Federal Court Cour fédérale

Date: 20180820

Docket: T-2224-16

Citation: 2018 FC 847

Ottawa, Ontario, August 20, 2018

PRESENT: The Honourable Madam Justice McVeigh

BETWEEN:

VALEANT CANADA LP/VALEANT CANADA S.E.C.

Applicant

and

RANBAXY PHARMACEUTICALS CANADA INC. AND THE MINISTER OF HEALTH

Respondent

and

VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L.

Respondent/Patentee

PUBLIC JUDGMENT AND REASONS

(Confidential Judgment and Reasons issued August 7, 2018)

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I. Introduction

[1] The Applicant, Valeant Canada LP/Valeant Canada S.E.C. [Valeant], applied to this Court on December 22, 2016, under the prior *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133 [*NOC Regulations*] for an order prohibiting the Minister of Health [the Minister] from issuing a Notice of Compliance [NOC] to the Respondent, Ranbaxy Pharmaceuticals Canada Inc. [Ranbaxy]. This prohibition order would prevent Ranbaxy from marketing Ran-Bupropion XL Tablets (150 mg and 300 mg), an extended relief medication that Valeant says infringes Patent No 2,524,300 [the 300 Patent]. The 300 Patent expires in five (5) years on August 8, 2023.

II. Background

A. *The Parties*

[2] The Applicant Valeant is a "first person" as required by the *NOC Regulations* and licenses the 300 Patent from Valeant Pharmaceuticals Luxembourg S.A.R.L.

[3] The Respondent Ranbaxy is a "second person" as stipulated in the *NOC Regulations.* As the *NOC Regulations* require, Ranbaxy served Valeant with a Notice of Allegation [NOA] dated November 8, 2016, giving notice that it had asked the Minister to issue a NOC for Ran-Bupropion XL Tablets.

B. *The 300 Patent*

[4] The 300 Patent is titled "Modified-Release Tablet of Bupropion Hydrochloride". The 300 Patent consists of one independent claim and 93 dependent claims. The 300 Patent discloses and claims a daily anti-depression medicine that improves patient compliance with extended drug release, which Valeant markets as "Wellbutrin XL".

[5] The 300 Patent was filed under the Patent Co-Operation Treaty, and has an international filing date of August 8, 2003, an international publication date of February 24, 2005, and was issued in Canada on October 28, 2008.

C. *Claim 1(iii)*

[6] Ranbaxy limited its argument in its NOA to non-infringement and made no validity attacks on the 300 Patent's claims. The only issue is whether Ranbaxy is justified in alleging that its product does not infringe the 300 Patent.

[7] Ranbaxy's argument is that its product falls outside of claim 1(iii) of the 300 Patent — namely, its tablets are not comprised of a permeation enhancer in the amount of "about 20% to about 40%" of the moisture barrier dry weight. Since claim 1 is the sole independent claim in the 300 Patent, Ranbaxy argued that its tablets cannot infringe any of the other claims in the 300 Patent as they are all dependent claims.

[8] Claim 1 in its entirety is set out below, with claim 1(iii) emphasized:

> A modified-release tablet comprising:
>
> (i) a core comprising an effective amount of pharmaceutically acceptable salt of bupropion, a binder, a lubricant and optionally other conventional excipients;
>
> (ii) a first control-releasing coat surrounding said core wherein said first control-releasing coat comprises a water-insoluble water-permeable film-forming polymer, a plasticizer and a water-soluble polymer, wherein the ratio of the water-insoluble water-permeable film-forming polymer to the water-soluble polymer is from about 3:4 to about 5:3; and
>
> (iii) **a moisture barrier surrounding said first control-releasing coat, wherein said moisture barrier comprises an enteric polymer and a permeation enhancer and optionally comprises a plasticizer and wherein the <u>permeation enhancer</u> is present in an amount of from <u>about 20% to about 40%</u> of the moisture barrier dry weight;**

> wherein the modified release tablet is bioequivalent to Wellbutrin® or Zyban®/Wellbutrin® SR tablets over a 24 hour period when administration of said modified-release tablet is as a once-a-day bupropion treatment regimen to a patient in need of such administration and wherein more than 10% of the pharmaceutically acceptable salt of bupropion is released in one hour in 0.1N HCL or less than 75% of the pharmaceutically acceptable salt of bupropion is released in 45 minutes in pH 6.8 buffer.
>
> [emphasis and underline added]

[9] Silicon dioxide is the preferred permeation enhancer in the 300 Patent, in the amount of "about 20% to about 40%" of the moisture barrier dry weight. Ranbaxy argues that the word "about" in the 300 Patent means plus or minus 10%, which works out to a range of 18% to 44%. And while Ranbaxy's formulation also uses silicon dioxide as the permeation enhancer, it argues it is present in an amount below the range claimed in the 300 Patent — specifically, [redacted] of the moisture barrier dry weight.

[10] But Valeant argues that two other chemicals in Ranbaxy's product — polyethylene glycol [PEG] and triethyl citrate [TEC] should not be limited to how Ranbaxy characterises them in its formulation and would be included as permeation enhancers and therefore are included in the weight calculation.

[11] Ranbaxy argues that in its Ran-Bupropion XL Tablets, these two chemicals are plasticizers and not permeation enhancers just as they are in the 300 Patent when the Patent is constructed purposefully.

[12] If I include these chemicals (as argued by Valeant) in the total moisture barrier dry weight, that would bring Ranbaxy's tablets up to [redacted] and well within the range of "about 20% to about 40%". If the permeation enhancer is found to be within the range of "about 20% to about 40%" then it infringes the 300 Patent.

[13] Valeant presented further argument that the word "about" should be construed to mean within a range of "10% to 45%" of the moisture barrier dry weight. This would mean the Ranbaxy Ran-Bupropion XL Tablet falls within this range and infringes the 300 Patent based on silicon dioxide alone or if PEG and TEC are included as permeation enhancers.

[14] In the alternative, Valeant argues that, even if PEG and TEC are not used in the permeation enhancer calculation, "permeation enhancer" is not an essential element. If a permeation enhancer is not essential then the Ranbaxy formulation infringes the 300 Patent as it has all the other essential elements.

[15] The submissions sometimes referred to PEG 1450, and sometimes to PEG 6000. At the hearing, it was confirmed that whether we discussed PEG 1450 or PEG 6000 is immaterial to this NOC and in this decision it is just referred to as PEG.

[16] For the reasons below, I will dismiss this application.

III. Issue

[17] The issue is:

A. Did Valeant satisfy the Court on a balance of probabilities that Ranbaxy's formulation for Ran-Bupropion XL tablets infringes the 300 Patent?

[18] To answer the issue I must answer the following questions:

(a) Is the "permeation enhancer" element in a range of about 20% to about 40% of the moisture barrier dry weight essential?

(b) What is the proper construction of the term "permeation enhancer"?; and

(c) What is the proper construction of the term "about"?

IV. Expert Evidence

[19] The evidence is comprised of expert witness affidavits. The affidavits are limited to issues of claim construction and infringement. The experts were all highly qualified and assistive to the Court.

[20] The Applicant's expert evidence came from two witnesses. The Applicant described Dr. Timko as a "practical expert" and Dr. Allen as an "academic". Dr. Timko provided his opinion on all the issues before the Court. Dr. Allen did not opine about the meaning of the word "about".

- Dr. Timko has a Ph.D. in Pharmaceutical Sciences from Rutgers University and over 40 years of experience in the pharmaceutical industry (including experience with modified release formulations). He also holds several patents for sustained release formulations, and is the author and co-author of peer-reviewed journal articles as well as

technical publications. For over 35 years, he worked at two large pharmaceutical companies (AstraZeneca LP and Ortho Pharmaceutical Corporation) where he filled a variety of roles.

- Dr. Allen has a Ph.D. in Pharmaceutics from the University of Texas at Austin, and is currently the CEO of Midwest Institute of Research and Technology. He is also Professor Emeritus of the University of Oklahoma College of Pharmacy. He is an expert in pharmaceutical formulation and pharmaceutical compounding and has over 40 years of experience as a pharmacist and pharmaceutics consultant, including for the U.S. Food and Drug Administration. He is the Editor-in-Chief of a highly regarded pharmacy reference book, and is the founder and Editor-in-Chief of the International Journal of Pharmaceutical Compounding.

[21] The Respondent relied on one expert witness who opined on all issues:

- Dr. Laskar has a Ph.D. in Pharmaceutical Sciences from Oregon State University, and is an expert in pharmaceutics. Dr. Laskar has over 35 years of experience formulating drugs and holds a number of U.S. patents related to drug formulations. He was previously an Assistant Professor of Pharmacy at the College of Pharmacy University of Illinois-Medical Centre, and was an Associate Professor of Pharmacy in the School of Pharmacy at Creighton University. In 1982, he left academia to work for Allergan. Currently, Dr. Laskar is President of Paul Laskar Associates Inc., a pharmaceutical research and development consulting service. He has experience with solid oral dosage formulations, but is primarily an ophthalmic and dermatological formulator.

[22] Valeant argued that Dr. Laskar received the Ranbaxy formulation before he rendered his opinion, and his evidence should be given less weight as it could be tailored or have a tainted construction due to knowing the Ranbaxy formulation. Valeant supported their position by arguing that Dr. Laskar could not have otherwise known to specifically deal with the terms at issue (paragraph 21 of his affidavit) in his claim construction, and submitted that his evidence was result driven. Since Valeant's experts were not provided with Ranbaxy's NOA until after they had provided their opinions, Valeant further argued that their blinded approach should have the Court give more consideration to their experts than to Dr. Laskar.

[23] I agree that the Supreme Court of Canada [SCC] has mandated that claims are construed without influence by the alleged infringing product. But that is not what occurred here. Here, Ranbaxy's counsel focused its expert on the terms needing construction, which is acceptable (*Teva Canada Innovation v Apotex Inc*, 2014 FC 1070 at para 96 citing *Shire Biochem Inc v Canada (Health)*, 2008 FC 538 at para 22).

[24] Dr. Laskar's affidavit explains he was asked to provide his opinion about specific terms: "in particular, my opinion of how the skilled person would understand the phrases "plasticizer" and "permeation enhancer" as used in the 300 Patent description and claims." He was also asked for his opinion of the word "about" as used in claim 1. After this discussion, he was given the affidavits of Drs. Allen and Timko to review and comment on. This is not, of course, the same as influencing an expert with the alleged infringing formulation.

[25] While it would certainly leave no doubt if counsel had waited until after Dr. Laskar gave his opinion before sending him the Ranbaxy materials, I do not believe Dr. Laskar reviewed or was influenced by his knowledge of the Ranbaxy formulation at the time he provided his opinion. In Dr. Laskar's affidavit, he deposed that he received the documents in August 2017 but "did not review this material at that time." He explained the reason he provided his opinion to counsel in September 2017 is because he was traveling and counsel was changing law firms. In addition, during the cross-examination—though not asked directly—he does not say he read the material beforehand. What he does agree to quite candidly is that he received the materials before he gave his opinion. Such was indicated during cross-examination when opposing counsel summarized the evidence given as he had been "provided with the patent and Ranbaxy's information and that [he] provided [his] opinions all in the scope of around the same time in September".

[26] In addition, Dr. Laskar's evidence (directed by counsel to what needed constructing) was not given in a way that would breach the Code of Conduct for Expert Witnesses. I get no whiff of tailored evidence from Dr. Laskar's evidence and will not give it less weight, as I do not believe he was influenced by the Ranbaxy formulation. His evidence was as fair and impartial as all Valeant's experts (who knew who both the Applicant and Respondent are, and so would of course surmise the positions of the parties).

[27] Valeant agreed that Dr. Laskar is an expert, but argued another reason I should not prefer his evidence is because the majority of his work is with eye and skin formulations. On the other

hand, Valeant argued I should rely on its experts because they both have extensive experience with solid oral dosage forms (tablet formation).

[28] I will give no less weight to Dr. Laskar's evidence because of him having more experience in one area than another, he has ample expertise in tablet formulation he just has more in eye and skin formulation.

V. Analysis

A. *The Law*

[29] The burden rests on Valeant to satisfy the Court, on a balance of probabilities, that Ranbaxy's allegation of non-infringement is not justified (*Bayer Inc v Cobalt Pharmaceuticals Co*, 2013 FC 1061 at para 32 [*Cobalt*], aff'd 2015 FCA 116 [*Cobalt FCA*]).

[30] In all cases, claims are construed prior to considering infringement issues (*Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 43 [*Whirlpool*]).The principles of claim construction were set out by the SCC in three cases: *Whirlpool* at paras 49-55, *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at paras 44-54 [*Free World Trust*], and *Consolboard Inc v MacMillan Bloedel (Saskatchewan) Ltd*, [1981] 1 SCR 504 at 520. A summary of the principles derived from these decisions is that:

- claims are read from the perspective of the person of ordinary skill in the art [POSITA] who is equipped with the common general knowledge. They are construed as of the date of publication in an informed way, done with a purpose and a mind willing to understand;

- fairness and predictability are promoted by maintaining the inventor's intent. Evidence of this intent is derived from the language of the claims, in a way that is sympathetic to accomplishing the inventor's purpose; and
- both the disclosure and the claims reveal the nature of the invention, and while the construction of the claims must be neither benevolent nor harsh, it must be reasonable and fair to both the patentee and the public.

[31] The Court will use these principles to undergo a purposive analysis of the scope of the claims (*Zero Spill Systems (Int'l) Inc v Heide,* 2015 FCA 115 at para 41). In the usual case, the Court relies on expert testimony to construe the claims purposively. The experts assist with understanding the POSITA's perspective and how to read the claims in light of the common general knowledge (*Cobalt FCA* at para 14). The POSITA's perspective is used because the claims are addressed to this POSITA, who is not just any ordinary member of the public (*Free World Trust* at para 44).

[32] As put forward by Ranbaxy, both of Valeant's expert witnesses came to different constructions of the 300 Patent. Based on this alone, Ranbaxy argues that Valeant must fail. But claim construction is a question of law, and while expert testimony enlightens the Court, enlightenment is not the end of the matter (*Novartis Pharmaceuticals Canada Inc v RhoxalPharma Inc*, 2005 FCA 11 at para 53). Indeed, it is a question of law, and I may "adopt a construction of the claims that differed from that put forward by the parties" (*Whirlpool* at para 61). I pause here to echo Justice Roy's comments in *Bombardier Recreational Products Inc*

v Arctic Cat Inc, 2017 FC 207 at paragraphs 298-299 [*Arctic Cat*] and remind the parties that the Court room is not a place devoid of common sense:

> 298 The mind willing to understand will be open to the purpose and intent disclosed by the patents. I was struck at trial by some attempts that were made by some of the expert witnesses to favour a reading of the patents that would lead to a construction of some of the essential elements that can only be described as defying any common understanding of language.
>
> 299 It may be worth repeating that claim construction is a question of law. As such, it is a question for the Court that will receive the assistance of experts for the purpose of ascertaining how those skilled in the art would construe the patent. But I wish to stress that common sense is not excluded from the Court room. The expert assists the Court in order to put the trial judge in a position to interpret the patents and their claims in a knowledgeable way. I repeat. Claim construction precedes the examination of possible infringements and the validity of claims. The use of experts is not enhanced when their interpretation is tainted by some pre-ordained outcome.

Since this hearing *Arctic Cat* was upheld by the Federal Court of Appeal (see 2018 FCA 125).

[33] After determining who the POSITA is, the Court will determine which of the claimed elements are essential and which are non-essential, with the presumption that all the elements are essential (*Free World Trust* at paras 57, 68, 75). This presumption is rebutted if either a contextual reading of the claims illustrates that the inventor intended for the element to be non-essential (*Whirlpool* at para 68) or if the POSITA would understand that changing the element would not change how the invention works or would not change its structure (*Free World Trust* at para 20).

B. *The POSITA*

[34] Not unexpectedly, all three experts presented to assist the Court are in fact far more qualified than the POSITA would be in this situation. As noted above, I do not believe any of the experts were tainted by a pre-ordained outcome.

[35] The experts and the parties are in substantial agreement regarding the POSITA's attributes on the relevant date (the publication date of February 24, 2005). Dr. Allen's evidence was that the POSITA would have a pharmacy degree and at least one year of pharmaceutical industry experience. Dr. Timko felt a POSITA should have a degree in pharmacy or pharmaceutics (or an equivalent), as well as a few years of experience in developing drug formulations. However, Dr. Laskar believed the POSITA would have even more education and experience. He felt that a POSITA would have a Ph.D. in either pharmacy, chemistry, chemical engineering or a related field with 3 to 5 years' experience in pharmaceutical formulation development focusing on solid dosage forms, or alternatively, a M.Sc. or B.Sc. degree and over 5 years' relevant experience.

[36] Although the experts are largely in agreement and the Court has found in the past that this is not a significant difference (*Cobalt* at para 38), I nevertheless considered all the views of the experts, and came to my own conclusion about who the POSITA is. I did so as this is a judicial function (*Pollard Banknote Limited v BABN Technologies Corp*, 2016 FC 883 at paras 82-83).

[37] I find that a POSITA would have a pharmacy degree and at least three years of experience in drug formulation and compounding, or have a degree in a related field (see para 35 above for examples of related fields) with five or more years' experience working in the field of drug formulation and compounding.

C. *The Claims*

(1) The Prosecution History

[38] Ranbaxy argued that I should consider the prosecution history as this matter fit within what it described as the "objective fact exception" in *Distrimedic Inc v Dispill Inc,* 2013 FC 1043.

[39] Valeant opposed and relied on numerous cases—*Merck & Co v Apotex Inc*, 2006 FC 524 at paragraphs 117-121 including my recent pronouncement in *Safe Gaming System v Atlantic Lottery Corp,* 2018 FC 542 at paragraph 55, that followed *Free World Trust* at paragraph 66—as examples where the Court did not consider extrinsic material to the patent itself.

[40] At the hearing, I advised the parties that I was unconvinced by Ranbaxy's arguments and confirm here that I am not considering the prosecution history for the same reasons as articulated in *Safe Gaming System v Atlantic Lottery Corp* at para 55.

(2) The Construction

[41] As set out above, Valeant and Ranbaxy focused their argument on the proper construction of **permeation enhancer** and **about** in claim 1(iii) as well as if permeation enhancer is an essential element. The parties are in agreement there are several other essential elements but only these are at issue.

(a) Is the "permeation enhancer" element in a range of about 20% to about 40% of the moisture barrier dry weight essential?

[42] Both Drs. Laskar and Timko opined that permeation enhancer is an essential element. Dr. Allen pronounced that a "key essential element in issue in this matter is the permeation enhancer in the moisture barrier" then moved on to discuss the percentages in relation to the infringement issue. But then Dr. Allen opined that it "may be" essential. However, he did include it in his chart titled "Essential Elements" within his affidavit.

[43] I considered if a POSITA would see the element as substitutional and understand that a change would not make a difference. Dr. Laskar's opinion points out that, unlike other substances listed in the claims, nothing in the patent says a permeation enhancer is optional. Further, his opinion is supported by Dr. Timko and somewhat by Dr. Allen's. Based on two experts saying yes and one saying maybe, I find that permeation enhancer is an essential element.

[44] As for the range, Dr. Timko opined that "about 20% to about 40%" is not an essential element. Dr. Timko explained it is not essential because all that is required is bioequivalence. Valeant also points to paragraph [0091] of the 300 Patent's description, which says that the amount of moisture barrier does not significantly impact the drug release characteristics.

[45] Dr. Allen opines "That said, a percentage in the range identified may be essential for this specific formulation." He then considered it essential for the purposes of his report.

[46] Dr. Laskar's opinion is that "about 20% to about 40%" of permeation enhancer is an essential element because claim 1 specifically requires the formulation to contain a permeation enhancer as part of the moisture barrier in an amount of about 20% to about 40%. Again nothing in the claims said it is optional, which is unlike other substances claimed, and so Dr. Laskar opined that it is the inventors' intent that it is an essential element.

[47] I find that the permeation enhancer in the amount of "about 20% to about 40%" is an essential element, and prefer Dr. Laskar's opinion on this. Although I have been asked to turn to the description which may imply the weight is optional, the claims hold the meaning (*Free World Trust* at para 66). Claim 1 unambiguously states that the permeation enhancer must be in the claimed percentage of the moisture barrier dry weight.

[48] In summary, I find that both "permeation enhancer" and "about 20% to about 40% of the moisture barrier dry weight" are essential elements in the 300 Patent. Accordingly, I have

considered the range of permeation enhancer as an essential element of claim 1 of the 300 Patent for the purpose of my analysis in this report.

*(b) What is the proper construction of the term "permeation enhancer"***?**

[49] Claim 1 states that the tablet, in addition to a core (i)and a first release coating (ii) , must have a moisture barrier (iii) that is composed of an enteric polymer, a permeation enhancer, and optionally a plasticizer. Claim 1 then finishes by saying that it must be "bioequivalent to Wellbutrin® or Zyban®/Wellbutrin® SR tablets over a 24 hour period".

[50] Valeant's position is that "permeation enhancer" can be a single substance or a combination of substances (based on claim 55 (see Appendix A)), and that the practical reality is PEG and TEC are permeation enhancers.

[51] Ranbaxy argued that Valeant's experts erred by using a functional rather than a purposive construction. Based on the language of the 300 Patent, Ranbaxy's expert says that PEG and TEC are not permeation enhancers.

[52] I agree that Valeant's experts did err by undergoing a functional approach. For example, Dr. Allen opined that a POSITA would look at the U.S. patents cited in the 300 Patent and "review these background patents and see the role of PEG as a permeation enhancer in addition to a plasticizer, which would be consistent with the common general knowledge at the time." Dr. Allen provided a chart comparing four of the U.S. patents. The chart lists PEG as a plasticizer for three of the U.S. patents. In all three U.S. patents it is noted that the release

through the coating is due to the presence of both PEG and another chemical. In the fourth U.S. patent, PEG is not listed as a plasticizer but is listed as a permeability modifying agent. Based on these U.S. patents, Dr. Allen's opinion is that a POSITA reading the 300 Patent would conclude that PEG's role was as a permeation enhancer in addition to a plasticizer based on what PEG is known to have been claimed as being in the U.S. patents. The other two experts' opinions did not include any of the seven U.S. patents which are mentioned in the 300 Patent, of which Dr. Allen mentions four that he sees as relevant.

[53] In addition to the U.S. patents, Dr. Allen believed a POSITA would understand that PEG is a permeation enhancer based on the article by J Kim et al, "The effect of pore formers on the controlled release of cefadroxil from a polyurethane matrix" (2000) *Intl J Pharmaceutics* 29, from the College of Pharmacy, Pusan National University in South Korea. This article is about: "Bacterial adhesion, colonization onto biomaterial surfaces and subsequent infectious complications are common reasons for the failure of many medical devices and implants such as, cardiovascular implants, catheters and urinary tract access." The purpose of the paper was to prevent or reduce infections by developing a method to prevent bacterial growth on the surface of a polymeric device. Due to the difference in scope, I do not believe this article falls within the common general knowledge of our POSITA in 2005 as this has nothing to do with compounding and drug formulation.

[54] Dr. Allen does then turn to the language of the 300 Patent, and he pointed out that it defines "permeation enhancer" as a "(i) hydrophilic substance; (ii) which allows water to enter;

(iii) without physical disruption of the coating." He states that "permeation enhancer" includes channels, voids, pores, or holes in the film that allow water to migrate.

[55] Dr. Allen's construction is how a substance functions and not what the 300 Patent says the permeation enhancer is in the 300 Patent.

[56] Valeant's other expert, Dr. Timko, also errs by using a functional analysis. He opines that PEG and TEC can function as:

> 87 …
>
> Attached as Exhibit "I" is a copy of the excerpts for triethyl citrate and various PEGs from the 1995 edition of the *Handbook of Pharmaceutical Additives* (Michael and Irene Ash, Gower Publishing Limited, 1995, pp. 660-667, 719-720, 829-829).
>
> 88 Because both triethyl citrate and PEG 1450 and 6000 exhibit good aqueous solubility, in addition to their function of helping in film formation, they can readily dissolve when placed in contact with the gastrointestinal fluids and, thus enhance the release of drug from the tablet matrix through the film coating. In this manner, they act as permeation enhancers. Attached as Exhibit "J" is a copy of an excerpt from *The Theory and Practice of Industrial Pharmacy* (2nd ed., Leon Lachman, Herbert A. Lieberman, and Joseph L. Kanig, Editors, Lea & Febiger, 1976, Chapter 12 – Tablet Coating, pp. 368-377), which discusses film-coatings.

[57] By taking the above quoted references together, Dr. Timko adds "that the properties of triethyl citrate and PEG lend themselves well to being not only plasticizers, but also permeation enhancers, in tablet coatings." He does not, however, consider how PEG and TEC are claimed in the 300 Patent claim 1(iii) of the moisture barrier itself and instead only looked how PEG and TEC could function.

[58] Dr. Timko does turn to the patent when opining about whether excipients have multiple functions. In particular, he refers to the 300 Patent where it says PEG may both increase hydrophilicity of the moisture barrier and also act as a glidant:

> [0087] …It is well known in the art that depending on the intended main function, excipients to be used in tablets are subcategorized into different groups. However, one excipient can affect the properties of a drug or the tablet as a whole in a series of ways, and many substances used in tablet formulations can therefore be described as multifunctional. Thus, the polyethylene glycol 1450 used in the plasticizer combination for the moisture barrier serves not only to increase the hydrophilicity of the moisture barrier, but also acts as a glidant.

[59] In his primer on drug formulation, Dr. Timko explained that a glidant reduces "friction and cohesion among the different excipients and API in the formulation and promote powder flow."

[60] In summary all this to say that the 300 Patent says PEG can be a glidant. Dr. Timko's did not opine that a glidant is a permeation enhancer. Nowhere in his affidavit, his primer, or in his cross-examination, does Dr. Timko say that a glidant is a permeation enhancer. So it does not follow that he reads the 300 Patent and when it says PEG is a glidant then it is a glidant but when the 300 Patent says PEG is a plasticizer he says it is a permeation enhancer.

[61] Dr. Timko cannot have it both ways. He followed the wording of the patent regarding the description of a glidant, yet turns to function to describe what, in his opinion, PEG does in the 300 Patent. He opines that PEG, in addition to its function as a plasticizer, is known to function as a permeation enhancer. In the words of the 300 Patent, PEG is a plasticizer and a glidant. So when the 300 Patent says PEG is a glidant or a plasticizer it does not follow that PEG is a

permeation enhancer unless you look at functionality. His focus on the function of PEG does not follow *Free World Trust* where the SCC held that the focus should be on the claim language and a purposive construction (at para 66).

[62] Valeant's experts have opined that PEG and TEC are acting as permeation enhancers in the Ranbaxy formula. For example, Dr. Timko stated that "at least some portion of the plasticizers in Ran-Bupropion XL may also be acting as a permeation enhancer." And Dr. Allen's opinion is that both PEG and silicon dioxide are permeation enhancers in Ranbaxy's tablets. In respect of Ranbaxy's formula Dr. Allen says "[r]egarding water permeability, when [PEG] is used as a plasticizer in film coats, it tends to increase their water permeability."

[63] Valeant has speculated about TEC and PEG acting as a permeation enhancer in the Ranbaxy product, but speculation does not satisfy its onus. Dr. Timko said only that "some" portion "may" be acting as a permeation enhancer, but was unable to give an unqualified answer.

[64] Dr. Allen's opinion relies on literature that discusses coats but not moisture barriers. In particular, he relied on JC Price, "Polyethlene Glycol" in RC Rowe, PJ Sheskey & Weller PJ, *Handbook of Pharmaceutical Excipients*, 4th ed, (Washington DC: American Pharmaceutical Association, 2003) at 454-459 [the Handbook], as well as D Hennig & H Kala "The Influence of plasticizers on the permeability of polymethacrylates films (Eudragit RS)" (1986), 41 Pharmazie H.5, at 335-338 [*Pharmazie*]. The article in *Pharmazie* is of no assistance because, with the exception of one short paragraph, the copy provided to the Court is untranslated. When the

Handbook is read it is clear the authors are only discussing PEG's use in a coating and not in the moisture barrier part of the tablet that includes a permeation enhancer.

[65] The 300 Patent teaches us that the plasticizer in the control releasing coating is sprayed on to the tablet core and dried before the moisture barrier is applied.

- [1002] … The tablet cores are then coated with the control–releasing coat formations shown in Table 3;
- Next the patent says in [0104] "…the dried and cooled coated tablet cores are next coated with the moisture barrier formulation shown in Table 5" (reproduced below);
- PEG is the listed plasticizer in Table 3 (see Appendix B);
- At [0103] the two different tablet coatings are discussed in the 300 Patent;
- The control releasing coat at paragraphs, [0072]-[0083] and Table 3;
- The moisture barrier coat in paragraphs [0084]-[0110] and Table 5.

[66] What is evident is that the first control-releasing coat in claim 1(ii) formulation of the 300 Patent is of no concern in this NOC proceeding as it is the construction of claim 1(iii) of the moisture barrier that surrounds the first control-releasing coat that speaks of a permeation enhancer which is the issue.

[67] This means that a POSITA would understand that the recipe of the formulation for the 300 Patent separates the two coats and their different ingredients. The formulation for the control-releasing coat in claim 1(ii) and the formulation for the moisture barrier found in claim 1(iii) can be likened to having one recipe for an iced cake. The recipe separates the

ingredients and methods for making the icing and the cake. You cannot just mix all the ingredients and methods together. Butter may be used as an ingredient in both but when looked at purposively it would be for different purposes.

[68] Dr. Timko repeatedly explains his reasoning is based on the function of the drug. But as each counsel explained to their experts, what is required is a purposive construction. This involves looking to the claim language to determine the invention—using an analysis of the functional equivalence to construe the claims is inconsistent with Canadian law (*Eurocopter v Bell Helicopter Textron Canada Ltée*, 2013 FCA 219 at paras 84, 96).

[69] Valeant argues that the Court should reject Dr. Laskar's interpretation because he improperly narrowed "permeation enhancer" in two ways. First, by reading Ranbaxy's formula prior to claim construction, and second by using the 300 Patent's disclosure to improperly narrow the claims. As I found above, Dr. Laskar did not read the Ranbaxy formula beforehand and I do not agree that he narrowed the claims.

[70] Ranbaxy's expert, Dr. Laskar, based his opinion on "permeation enhancer" in the context of the 300 Patent and used a purposive construction.

[71] When Dr. Laskar looked at the 300 Patent, he found that permeation enhancer and plasticizer each had a specific meaning, and that PEG was consistently used in the 300 Patent as a plasticizer or a glidant. For example, Dr. Laskar points out that at paragraph [0024] of the 300 Patent the preferred plasticizer is named as PEG 1450, and at paragraph [0030] it states the

moisture barrier's preferred plasticizer is a combination of PEG and the preferred organic ester is TEC. Other examples he provided are paragraph [0078] where PEG is named as a plasticizer, paragraph [0087] where PEG can be a combination of a plasticizer and a glidant, and Table 5 where PEG is referred to as part of the plasticizer combination along with TEC:

TABLE 5

MOISTURE BARRIER FORMULATION

Ingredients	150 mg			300 mg		
	A (mg/%)[1]	B (mg/%)	C (mg/%)	A' (mg/%)	B' (mg/%)	C' (mg/%)
Methacrylic Acid Co-Polymer[2]	4.59/2.48	4.59/2.52	4.59/2.40	10.99/2.9	4.88/1.42	6.86/1.91
Plasticizer Combination (D+E)[3]	(D=0.46 E=0.23)	(D=0.46 E=0.23)	(D=0.46 E=0.23)	(D=1.1 E=0.56)	(D=0.49 E=0.25)	(D=0.69 E=0.35)
	0.69/0.38	0.69/0.38	0.69/0.36	1.66/0.44	0.74/0.21	1.04/0.29
Permeation enhancer[4]	1.72/0.93	1.72/0.95	1.72/0.90	4.11/1.08	1.83/0.53	2.57/0.71
Purified Water[5]	*	*	*	*	*	*
Dry weight of moisture barrier	7/3.78	7/3.85	7/3.66	16.76/4.42	7.45/2.18	10.47/2.91

[1] The mg/% values represent the total proportion of the ingredient in relation to the tablet dry weight

[2] poly(methacrylic acid, methyl methacrylate) 1:1 (Eudragit® L 30 D-55)

[3] D=Polyethylene Glycol 1450 (Carbowax®), E=Triethyl Citrate

[4] Silicon Dioxide (Syloid® 244)

[5] Evaporated during drying

[72] Paragraph [0029] of the 300 Patent is another example that Dr. Laskar says supports his opinion that the inventors saw PEG as a separate compound from any permeation enhancers. This paragraph says that the moisture barrier is comprised of three elements: an enteric/acrylic polymer, a plasticizer and a permeation enhancer, and that they are present in a ratio of about 13:2:5.

[73] In Dr. Laskar's opinion, the POSITA would know that calculating a three-part ratio like this requires three separate elements. He could not point to anywhere in the 300 Patent where it said how to calculate such a ratio if PEG was acting as both a permeation enhancer and a plasticizer. He concluded that the POSITA would not include PEG as a permeation enhancer in the 300 Patent.

[74] Valeant also argues that in order to construe this patent, the Court must consider dependant claim 55. The reference to claim 55 came about for the first time in Dr. Allen's cross-examination when questioned about Table 5 (reproduced above) being very specific and why he did not mention it in his opinion. When Dr. Allen was asked whether silicon dioxide is the only permeation enhancer in the 300 Patent, Dr. Allen pointed to claim 55 and paragraph [0088], because they both list permeation enhancers, one of which broadly is "hydrophilic polymers". He said that his report concludes that PEG is a hydrophilic polymer. Therefore, based on claim 55, he did not believe silicon dioxide was "necessarily" the only permeation enhancer. And although PEG and TEC are not explicitly mentioned, he said: "So this claim space we can use silica and [PEG] that it is considered a permeation enhancer." He also confirmed that he had recently discussed claim 55 with counsel. When pressed, he said he did not mention claim 55 or paragraph [0088] in his affidavit, but adds that hydrophilic polymers have always been considered to include PEG, and he listed PEG as a permeation enhancer in the table he created and included in his affidavit.

[75] Consistent with the rest of the patent, Table 5 lists PEG and TEC as plasticizers and the permeation enhancer named is silicon dioxide. Dr. Allen's reference to claim 55 reads like a

strained last minute addition to fit the narrative. Though Dr. Allen does state it is his idea, the evidence is not in his affidavit and was made only after the opposing expert had given his critic of Dr. Allen's opinion, and after a discussion with counsel.

[76] It is unfair to give a broader interpretation to this patent than what is provided in the language of the claims. Furthermore, though he refers to paragraph [0088] as support, Dr. Allen ignores the distinction made between PEG and permeation enhancer in paragraphs [0087 and 0088]. I will give little weight to this linkage between the dependant claim 55, paragraph [0088], and the construction of permeation enhancer in the context of the 300 Patent.

[77] Dr. Laskar in his cross-examination, when questioned extensively about hydrophilic polymers listed in claim 55, his answers were that the 300 Patent only includes those permeation enhancers that compile with the definition in paragraph [0014] of the 300 Patent. Though he did not discuss paragraph [0014] of the 300 Patent in his affidavit, he had no reasons to as claim 55 was not referenced in this context in the affidavits of the other experts.

[78] Dr. Laskar stated that PEG is a hydrophilic polymer that does not comply with the definition used in paragraph [0014]. Of the list in claim 55, he said to fit the description found in [0014] he would exclude PEG as well as lactose, colloidal silicone, sodium chloride, as "… I would eliminate those hydrophilic polymers that are water soluble". This is because they do not comply with the definition in the 300 Patent. To support his opinion, he refers to the same definition of "permeation enhancer" that Dr. Allen refers to, but Dr. Laskar focuses on the words within the definition and not possible functions. Dr. Laskar points out that the 300 Patent's own

definition [0014] that excludes those permeation enhancers which would physically disrupt the coat: “a hydrophilic substance, which allows water to enter without physical disruption of the coating”. He states that PEG “would result in physical disruption of the coating by virtue of the polyethylene glycol dissolving when exposed to water and thereby creating a defect in the coating and therefore physically disruption the coat.”

[79] I agree with Dr. Laskar’s opinion that the claims themselves distinguish permeation enhancers from plasticizers by repeatedly using a three-part ratio that requires different amounts of plasticizer and permeation enhancer. This gives more strength to the position that the POSITA would understand that PEG and TEC are outside the scope of “permeation enhancer” as it is claimed in the 300 Patent. There is no explanation about how an expedient could have dual components and yet still achieve this ratio.

[80] PEG and TEC are never described as hydrophilic polymers in the 300 Patent and I will not read into the patent that they are anything other than plasticizers and glidants as taught in the patent. In addition, I agree with Dr. Laskar that a POSITA would understand that the definition of “permeation enhancer” in the 300 Patent excludes the hydrophilic polymers that are water soluble such as PEG.

[81] Dr. Laskar did not directly opine that TEC is not a permeation enhancer. However, he explains his opinion that the intent of the 300 Patent’s inventor was to separate plasticizers from permeation enhancers, and “the plasticizer combination is PEG 1450 plus [TEC].” Again it is Dr. Laskar’s opinion that the 300 Patent contemplates a three-part ratio which requires three

separate elements (an enteric/acrylic polymer, a plasticizer, and a permeation enhancer). At least implicitly, Dr. Laskar has concluded that TEC is outside the scope of "permeation enhancer" in the 300 Patent for the same reasons that PEG is.

[82] Relying on Dr. Laskar's opinion I construe the 300 Patent to mean that PEG and TEC are outside the scope of "permeation enhancer" in claim 1(iii).

*(c) What is the proper construction of the term **"about"**?*

[83] The 300 Patent does not define "about". The experts disagree about how the term "about" modifies the quantity of permeation enhancer in this patent. A review of this Court's jurisprudence illustrates that construction of "about" is purely on the particular patent in question.

[84] Dr. Allen does not construe "about" in his affidavit. On cross-examination he stated that he had not been asked to opine on it. And when asked about Ranbaxy's position that "about" meant 10% he disagreed. In response to this position he said:

> "It depends on the situation. The word "about" basically is defined as approximately, and it depends upon the situation. In some situations "about" maybe 10 percent, in some it may be 15. It depends on the context in which it is applied."

[85] Counsel for Ranbaxy then showed Dr. Allen a newsletter editorial he previously wrote called "What is "about" All About?" *CompoundingToday.com*, 8:34 (August 26, 2011). In that editorial, reference is made to the USP 8.20 (the official standards for drug substances and drug products) and states that ""about" indicates a quantity within 10%" [emphasis added].

[86] Dr. Allen explained that he wrote this for a different audience, one made up of compounding pharmacists who work with particular formulas. And while it is of interest to formulators, Dr. Allen said that "the products do not have a standard in the USP until they are incorporated in the USP after they have been approved by the FDA."

[87] The evidence before the Court includes an excerpt of the General Notices section of *The United States Pharmacopeia - The National Formulary*, (USI 28-NF 23), Rockville, MD: United States Pharmacopeial Convention, (January 1, 2005) at 7, (referred to in Dr. Allen's editorial) which states that "the word 'about' indicates a quantify within 10% of the specified weight or volume" when determining appropriate quantities for assays and tests.

[88] I give some weight to Dr. Allen's definition of "about" in his independent 2005 article. I find it useful where, though in the context of compounding and not formulation, the USP said that even in the context of tests and assays "about" means 10%:

> In stating the appropriate quantities to be taken for assays and tests, the use of the word 'about' indicates quantity within 10 percent of the specified weight or volume.

[89] Dr. Allen in cross-examination said that the USP is of interest to compounders and the word about is used in a different context for compounders than formulators. He agreed that the USP was of interest to formulators but products are only incorporated into the USP after they are approved by the FDA. Later Dr. Allen discusses that the "… National formulary consists of excipients and the USP portion consists of active drugs". Dr. Allen agreed that the formulas for compounding are like a recipe of ingredients and amounts.

[90] I also note that in Dr. Allen's article he says

> As the standards-setting compendia in pharmacy, what does the *USP* say about the word "about"? At the beginning of the *USP-NF* are the General Notices and Requirements. This section presents the basic assumptions, definitions, and default conditions for the interpretation and application of the *USP* and ***NF***. **Requirements in this section apply to all articles recognized in the *USP-NF* and to all general chapters, unless specifically stated otherwise.**
>
> [emphasis added]

[91] In the general notices and requirements section of the USP-NF, it states "[i]n stating the appropriate quantities to be taken for assays and tests, the use of the word 'about' indicates quantity within 10 percent of the specified weight or volume".

[92] Importantly, the excerpt at paragraph 90(above) indicated that the USP is the standards-setting compendia so this definition of "about" would be in the POSITA's common general knowledge.

[93] Though I acknowledge that Dr. Allen says that his definition of "about" in the article is in a different context when it is all unpacked it would appear that generally when looking at the "recipe of the ingredients and amounts" (see paragraph 89 above) that "about" means 10% and this does fit what formulators are doing so I think the article is useful in defining "about".

[94] Unlike Dr. Allen, Dr. Timko opined about what the word "about" means. His opinion says that the meaning of "from about 20% to about 40% of the moisture barrier dry weight" is "clear that the range of amount of permeation enhancer is not fixed, and that the Skilled Person

can deviate from this specific range." He then opines that in this case, that would mean a range of "at least 15% to 44%, and more likely 10% to 45% in the context of the 300 Patent."

[95] Dr. Timko also believed that as long as the formula is bioequivalent, then the amount of permeation enhancer could vary below or above the range. His evidence was that the amount of permeation enhancer could widely vary because paragraph [0091] of the patent says the amount of moisture barrier has no significant impact on the drug release characteristics. Based on his experience, he says "about" could be as little as 10% permeation enhancer as well as 10% plasticizer and at least 45% of enteric polymer to ensure the integrity of the coat.

[96] Dr. Timko as an alternative used the mathematical convention of rounding to interpret the patent. Simply, numbers ending in 5 or higher are rounded up, and numbers ending in 4 or lower are rounded down. Using rounding, he opined that the range must be at least 15% to 44%.

[97] To summarize Dr. Timko's opinion, the phrase would be read by a POSITA as 10% to 45%, or at least 15% to 44%.

[98] Valeant argued that Dr. Laskar's construction is arbitrary and internally inconsistent. They submit that because the range of 20% to 40% is a 100% increase, Dr. Laskar cannot opine that "about 20%" did not mean "17%" (which is only a 15% decrease). In addition, Valeant points out that Dr. Laskar conceded he did not know if 15%, 16%, or 17 % would affect the performance.

[99] Dr. Laskar's opinion on the meaning of "about" was based on his knowledge of what the POSITA would understand:

> 44 …given the field of art to which the 300 Patent is directed (pharmaceutical formulation) and my knowledge of constitutes typical and acceptable deviations from a value in this context (the pharmaceutical formulation area), the skilled person would understand the word "about" to be one of the following:
>
> a) A 5% deviation from the value; or
>
> b) A 10% deviation from the value.

[100] As the above quote illustrates, Dr. Laskar came to two conclusions. First, he opined that based on the convention in the Food & Drug Administration "to assess the quantitative identity of generic and reference listed drugs", "about" could mean a 5% deviation. Second, Dr. Laskar opined "about" may mean a 10% deviation because the majority of United States Pharmacopeia drug monographs "use the range 90.0-110.0% of label claim as the quality standard…which is 100%±10%". He goes on to note that using any of these methods all yield similar ranges.

[101] At the hearing, Ranbaxy's counsel limited their arguments to "about" meaning plus or minus 10%. This would mean that Ranbaxy relied on Dr. Laskar's opinion that "about 20% to about 40%" is equal to a range of 18%-22% to 36%-44%.

[102] I prefer and will rely on Dr. Laskar's opinion that a POSITA would understand that "about" means a 10% deviation of the percentage range in the 300 Patent's formulation based on his authorities.

[103] This is one of those circumstances as referred to by Justice Roy in *Arctic Cat* when a Judge may have regard to the common sense and determine that the POSITA would understand "about" to mean a deviation of no more than 10%. It makes sense that about would mean approximately and certainly in the compounding world it would more than likely be even less than 10%. To summarize, in this patent I construe the word "about" to mean a range of plus or minus 10%. In this case that means a range of 18% to 44%.

VI. Question at issue

A. *Did Valeant satisfy the Court on a balance of probabilities that Ranbaxy's formulation for Ran-Bupropion XL Tablets infringe the 300 Patent?*

[104] The question that must be answered now that I have constructed the claim is "Did Valeant satisfy the Court on a balance of probabilities that Ranbaxy's formulation for Ran-Bupropion XL Tablets infringe the 300 Patent?"

[105] Patent infringement occurs when another product includes all of a patent's essential elements (*Free World Trust* at paras 68, 75).

[106] There is no disagreement that all the essential elements are present in the Ranbaxy formula except whether the essential element of permeation enhancer is present in a range of 18% to 44% of the moisture barrier dry weight.

[107] Both parties agree that the Ran-Bupropion XL Tablets contain silicon dioxide as a permeation enhancer. Ranbaxy submits this is the only permeation enhancer in their formulation, and that it is present in an amount of [redacted] of the moisture barrier dry weight.

[108] Moreover, as set out above, I have construed "permeation enhancer" in the 300 Patent to exclude PEG and TEC. I have also construed the essential element of "about 20% to about 40%" to mean a deviation of 18% to 44%. Thus, the permeation enhancer in the Ranbaxy formulation is outside the scope of "about 20% to about 40%" of the moisture barrier dry weight as claimed in the 300 Patent.

[109] In summary, I find that Valeant failed to satisfy its onus to show on a balance of probabilities that Ranbaxy's allegation of non-infringement is unjustified.

VII. Conclusion

[110] I will dismiss the application to prohibit the Minister from issuing a NOC to Ranbaxy for its Ran-Bupropion XL Tablets.

VIII. Costs

[111] The parties were unable to come to an agreement on costs post hearing so they each provided written submissions.

[112] Valeant argued the proceeding was not overly complex and asked for a lump sum of $150,000.00 in legal fees, plus disbursements for the experts, to whoever the successful party is. Valeant's expert invoice totalled $99,347.16, and it pointed out that large cost awards in NOC proceedings are common (*Sanofi-Aventis Canada Inc v Novopharm Ltd,* 2007 FCA 384). In addition, Valeant argued that when the parties are sophisticated, it is common to award a percentage of the actual costs incurred (*Philip Morris Products SA v Marlboro Canada Ltd,* 2015 FCA 9 at para 4).

[113] Ranbaxy argued that if the general rule is applied and costs follow the successful party, then the Court should apply Rule 407 of the *Federal Courts Rules,* SOR/98-106 and use the mid-point of Column III of Tariff B and not a percentage of fees amount. Ranbaxy added that if Valeant is successful then the reason to deviate from the general rule that each party should bear their own cost. The reason for this deviate is the contradictory position of Valeant during its patent prosecution versus its patent litigation as well it should not have to pay for Valeant's staffing choice (three partners and one associate worked on this matter), nor for both experts since they gave contradictory testimony.

[114] Ranbaxy states that if successful then its total fees including taxes are just over $100,000.00 and its disbursements were $22,000.00.

[115] I will award costs to Ranbaxy in the lump sum amount of $100,000.00 inclusive of tax plus disbursements of no more than $22,000.00.

JUDGMENT in T-2224-16

THIS COURT'S JUDGMENT is that:

1. The application to prohibit the Minister of Health from issuing a NOC to Ranbaxy for its Ran-Bupropion XL Tablets is dismissed.

2. Lump sum costs are awarded to Ranbaxy in the inclusive of tax amount of $100,000.00 plus disbursements of no more than $22,000.00.

"Glennys L. McVeigh"
Judge

APPENDIX A

Claims 55-57 of the 300 Patent are as follows:

Permeation enhancer is present at about 25% by weight of the moisture barrier dry weight.

55. The modified-release tablet of any one of claims 1-54 wherein said permeation enhancer is selected from the group consisting of silicon dioxide, colloidal silicon, lactose, hydrophilic polymers, sodium chloride, aluminum oxide, colloidal aluminum oxide, silica, microcrystalline cellulose and any combination thereof.

56. The modified-release tablet of claim 55 wherein said permeation enhancer is silicon dioxide.

57. The modified-release tablet of any one of claims 1-56 wherein said enteric polymer, plasticizer and permeation enhancer is present in a ratio of about 13:2:5.

APPENDIX B

TABLE 3

CONTROL-RELEASING COAT FORMULATION

Ingredients	150 mg			300 mg		
	A (mg/%[1])	B (mg/%)	C (mg/%)	A' (mg/%)	B' (mg/%)	C' (mg/%)
Water-insoluble water-permeable film forming polymer[2]	10.26/5.55	5.63/3.1	12/6.28	19/5.01	6.71/1.96	13.05/3.63
Water soluble polymer[3]	5.64/3.05	7.5/4.1	9/4.7	18.06/4.77	6.37/1.86	12.40/3.45
Plasticizer[4]	2.1/1.14	1.88/1.03	3/1.6	5.16/1.36	1.82/0.53	3.55/0.99
Denatured Ethyl Alcohol 95%[5]	*	*	*	*	*	*
Isopropyl Alcohol 99%[5]	*	*	*	*	*	*
Dry weight of control-releasing coat	18/9.73	15/8.24	24/12.56	42.22/11.14	14.9/4.35	29/8.07

[1] The % values represent the proportion of the ingredient in relation to the tablet dry weight

[2] Ethylcellulose 100 (Ethocel®)

[3] Polyvinylpyrrolidone (Kollidon® 90F)

[4] Polyethylene Glycol 1450 (Carbowax®)

[5] Evaporated during drying

FEDERAL COURT

SOLICITORS OF RECORD

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