, have the required dissolution properties. And as also described above, the disclosure of the '426 Patent extends to drospirenone in forms other than micronized particles. Therefore Claim 31 is not broader than the invention disclosed. Rather, Claim 31 claims exactly what was invented – the particular solution to a particular problem.

[77] While the Federal Court erred in failing to adjudicate Cobalt's allegation of overbreadth, it would not have affected Bayer's entitlement to a prohibition order. Cobalt's allegation is not justified.

### (7) Conclusion on Cobalt's appeal concerning the '426 Patent (A-376-13)

[78] Cobalt has not established any reviewable errors in the Federal Court's decision relating to claim construction, obviousness, or lack of utility for lack of sound prediction. While the Federal Court ought to have considered insufficiency and overbreadth, it would not have prevented it from issuing a prohibition order pending the expiry of the '426 Patent.

[79] Therefore I would dismiss Cobalt's appeal.

## B. Bayer's appeal concerning the '728 Patent (A-385-13)

[80] In the Federal Court, Bayer applied for a prohibition order against the '728 Patent on the ground that Cobalt's allegation of non-infringement of Claim 8 was justified. The Federal Court dismissed the application.

[81] On appeal, Bayer begins by challenging the Federal Court's construction of the '728 Patent.

### (1) Patent construction

[82] The claim at issue on appeal reads as follows:

> 8. Use according to claim 1, whereby the estrogen is present in a dose of 20 µg of ethinylestradiol or an equivalent dose of 17β-estradiol and the gestagen is present in a dose of 75 µg of gestodene or an equivalent dose of levonorgestrel, cyproterone acetate or drospirenone. [emphasis added]

[83] The Federal Court rightly focused its analysis (at paragraph 109) on "where the shoe pinches," a drospirenone dose equivalent of 75 µg of gestodene (at paragraph 134):

> [134] I find that there is no certainty as to what precise dosage would be found to be the drospirenone equivalent of 75µg of gestodene. The most likely answer is that it is 2 mg, an amount that would suppress ovulation. To find otherwise would require the reader to scour the literature as of the relevant time, the date of publication, and either pick the highest number then available, or to attempt to make a reasoned choice among the numbers available. In neither case does any claim at issue define "distinctly and in explicit terms the subject matter of the invention" as required by subsection 27(4) of the *Patent Act*. [emphasis added]

[84] This paragraph of the Federal Court's reasons leaves the reader in some doubt about what was decided. On the one hand, that court appears to conclude that claim 8 is ambiguous. On the other, it appears to find that the drospirenone dose equivalent of 75 µg of gestodene is 2 mg. These conclusions are difficult to reconcile.

[85] On appeal, Bayer submits that the Federal Court did not find that the drospirenone dose equivalent of 75µg of gestodene is 2 mg because the claim was found to be ambiguous, and that the Federal Court's finding of ambiguity was a clear legal error. Additionally, Bayer says that if the Federal Court did find that the dose equivalent was 2 mg, then that finding was also a reversible error.

[86] To deal with this submission, it is necessary to look closely at the Federal Court's reasons. I disagree with Bayer's view that the Federal Court did not find 2 mg to be the drospirenone equivalent of 75µg of gestodene. On a fair reading of paragraph 134 of the Federal Court's reasons, the reference to 2 mg of drospirenone is a finding. Only two possibilities were

put to the Federal Court, 2 mg and 3 mg and the Federal Court clearly did not accept 3 mg: Federal Court's reasons, settling upon 2 mg as the "likely" dosage: at paragraphs 129-35.

[87] We should not attach too much significance to the Federal Court's use of the word "likely" and leap to a finding of ambiguity. Where a claim can be construed in a meaningful way, that construction is to be preferred over finding ambiguity: *Mobil Oil Corp. v. Hercules Canada Inc.* (1995), 63 C.P.R. (3d) 473 at pages 483-84, 118 N.R. 382 (Fed. C.A.); *Lubrizol Corp. v. Imperial Oil Ltd.* (1990), 33 C.P.R. (3d) 1 at page 26, 39 F.T.R. 161 (T.D.), var'd (1992), 45 C.P.R. (3d) 449, 150 N.R. 207 (C.A.); *Apotex Inc. v. Wellcome Foundation Ltd.* (1998), 79 C.P.R. (3d) 193 at page 287 (Fed. T.D.), aff'd on this point 10 C.P.R. (4th) 65, 262 N.R. 137 (C.A.), aff'd (S.C.C.), above. The Federal Court was able to construe the claim in a meaningful way and it arrived at 2 mg as the dosage, not the other alternative, 3 mg. Its further observations concerning ambiguity should be regarded as unnecessary.

[88] I would add that when the Federal Court set out the issues it had to decide, ambiguity was listed as an issue in relation to the '426 Patent only (at paragraph 29). Ambiguity was not raised for the '728 Patent. This adds force to my view that the Federal Court's comments about ambiguity were *obiter*.

[89] In short, the Federal Court found that Claim 8 posed a challenging question of construction. The Federal Court came close to being unable to construe the "drospirenone dose equivalent of 75µg of gestodene," but plainly it was able to, and did. The Federal Court found that the dosage equivalent was 2 mg.

[90] Adopting the appellate standard of review for decisions concerning the construction of patents, discussed above, I find no basis for setting aside the Federal Court's construction as argued by Bayer.

[91] Incorporating the "[u]se according to claim 1" and the Federal Court's finding on dosage equivalent of drospirenone, Claim 8 reads:

> Use of an oral dosage form comprising an estrogen… and a gestagen… for contraception for a female of reproductive age who has not yet reached premenopause, by administration of the form of dosage for 23 or 24 days, beginning on day one of the menstrual cycle, followed by 5 or 4 pill-free or placebo pill days, for a total of 28 days in the administration cycle, whereby the estrogen is present in a dose of 20 µg of ethinylestradiol or an equivalent dose of 17β-estradiol and the gestagen is present in a dose of 2 mg of drospirenone. [emphasis added]

[92] I begin by examining the '728 Patent as a whole. The '728 Patent describes, on pages 2-6, that reducing hormone dosages is desirable to minimize undesired side effects:

> The development of new oral contraceptives for females of reproductive age before premenopause was characterized during the last twenty years above all by the reduction of the estrogen and gestagen dosages.
>
> The reduction of the daily hormone dose was connected with the expectation to minimize the frequency of undesired side effects…
>
> It is assumed that a correlation exists above all between the level of the estrogen dose and the incidence of cardiovascular diseases. But the maintenance of the contraceptive effectiveness stands in the way of an extreme reduction of the daily estrogen dose. Although the ovulation-inhibiting effect of the low-dosed oral contraceptives is caused mainly by the gestagenic component, the estrogenic component also makes a significant contribution to the central inhibition action and to the ovarian suppression (ovulation inhibition). Moreover, the daily estrogen dose must not fall below the minimum dose ranges, so that a satisfactory cycle control can be assured…
>
> The object of this invention is an improved single-phase combination preparation for a female of reproductive age, who is not yet in premenopause, containing an estrogen and gestagen in each individual dosage unit, with the lowest possible

> estrogen content in each individual dosage unit, but also with a low total hormone content per administration cycle…
>
> The daily hormone dose is kept to a very low level here, while the usual 21-day intake is extended by two or three days… [emphasis added]

[93] The ’728 Patent does not disclose the dose equivalent of drospirenone: Federal Court’s reasons at paragraph 127. However, the purpose of the invention is to minimize the overall hormone dosage, while maintaining contraceptive efficacy by extending the dosege regimen by a few days. The particular advantage hoped to be achieved is the reduction in side effects. While not determinative, the patent also acknowledges the particular role of the gestagenic component in ovulation suppression.

[94] Cobalt’s expert pointed out, and the Federal Court accepted, that the dose equivalent depends on how the activity of the compound is measured and the intended pharmacological effect/endpoint: Federal Court’s reasons at paragraph 129.

[95] For contraception, there are several potential endpoints, including endometrial transformation (egg implantation inhibition), ovulation inhibition and clinical usage including a safety margin. The Federal Court accepted that the skilled reader would understand the relevant endpoint to be either ovulation inhibition or endometrial transformation: Federal Court’s reasons at paragraphs 130 and 134. In accordance with the patent’s direction to minimize hormone dosages, the Federal Court found that 2 mg drospirenone was the minimum dose to achieve contraception: Federal Court’s reasons at paragraph 134. I find no ground to interfere with this finding.

[96] On appeal, Bayer argued that the Federal Court considered the wrong endpoint, arguing that clinical use was the correct paradigm. Bayer urged the court to essentially re-weigh the expert testimony to find that 3 mg was the dosage equivalent. Absent palpable and overriding error, we cannot interfere with the Federal Court's assessment of the expert evidence and its preference for one expert over another.

[97] Bayer also urged this Court to consider a paper by Oelkers, published in 1995, the same year as the publication of the '728 Patent (June 29, 1995). Exactly when it was published in 1995 is unclear. A patent is read by the skilled reader as of its publication date: *Free World Trust*, above at paragraph 54. For the Federal Court to consider the Oelkers paper, Bayer had to establish that it was published prior to June 29, 1995. Bayer failed to do so and the Federal Court was correct not to consider it.

[98] Based on the foregoing, I am unable to accept any of Bayer's grounds of appeal regarding the construction of Claim 8 of the '728 Patent. The Federal Court was able to construct the necessary element "drospirenone dose equivalent of 75µg of gestodene" finding that it was 2 mg. That finding was not tainted by any reversible error.

**(2) Allegation of non-infringement**

[99] In a case such as this, infringement is a question of mixed fact and law that follows directly from claim construction. Claim 8 does not claim 3 mg of drospirenone – the amount

contained in Cobalt's combination oral contraceptive product. The Federal Court made no reviewable error in concluding that Cobalt's allegation of non-infringement was justified.

### (3) Allegation of invalidity of the '728 Patent based on improper subject-matter: method of medical treatment

[100] Cobalt submitted that Claim 8 of the '728 Patent was invalid because it impermissibly claimed a method of medical treatment. In light of my conclusion that Cobalt's allegation of non-infringement is justified, I need not deal with this submission. However, I wish to offer an observation for future consideration.

[101] The current law in this Court is that methods of medical treatment are not patentable: *Novartis Pharmaceuticals Canada Inc v. Cobalt Pharmaceuticals Company*, 2013 FC 985, 440 F.T.R. 1 at paragraphs 70-101, endorsed by this Court at 2014 FCA 17, 459 N.R. 17, in very brief reasons based on the particular arguments made. The provenance of this is *Tennessee Eastman Co. et al. v. Commissioner of Patents*, [1974] S.C.R. 111, 33 D.L.R. (3d) 459, a decision based on former subsection 41(1) of the *Patent Act*, now repealed. In his blog, "Sufficient Description," Professor Norman Siebrasse has forcefully advanced arguments of policy and logic against the current position. In my view, this calls for full consideration by this Court or the Supreme Court in a case where the issue is squarely raised on the facts.

### (4) Conclusion on Bayer's appeal concerning the '728 Patent (A-385-13)

[102] As Cobalt's allegation of non-infringement is justified, the Federal Court's dismissal of Bayer's application for prohibition must stand.

[103] Therefore, for the foregoing reasons, I would dismiss Bayer's appeal with costs.

## C. Proposed disposition

[104] I would dismiss both appeals with costs.

"David Stratas"

J.A.

"I agree
Wyman W. Webb J.A."

**PELLETIER J.A. (concurring reasons)**

[105] I agree with the reasons and conclusions of my colleague, save for paragraphs 16-24 which are not necessary for the disposition of this appeal.

"J.D. Denis Pelletier"
J.A.

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

| | |
|---|---|
| **DOCKETS:** | A-376-13 AND A-385-13 |
| **APPEAL FROM A JUDGMENT OF THE HONOURABLE MR. JUSTICE HUGHES DATED OCTOBER 22, 2013, NO. T-215-12** | |
| **DOCKET:** | A-376-13 |
| **STYLE OF CAUSE:** | COBALT PHARMACEUTICALS COMPANY v. BAYER INC. and BAYER PHARMA AKTIENGESELLSCHAFT and THE MINISTER OF HEALTH |
| **AND DOCKET:** | A-385-13 |
| **STYLE OF CAUSE:** | BAYER INC. and BAYER PHARMA AKTIENGESELLSCHAFT v. COBALT PHARMACEUTICALS COMPANY and THE MINISTER OF HEALTH |
| **PLACE OF HEARING:** | TORONTO, ONTARIO |
| **DATE OF HEARING:** | SEPTEMBER 11, 2014 |
| **REASONS FOR JUDGMENT BY:** | STRATAS J.A. |
| **CONCURRED IN BY:** | WEBB J.A. |
| **CONCURRING REASONS BY:** | PELLETIER J.A. |
| **DATED:** | MAY 4, 2015 |

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