Federal Court of Appeal  Cour d'appel fédérale

Date:20140522

Docket:A-470-12

Citation:2014 FCA 133

CORAM: **SHARLOW J.A.**
PELLETIER J.A.
MAINVILLE J.A.

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

ASTRAZENECA CANADA INC. AND ASTRAZENECA AB AND THE MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on October 28, 2013.

Judgment delivered at Ottawa, Ontario, on May 22 2014.

REASONS FOR JUDGMENT BY: PELLETIER J.A.

CONCURRED IN BY: SHARLOW J.A.
MAINVILLE J.A.

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REASONS FOR JUDGMENT

PELLETIER J.A.

[1] Pharmascience Inc. (Pharmascience) appeals from the decision of O'Keefe J. of the Federal Court (reported as *AstraZeneca Canada Inc. v. Pharmascience Inc.*, 2012 FC 1189, 105 C.P.R. (4th) 267) prohibiting the Minister of Health from issuing a notice of compliance to Pharmascience for its version of the drug omeprazole formulated using a low viscosity

hydroxypropyl methylcellulose (HPMC). AstraZeneca Canada Inc. (AstraZeneca) brought the application for prohibition in response to Pharmascience's notice of allegation which claimed that Canadian Patent No. 2,290,531 (the '531 patent) was invalid on a number of grounds including lack of utility and obviousness.

[2] For the reasons that follow, I am of the view that the appeal should be allowed.

I. THE PATENT IN ISSUE

[3] The '531 patent describes a multiple unit dosage form comprising enteric coating layered units of omeprazole, the (-) enantiomer of omeprazole (esomeprazole) or the magnesium salt of omeprazole, all of which are referred to as omeprazole. Omeprazole is useful for inhibiting gastric acid secretions in mammals, including humans. More specifically, the invention described in the patent is the use of a "specific quality" of HPMC, defined by reference to a specific cloud point, as a separation layer in an enteric coated oral dosage form of omeprazole with a view to reducing the amount of product discard due to a failure to meet the standard for release of omeprazole.

[4] Because omeprazole degrades in acid conditions, an oral solid dosage form must be protected from contact with gastric acid so as to reach the gastrointestinal tract, where it can be absorbed, intact. Such a dosage form can be protected from contact with acidic gastric fluid by an enteric coating. "Enteric" is defined in *The New Shorter Oxford Dictionary* (Oxford

University Press, Oxford, 1993) as "coated so that the contents are released in the intestine after passage through the stomach unaltered." Since the enteric coating is itself acidic, it will discolour or degrade the omeprazole if the latter is not protected by a separating layer. The prior art teaches the use of a separating layer consisting of low viscosity HPMC that will dissolve in intestinal fluid. The rate at which the separating layer dissolves and releases the omeprazole into the gastrointestinal tract is related to the water solubility of HPMC.

[5] The water solubility of HPMC decreases with increasing temperature due to polymer phase separation which results in the clouding of the polymer solution. Clouding of the polymer solution reduces light transmission through the solution. Cloud point is the temperature at which polymer phase separation occurs and is determined by measuring light transmission through the polymer solution. In the '531 patent, cloud point is defined as the temperature where light transmission of a polymer solution is 96% of the light transmission of the same solution prior to phase separation, measured using a particular instrument (or 95% using a different instrument).

[6] The patent recites that it has surprisingly been found that different batches of low viscosity HPMC, which meet all regulatory and pharmacopoeial requirements, may differ with respect to their ability to influence the rate of release of omeprazole in simulated intestinal fluid. The '531 patent teaches that low viscosity HPMC with a cloud point of not less than 45.6 degrees Celsius as measured using a Mettler FP90/FP81C instrument is desirable in meeting the regulatory standard for the release rate for the oral administration of omeprazole. When

measured using a different instrument, a spectrophotometer, with the cloud point defined as 95% light transmission, the cloud point occurs at 44.5 degrees Celsius.

[7] Figures 1 and 2 of the patent deal with the characteristics of two different quantities of HPMC, labelled Type A and Type B. The patent uses the words "type" and "batch" of HPMC ambiguously. Generally speaking, a type of HPMC is a commercially available grade of HPMC. Examples given in the evidence are METHOCEL E5, E10 and E15 manufactured by Dow Chemical. Batch would normally refer to a quantity of a type of HPMC manufactured in a single operation and designated by a lot or batch number. As a result, a single type of HPMC is represented by multiple batches of that product. Confusingly, the patent labels samples from different batches of a single type of HPMC as Type A and Type B. At other times, the patent uses type and batch interchangeably. This led to certain difficulties which will be discussed below.

[8] Figure 1 of the patent is a graph representing the degree of light transmission of Type A and Type B HPMC as a function of temperature. Figure 2 is a graph of the light transmission of the same two batches of HPMC, measured using a different instrument, as a function of temperature.

[9] Figures 1 and 2 show a difference in the cloud point between the two batches of HPMC.

[10] Figure 3 is a graph showing the percentage of omeprazole released from pellets formulated using Type A and Type B HPMC as a binder as a function of time. Figure 3 shows that there is a difference in the percentage of release over time as between pellets using Type A and Type B HPMC.

[11] The patent also describes the results of an experiment in which enteric coated pellets with a separation layer of Type A or Type B HPMC were first exposed to simulated gastric juice at 37 degrees Celsius for 2 hours and then exposed to a buffer solution. The details of the precise formulation of the pellets and of the solutions to which they were exposed are found at pages 9-12 of the patent. The extent of the release of omeprazole in the buffer solution was then determined by liquid chromatography. The results of the experiment are shown in the following table which appears at p.11 of the patent.

Pellets containing HPMC	Cloud point [°C] Ex. 1 (n=2)	Cloud point [°C] Ex. 2 (n=1)	Release of omeprazole from pellets [%]
Type A	44.4	42.5	69 (60-84)
Type B	47.5	47.2	93 (93-94)

[12] The cloud point determinations shown under Ex. 1 were performed using a Mettler instrument while those shown under Ex. 2 were performed using a spectrophotometer equipped with a heating coil and stirring function.

[13] The patent describes the significance of these experimental results as follows:

> As can be seen from the table above with the HPMC Type A the release of omeprazole was not acceptable for a pharmaceutical product, but with the HPMC Type B none of the discussed problems with the rate of release of omeprazole in an oral formulation occurred.
>
> Results from a number of experiments with different batches of HPMC indicate that HPMC with a cloud point of at least 45.6° C is desirable in fulfilling the regulatory requirements on rate of release of omeprazole, when cloud point determination is performed in a commercial Mettler instrument.
>
> Patent at p. 12.

[14] The "discussed problems with the rate of release of omeprazole" are found at p. 4 of the patent where it is said that:

> One problem which can be avoided by the new formulation and use of a specific quality of HPMC is that the amount of product discard can be reduced. From an economical aspect it is advantageous to specify and check the HPMC quality and keep the discard of produced pharmaceutical product low.

[15] The "regulatory requirements on rate of release of omeprazole" are defined in the patent by reference to the marketing approval for Losec capsule formulations which require that at least 75% of the omeprazole must be released within 30 minutes in a buffer solution. Losec is a commercially marketed formulation of enteric coated esomeprazole, the (-) enantiomer of omeprazole.

[16] The claims of the patent all deal with the use of low viscosity HPMC with a cloud point equal to or greater than that specified in the patent in the manufacture of an enteric coated oral dosage formulation of omeprazole, the (-) enantiomer of omeprazole or the magnesium salt of omeprazole.

II. THE DECISION UNDER APPEAL

[17] In my view, this case can be decided on the basis AstaZeneca failed to put before the Court the evidence necessary to support the conclusion that Pharmasciences' allegations of lack of utility were not justified. In keeping with this perspective, I will limit my discussion of the decision under appeal to the issue of utility.

[18] In his analysis, the application judge first dealt with Pharmascience's allegation that the patent did not disclose an invention because it merely ascertained the properties of a known substance.

[19] Pharmascience argued that the cloud point of low viscosity HMPC was consistently higher than the cloud point identified in the patent, when tested according to the teachings of the patent. Pharmascience relied on the testing done by one of its experts, Dr. DesBrières in support of its position. Dr. DesBrières conducted cloud point determinations on five types of commercially available low viscosity HPMC, namely METHOCEL E5, E6 and E15 from Dow Chemical and Pharmacoat 603 and 606 from Shin-Etsu Corporation. Dr. DesBrières' results are summarized in the table reproduced at paragraph 56 of the application judge's reasons. It is sufficient for present purposes to note that the cloud point was, in each case, higher than the cloud point taught by the patent.

[20] AstraZeneca argued that Pharmascience's experimental results were of no use as they were based on an incorrect reading of the patent. AstraZeneca's position was that the patent taught that there was batch to batch variability of the cloud point within one type of low viscosity HPMC as opposed to variation between different types of HPMC, as tested by Dr. DesBrières. This is the difficulty to which I referred to earlier which arose from the patent's ambiguous use of the words batch and type.

[21] Very early on in his analysis (at paragraph 164), the application judge accepted the evidence of AstraZeneca's expert, Dr. Bodmeier to the effect that the patent referred to different batches of the same type of HPMC, and not to different types of low viscosity HPMC. According to Dr. Bodmeier, a person skilled in the art would understand that a specific type of HPMC would have been selected for manufacturing purposes and that batch-to-batch variations therefore refer to different batches of that type.

[22] As a result, the application judge accepted AstraZeneca's argument that the invention deals with batch to batch variation within a type of HPMC which can be tested so as to ensure consistent release of omeprazole in accordance with the regulatory standard. Because of this variability, the application judge found that the patent disclosed more than the physical characteristics of a known compound.

[23] On the question of utility, the application judge began by surveying the law of utility. He found that where no particular result has been promised, a mere scintilla of utility will suffice;

but where a specific result has been promised, then that result must be achieved. The application judge found that the '531 patent taught that:

> [t]hat predetermining the CP of a particular batch of low viscosity HPMC and limiting selection for use in enteric coated oral pharmaceutical formulations to those batches with CPs that exceed the claimed CP, will ensure that the release rate of omeprazole will meet the marketing standard. Without this teaching, some batches of low viscosity HPMC may be used in the manufacture of enteric coated oral pharmaceutical formulations; formulations that must later be discarded for failure to adequately release omeprazole.
>
> Reasons, at paragraph 195.

[24] I take this to mean that the utility of the invention is found in the ability to identify by means of the cloud point those batches of a type of HPMC which will consistently meet the regulatory standard for the release of omeprazole.

[25] The application judge summarized Pharmascience's allegations with respect to utility at paragraph 189 of his Reasons:

> In this case, Pharmascience submits that the '531 Patent did not indicate that any tests were performed to demonstrate that low viscosity HPMC actually possessed the claimed utility and no substantive data was provided to demonstrate the promised utility. Once utility is challenged, Pharmascience submits that it is insufficient to state that tests were run; evidence must be filed of those tests. In addition, as AstraZeneca promised commercial utility, the patent must be held to that standard, a burden that Pharmascience submits AstraZeneca has failed to meet.

[26] In this regard, the application judge found at paragraph 172 of his Reasons that "Pharmascience has met its evidentiary burden of putting its case into play […] the burden of

proof now rests on AstraZeneca to establish that Pharmascience's allegations […] are not justified."

[27] In response to Pharmascience's allegations, AstraZeneca pointed to the statement in the patent that "results from a number of experiments with different batches of HPMC indicate that HPMC with a cloud point of at least 45.6° C is desirable in fulfilling the regulatory requirements on rate of release of omeprazole." According to AstraZeneca, this statement was sufficient to meet its burden for proving utility.

[28] The application judge accepted AstraZeneca's submission and held that "[a]lthough this evidence is relatively non-descriptive, I do not find that the law requires that AstraZeneca meet a higher burden": Reasons, at paragraph 191.

[29] In closing, the application judge found that Pharmascience had failed to demonstrate that the invention did not work at all or did not do what the specification promised it would do. In effect, the application judge found that AstraZeneca had shown that Pharmascience's allegations of lack of utility were not justified.

III. ISSUES

[30] The issues to be decided are the following:

1. What is the standard of review?
2. Has AstraZeneca shown that the allegation of lack of utility is not justified?

IV. WHAT IS THE STANDARD OF REVIEW?

[31] An appeal from the decision of a Federal Court judge on a prohibition application is the equivalent of an appeal from a judgment rendered after trial. An application judge is a primary fact-finder who draws conclusions after having reviewed all of the evidence; his position is indistinguishable from that of a trial judge. There is accordingly no reason to depart from this Court's existing practice of applying the standards of review established in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 to application judges in the context of pharmaceutical litigation: see *Abbott Laboratories v. Canada (Minister of Health)*, 2010 FCA 168, [2010] F.C.J. No. 817 at paragraph 9, *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 54, [2014] F.C.J. No. 224, at paragraph 20, *Teva Canada Ltd. v. Novartis Pharmaceuticals Canada Inc.*, 2013 FCA 244, [2013] F.C.J. No. 1108, at paragraphs 11-12, *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64, [2008] F.C.J. No. 208, at paragraphs 18-22.

V. HAS ASTRAZENECA SHOWN THAT THE ALLEGATION OF LACK OF UTILITY IS NOT JUSTIFIED?

[32] Due to the peculiar nature of notice of compliance proceedings, the issue of the onus of proof has been the subject of considerable discussion in the jurisprudence. The peculiarity at the root of the issue is the fact that the applicant for an order of prohibition must tailor its application to respond to the respondent's notice of allegation. As a result, the applicant finds itself in the

position of having to show that the respondent's allegations are not justified. But, because of the presumption of validity set out at subsection 43(2) of the Act, the jurisprudence has held that the respondent has the onus of putting its allegations "into play". There has been some debate as to what standard of proof the respondent must meet to discharge this onus.

[33] The competing views as to what standard of proof the respondent had to meet were reviewed in *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 971, [2007] F.C.J. No. 1271 (*Pfizer*), aff'd 2009 FCA 8, at paragraphs 44-51. Some of the jurisprudence has held that the respondent must prove its allegations on a balance of probabilities while other cases have held that the respondent must simply lead sufficient evidence to give its allegations "an air of reality". After reviewing the jurisprudence and the distinction between evidential burden and persuasive burden, the judge in *Pfizer* concluded that:

> In this context, what constitutes "any evidence to the contrary" [the phrase used in subsection 43(2) of the Act] is, as the Court of Appeal put it in paragraph 109 of the *Pfizer* 2007 FCA 209 decision, evidence which is sufficient to put the allegations of invalidity "in play" and which is not clearly incapable of establishing those allegations. That does not require Apotex to meet the standard of proof on a balance of probabilities but rather, to satisfy the Court that the evidence discloses an air of reality for its allegations of invalidity and that Pfizer must meet its legal burden. To interpret the effects of the presumption otherwise would lead to the absurd result that both parties would bear the burden of establishing the invalidity or validity of the patent at issue on the same standard.
>
> *Pfizer*, at paragraph 51.

[34] *Pfizer* was affirmed by this Court, without comment on this point, in *Pfizer Canada Inc. v. Apotex Inc.*, 2009 FCA 8, [2009] 4 F.C.R. 223

[35] My object in sketching this out is to contrast it with the application judge's treatment of this question. Pharmascience, as the respondent in the prohibition proceedings, had the onus of leading evidence sufficient to put the allegations of invalidity 'in play'. For his part, the application judge reasoned that:

> In this proceeding, Pharmascience limited its submissions to the grounds of: not an invention (#6), lack of utility (#7), insufficient disclosure (#1) and lack of inventive step obviousness (#5). As all of these grounds were adequately raised by Pharmascience in the NOA [notice of allegation], I find that Pharmascience has met its evidentiary burden of putting its case into play. Thus, pursuant to subsection 6(2) of the NOC Regulations, the burden of proof now rests on AstraZeneca to establish that Pharmascience's allegations on these issues are not justified.
>
> Reasons, at paragraph 172.

[36] With respect, the onus on Pharmascience to put its allegations "into play" cannot be satisfied by the mere fact of detailing its allegation in its notice of allegation. In holding that the amount of detail in the notice of allegation satisfied the onus on Pharmascience to put its allegations into play, the application judge failed to identify and to apply the legal standard that Pharmascience was required to meet. That is an error of law reviewable on a standard of correctness: *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, at paragraph 33.

[37] Later in his Reasons, the application judge turned to the question of whether AstraZeneca had met the burden which fell upon it once Pharmascience's allegations were put in play. He accepted AstraZeneca's argument that the reference in the patent to "results from a number of experiments" which showed that use of a low viscosity HPMC with a cloud point above that described in the patent was "desirable in fulfilling the regulatory requirements on rate of release

of omeprazole", was sufficient to meet the burden of proving utility. He held that "Although this evidence is relatively non-descriptive, I do not find that the law requires that AstraZeneca meet a higher burden": Reasons, at paragraph 191.

[38] In fact, the law does require a higher burden., namely proof on the balance of probabilities: *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209, [2007] F.C.J. No. 767 The application judge erred in law in failing to apply the correct legal standard to the question of the proof of utility.

[39] The application judge's reasoning appears to be based on a misunderstanding of the jurisprudence of this Court. At paragraph 190 of his Reasons, the application judge quoted a long passage from this Court's decision in *Pfizer Canada Inc. v. Novopharm Ltd*, 2010 FCA 242, [2012] 2 F.C.R. 69 (*Pfizer 2010*), in which the Court discussed the question of whether an inventor must include evidence of demonstrated utility in the patent. This Court concluded that the inventor was not required to do so. It then went on to say the following, which appears to have lead the application judge into error:

> So long as the disclosure makes reference to a study demonstrating utility, there do not appear to any other requirements to fulfill section 2.
>
> Pfizer 2010, at paragraph 90.

[40] This sentence must be understood in the context of a proceeding in which it was alleged that, at the material time, the utility of the invention had neither been demonstrated nor soundly predicted: *Pfizer 2010*, at paragraph 19. The Court found that, in the case of demonstrated utility,

it was not necessary to include evidence of utility in the patent document itself. Evidence of utility could be presented in invalidity proceedings. All that was required to establish that utility was demonstrated as opposed to soundly predicted was a reference in the patent to a study demonstrating utility.

[41] The application judge appears to have misunderstood this sentence and taken it as a description of the kind of evidence which would establish utility.

[42] As a result, the application judge erred in law with respect to both the legal standard to be met by Pharmascience in order to put its allegations into play, and the legal standard AstraZeneca was required to meet to prove that its invention was useful.

[43] Due to these errors, the application judge did not apply his mind to the question of whether Pharmascience led sufficient evidence to put its allegation of lack of utility into play and, if it had, whether AstraZeneca showed, on a balance of probabilities, that Pharmascience's allegations of lack of utility were not justified. Since the application judge did not resolve the conflicts between the evidence of the parties' experts on these issues, we cannot draw the appropriate conclusions from his findings. It accordingly falls to us to do this analysis as at first instance.

[44] The application judge found that the utility of the invention was its desirable effect on the release of omeprazole such that product discard due to failure to meet the regulatory standard is reduced Product discard is reduced because low viscosity HPMC with a cloud point equal to or higher than that taught in the patent "ensure[s] consistent release of omeprazole in accordance with the marketing standard": Reasons, at paragraph 175-176.

[45] The patent contains the results of experiments conducted by the inventor which purport to prove that the invention has the asserted utility. The experimental data shown in Figures 1 and 2 of the patent appear to show that different batches of the same type of low viscosity HPMC have different cloud points. While this supports the surprising finding which gave rise to the invention, it is not, in and of itself, relevant to the issue of utility. Figure 3 of the patent and the experiment whose results are shown in the table found at page 11 of the patent (the Table Experiment) are directly relevant to the question of utility.

[46] According to the patent, these experiments demonstrate two things. First, different batches of the same type of HPMC can have different cloud points. Second, batches of HPMC with a cloud point above the cloud points stipulated in the patent (44.5° C or 45.6° C, depending upon the method of measurement) consistently release more that 75% of omeprazole after 30 minutes of exposure to simulated intestinal fluid.

[47] The table at page 11 compares two batches of HPMC: Type A and Type B. Type A is a batch of low viscosity HPMC whose cloud point is below those specified in the patent while

Type B is another batch of the same type of low viscosity HPMC whose cloud point exceeds those specified in the patent. The table shows the cloud points of the two Types as measured by each of the instruments described in the patent. The table also shows the results of the experiment which tested the rate at which omeprazole is released from a formulation made with Type A and Type B low viscosity HPMC. For ease of reference, I reproduce the table below:

Pellets containing HPMC	Cloud point [°C] Ex. 1 (n=2)	Cloud point [°C] Ex. 2 (n=1)	Release of omeprazole from pellets [%]
Type A	44.4	42.5	69 (60-84)
Type B	47.5	47.2	93 (93-94)

[48] The table shows that for Type A the rate of release fluctuated between 60 and 84 per cent with, presumably, a mean release rate of 69%. On the other hand, the Type B samples all tested above 75% (93-94%) with a mean release rate of 93%.

[49] Pharmascience's expert, Dr. Colombo, criticized these test results, saying that the protocol used in the United States Pharmacopeia (USP) required that a first group of 6 samples should be tested with a further 6 or 12 being tested, depending on the variability of the results obtained: A.B. Vol. 6, p. 1978, paragraph 63. Dr. Colombo also stated that the results of these tests should be submitted to a statistical analysis: A.B. Vol. 6, p. 1971, paragraph 48. Dr. Colombo noted that the number of samples tested is not given in the patent and the number of studies conducted for each Type of HPMC was not known.

[50] Dr. Colombo also conducted a statistical analysis of the data contained in the patent using a statistical tool known as the Similarity Factor. When applied to the data in the patent, this complex formula generated a score which indicated that the "dissolution profiles of core units containing HPMC Type A and HPMC Type B are similar": A.B. Vol. 6, pp. 1981-1982. Dr. Colombo concluded from this analysis that the allegation that "the rate of omeprazole release is affected by either HPMC Type A or HPMC Type B when used as a binding agent as described in Example 3 on page 11 and demonstrated by the dissolution profiles in Figure 3 is unfounded": A.B. Vol. 6 p. 1982, paragraph 73.

[51] I understand Dr. Colombo's criticism to be directed to the validity of the test results. I take him to be saying that the test results shown in Figure 3 and in the data from the Table Experiment are insufficient, in themselves, to prove that the release of omeprazole is directly and consistently related to the cloud point of the batch of low viscosity HPMC used in the formulation of an oral dosage form of omeprazole. If the test results are not valid, then they do prove that all types of low viscosity HPMC which have a cloud point equal to or higher than the cloud points described in the patent will meet the regulatory standard for the release of omeprazole, and thereby reduce the amount of product discard. In short, I understand the impact of Dr. Colombo's evidence on this point to be that the utility of the invention is not proved by the experimental results contained in the patent.

[52] In my view, this evidence is sufficient to put Pharmascience's allegation of lack of utility into play. This evidence, if uncontradicted, supports the conclusion that the utility of the

invention has not been proved. As a result, AstraZeneca was called upon to prove the utility of the invention described in the '531 patent.

[53] AstraZeneca's only witness was Dr. Bodmeier whose evidence consisted of providing background information and criticizing the evidence of Pharmascience's witnesses. With respect to Dr. Colombo's evidence, Dr. Bodmeier disputed the latter's assertion that accepted research methods required that 12 samples be tested. In his view, 3 to 6 samples are normally all that is tested: A.B. Vol. 7 p. 2366. Dr. Bodmeier attached to his affidavit examples of Dr. Colombo's research in which only 3 samples were tested, thereby showing that Dr. Colombo did not implement in his own research the protocol which he sought to impose on the inventors.

[54] As for Dr. Colombo's calculation of the Similarity Factor, Dr. Bodmeier said the following:

> Dr. Colombo applies this calculation without having the necessary information to perform these calculations or without mentioning his assumptions to perform these calculations. For example, according to the guidance, in order to apply this similarity testing, at least 12 test and reference units have to be used, the coefficient of variation should not be more than 20% for the early time points and not more than 10% for the other time points and only one time point after 85% releases should be considered. Dr. Colombo does not have the required information from the '531 patent and thus cannot apply this testing or draw conclusions from his calculations.
>
> A.B. Vol. 7, p. 2368, paragraph 87.

[55] Dr. Bodmeier did not provide further information about the experiments described in the patent and, in particular, the Table Experiment.

[56] In my view, Dr. Bodmeier's evidence is non-responsive to the real issue raised by Dr. Colombo's evidence which is that it is not known how many samples were tested in the experiments reported in Figures 1 to 3 and in the table. While Dr. Bodmeier made the point that it was sufficient to test 3 samples to obtain valid results, he did not assert that the inventors had, in fact, tested 3 samples. Without knowing how many samples were tested and what the individual results were, it is impossible to assess the significance of the results. Without being able to assess the results, it is impossible to say that the experiments actually prove that which the inventors claim they prove.

[57] My conclusion is confirmed by Dr. Bodmeier's criticism of Dr. Colombo's Similarity Factor calculation. Dr. Bodmeier's assertion that Dr. Colombo did not have and was not able to obtain from the patent the information required to perform the Similarity Factor calculation, while putting into question Dr. Colombo's calculation, confirmed that there was insufficient information in the patent to allow a third party to confirm the validity of the experimental results, statistically or otherwise. Since the patent did not provide that information and Dr. Bodmeier did not supply it, it follows that there is no evidence before the Court capable of establishing that low viscosity HPMC with a cloud point equal to or higher than that described in the patent will consistently result in release rates in excess of the regulatory standard, thereby reducing the amount of product discard.

[58] As a result, I am of the view that AstraZeneca has not satisfied the onus of showing that Pharmascience's allegations of invalidity are not justified.

VI. CONCLUSION

[59] I would therefore allow the appeal with costs in this Court and in Federal Court, set aside the order of the Federal Court, and dismiss the application for a prohibition order.

"J.D. Denis Pelletier"

J.A.

“I agree
K. Sharlow J.A.”

“I agree
Robert M. Mainville J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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