Federal Court  Cour fédérale

**Date: 20090716**

**Docket: T-1837-07**

**Citation: 2009 FC 726**

**BETWEEN:**

**PURDUE PHARMA**

**Applicant**

**and**

**PHARMASCIENCE INC. AND THE MINISTER OF HEALTH**

**Respondents**

**PUBLIC REASONS FOR ORDER**

**HARRINGTON J.**

[1] The issue in this application is whether any one of Pharmascience's barrage of allegations of invalidity with respect to Purdue's patent for "Controlled Release Oxycodone Compositions" is justified. If so, the Court will not prevent the Minister of Health from permitting Pharmascience to market its generic version of oxycodone hydrochloride controlled release tablets. If not, the Minister

will be prohibited from giving it the go-ahead (a Notice of Compliance) until Purdue's patent expires in 2012.

[2] Although Pharmascience was entitled to assert as many grounds of invalidity as it saw fit, I think it fair to say that if Purdue had not claimed such a broad range of methods to control or spread out over time the dissolution of oxycodone within the body, these proceedings would have been moot.

[3] This application was taken by Purdue pursuant to the *Patented Medicines (Notice of Compliance) Regulations*. Although byzantine in nature, they are so well-known that they need not be analyzed in detail here. See for instance *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, [1998] 2 S.C.R. 193, 80 C.P.R. (3rd) 368, *Brystol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, 39 C.P.R. (4th) 449 (*Biolyse*) at paragraphs 5-24, *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265, 69 C.P.R. (4th) 251 (*Plavix*) at paragraphs 7 and 12-17, as well as the decision of Mr. Justice Hughes in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, 55 C.P.R. (4th) 271.

[4] Suffice it to say that Purdue's Canadian patent 2,098,738 ('738), which claims a novel 12-hour controlled release formulation of oxycodone having a specific pharmacokinetic profile, is on the list maintained by the Minister pursuant to s. 4 of the Regulations. As Pharmascience filed an Abbreviated New Drug Submission comparing its tablets to Purdue's, in order to get to market sooner rather than later it was required to give Purdue a Notice of Allegation to which Purdue, in

turn, responded by seeking a prohibition order. That mere application serves, in effect, as a statutory injunction for up to two years.

[5] I shall deal with the application as follows:



## PATENTS OF INVENTION – A FEW BASICS

[6] An invention need not be patented. If it is, however, the patent is construed as a bargain between the inventor and the public. In consideration of disclosing the invention and how to work it, the inventor is given a temporary monopoly to exploit it, currently 20 years retroactive to the date the application was filed.

[7] What governs this case is the *Patent Act* as in force when the application was filed in November 1992. References to specific sections of the Act are references to the sections as they were at that time. The patent is notionally addressed to a person skilled in the art or science of the subject-matter and is to be read as such a person would have read it when it first became public

(*Patent Act*, s. 34). It is the specification thereof which discloses the invention and how to work it. The specification ends with a claim or list of claims over which a monopoly is asserted.

[8] To be patentable an invention must be both new and shown to be useful, either by demonstration or by sound prediction. An invention may be new even if only an improvement on what already exists, and may be useful even if only a poorer alternative to what already exists. The inventor of a new pain killer will not be denied a patent simply because it is only half as effective as aspirin and twice as expensive.

[9] The patent is written by or for the inventor and its language must be carefully construed. It is addressed to those who are able to "make, construct, compound or use it" (s. 34(1)(*b*) of the Act), which, it goes without saying, is not the Court. The Court is likely to need the assistance of experts to determine if what is claimed to be invented is new and useful, and to give meaning to such technical language as may be found in the claims.

[10] As stated, language is crucial. There tends to be a tension between what, if anything, was invented and what the inventor claims to have invented. If, which is not the case here, more was invented than claimed, the Court will not save the day by giving effect to the "spirit" of the invention. If, on the other hand, the inventor claims or promises more than what was invented, the patent is invalid. To minimize this possibility the inventor asserts cascading claims, each narrower than the other. Such limitations serve as a potential safety net so that, if the broadest claims fall, the monopoly may be saved in part by the more modest claims. Mr. Justice Binnie has described them as "...complex layers of definitions of different elements (or "components" or "features" or

"integers") of differing complexity, substitutability and ingenuity)..." (*Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1042, 9 C.P.R. (4th) 168, at paragraph 15).

[11] The claims are to be read in an informed and purposeful way so as to permit fairness and predictability and to define the limits of the monopoly. The claims cannot be so largely construed as to permit the patentee to monopolize anything that achieves a desired result. On the other hand, one should not be permitted to avoid the monopoly by using a non-essential variant which makes no material difference to the working of the invention.

[12] Some elements of the claimed invention are essential, while others are not, based either on common knowledge when the invention was made public, or according to the inventor's intent, expressed or implied, gleaned from the claim language. It is only such novel features that the inventor claims are essential that constitute the "pith and marrow" of the claim.

[13] In construing the meaning of a claim, recourse should be had to the disclosure to gain insight into what was meant by a particular word or phrase. Otherwise the scope of the claim or claims as written and so understood can be neither restricted nor enlarged.

[14] These principles are drawn from *Free World*, above, and *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067, 9 C.P.R. (4th) 129.

[15] Patents are strictly a creature of statute and so these cases, as well as those earlier Canadian, English and American cases referred to therein, are all based on the specific language of the various

*Patent Act*s as in force in those jurisdictions from time to time. The general principles therein enunciated cannot be severed from the statutory language under consideration.

[16] The "newness" requirement is found in the definition of "invention" set out in s. 2 of the Act. The definition specifically provides that the patent may simply be an improvement, as does s. 32.

[17] To drill down into "newness", ss. 27(c) and (d) provide that the claim must not have been previously disclosed (and must not have been previously obvious to a person skilled in the art or science to which it pertains). "Previous" means more than one year before the filing of the application.

[18] Finally, pursuant to the Regulations, the presumption of validity set out in s. 43 of the Act is displaced as long as the person issuing the Notice of Allegation leads any evidence of invalidity. Thereafter, the burden falls upon the applicant, in this case Purdue, to prove on the balance of probabilities that no such allegation was justified. The steps to take into account in considering the burden as to validity were clearly summarized by Mr. Justice Hughes in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FC 11, 69 C.P.R. (4th) 191 at paragraph 32 and recently reiterated in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 235 at paragraphs 22 through 25.

[19] The shortcomings and limited value of PM (NOC) applications are well-known. The evidence of the experts consists of affidavits and cross-examinations. These witnesses are supposed to aid the Court in explaining technical terms and in advising as to what was commonly

known in the field at relevant times. Yet the judge is unable to ask clarifying questions and, because of lack of personal observation, is hard-pressed to form a view as to whether an opinion is overblown and whether what is said to have been previously disclosed or obvious comes with the benefit of hindsight.

[20] All that is to be decided in this application is whether the Minister is to be prohibited from issuing Pharmascience a Notice of Compliance. Determinations as to the validity of the patent are not even binding on the parties themselves. This must be kept in mind, as the invention has been the subject of litigation in other jurisdictions. More particularly, Purdue has drawn to my attention the decision of Mr. Justice Floyd in *Ratiopharm GmbH v. Napp Pharmaceutical Holdings Ltd.*, [2008] EWHC 3070 (Pat), [2009] R.P.C. 11. He held that the claims of the patent which were under attack there (which are not the same as the ones under attack here) were valid and were not infringed. The Court of Appeal, [2009] EWCA Civ 252, agreed that the claims were valid but held that they were infringed. Since, at the end of the day, Pharmascience did not pursue any allegation of non-infringement, that question is not directly before me.

**OXYCODONE AND PATENT '738**

[21] Patent '738 is titled "Controlled Release Oxycodone Compositions". Oxycodone is not new and neither are ways and means of spreading out the release of a medicine into the blood stream over time. An obvious advantage of a controlled release tablet taken by mouth is that, if effective over a longer period of time, the medicine may be taken less frequently. Most anyone would rather take a pill every 12 hours than every 4 or 6 hours. The amount of the medicine in play at any one time should also be more consistent.

[22] Oxycodone has been in use since 1917 and is not covered by any current patent. It is one of a group of medications known as “opioid analgesics” that relieve pain by acting upon various opioid receptors in the body, in this case what are known as *mu* receptors. They are natural, semi-synthetic or synthetic derivatives of opium. Oxycodone is semi-synthetic. The very word “opium” conjures up fears of addiction. It is common ground, however, that if carefully and professionally administered for proper purposes, the fear of addiction is overstated. Opioids include morphine, codeine, dihydrocodeine, heroin, hydromorphone, oxycodone and methadone. Opioids have both common and dissimilar characteristics and may produce different nasty side effects in different people.

[23] The patent application was filed in Canada in November 1992, and asserts priority based on a U.S. patent application filed in November 1991. It was published, i.e. laid open, here in May 1993. These dates are important because yesterday’s news is old hat. As regards novelty and obviousness, the reference date is the priority date of November 1991. Utility is assessed against the Canadian filing date in November 1992 and construction and sufficiency against the date of publication in May 1993. Pharmascience argues that Purdue cannot rely on the priority date because the U.S. patent specification is somewhat different. In the light of my findings nothing turns thereon.

[24] According to Purdue, the patent specification discloses an invention with three primary elements: 1) the choice of oxycodone as the active ingredient for a product to be used in the treatment of moderate to severe pain; 2) the choice of a particular pharmacokinetic profile; and 3) the development of formulations which would result in the type of profile being sought (12-hour controlled release). Pharmacokinetics is that branch of pharmacology which deals with the

movement of drugs within the body. Each of these three elements is considered essential to the invention. Put another way, in order for Pharmascience's product to infringe, it must fall within each of these three elements.

[25] In broad strokes, Pharmascience's allegations are to the effect that the patent discloses nothing new or useful. In the alternative, in some respects the patent falls short of what was promised, and even if something new and useful was invented, the claims in issue are overbroad and capture, in the same breath, matters which were old or useless. Consequently, the claims in issue are invalid.

[26] More specifically, Pharmascience alleges that the two claims in question, claims 5 and 11, are invalid for any of these three prime reasons: overbreadth, obviousness and false promise. They are also invalid for anticipation, ambiguity, insufficiency, lack of invention, lack of sound prediction and lack of utility.

[27] Turning now to patent '738 itself, the Abstract states:

> A method for substantially reducing the range in daily dosages required to control pain in approximately 80 % of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of oxycodone or a salt thereof is administered to a patient. The formulation provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hours) administration through stead-state conditions. Another embodiment is directed to a method for substantially reducing the range in daily dosages required to control pain in substantially all patients. The figure is a graph showing the mean plasma oxycodone concentration for a 10 mg controlled release

> oxycodone formulation prepared in accordance with the present invention and a study reference standard.

[28] The patent, which contains 47 pages of text, tables, examples and charts, includes, as required, a specification, being a disclosure which ends with claims of what has been invented (in this case 28 claims). By way of background it is stated with respect to opioid analgesics in general that approximately an 8-fold range in daily dosages is required to control pain in approximately 90 percent of patients. Humans relate to pain and pain relief quite differently. The wide range makes titration difficult and leaves the patient without appropriate pain control for unacceptably long periods. Titration is the made-to-measure dosage suitable for each individual patient, i.e. optimal relief while avoiding toxicity. According to the inventors, the invention provides methods and formulations which improve the efficiency and quality of pain management, substantially reduce variability and daily dosages, and the time and resources needed to titrate patients.

[29] The specification describes various solid oral dosage forms containing about 10 to about 160 mg of oxycodone, or a salt thereof, in which release after ingestion is spread out either by a retardant coating or by a matrix. A matrix system consists of an active ingredient, in this case oxycodone, being dispersed homogeneously throughout a matrix of inert, erodible or swelling-controlled material, generally a polymer. It calls for certain dissolution ranges *in vitro* and blood plasma levels over time, “substantially independent of pH”.

[30] Although only claims 5 and 11 of the 28 claims are alleged to be invalid, particular attention must also be given to claim 9 from which claim 11 is derived.

[31] Claim 5:

> A solid controlled release oral dosage form, comprising oxycodone or a salt thereof in an amount from about 10 to about 160 mg said oxycodone or salt thereof being dispensed in a matrix which includes;
>
> an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing; and
>
> a suitable amount of a suitable pharmaceutical diluent, wherein said composition provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

[32] Claim 9:

> A controlled release tablet for oral administration comprising from about 10 to about 160 mg oxycodone or an oxycodone salt dispersed in a controlled release matrix, said tablet providing an in-vitro dissolution of the dosage form, when measured by the USP Paddle Method at 100 rpm at 900 ml aqueous buffer (pH between 1.6 and 7.2) at 37$^{o}$ C, between 12.5% and 42.5% (by wt) oxycodone released after 1 hour, between 25% and 55% (by wt) oxycodone released after 2 hours, between 45% and 75% (by wt) oxycodone released after 4 hours and between 55% and 85% (by wt) oxycodone released after 6 hours, the in vitro release rate being substantially independent of pH and chosen such that a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml is obtained in vivo from a mean of about 2 to about 4.5 hours after administration of the dosage form, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

[33] Claim 11:

> A dosage form according to claim 9, wherein the in vitro dissolution rate is between 17.5% and 32.5% (by wt) oxycodone released after 1 jour, between 35% and 45% (by wt) oxycodone

> released after 2 hours, between 55% and 65% (by wt) oxycodone
> released after 4 hours between 65% and 75% (by wt) oxycodone
> released after 6 hours.

[34] The real nub of Pharmascience's complaint is that it proposes using hydroxypylmethycellulose (HPMC) in its matrix, which would appear to fall within the group of matrixes claimed. HPMC is specifically mentioned in the disclosure.

**SKILLED ADDRESSEE**

[35] The parties agree, and the Court has no reason to disagree, that the person skilled in the art or science to which the patent relates has three special skill sets. Such a person, or persons, would have some years of academic training and practical experience in pharmacokinetics, formulation chemistry and clinical pain treatment.

**THE EXPERT WITNESSES**

[36] Purdue called two of the four American inventors: Benjamin Oshlack, a formulator, and Dr. Robert Kaiko, whose background was in pharmacokinetics but, because of earlier years at the Sloan Kettering Institute for Cancer Research, was also familiar with clinical pharmacology as regards pain relievers and pain management. Although they have the skill sets required, the patent obviously is not addressed to them. Rather, they set out in considerable detail what they invented and how they went about it. They are treated as fact witnesses.

[37] The experts called by both sides were all superbly qualified to assist the Court and their expertise was not put in doubt. Although they all assisted the Court, some went beyond giving the technical information necessary to construe the patent and construed it themselves. Keep in mind

that “Claims construction is a matter of law for the judge, and he was quite entitled to adopt a construction of the claims that differed from that put forward by the parties” (*Whirlpool*, para. 61).

[38] Purdue called four experts:

a. Dr. Donald Stanski who dealt with pharmacokinetics;

b. Dr. Roland Bodmeier, a formulator;

c. Dr. Louis Cartilier, another formulator; and

d. Dr. Romaine Gallagher who has considerable experience in pain management.

[39] Pharmascience also called four experts:

a. Dr. Christopher Rhodes, a formulator;

b. Dr. Donald Denson who deals with pharmacokinetics;

c. Dr. Stephen Abram who specializes in anaesthesiology and pain management; and

d. Dr. Gerhard Levy who also dealt with pharmacokinetics.

[40] Dr. Stanski, currently employed by Novartis International AG, is an anaesthesiologist, was a member of the Faculty of the Department of Anesthesia at Stanford University, School of Medicine, from 1979 to 2005, and spent five years as Chairman of that Department. In addition to being currently employed by Novartis, he has a two-year public service appointment to the United States Food and Drug Administration where he is a Scientific Advisor to the Director, Centre for Drug Evaluation and Research. During his years with Stanford he also had commercial experience and established a clinical practice at the Palo Alto Veterans Administration Hospital.

[41] Dr. Bodmeier is Professor of Pharmaceutical Technology at the College of Pharmacy, Freie Universität Berlin, Germany. He obtained his Ph.D. in Pharmaceutics in 1986 from the University of Texas at Austin where he was an Associate Professor before joining the Freie Universität Berlin. His major research interests relate to controlled drug delivery systems and would qualify him for present purposes as a formulator, which is not to suggest that the three special attributes of the skilled addressee are mutually exclusive.

[42] Dr. Cartilier, who received his Ph.D. in Pharmaceutical Science at l'Institut de Pharmacie of the Université Libre de Bruxelles, had been a Post-Doctoral Fellow at the Université de Montréal where he has taught since 1989. He is currently titular Professor with the Faculty of Pharmacy and considers himself primarily an academic formulator, although he has been consulted by the pharmaceutical industry on a number of occasions.

[43] Dr. Gallagher is a family doctor in Vancouver. She has considerable experience in pain management and has served as Director of the Palliative Care Division in the Department of Family Medicine at the University of British Columbia. She has been on the faculty since 1996 and holds the rank of Clinical Professor.

[44] Dr. Rhodes obtained his Ph.D. in Pharmacy from the Faculty of Medicine of the University of London in 1964 and for many years was Professor and Chair of the Department of Pharmacy Practice at the University of Rhode Island.

[45] Dr. Denson obtained his Ph.D. in Organic Chemistry from the University of Georgia in 1970. He is currently an Assistant Professor of Anesthesiology at the Emory University School of Medicine and Director of their Anesthesiology Research Laboratories. He deals with pharmacokinetics.

[46] Dr. Abram graduated with his medical degree from Jefferson Medical College in 1970. He is a physician specializing in the practice of anaesthesiology and pain management, is currently a Professor in the Department of Anesthesiology at the Medical College of Wisconsin in Milwaukee and serves as Director of its Pain Fellowship Program.

[47] Dr. Levy obtained his Doctorate in Pharmaceutics from the University of California, San Francisco in 1958 and, after a long and distinguished career, is currently the University Distinguished Professor of Pharmaceutics Emeritus at the State University of New York in Buffalo. He served as Director of the Clinical Pharmacokinetics Research Center from 1978 to 1988, and has been a consultant to the World Health Organization, the United States Food and Drug Administration and the pharmaceutical industry. He has been called the father of pharmacokinetics.

## ANALYSIS

[48] I mention two issues at the outset in order to immediately discard them: anticipation by prior use and commercial success.

[49] Pharmascience has alleged that the invention had been previously anticipated by prior use. That use consisted of *in vivo* testing. The experts agree that *in vitro* (in a beaker) testing might give

an indication of promising results, but that *in vivo* testing is also necessary. The allegation is to the effect that the clinical study on humans commissioned by Purdue was not sufficiently confidential. However, the evidence of Dr. Miguel Zinny, Medical Director of Medical Technical Research Associates Inc. in the United States, who acted as principal investigator, completely refutes that allegation.

[50] I also put no value on Purdue's evidence that controlled release oxycodone has been a commercial success. Commercial success may serve as a secondary indication that there was a need in the market place which was fulfilled by something new and useful (*Janssen-Ortho Inc. v. Novopharm Ltd.*, 2007 FCA 217, 59 C.P.R. (4th) 116). Purdue produced sales records and hearsay prescription records. Dr. Abram was of the view that controlled release oxycodone was a commercial success in the United States because of Purdue's marketing. Dr. Gallagher did not recall a particular marketing effort in Canada. Lawyers and judges do not need lessons in logic. The data supplied cannot possibly lead to the inference that this particular patent is valid. We are in the realm of conjecture. Furthermore, neither Dr. Abram nor Dr. Gallagher has expertise in the market place. They have stepped outside their expert qualifications. Courts must treat such evidence with great care. See the comments of Mr. Justice Goudge of the Ontario Court of Appeal in the *Inquiry into Pediatric Forensic Pathology in Ontario*, in volume 2, chapter 8, with respect to evidence beyond expertise and speculative evidence.

[51] As to the other allegations of invalidity, the approach thereto urged upon me by Purdue is that allegations should be treated as separate and distinct and are watertight compartments, with limited leakage. Pharmascience is criticized for asserting a number of allegations in the same breath.

For instance, one of the headings in its written memorandum is "'738 Patent - Nothing Was Invented (Obviousness, Anticipation, No Invention, Lack of Utility)." However, I prefer the "seamless garment of the law" approach since, after all, the patent is a legal document, a regulation within the meaning of the *Interpretation Act*. I can do no better than to refer to *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, where Mr. Justice Hughes said:

> [64] I have deliberately bundled all of the topics listed in the title of this portion of these Reasons, "Anticipation/Obviousness/Sound Prediction/Sufficiency of Disclosure" together. There is one issue to be considered namely, the validity of the '356 patent. There is a tendency in the jurisprudence to pigeonhole arguments respecting validity into certain categories such as "anticipation" or "obviousness" and so forth. Each category has collected about itself an accumulation of jurisprudence. Each category tends to be argued separately creating, on occasion, contradictions, inconsistencies and gaps. This is an occasion when one should step back and examine the fundamentals of the patent system and determine whether a more holistic approach is appropriate.

[52] After reviewing the patent system he concluded:

> [74] Thus, one must both advance the state of the art and disclose that advance in order to gain the patent monopoly. Failing to do so, thus invalidating the monopoly, can be in the form of one or more of several matters such as, the "invention" was not new, or the so-called invention was "obvious" or the disclosure was "insufficient" or "what you disclosed doesn't support the monopoly that you claim".
>
> [75] The factual circumstances of each case must be canvassed before trying to examine them through the lens of any particular argument as to validity to determine if truly, a proper invention has been made and whether it has been properly disclosed and whether it has been properly claimed.

[53] Although I agree with Pharmascience that oxycodone was not new, that its use to alleviate moderate to severe pain was not new, that controlled release formulations of opioids were not new

and even that a controlled release formulation of oxycodone had been previously disclosed, it does not necessarily follow that the patent is invalid. As Mr. Justice Martland stated in *Ciba Ltd. v. Commissioner of Patents*, [1959] S.C.R. 378 at page 383:

> …The method may be known and the materials may be known, but the idea of making the application of the one to the other to produce a new and useful compound may be new, and in this case I think it was.

See also *Free World*, above, at paragraphs 23 and 30.

[54] I am satisfied on the evidence that the creation of a 12-hour controlled release oxycodone tablet in different dosages was new and useful. The real question is whether claims 5 and 11 have been written in such a way to monopolize things which were not invented at all, particularly HPMC matrixes.

[55] Certainly the selection of oxycodone for the treatment of moderate to severe pain was not inventive. Although oxycodone was generally prescribed for the treatment of mild to moderate pain, the prime reason was that it was formulated with other medicines such as aspirin or acetaminophen. To prescribe such tablets in sufficient quantity to relieve moderate to severe pain, the resulting levels of aspirin or acetaminophen might be toxic. However, the evidence of Dr. Abram and Dr. Gallagher is that immediate release oxycodone without a co-medicine was available in both Canada and the United States. Dr. Gallagher complained that only a 10 mg tablet was available which was impractical in treating cancer patients who might need 300 mg a day. This has nothing to do with potency and everything to do with convenience. The fact of the matter is that oxycodone HCL trihydrate was available in Canada in 10 mg tablets in a product known as Supeudol, and

another product, Roxicodone, was available in the United States. According to the *Compendium of Pharmaceuticals and Specialties 1988*, published by the Canadian Pharmaceutical Association, Supeudol was indicated for the relief of moderate to severe pain. As with other narcotics, precautions were stated to be necessary because of potential addiction and respiratory depressant effects, among other things. In any event, claims 5, 9 and 11 do not specifically promise relief from a particular intensity of pain.

[56] In *Ratiopharm v. Napp*, above, Mr. Justice Floyd said at paragraph 219 that "…it would not occur to a skilled team in 1991 to place oxycodone on a list of potential alternatives to morphine for making into an oral controlled release formulation." Morphine was generally considered to be the gold standard. That finding of fact was based on the evidence before him. No mention was made of the Canadian Compendium. I find that immediate release oxycodone was known to effectively treat a wide range of pain. To then consider a controlled release tablet does not constitute a quantum leap.

[57] Other opioids were available in controlled release formulations. Morphine was available and Mr. Oshlack himself had disclosed and claimed an oxycodone controlled release formulation in U.S. patent 4,861,598, a patent which disclosed formulations which could be used for a number of opioids. In addition, Purdue, through its Mr. Goldie, had U.S. patents on two other controlled release opioids, hydromorphone and dihydrocodeine.

[58] Bearing in mind that each claim should be taken as self-standing (or in conjunction with its progenitor such as claims 9 and 11), a number of Pharmascience's allegations can be quickly dismissed.

[59] The patent discloses that controlled release oxycodone would be effective under a narrower dosage regime when compared to controlled release morphine. Pharmascience alleges that this narrower range was never demonstrated and that there was no sound basis for making that prediction. Be that as it may, that so-called reduction in dosage does not form part of the language used in claims 5, 9 and 11 and cannot be implied by an overall reading of the specification.

[60] To quote from the disclosure: “In yet another aspect the present invention provides a method for substantially reducing the time and resources need(ed) to titrate patients requiring pain relief on opioid analgesics.” This statement has been attacked as not being proven and pointless in that titration is usually first established with immediate release tablets, before moving on to a single dose of a controlled release tablet and then to a regular regime of controlled release dosages. However, again, these assertions do not form part of claims 5, 9 or 11.

[61] Claims 5, 9 and 11 relate to two profiles, an *in vitro* dissolution profile and an *in vivo* pharmacokinetic profile. Both may be envisaged as a line running from left to right within a rectangle. In both, the horizontal is marked from ingestion to 12 hours hence, i.e. Tmin and Tmax. In the *in vitro* profile, the amount of dissolution is measured at various times, as shown on the vertical. Claim 9 is for a release of between 12.5 percent and 42.5 percent by weight in the first hour, between 45 and 75 percent after 4 hours and so on. Claim 11 is narrower.

[62] In the pharmacokinetic *in vivo* profile, the vertical is measured by the mean maximum plasma concentration of oxycodone from administration onwards. The concentration from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration drops to from

about 3 to about 120 ng/ml. at about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions (Cmax and Cmin). This wide range is attributable to the fact that the active ingredient is oxycodone, or a salt thereof, in an amount ranging from about 10 to about 160 mg dispensed through a matrix.

[63] It is significant that these claims deal with a matrix. The product which was eventually found in England to infringe the U.K. patent controlled the release of oxycodone through an exterior coating. Apart from matrixes and coatings, there are many other ways to control the release of the active ingredient. Dr. Bodmeier refers to reservoir devices, osmotic systems and swelling systems.

**DEVELOPMENT OF PATENT '738**

[64] Patent '738 derives in large measure from the collaboration of two of the named inventors, Benjamin Oshlack and Dr. Robert Kaiko, who at relevant times were employed by Purdue Pharma L.P., a corporation based in the United States with which the Applicant is affiliated. Mr. Oshlack, a formulator, joined Purdue in 1980. During the four years prior thereto he was employed in the Netherlands at a company which later became associated with Purdue. While there, his primary work was on immediate release tablets.

[65] After joining Purdue, and after a stint at its United Kingdom affiliate, Napp, where he obtained formal training in the development of controlled release formulations, he worked with a number of products including oxycodone and other opioids, focussing on the development of controlled solid dosage forms.

[66] By the early 1980s, Napp had developed a controlled released morphine product: MS CONTIN. Release was controlled by a matrix which included, among other things, a cellulose polymer and a higher aliphatic alcohol. The CONTIN system produced a pharmacokinetic profile in which the peak concentration of morphine occurred relatively early compared to other controlled release formulations, followed by a decrease in concentration.

[67] MS CONTIN became a commercial success upon its market entry in the United States in 1985. It meant a patient could be treated with morphine outside the hospital, allowed for a more sustained release over time, and did not have to be taken as frequently.

[68] Mr. Oshlack was not involved in the early stages of MS CONTIN but was involved in the development of a controlled release codeine formulation based on the CONTIN system. Initial experiments with a codeine salt were not successful as the dissolution rate was too fast for twice-a-day administration. However, by ultimately combining a codeine salt with freebase codeine within the CONTIN system, a better dissolution profile was established and, after the formulation was tested in humans, it was eventually developed into a commercial product.

[69] Mr. Oshlack actually began to experiment with controlled release oxycodone tablets in 1981. He used oxycodone hydrochloride which was released too quickly. Then, based on his experience with codeine, he tried a combination of oxycodone salt and freebase oxycodone which still released too quickly in the *in vitro* dissolution profile.

[70] It was really with Dr. Kaiko's arrival at Purdue in 1985 that things began to happen. Dr. Kaiko was very keen on an *in vivo* blood plasma profile with an early peak release followed by a gradual release over a 12-hour period. This concept was somewhat counterintuitive. Although immediate release tablets peaked early, conventional wisdom was that the peak plasma level in a controlled release tablet should occur much later in time, say between 4 and 8 hours. Previously, the goal had been to keep as much as possible to a relatively straight line or flat profile.

[71] After a number of experiments involving the CONTIN system, all of which failed to establish a satisfactory dissolution profile, Mr. Oshlack began to use different retardants and in particular considered an acrylic resin in combination with a higher aliphatic alcohol. Acrylic resins are, in essence, Plexiglass. He used the commercial product Eudragit, with which he was familiar, and which had various compositions.

[72] He also worked with organic solvents. They have several disadvantages such as a low flashpoint and environmental restrictions. That formulation was never tested.

[73] These experiments led to U.S. patent 4,861,598, the AcroContin system, which uses a combination of an acrylic polymer, such as Eudragit, with a high aliphatic alcohol to retard the dissolution of pharmaceuticals from 5 to 24 hours. One of the examples was oxycodone. The patent does not specifically disclose a 12-hour controlled release formulation for oxycodone, or any other active ingredient, but certainly explains how release may be lengthened or shortened depending on the amount of retardant used. It does not disclose any *in vivo* testing.

[74] Eventually he produced a fully aqueous tablet. A single dose bioavailability study was performed. This formulation eventually became the formulation for the 10 mg dosage strength marketed by the company.

[75] During the prosecution of the ‘598 patent in the United States, Mr. Oshlack submitted a declaration to which some pages from his lab notebooks were attached including tablets A12 and A13. Although he had performed *in vitro* dissolution testing of those formulations, there had been no *in vivo* testing.

**GROUNDS OF INVALIDITY**

[76] What is claimed must be new and useful, and the patent must disclose to those to whom it is addressed the ways and means to “make, construct, compound or use it”. Allegations of invalidity, apart from unpatentable subject matter, such as the Harvard Mouse (*Harvard College v. Canada (Commissioner of Patents)* 2002 SCC 76, [2002] 4 S.C.R. 45, 21 C.P.R. (4th) 417), are grounded in these three broad categories. One may not claim what one did not invent either because it was previously invented, disclosed, obvious or because the invention falls short of what was claimed.

[77] The well-known allegations of invalidity asserted here - overbreadth, obviousness, false promise, anticipation, ambiguity, insufficiency, lack of invention, lack of sound prediction and lack of utility - should not take on separate lives of their own. They are tied to the specific language of the *Patent Act*. Nevertheless, they are useful terms of reference so as to put some order into what might otherwise be an overwhelmingly amorphous exercise.

***Anticipation***

[78] Claims of a patent are, as said at the outset, invalid if anticipated by prior disclosure or by prior use. The prior use was within a confidential *in vivo* test and so can safely be ignored as not being publicly disclosed.

[79] Prior written disclosure was recently considered by the Supreme Court in *Plavix*, above, [2008] 3 S.C.R. 265. The Court started with *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289, where Mr. Justice Hugessen, speaking for the Court of Appeal, said at page 297:

> ...One must, in effect, be able to look at a prior, single publication and find in it all the information which for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention...

[80] However in *Plavix*, Mr. Justice Rothstein, basing himself on more recent U.K. jurisprudence, held that there are actually two requirements and *Beloit* was limited to the first. The first stage is that the prior document must disclose subject matter which, if performed, would necessarily result in infringement of the invention. If, and only if, that disclosure requirement is satisfied, there is a second requirement which is “enablement”, i.e. what may be required in order to make it work. Mr. Justice Rothstein left open the question whether enablement for the purpose of anticipation is the same as enablement for the purpose of sufficiency. In England they are the same.

[81] Not one of the prior documents sets out all the information needed to produce the claimed invention and so it is not necessary to consider what trial and error might be allowed to get the invention to work. Mr. Oshlack’s efforts established that the release of oxycodone could be

successfully controlled *in vitro*. However, the experts agree that although one would not work up an *in vivo* testing unless the rate of dissolution fell within certain parameters, it by no means follows that a promising dissolution profile will lead to successful *in vivo* testing. Working the Oshlack disclosure would not necessarily infringe the '738 patent.

[82] The fact of the matter is that what was claimed to be invented was not "described" in any patent or any other publication or used more than a year before the patent application was filed.

***Obviousness***

[83] Even if not previously disclosed, the invention may have been obvious.

[84] Again we not need go much further than the Supreme Court's decision in *Plavix*, above, which clarified the law as to how much effort must go into making the prior art work before it can be said that the invention was not obvious. Courts in this and other jurisdictions have considered whether it was "worth a try" or "obvious to try". However, the law in Canada is now clear as Mr. Justice Rothstein said at paragraph 66:

> [66] For a finding that an invention was "obvious to try", there must be evidence to convince a Judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.

[85] He went on to say:

> [67] It will be useful in an obviousness inquiry to follow the four-step approach first outlined by Oliver L.J. in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (C.A.). This approach should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis. The *Windsurfing* approach was recently updated by

> Jacob L.J. in *Pozzoli SPA v. BDMO SA*, [2007] F.S.R. 37, [2007] EWCA Civ 588, at para. 23:
>
> In the result I would restate the *Windsurfing* questions thus:
>
> (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, differences 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? [Emphasis added.]
>
> It will be at the fourth step of the *Windsurfing/Pozzoli* approach to obviousness that the issue of "obvious to try" will arise.

[86] We have identified the notional "person skilled in the art". Such a person, or group of persons, knew oxycodone was a pain killer, knew that with co-medicines it was useful in the relief of mild to moderate pain, knew that as the sole active ingredient it was useful in the relief of moderate to severe pain, and that formulations were available to control its release *in vitro*. Indeed, enough was known about its properties, such as its half-life elimination from the body, that it might well be a welcome addition as a controlled release product, given that many patients react adversely to different opioids.

[87] The inventive concept was controlled release oxycodone staying within the boundaries of a particular dissolution and pharmacokinetic profile from 10 to 14 hours.

[88] This combination was different from anything which formed part of the "state of the art". The inventive concept was not the idea, but rather getting it to work. The question therefore is whether these differences constitute steps which would have been obvious or did they require any degree of invention.

[89] Some cases have conflated the concept of "obvious to try" with "obvious to work". However, as Mr. Justice Rothstein stated in *Plavix* at paragraph 65: "…I am of the opinion that the "obvious to try" test will work only where it is very plain or, to use the words of the Jacob L.J. [in *Saint-Gobain PAM SA v. Fusion Provida Ltd.*, [2005] EWCA Civ 177], more or less self-evident that what is being tested ought to work."

[90] As stated earlier, in my opinion it is this combination which is new and useful, not necessarily any particular part thereof.

[91] Dr. Kaiko's blood plasma profile, Pharmascience says, is simply drawn from data available from immediate release oxycodone and the fairly early peak in MS CONTIN. However there were some difficulties with MS CONTIN as in some patients the blood plasma concentration fell off too soon. Dr. Levy created a mathematical model which was not dissimilar, to be met with Purdue's argument that his was not common general knowledge. As the father of pharmacokinetics, he was blessed with extraordinary knowledge. Be that as it may, it is not necessary to reach any conclusion as one had to come up with a formulation which would achieve that result. It is in this regard that I find the evidence of Dr. Bodmeier most persuasive. Once it has been decided by marketing people, clinicians or pharmacokineticists that a controlled release formulation of a particular drug

would be beneficial, the formulator is provided with a target profile. A first step will be to look at the immediate release formulation to determine if it would even be possible to make a controlled release formulation. If the immediate release formulation already contains a high dose it may not be wise to increase that dosage.

[92] The formulator has to consider the drug's solubility, partition coefficient, polymorphism and other factors. The length of the drug's half-life and chemical stability in a solid and in a dissolved state are most important. If one wants an oral solid dosage form one might consider tablets, capsules, pellets or granules.

[93] As to the method of controlled release, if a matrix system is used there are still a number of choices. Will the matrix formula be water-soluble (hydrophilic) or water-insoluble (hydrophobic). The list goes on. Once preliminary formulations have been made they will be tested *in vitro* with variations to get a slow, medium or fast profile so as to get an idea of the release characteristics of the excipients and the drug.

[94] In Dr. Bodmeier's opinion:

> … there are numerous choices with respect to the delivery system, excipients and processing, which a formulator has available for the development of a controlled release drug delivery system. In addition, each drug is different with respect to its physicochemical and pharmacokinetic properties. These drug properties (e.g., dose, solubility, stability, pharmacokinetic, etc.) add to the complexity of the development process. As said above, there are no set steps that a formulator can follow in developing a controlled release formulation with any given drug.

[95] Given these parameters, and the years of work carried out by Mr. Oshlack with so many trials and so many errors, I am of the opinion that it was not self-evident that what was being tried ought to work. There was a considerable amount of work required to achieve the invention, and the trials were not routine. The work was inventive.

[96] In *Plavix* Mr. Justice Rothstein set out a non-exhaustive list of factors to be taken into account in determining whether it was “obvious to try” what is now being claimed:

> [69] If an "obvious to try" test is warranted, the following factors should be taken into consideration at the fourth step of the obviousness inquiry. As with anticipation, this list is not exhaustive. The factors will apply in accordance with the evidence in each case.
>
> > (1) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
> >
> > (2) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
> >
> > (3) Is there a motive provided in the prior art to find the solution the patent addresses?

[97] I have already considered whether it was more or less self evident that it would work and the amount of effort required. In the light of my findings, it may not even be necessary to consider motive.

[98] Although Purdue certainly had motive in that it was developing a stable of controlled release opioid tablets, there does not appear to have been much motive within the pharmaceutical industry at large. If someone cared to think about it, oxycodone was a suitable candidate, but it had been around for a long time.

[99] In *Apotex Inc. v. Pfizer Canada Inc.*, 2009 FCA 8, 72 C.P.R. (4th) 141, the Federal Court of Appeal noted that motivation is treated differently in Canada and in England. Mr. Justice Noël referred to the decision of Mr. Justice Laddie in first instance in *Lilly Icos Ltd. v. Pfizer Ltd.*, [2001] F.S.R. 16, affirmed by the English Court of Appeal at [2002] EWCA Civ 1, and concluded:

> [43] The reasoning advanced by Mr. Justice Laddie and approved by the English Court of Appeal is that where the motivation to achieve a result is very high, the degree of expected success becomes a minor matter. In such circumstances, the skilled person may feel compelled to pursue experimentation even though the chances of success are not particularly high.

[100] However, Mr. Justice Noël went on to say that an approach based on the mere possibility that something might work was expressly rejected in *Plavix*, above, at paragraph 66, which I quoted earlier.

***Sound Prediction of Usefulness***

[101] Purdue has been criticized for claiming profiles on compositions containing from about 10 to about 160 mg of oxycodone. Yet, the range tested *in vivo* was only 4 mg to 30 mg. It has not proven the viability of the invention at higher dosages. However, an invention may be based on “sound prediction”. A prediction may turn out to be correct, but there may have been no

sound basis for making it in the first place. In effect it was a lucky guess. If so the claim falls. On the other hand, a prediction may be sound, but later prove to be incorrect. In that case the claim falls, not because of lack of sound prediction, but rather because the invention was not useful.

[102] As stated by Mr. Justice Binnie in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] S.C.R. 153, (2002) 21 C.P.R. (4th) 499 (*AZT*) at paragraph 70:

> [70] The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction.-- Secondly, the inventor must have at the date of the patent application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis.-- Thirdly, there must be proper disclosure.

[103] The factual basis and sound line of reasoning from which the desired result could be inferred is grounded in the immediate release oxycodone tablets already on the market which were useful pain killers and which possessed a particular pharmacokinetic profile. Although these were 10 mg tablets, Dr. Kaiko was able to predict the characteristics of larger dosages by “partition coefficient”. For most, but not all, drugs, doubling the dosage would result in a doubling of the concentration in the blood plasma at any particular point in time. This would be achieved by multiplying the data for 10 mg dosages by 16. This is what he did with respect to the peak blood plasma concentration. However, he also sought a range after 12 hours in which the maximum concentration might be as much as one-half of the peak level. This variant was articulate and certainly has not been shown to have been a failure in practice. Indeed, it is more restrictive than partition coefficients would suggest.

[104] Pharmascience alleges that claim 11 was made simply to get around claim 9. It asserts that claim 9 is invalid as it was obvious in the light of the earlier Oshlack formulation patent in the United States. In my view that is not the case. Furthermore, even if it could be said the *in vitro* dissolution rate in claim 9 was too broad to give rise to an appropriate *in vivo* profile, it does not follow that the same would hold true for the narrower range in claim 11.

***Overbreadth and Lack of Disclosure***

[105] As I said at the outset, this application would be moot had Purdue not claimed matrixes which could lead to literally hundreds upon hundreds of different formulations. Yet, according to Pharmascience, it only disclosed variants of the previously patented AcroContin system. Although some leeway may be allowed, the invention teaches nothing about the use of HPMC in a matrix.

[106] As was said by President Thorson in *Minerals Separation North American Corp. v. Noranda Mines Ltd.*, [1947] Ex. C.R. 306 at page 352:

> By his claims the inventor puts fences around the fields of his monopoly and warns the public against trespassing on his property. His fences must be clearly placed in order to give the necessary warning and he must not fence in any property that is not his own.
>
> (Cited in *Free World*, above, at paragraph 14)

[107] I quoted part of paragraph 15 of *Free World* earlier in these reasons. I now repeat the paragraph in its entirety:

> 15 In reality, the “fences” often consist of complex layers of definitions of different elements (or “components” or “features” or “integers”) of differing complexity, substitutability and ingenuity.

> A matrix of descriptive words and phrases defines the monopoly, warns the public and ensnares the infringer. In some instances, the precise elements of the "fence" may be crucial or "essential" to the working of the invention as claimed; in others the inventor may contemplate, and the reader skilled in the art appreciate, that variants could easily be used or substituted without making any material difference to the working of the invention. The interpretative task of the court in claims construction is to separate the one from the other, to distinguish the essential from the inessential, and to give to the "field" framed by the former the legal protection to which the holder of a valid patent is entitled.

[108] Pharmascience relies upon paragraph 32 of *Free World*, which reads in part:

> ... As stated, the ingenuity of the patent lies not in the identification of a desirable result but in teaching one particular means to achieve it. The claims cannot be stretched to allow the patentee to monopolize anything that achieves the desirable result. It is not legitimate, for example, to obtain a patent for a particular method that grows hair on bald men and thereafter claim that *anything* that grows hair on bald men infringes.

[109] In my opinion, once the dissolution and pharmacokinetic profiles were established by means of a matrix system, it would be a relatively simple matter to skirt the claims by putting excipients in a matrix which were not the ones specifically used in the disclosed examples. Had the inventors worded the claims in such a way that AcroContin or slight variants thereof were essential, then Pharmascience's product would not infringe. This is what happened in *Biovail Pharmaceuticals Inc. v. Canada (Minister of National Health and Welfare)*, 2005 FC 9, 37 C.P.R. (4th) 487 in which what might have been a non-essential variant became essential because the inventors said so. Even without the express language of the claims, there is a presumption that a non-essential variant falls within its scope. (*Free World*, para. 57).

[110] No bargain is struck for disclosing the invention if it can be worked around by using a non-essential variant in a matrix.

[111] The question is whether what is claimed as the monopoly is something which the public already has. As stated by Professor Vaver in *Intellectual Property Law*, (Irwin Law, Concord, Ontario: 1997) at page 133:

> A double standard operates here. Courts give patents a non-literal "purposive" construction when they are testing for internal validity or trying to catch infringers. When testing prior documents for novelty, however, they construe them narrowly. The documents are then subjected to "the closest scrutiny," and a "weighty burden" is placed on the challenger. Sauce for the patent goose should perhaps also be sauce for the prior art gander. Prior documents should be examined purposively as a skilled reader would read them. This examination should cover obvious equivalents to described or claimed elements.

See *Shire Biochem Inc. v. Canada (Minister of Health)*, 2008 FC 538, 67 C.P.R. (4th) 94 at para. 60 and following.

[112] I believe the same approach should be taken with respect to allegations of invalidity on the grounds of obviousness in the light of the prior art. It is indeed difficult to apply the fourth step in the *Windsurfing/Pozzoli* approach, i.e. “viewed without any knowledge of the alleged invention as claimed –”.

[113] Furthermore as stated by Mr. Justice Binnie in *Free World* at paragraph 25 “It takes little ingenuity to assemble a dossier of prior art with the benefit of 20-20 hindsight.”

[114] In my opinion Purdue advanced the state of the art with something that was both useful and new. It is one thing to try, not knowing if the desired result is achievable. It is quite another when the path has been shown and it is known that the result is achievable.

[115] Furthermore, Purdue did not claim all routes to the desired result. The patent does not prevent Pharmascience from using other methods to control the release of oxycodone such as a reservoir or osmotic system, or to use a different *in vitro* profile or a different *in vivo* profile.

[116] Even though the groundwork had been laid, claims 5 and 11 have advanced the state of the art. They are an improvement on what was. At paragraph 95 of *AZT*, above, Mr. Justice Binnie quoted the *London Journal of Arts and Sciences* from1831, which opined that inventors are of three classes. The first are persons of genius. The second are those whose imagination is not so extensive but who are capable of making marked improvements. The third class may be made up of those with small imagination, without any great originality of thought, but who have a certain ingenuity. I would say this invention falls within the second category.

**CONCLUSION**

[117] For these reasons I would grant the application and prohibit the Minister from issuing a Notice of Compliance to Pharmascience until the expiry of patent ‘738.

[118] Purdue shall have its costs. As the Minister did not participate he shall neither be burdened nor favoured with costs. The parties are aware of recent jurisprudence which sets out reasonable cost parameters in applications such as these. Hopefully, they will agree. If not, directions may be

sought.

[119] These reasons were issued on a confidential basis July 16, 2009. The parties have not requested that any part thereof be redacted for this public version.

"Sean Harrington"
Judge

Vancouver, British Columbia
July 16, 2009

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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|---|---|
| **DOCKET:** | T-1837-07 |
| **STYLE OF CAUSE:** | Purdue Pharma v. Pharma Science Inc. et al. |
| **PLACE OF HEARING:** | Ottawa, Ontario |
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| Ms. Carol Hitchman<br>Ms. Paula Bremner | FOR THE RESPONDENT,<br>PHARMASCIENCE INC. |
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