Federal Court of Appeal | Cour d'appel fédérale

Date: 20210311

Dockets: A-282-18
A-283-18

Citation: 2021 FCA 52

CORAM: **RENNIE J.A.**
DE MONTIGNY J.A.
GLEASON J.A.

Docket: A-282-18

BETWEEN:

APOTEX INC.

Appellant

and

SHIRE LLC and SHIRE PHARMA CANADA ULC

Respondents

Docket: A-283-18

AND BETWEEN:

APOTEX INC.

Appellant

and

SHIRE PHARMA CANADA ULC, SHIRE LLC
and THE MINISTER OF HEALTH

Respondents

Heard by online video conference hosted by the Registry on December 15 and 16, 2020.

Judgment delivered at Ottawa, Ontario, on March 11, 2021.

REASONS FOR JUDGMENT BY: RENNIE J.A.

CONCURRED IN BY: DE MONTIGNY J.A.
GLEASON J.A.

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REASONS FOR JUDGMENT

RENNIE J.A.

I. Overview

[1] Lisdexamfetamine, or L-lysine-d-amphetamine (LDX), is a chemical compound. It is sold as a prescription medication under the trade name Vyvanse by the respondents Shire LLC and Shire Pharma Canada ULC and is designed to treat attention deficit and hyperactivity disorder (ADHD). The respondents hold the Canadian patent for LDX.

[2] In February 2016 Apotex Inc. filed an abbreviated new drug submission with Health Canada seeking a Notice of Compliance (NOC) to manufacture and sell Apo-Lisdexamfetamine and served Shire with a Notice of Allegation under the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-113 (*PM(NOC) Regulations*). In response, Shire sought an order from the Federal Court prohibiting the Minister from granting Apotex the NOC until the expiry of Canadian Patent No 2,527,646 (CA 646) pursuant to subsection 6(1) of the *PM(NOC) Regulations.*

[3] Apotex subsequently commenced an action against Shire pursuant to section 60 of the *Patent Act*, R.S.C. 1985, c. P-4 (*Patent Act*) seeking a declaration that CA 646 was invalid, or, alternatively, that Apo-Lisdexamfetamine would not infringe any valid claim of CA 646. The prohibition and invalidity proceedings were consolidated prior to trial in the Federal Court.

[4] The claims of CA 646 fall into various subject matter categories: some are bare chemical formulae, others describe a reduced potential for abuse of LDX, others describe some of LDX's pharmacokinetic properties, others describe its use, others describe dosing amounts and frequencies. Shire asserted that some, but not all of the claims of CA 646 would be infringed by Apotex. Claims 1 to 5, 8, 10 to 12, 22, 24 to 30, 33 to 36, and 43, the claims in issue, are reproduced in Annex A to these reasons.

[5] In reasons reported at 2018 FC 637 (*Decision*), Fothergill J. concluded that the asserted claims of CA 646 were valid and that the Minister should be prohibited from issuing an NOC for LDX to Apotex.

[6] Apotex appeals both judgments. It contends that the judge erred in not finding the asserted claims of CA 646 both obvious and anticipated.

[7] For the reasons that follow, I would dismiss the appeals with costs.

II. Facts

[8] Amphetamine is an established treatment for ADHD, obesity and narcolepsy due to its stimulating effects on the central nervous system. In its bare form, amphetamine is an immediate release compound: it is absorbed immediately upon entering the body. This rapid assimilation requires patients to take doses more frequently throughout the day in order to maintain therapeutic blood plasma levels. In contrast, a sustained release compound slowly absorbs into

the bloodstream. The slower release allows patients to take less frequent doses while still maintaining consistent, therapeutic blood plasma levels of the compound.

[9] LDX is a type of sustained release compound known as a "prodrug" – a molecule that is metabolically converted into its active form. It is formed when amphetamine attaches to the amino acid L-lysine via an amide bond. Upon entering the body, the amphetamine cleaves from the amino acid, liberating the active moiety of d-amphetamine.

[10] The immediate and sustained released formulations of amphetamine were susceptible to abuse. LDX reduced that abuse potential; the amphetamine is covalently modified in a manner that decreases its pharmacological activity compared to unmodified amphetamine whether taken at doses above those considered therapeutic or using methods other than those prescribed.

III. Decision of the Federal Court

[11] In addressing the anticipation requirement pursuant to section 28.2 of the *Patent Act*, the judge adopted as the starting point the test articulated in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at para. 25 (*Sanofi*): "the prior patent must disclose subject matter which, if performed, would necessarily result in infringement of the patent" (*Decision* at para. 99).

[12] On this issue, Apotex claimed Australian Patent 1,965,054,168 (AU 168) discloses the asserted claims of CA 646. After reviewing the expert testimony and the two patents, the judge disagreed, concluding Apotex had not met its burden with respect to the disclosure requirement.

[13] Turning to the issue of obviousness, the judge followed the four-part test specified in *Sanofi* (at para. 67). Upon ascertaining the person skilled in the art (PSIA) and their common general knowledge, the judge concluded that the claims' inventive concept was grasped without difficulty. The judge defined CA 646's inventive concept as "a sustained release formulation of a therapeutically useful dose of amphetamine that is resistant to abuse" (*Decision* at para. 122).

[14] In reaching this decision, the judge rejected Apotex's argument that, based on the guidance of *Ciba Specialty Chemicals Water Treatments Limited v. SNF Inc.*, 2017 FCA 225 (*Ciba*), claims construction was dispositive and the judge would err in searching for an inventive concept. In rejecting this proposition, the judge commented that, as a matter of *stare decisis*, *Ciba* could not be understood as departing from *Sanofi*, and in any event, *Ciba* pertained to a process patent, while *Sanofi* concerned a patent for a bare chemical and was more applicable to the facts of the case before the Court.

[15] On the issue of the differences between the prior art and the inventive concept, the judge concluded that as of the relevant date, May 2003, there were numerous differences between the state of the art and the inventive concept. He found those to include that in the state of the art no prodrug had yet been developed as a means of reducing the potential for abuse, that the development of LDX was expensive and time-consuming and that even minor changes to

covalent bonds required potential prodrugs to undergo extensive testing in order to ascertain their properties.

[16] In light of these specific differences, the judge concluded that the overall difference between the inventive concept and the prior art was the compound LDX and its advantageous properties, as none of the prior art indicated LDX would provide a sustained release treatment of amphetamine with a reduced potential for oral, intranasal, and intravenous abuse. He concluded that these differences were not obvious to try, the fourth *Sanofi* factor, largely as it was not more or less self-evident that LDX ought to work as an abuse resistant and sustained release formulation using only routine tests. Additionally, the judge found that the received teaching taught away from the use of prodrugs, that the inventors of LDX conducted extensive work prior to the discovery of LDX, and including failed attempts to find a prodrug version of amphetamine.

[17] After concluding the asserted claims of CA 646 were neither anticipated nor obvious, the judge also found them sufficiently specific, not overbroad and therefore valid. As no exceptional circumstances existed that would warrant departing from the general guidance that the prohibition action follows the result of the impeachment action, the judge granted Shire's request for a prohibition order pursuant to subsection 6(1) of the *PM(NOC) Regulations*.

IV. Arguments in Brief

[18] The thrust of Apotex's argument before us is that the tests for anticipation and obviousness are claim-by-claim analyses that focus on the subject matter of the claims alone. By examining the patent as a whole and working from the notion of "inventive concept" as opposed to the precise language of the claims, the judge did not do what sections 28.2 and 28.3 of the *Patent Act* mandate – assessing validity on the basis of each individual claim. It argues that the judge's approach was inconsistent with the changes to the *Patent Act* following *Sanofi*, with the Supreme Court decision in *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 at para. 31 (*AstraZeneca Canada Inc.*), and with recent decisions of this court in *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30 (*Hospira*) and, as noted, *Ciba*.

[19] Turning to anticipation, Apotex argues only the claimed bare chemical formula itself should be compared to the genus disclosed in the prior art. It is only in a selection patent that the advantageous qualities of a compound are also examined against the prior art (*Hoffman-La Roche Limited v. Apotex Inc.*, 2013 FC 718 at paras. 177, 196, 237-241). As CA 646 was not categorised by the judge as a selection patent, it was an error to consider the advantages of LDX in the anticipation analysis, particularly as these properties were not essential elements of the asserted claims in question. Since LDX would fit into the "advantageous" category of compounds described in AU 168, it disclosed CA 646's claims 1-5, 8, 10-12, 22, 24-30, 33-36, and 43, as LDX is created when AU 168 is performed across the scope of its genus.

[20] On the issue of obviousness, Apotex challenges the judge's analysis of CA 646's inventive concept. In concluding there was only one inventive concept for the entire patent, the judge departed from the claim-by-claim approach mandated by section 28.3 of the *Patent Act.* This, according to Apotex, was an egregious error in light of criticism, both judicial and academic, of the "inventive concept" as a circular, illogical, and redundant inquiry (*Bristol-Myers Squibb Canada Co. v. Teva Canada Limited*, 2017 FCA 76 at para. 69 (*Bristol-Myers*); *Ciba* at paras. 72-77). Additionally, the inventive concept identified by the judge created redundancies within some of CA 646's enumerated claims, which, as discussed in *Tetra Tech EBA Inc. v. Georgetown Rail Equipment Company*, 2019 FCA 203 (*Tetra Tech EBA Inc.*) and *Tearlab Corporation v. I-MED Pharma Inc.*, 2019 FCA 179 (*Tearlab*), suggests a fundamental problem in the analysis.

[21] Apotex also says that the judge erred in stage 4 of the *Sanofi* analysis by considering whether the properties of LDX were predictable without experimentation in the obvious and obvious to try analyses, failing to examine each factor in the obvious to try framework (*Hospira* at paras. 90, 95), and failing to recognize that secondary factors (in this case, evidence of experimentation beyond the experimentation necessary to reach that claim) were not determinative and were to be applied narrowly to the subject matter of each claim.

[22] Shire, on anticipation, responds that AU 168 does not disclose any claim of CA 646. Shire rests its case on *Sanofi* at paragraph 25 and the requirement that performing the subject matter of a piece of prior art must necessarily infringe the subject matter of a claim of a patent to disclose it. Further, if the PSIA must make a choice in order to infringe the subject matter of the

claim, the claim is not disclosed. Here, because LDX is not a specifically enumerated example of AU 168, and is instead only one member of a described class of "advantageous compounds", the PSIA would have to make a choice to make LDX. Because choice is necessary to land on LDX, LDX is not disclosed by AU 168.

[23] On obviousness, Shire contends that *Sanofi*, *Apotex Inc. v. Allergan Inc.*, 2012 FCA 308 (*Apotex Inc. v. Allergan*), and *Bell Helicopter Textron Canada Limitée v. Eurocopter, société par actions simplifiée*, 2013 FCA 219 at paras. 122-126 (*Bell Helicopter*), support the identification of a singular inventive concept for the entire patent. Further, in a flexible, contextual and fact driven inquiry it is open to the judge to consider the properties of the subject-matter of the claim when ascertaining a singular inventive concept (*Apotex Inc. v. Pfizer Canada Inc.*, 2019 FCA 16 at paras. 32, 37-38 (*Apotex Inc. v. Pfizer*)). This is because the subject matter of the claim describes its scope of protection, not why the subject-matter is patentable (*Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para. 14 (*Free World*); *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, 122 D.L.R. (3d) 203 at 525-526, 531-533).

[24] With respect to the argument that the judge erred in the *Sanofi* stage 4 analysis, Shire claims that stage 4 is a contextual analysis aimed at addressing the problem the invention was created to solve. Thus, in the case of a bare chemical claim, the focus should not be limited to the experimentation required to create the compound but rather on the experimentation and motivation required to reach a particular compound as a solution to the problem at hand. That the

process could have been easy to carry out or the result of routine testing is an insufficient basis for concluding the invention was obvious to try (*Sanofi* at para. 85).

V. Analysis

[25] I begin with a review of a few basic principles governing patent infringement.

[26] In a patent dispute, the emphasis is on the claims as worded. While the assessment of a patent's subject matter or utility may require a more holistic appreciation of the patent and its claims, the tests for obviousness and anticipation require a claim-by-claim analysis (*AstraZeneca Canada Inc.* at para. 54; *Hospira* at para. 71).

[27] Only if every claim in a patent is invalid will the entire patent be invalid. If an independent claim is declared invalid, section 58 of the *Patent Act* allows for the examination of dependent claims in order to determine if their additional elements rectify the deficiencies in the independent claim. If so, the dependent claim remains valid despite the independent claim's invalidity (*AstraZeneca Canada Inc.* at para. 46; *Zero Spill Systems (Int'l) Inc. v. Heide*, 2015 FCA 115 at para. 94 (*Zero Spill Systems*); *Safe Gaming System v. Atlantic Lottery Corporation*, 2018 FC 542 at para. 159; *Seedlings Life Science Ventures, LLC v. Pfizer Canada ULC*, 2020 FC 1 at para. 71).

[28] Much of the argument before us focused on whether, and if so how, these principles of claim construction vary or apply at all depending on whether the patent is a selection patent. A

selection patent is a patent whose subject matter is a fraction of a larger known class which was the subject matter of a previous disclosure (*Sanofi* at para. 1).

[29] The judge did not decide whether CA 646 was a selection patent, and the arguments before us pivot on the consequences of that. The judge did not find CA 646 to be a selection patent on the basis that CA 646 did not explicitly reference or discuss the advantages of LDX in relation to the compounds claimed in AU 168 (*Decision* at paras. 93, 98). Apotex says because of this, the patent is not a selection patent and that this had consequences for the correctness of the judge's analysis – the judge erred in having regard to the specification.

[30] Shire, in turn, claims the judge's analysis was correct, regardless of whether CA 646 was a selection patent or not. As this conversation occurs throughout the arguments on both anticipation and obviousness, I will address the substance of the matter here.

[31] There is no magic to the term "selection patent". A selection patent is simply a patent devoted to a selection of a particular compound, or compounds, from a larger grouping of compounds previously disclosed in general terms and claimed in a pre-existing genus patent. The *Patent Act* does not refer to selection patents and the jurisprudence is clear that a selection patent does not differ in substance or form from other patents (*Sanofi* at para. 9).

[32] A selection patent is subject to the same requirements and vulnerable to the same attacks as any other patent, including attacks based on anticipation and obviousness (*Sanofi* at paras. 9, 108; *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, [2012] 1 F.C.R. 349 at para.

33 (*Eli Lilly*)). Although the failure of a judge to characterize a patent one way or another may reflect a lack of understanding of the patent and its factual context, the failure to do so, in and of itself, is not an error of law. Put otherwise, a finding that the characteristics of a selection patent have, or have not, been met, "does not constitute an independent basis upon which to attack the validity of the patent" (*Eli Lilly* at paras. 27-28, 33, 48). I note, parenthetically, that I am not suggesting that the judge in this case did not have that understanding of the patent or its context.

[33] The exercise of classification of a patent as a "selection" or "process" patent is to assist the Court in understanding "the nature of the beast" it is dealing with (*Eli Lilly* at para. 28). Essentially, classification contextualizes what specific claims profess to do while also making it easier to compare the facts of the particular case before the Court to other previous fact scenarios (*Eli Lilly* at paras. 27-28). For example, selection patents commonly attest that their inventiveness lies in "the making of the selected compound, coupled with its advantage or advantages" (*Eli Lilly* at para. 78).

[34] As noted, the validity analysis does not change depending on whether the patent was formally classified as a selection patent or not. The focus of an anticipation or obviousness inquiry is, as always, on what the patent actually claims in comparison to what is disclosed in the prior art. Each validity analysis should be entered into with open eyes as to the application of the specific facts against the panoply of tests – utility, novelty, anticipation, and obviousness, etc.

[35] These principles, I suggest, frame the approach to this appeal. There is no divergence between the requirements for a valid patent claim depending on whether it is found in a selection patent or not.

A. *Anticipation*

[36] The law on anticipation is clear. "[A]nticipation requires proof of both disclosure and enablement" (*Sanofi* at para. 42). If a published reference fails to either disclose or enable the essential elements of a claim, the patent claim is novel, or not-anticipated (*Hospira* at para. 71; *Sanofi* at paras. 25-28).

[37] A prior art reference discloses the claimed invention when, if performed, the prior art reference would necessarily result in the infringement of the patent claim. Phrased another way:

> To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented […] A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee.

(General Tire & Rubber Company v. Firestone Tyre & Rubber Company Limited, [1972] RPC 457 at 486 (*General Tire*), cited in *Sanofi* at para. 21).

[38] If the flag is planted, the claim has been disclosed (*Sanofi* at para. 21).

[39] The second requirement is enablement. The reference in the prior art must be sufficiently detailed as to enable a PSIA to perform the claimed invention without the exercise of inventive

ingenuity or undue experimentation (*Sanofi* at paras. 25, 33-37). In this instance, both parties concede there is no enablement issue (*Decision* at para. 100).

[40] The language of the *Sanofi* test is important: if the performance of a published reference does not necessarily result in infringement of the claim, then the published reference does not disclose that claim. This test takes on particular meaning in the context of patents such as AU 168 and CA 646.

[41] The core of Apotex's argument is that the judge erred by failing to conduct the anticipation analysis by comparing AU 168 to the subject matter defined by each of the individual claims asserted by the 646 patent, as required by section 28.2 of the *Patent Act*. The judge, instead, asked whether AU 168 disclosed both the subject matter of the claim and the advantages and properties of that subject matter. Apotex says that to be anticipatory, the patent need not disclose the properties of, or the advantages in using, the claimed invention. The judge's methodology was therefore, according to Apotex, inconsistent with this Court's guidance in *Hospira*.

[42] Viewed in this light, the judge's factual findings are irrelevant, as, according to Apotex, the wrong approach was applied to the test of anticipation (Appellant's factum at para. 46). It asserts that AU 168 necessarily encompasses the compound LDX because, if AU 168 was practiced "across its scope" it would necessarily infringe CA 646 (Appellant's factum at para. 38).

[43] Apotex's argument, distilled, amounts to no more than an assertion that genus patents necessarily anticipate the chemical composition claims in species patents.

[44] To accede to this proposition would, in these circumstances, be a marked departure from established precedent, including, most recently, the decision of this Court in *Hospira* at para. 66 that "the prior art reference must disclose the claimed invention such that, if performed, it would necessarily result in infringement." The necessarily infringe test, most recently endorsed in *Hospira*, applies to all patents, as do the requirements of section 28.2 of the *Patent Act*.

[45] It would also be inconsistent with the principle articulated, and noted earlier, in *General Tire*, that "[t]he prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee" (at 486). The point was also made succinctly in *Ranbaxy Laboratories Limited v. AstraZeneca AB*, [2013] FCA 368 (Aus.) at para. 170:

> […] it is not sufficient for a prior publication to merely "include" or "encompass" the claimed invention — a broad disclosure will not necessarily anticipate a later, more specific claim: see eg *Eli Lilly* [2013] FCA 214 at [272]–[293] and the authorities cited therein.

[46] This is not to say that anticipation has no role in the context of genus disclosures – to the contrary, it is very much alive. A genus may, depending on its size, the language of the claims, context and included examples, anticipate the individual species (see, *e.g.*, *Aux Sable Liquid Products LP v. JL Energy Transportation Inc.*, 2019 FC 581 at paras. 90, 98; *Valence Technology Inc. v. Phostech Lithium Inc.*, 2011 FC 174, aff'd 2011 FCA 237 at paras. 228-230).

[47] Therefore, the ultimate answer to the question of whether the inventor "planted a flag" at the compound is driven by the specific evidence in each case. Here, the judge identified differences that relate to the specific asserted claims within CA 646. In doing so, he found that those specific claims were not anticipated. The judge undertook the exercise required of him by *Sanofi*. The judge identified the correct test for anticipation (*Decision* at paras. 99-100) and his conclusion that CA 646 was not anticipated by AU 168 was amply supported by the evidence.

[48] The reasoning in *Ranbaxy* is directly on point and, as the following review of the facts as found by the judge show, dispositive of Apotex's argument.

[49] The judge identified the various ways CA 646 and AU 168 are different. While AU 168 refers to a class of advantageous compounds, LDX is not specifically mentioned in any of its 30 examples. None of the compounds in AU 168 were said to be for the treatment of ADHD and none related to the reduction in abuse potential. AU 168 does not mention prodrugs, any of LDX's pharmacokinetic data, such as its equivalent area under curve (AUC) and lowered maximum amphetamine concentration (C_{max}), nor was the intended functionality explained. (*Decision* at paras. 106-108, 137).

[50] Claims 1 to 5 and claim 8 of CA 646 describe various compositions and examples of LDX, the linkage of LDX and a therapeutically acceptable salt, potentially with an additive. For these claims, the wording of the "necessarily infringe" test becomes particularly relevant. As found by the judge, LDX was not an example described in AU 168, it was merely one of a large class of "advantageous" compounds (*Decision* at paras. 104-105). As such, the PSIA would have

to adopt a specific way forward in order to make LDX. Phrased another way, there are numerous other ways to "perform" AU 168 without necessarily infringing CA 646. Therefore, LDX, as claimed in claims 1-5 and 8, was not specifically disclosed by AU 168 (*Eli Lilly* at para. 52; *Sanofi* at para. 39).

[51] Although this finding is dispositive of the issue for each of its dependant claims, the judge also found claims 10-12 to be novel. Claim 10 discusses the release of amphetamine. Claim 11 discusses the provision of a therapeutically effective amount of amphetamine. Claim 12 discusses the reduction in C_{max} associated with the use of LDX, which, as discussed in the patent disclosure, is one aspect of the compound that makes it abuse resistant.

[52] Asserted claims 22 and 24-30 are dependent on claims 11-15. Since the essential elements of claims 11-15 include the therapeutic benefits, prolonged release, and abuse-resistant properties of LDX, so do their dependent claims, 22 and 24-30, which stand or fall accordingly. Apotex did not contest the validity of claims 13-15 and the onus was on it to show how the dependent claims were invalid notwithstanding the presumed validity of the un-asserted claims in the 11-15 claim range (*Patent Act* at s. 43(2)).

[53] Claims 33-36 relate to the use of LDX for the treatment of ADHD. Since the subject matter of these claims had not previously been disclosed, dependent claim 43 was also not disclosed.

[54] Apotex is correct that the judge's comment specifying, "[t]he process of making LDX is not disclosed by AU 168" (*Decision* at para. 108) was irrelevant to the disclosure analysis as it speaks to the enablement requirement, which both parties admitted was not in issue. Whether this error has any consequence on the integrity of the anticipation analysis is another matter. When read in light of the list of enumerated differences, the error is akin to an "imperfection" (*Millennium Pharmaceuticals Inc. v. Teva Canada Limited*, 2019 FCA 273 leave to appeal to SCC refused, 39007 (7 May 2020) at paras. 8-12). It does not rise to the level of a reversible error.

B. *Obviousness*

[55] As with anticipation, obviousness is assessed on a claim-by-claim basis (*Zero Spill Systems* at paras. 83, 85). Each claim is evaluated against the four-part *Sanofi* test (at para. 67):

> (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?

[56] As I indicated earlier, the issues on appeal relate to stages 2-4. However, as these stages build upon each other, I will briefly revisit the judge's conclusions in relation to stage 1.

Stage 1: The Person Ordinarily Skilled in the Art and their Common General Knowledge

[57] The judge defined the PSIA as (*Decision* at para. 60):

> [A] drug development team with expertise in medicinal chemistry, pharmacology, pharmaceutical formulation and medicine. Shire described the members of the team as having "knowledge of (a) medicinal chemistry; (b) pharmaceutical formulation; (c) pharmacology; and (d) the treatment of ADHD." Each of the team members would have an advanced degree such as a PhD or MD, and would have approximately three to five years of work experience.

[58] The judge then determined that the PSIA's relevant common general knowledge comprised the following elements (*Decision* at paras. 66, 70):

> (a) ADHD is a common neurobehavioural disorder in both children and adults that is characterized by a persistent pattern of hyperactivity, impulsivity and inattention.
>
> (b) Physicians could treat the symptoms of ADHD with stimulants, including amphetamine.
>
> (c) Amphetamine products were available as immediate and sustained release formulations, each of which produced different durations of action.
>
> (d) In sustained release formulations, the dosage form was designed to release the drug at a continuous and controlled rate for a longer period than would normally be achieved using an immediate release formulation.
>
> (e) One significant drawback of both immediate and sustained release formulations of amphetamine was their potential for abuse. Those who abused amphetamine wished to attain the euphoria that results from exposure to a rapid and elevated dose. In pharmacokinetic terms, abusers were seeking a short time to maximum plasma concentration [T_{max}] and a high peak plasma concentration [C_{max}] of amphetamine.
>
> (f) As of May 2003, the PSIA would have recognized the need for an amphetamine product that could not be abused by crushing and snorting, dissolving and injecting, or taking an oral overdose.
>
> (g) The PSIA would have understood that one of the known strategies to reduce the abuse of amphetamine was to reduce its C_{max} and extend its T_{max}.

> (h) As of May 2003, no known formulation could address all principal routes of abuse of amphetamine (i.e., crushing and snorting, dissolving and injection, oral overdose). Adderall XR was an extended release formulation which reduced C_{max} and extended T_{max}, but did not provide a means to prevent abusers from circumventing the extended release mechanism, either by crushing or dissolution.
>
> (i) Concerta was a known methylphenidate composition that was designed to form a paste when crushed so it could not be snorted. However, Concerta would dissolve in water and release its active ingredient for injection or swallowing, and thus its abuse protection was limited. Further, the extended release mechanism in Concerta could be undone by crushing or chewing the tablet.
>
> (j) An irritant could be added to a formulation that was intended to sting if snorted or injected. However, the irritant would do nothing to alter the pharmacokinetics of amphetamine, or stop someone from dissolving the drug and ingesting it orally. No formulation containing an irritant to discourage abuse had ever reached the market.
>
> […]
>
> [70] […] [T]he PSIA's common general knowledge would include an awareness of the development of prodrugs to overcome barriers to a drug's usefulness, including its pharmacokinetic limitations. […]

Stage 2: The Inventive Concept

[59] It is at stage 2, where the Court is to "identify the inventive concept of the claim in question or if that cannot readily be done, construe it", that the parties join issue. Distilled, the dispute before us is the end point of the obviousness inquiry – both how it is determined and whether the judge erred in his application of the concept.

[60] The judge held that the inventive concept could "be grasped without difficulty", finding that "the inventive concept of the 646 Patent is a sustained release formulation of a therapeutically useful dose of amphetamine that is resistant to abuse" (*Decision* at paras. 117,

122, 132). He characterized the inventive concept following a review of the claims and the problem that CA 646 was intended to solve (paras. 117, 120, 132).

[61] Apotex contends the judge erred in doing so as section 28.3 mandates a narrow, claim-based end point, focussed solely on the "subject matter of the claim". Recourse to the specification or disclosure is not allowed. The consequence of this is that the claims in issue are limited to their bare formulae and the process of their making, excluding their beneficial properties or anything that is not an "essential element" of the claim. The essential element of the claim in issue was LDX – the bare chemical compound, without its features or advantages, as those can only be found in the specification.

[62] Apotex further argues the judge erred in declaring the inventive concept "could be grasped without difficulty" in the absence of agreement of the parties or an analysis of whether any of the claims' inventive concepts could be readily identified from the wording of the claim itself, as was done in *Sanofi* and is now required by both section 28.3 of the *Patent Act* and *AstraZeneca Canada Inc*. Instead, according to Apotex, the judge focussed on the "amorphous and ill-defined" inventive concept that could be derived from the specification as a whole rather than the claims themselves, contrary to established jurisprudence (*Tearlab* at para. 49; *Ciba* at paras. 72, 74).

[63] Further, the judge adopted the inventive concept without explaining why it was readily apparent (*Decision* at para. 122). Apotex argues that none of the asserted claims related to sustained release or abuse resistance. Those concepts were present in claims 16-21 (sustained

release profile) and 45 (abuse resistance) of CA 646, which were not asserted. As a consequence, the specific inventive concept(s) of some of the claims were rendered redundant, giving rise to a palpable and overriding error.

[64] Apotex's arguments cannot succeed. I say this for two reasons.

[65] Section 28.3 of the *Patent Act* does not displace the common law test for obviousness. The inventive concept, properly construed and applied, remains the end point for the obviousness inquiry. Second, I do not see an error in the judge's analysis of the inventive concept, nor in its application. Further, the arguments raised by Apotex, interesting as they may be, are of no consequence in light of the judge's factual findings. I will elaborate on this later.

[66] I begin with three basic principles.

[67] First, on occasion, the inventive concept may be "readily apparent" where there is agreement on it. If not, the inventive concept needs to be construed. To do that, the judge is to first determine whether it can be identified from the previously completed claims construction exercise (*Ciba* at paras. 76-77). Second, where it is not possible to fully grasp the nature of the inventive concept solely from those claims, the judge may have regard to the patent specification to determine if it provides any insight or clarification into the inventive concept of the claim(s) in issue (*Sanofi* at para. 77; *AstraZeneca Canada Inc.* at para. 31). If this step is necessary, "it is not permissible to read the specification in order to construe the [inventive concept of the] claims more narrowly or widely than the text will allow" (*Sanofi* at para. 77).

[68] Second, insight from *Sanofi* shows that while an inventive concept is an attribute of the claims, it differs from claims construction (Joshua Sealy-Harrington, "The Inventive Concept in Patent Law: Not so Obvious", (2015) 27 I.P.J. 385). As such, though the process for the identification of an inventive concept bears a striking resemblance to that of claims construction, as seen in longstanding Supreme Court of Canada rulings (see, *e.g.*, *Free World* at paras. 33-50; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at paras. 43, 49), it is nonetheless a distinct, separate exercise.

[69] Third, the caution expressed in *Unilever PLC. v. Chefaro Proprietaries Ltd.*, [1994] R.P.C. 567 (Eng. C.A.) at 580 (*Unilever PLC*) remains a governing legal principle: "[i]t is the 'inventive concept' of the claim in question which must be considered, not some generalised concept to be derived from the specification as a whole." Thus, as required by section 28.3 as well as the wording of *Sanofi*, it is the inventive concept(s) of the claim(s) in issue that must be the focus of an obviousness inquiry, not the inventive concept of the patent (*Ciba* at para. 72; *Bauer Hockey Corp. v. Easton Sports Canada Inc.*, 2010 FC 361 at para. 250, aff'd 2011 FCA 83; *Pfizer Canada Inc. v. Apotex Inc.*, 2017 FC 774 at para. 247, aff'd 2019 FCA 16 (*Pfizer Canada Inc.*)).

[70] The judge did not determine the inventive concept based on some "generalized concept"; rather it was based on a reading of the claims informed by the specification.

[71] A reading of the *Decision* as a whole shows that the finding that the inventive concept could "be grasped without difficulty" was based on an analysis of the claims as informed by the

specification (see, *e.g.*, the *Decision* at paras. 119-122). This aligns with the process applied by the Supreme Court in *Sanofi* and described above. I cannot agree with the conclusion that the inventive concept was faulty by reason of a failure of the judge to explain its origins in copious detail. As will be explained, it was, in fact, easily deciphered from the claims and specification.

[72] As in *Sanofi*, claims 1-5 of the patent in suit in this appeal are to bare chemical compounds. The essential element of each of these claims is simply the chemical formula itself which, standing alone, says nothing as to the "inventiveness" of the patent claims. As such, it is necessary to turn to the specification for amplification. The language of *Sanofi* is directly applicable:

> [77] The inventive concept of the claims is not readily discernable from the claims themselves. A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims. Of course, it is not permissible to read the specification in order to construe the claims more narrowly or widely than the text will allow.
>
> [78] In the present case, it is apparent that the inventive concept of the claims in the '777 patent is a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the '875 patent and the methods for obtaining that compound.

[73] It should be recalled that in *Sanofi* the Supreme Court found that the inventive concept was "not readily discernable from the claims themselves" (at para. 77). What Rothstein J. did next is, however, very instructive; the beneficial properties of the bare formulae were examined (para. 78).

[74] I cannot agree that the effect of section 28.3 of the *Patent Act* is to narrow the inventive concept to the essential elements of the claim itself. This conflates the claims construction exercise with the identification of the inventive concept, and would alter, in a very significant manner, the inquiry into "inventiveness", which is the sole purpose of the obviousness inquiry. Beyond *Sanofi* , there are many cases in which this Court has upheld the use of a specification to determine the inventive concept where it was not readily discernable from the claims themselves (*Apotex Inc. v. Allergan* at para. 72, citing *Apotex Inc. v. ADIR*, 2009 FCA 222 at para. 58; see also *Apotex Inc. v. Pfizer* at para. 39).

[75] Although identification of the inventive concept follows from claims construction and is necessarily informed by it, they are nonetheless discrete exercises, with discrete purposes (*Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc.*, 2016 FCA 119 at paras. 40-41; *Bell Helicopter* at paras. 122-126). As noted earlier, the purpose of claims construction is to determine the scope of the claim by looking at the "subject matter of the claim". It does not, on its own, determine a claim's validity. Section 28.3, in codifying the common law requirement that an invention not be obvious, did not displace the longstanding jurisprudence that tells us *how* obviousness is determined.

[76] The inventive concept is an element of that determination. Its purpose is to help determine what, if anything, makes the claim, as constructed, inventive. This is the very inquiry section 28.3 asks of us. As noted in *Bristol-Myers*, *Sanofi* did not change the substantive law of obviousness by implication, and the term "inventive concept" is not materially different than the previously used term of "solution taught by the patent" (*Bristol-Myers* at paras. 65-68, 75). This

is the lens that we should keep in mind when determining the inventive concept. This lens becomes particularly important if recourse to the specification is required. For example, in the case of a bare chemical formula claim, not all the chemical's properties will inform its inventive concept (*Bristol-Myers* at para. 74; *Teva Canada Limited v. Pfizer Canada Inc.*, 2019 FCA 15 at para. 34).

[77] In sum, a single inventive concept must flow through a patent, but each claim's specific inventive concept may be different. I will return to this point later when I consider Apotex's argument that the judge erred in adopting an inventive concept that was redundant with some of the claims.

[78] I turn to Apotex's second argument that, in any event, the judge erred in construing the inventive concept.

[79] As previously explained, similar to *Sanofi*, the independent claims in issue were bare chemical formula claims. Thus, an examination of the essential elements of the claims did not reveal their inventive concept(s). Recourse to the specification was required (*Sanofi* at para. 77).

[80] In this case, as is typically seen in many patents, including the patent at issue in *Sanofi*, the description of CA 646 contains a background statement describing the beneficial properties of the invention. Here, this occurs in paragraph 003 of the description. Also similar to *Sanofi*, CA 646 contains a study comparing the performance of several chemicals to amphetamine, as summarised in Table 46. Some of these chemicals are examples of chemicals encompassed by

AU 168. Though the judge was correct in finding that "[t]he claimed advantages of LDX are principally in comparison to the parent compound amphetamine, not to other conjugates of d-amphetamine" (*Decision* at para. 93), by comparing all the chemicals against the same standard, Table 46 also demonstrates how the chemicals perform in relation to each other.

[81] Beyond comparing LDX to some other compounds encompassed by AU 168, the study and summary statement also lends itself to an inventive concept of "a sustained release formulation of a therapeutically useful dose of amphetamine that is resistant to abuse" (*Decision* at para. 122). This is because the study, by demonstrating that LDX has both a lower absorption rate and lower C_{max} when taken either intranasally or intravenously, demonstrates LDX's property of abuse resistance upon introduction into the body.

[82] Other elements of the inventive concept are rooted in the specification. As the judge found, abuse resistance upon oral administration and a sustained release formulation arise from the demonstration of how LDX has a combination of a lower C_{max} with a similar percent AUC. As discussed by Dr. Eldon in his report, the same amount of amphetamine is being released, but with a lower maximum concentration. This flattens, or extends, the curve. Indeed, both these aspects are described in the summary statement as a property of the compound, at paragraph 003 of the description:

> Additionally, release of amphetamine following oral administration [of the compound] occurs gradually over an extended period of time thereby eliminating spiking of drug levels. When taken at doses above the intended prescription, the bioavailability of amphetamine, including peak levels and total amount of drug absorbed, is substantially decreased. This decreases the potential for amphetamine abuse which often entails the use of extreme doses (1 g or more a day). The compositions are also resistant to abuse by parenteral routes of administration,

> such as intravenous - "shooting", intranasal "snorting", or inhalation "smoking", that are often employed in illicit use.

[83] Further, the summary statement at paragraph 003 of the description refers to “a therapeutically useful dose”. The supporting study, as summarised in Table 46, validates this statement by comparing the percent AUC’s of the various compounds. Particularly, it demonstrates how LDX provides a therapeutically effective release of amphetamine that is both roughly equivalent to straight amphetamine’s release and superior to the other compounds.

[84] In sum, the judge committed no error in having regard to these properties and beneficial features of LDX in determining the inventive concept of the claims in issue. I am also satisfied that the description was sufficient to allow the judge to construe these properties as features of the compound as claimed in the independent claims, such that they should form part of the inventive concept. Unlike the situation seen in *Bristol-Myers*, these beneficial properties were the “solution taught by the patent” claim. They explain the source of the motivation to pursue the solution (*Bristol-Myers* at para. 75).

[85] I now turn to Apotex’s argument that the inventive concept was faulty because it made the inventive concept of some of the claims “necessarily redundant”. Here again, it is useful to revisit a few basic principles.

[86] Although a claim by claim analysis of each claim’s inventive concept is to be conducted, it is important to remember that a single, overarching inventive concept connects every claim of a patent, with its genesis usually in the independent claim(s). As seen in *AstraZeneca Canada*

Inc., the "subject matter" of an invention can be multi-faceted (at para. 49). There, Rowe J., quoting David Vaver, Intellectual Property Law 2nd ed. (Toronto: Irwin Law, 2011), at 275, noted:

> For simplicity's sake, the rule is "one invention, one application, one patent." But inventions are like a many-faceted prism: multiple claims (sometimes running into the hundreds) covering all facets are allowed in the same patent if a "single general inventive concept" links them.

[87] Despite the singular common inventive concept, "[d]ifferent claims can, and generally will, have different inventive concepts" (*Unilever PLC* at 580 as quoted in *Ciba* at para. 72). These are, in effect, inventive concepts that are stitched on, or bound to, the single, common concept (*Ciba* at para. 72, quoting *Unilever PLC* at 580; *Pozzoli SPA v. BDMO SA*, [2007] EWCA Civ. 588 (BAILII), [2007] F.S.R. 37 at para. 17; *Pfizer Canada Inc.* at para. 247; *Teva Canada Limited v. Janssen Inc.*, 2018 FC 754 at para. 176, aff'd (*sub nom Millenium Pharmaceuticals Inc. v. Teva Canada Limited*), 2019 FCA 273, leave to appeal to SCC refused, 39007 (7 May 2020)). Practically speaking, however, so long as the single common inventive concept is found to be non-obvious, the Court will typically not need to explicitly consider any amendments to it made by later claims.

[88] I have spent some time elaborating the principles pertaining to the definition and role of the inventive concept of a claim or claims. At the risk of repetition (see paras. 72-77, above), each claim can give rise to its own inventive concept, and the inventive concepts of the various claims may overlap or replicate each other. This is permissible, provided they are joined or unified by an over arching, single inventive concept. Put otherwise, the potential for redundancy is inherent in the inventive concept exercise.

[89] Despite this, a claim's limitation should not be read into a more generally worded claim to avoid either infringement or invalidity; "Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement" (cited in *Halford v. Seed Hawk Inc.*, 2004 FC 88 at paras. 91-97, rev'd in part on other grounds, 2006 FCA 275, as approved by our Court in *Tetra Tech EBA Inc.* at para. 113-115). These principles also apply at the inventive concept stage.

[90] As in the claims construction exercise, a redundancy should only be permitted at the inventive concept stage where "a purposive analysis shows that claims are in effect duplicated" (*Ratiopharm Inc. v. Canada (Health)*, 2007 FCA 83 at para. 33 (*Ratiopharm Inc.*)). Generally, it would make little sense to specifically read away from a redundancy at the claims construction stage (*Tetra Tech EBA Inc.* at paras. 113-115, 123, 128-130; *Ratiopharm Inc.* at para. 33), only to read it back in at stage 2 of the obviousness analysis.

[91] *Tetra Tech EBA Inc.* and *Tearlab* are instructive in this respect.

[92] *Tetra Tech EBA Inc.* read away from a redundancy at the claims construction stage, then selected an inventive concept based on the essential elements of the claims alone. *Tearlab* also read away from redundancy at the construction stage, then refused to read it back in at the inventive concept stage. In both situations, the redundancy was inappropriate at both the claims construction and inventive concept stages as the proposed addition(s), explicitly stated in the dependent claims, amounted to a limitation on the independent claims. The wording of the independent claims indicated that the invention described by that claim could work without that

limitation (*Regents of the University of California v. I-MED Pharma Inc.*, 2018 FC 164 at para. 192, aff'd 2019 FCA 179 at para. 49; *Tetra Tech EBA Inc.* at paras. 113-115). The redundancy, caused by the proposed limitation, was inappropriate at both the claims construction and inventive concept stages, despite their separate purposes.

[93] To recapitulate, although a certain degree of redundancy is often inherent at the inventive concept stage, an inventive concept cannot be used as a vehicle to construe or read the inventive concept of claims more narrowly or broadly than their text, or plain language, will allow. As such, redundancy is only permitted where a purposive analysis shows that claims are in effect duplicated. This purposive analysis is necessarily informed by the purpose behind an identification of the inventive concept, which is different than the purpose behind a claims construction.

[94] Turning to the specifics of the case before us, the judge was aware of this limitation on the use of the inventive concept, noting, for example, that it would be inappropriate to include "a 'once daily' administration to treat ADHD within the inventive concept" underlying every claim as certain claims relate to the administration of LDX more than once a day, while others reference using LDX to treat narcolepsy and obesity (*Decision* at para. 121).

[95] None of the claims of CA 646 contains wording that conflicts with the inventive concept as identified by the judge, although it does render some of the later claims redundant. Examples of these dependent claims include claims 11, 12, 14, 15, 16, etc. However, a purposive analysis

shows that these claims are a permissible duplication of, or merely dependent upon, the specific inherent properties of LDX that inform the single common inventive concept.

[96] LDX cannot exist without these inherent properties: every molecule of LDX necessarily has these properties. For example, the study in paragraphs 228-231 of the description, and summarised in Table 46, discusses these pharmacokinetic properties. These properties, at the claims construction stage, import a limitation into the essential element(s) of the independent claims – the chemical LDX. At the inventive concept stage, these properties do not limit the chemical in any way; the narrow claim is not importing a limitation onto the more general claim, but merely highlighting one inherent aspect of it. Further, these properties, in turn, describe the problem taught by the solution, the chemical LDX.

[97] Although these pharmacokinetic properties are the subject of later claims, such as claim 11, which reads as, “the pharmaceutical composition according to any one of claims 6-9, wherein the L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof provides a therapeutically effective amount of amphetamine”, these claims merely reiterate these properties, emphasising that the chemical is the solution to the problem. This, in effect, duplicates the inventive concepts.

[98] The inventive concept as determined by the judge is therefore not affected by any impermissible redundancy or duplication in its application.

[99] As I will explain next, when considering stages 3 and 4 of the *Sanofi* test, I do not see any error in the judge's analysis. Therefore, I need not turn my attention to any arguments relating to the dependent claims. However, before leaving this analysis of stage 2, there are two points arising from the reasons that merit brief comment.

[100] The judge was of the view that *Ciba* stood for the proposition that a judge should only consider the claims construction of each claim to reduce the uncertainty associated with the search for an inventive concept (*Decision* at para. 116-117). The judge concluded this commentary was inconsistent with *Sanofi*. *Ciba* does not, however, contradict *Sanofi*. *Ciba* recognises that an inventive concept must be based on a claim, and not some vague paraphrase in the disclosure. Thus, if the identification about an inventive concept is not readily apparent, the judge should "simply work on the features of the claim" (*Ciba* at paras. 74-76). This ensures that obviousness is grounded in the claims themselves, a requirement discussed in both *Sanofi* and the *Patent Act*. *Ciba* does not address what should happen when, after examination of the claims construction, the inventive concept is still not "readily discernible". Pursuant to *Sanofi*, that is when recourse to the specification is allowed (at para. 77).

[101] Nor is the judge's distinction between *Ciba* and *Sanofi* on the basis that *Ciba* was a process patent and *Sanofi* a bare chemical patent relevant. The legal principles surrounding the obviousness analysis do not pertain solely to process patents, just as the comments in *Sanofi* were not solely geared to selection patents or bare chemical formula claims. *Sanofi* makes this clear. At paragraph 29 Rothstein J. wrote:

> Subject to any limitations expressed in the Patent Act, I see no reason why the discussion of anticipation should not apply to other prior art than merely genus

> patents. Again, subject to limitations in the Patent Act, the discussion of anticipation and obviousness would seem applicable to patents generally.

Stage 3: Difference between the Prior Art and the Inventive Concept

[102] As I conclude the judge's inventive concept of "a sustained release formulation of a therapeutically useful dose of amphetamine that is resistant to abuse" applies to the independent claims and the appellant has pointed to no specific error, I agree with the judge's finding that:

> [T]he key difference between the state of the art and the inventive concept is the compound LDX and its advantageous properties. Nothing in the prior art indicated or suggested that LDX would provide a sustained release treatment of amphetamine with a reduced potential for oral, intravenous and intranasal abuse.

(*Decision* at paras. 122, 132)

Stage 4: The Degree of Inventiveness of those Differences

[103] Stage 4 of the obviousness inquiry asks whether the differences, in light of the prior art and viewed without any knowledge of the alleged invention as claimed, constitute steps which would have been obvious to the PSIA, or if they instead required any degree of invention (*Sanofi* at paras. 67, 70). Obviousness is assessed objectively and purposively, having regard to the problem addressed by the patent (*Apotex Inc. v. Pfizer* at paras. 32, 35 and 39).

[104] If a patent pertains to an area "of endeavour where advances are often won by experimentation", as here, "an 'obvious to try' test might be appropriate" (*Sanofi* at para. 68). However, an "obvious to try" analysis remains but one of many potentially relevant factors in the

stage 4 analysis (*Bristol-Myers* at para. 38; *Sanofi* at paras. 64-65). As noted in *Apotex Inc. v. Pfizer* at para. 32:

> […] while the Supreme Court introduced the "obvious to try" test, it favours "an expansive and flexible approach that would include 'any secondary considerations that [will] prove instructive'" (*Atazanavir* at para. 61, referring to *Sanofi* at para. 63). As a result, a categorical approach to the obviousness inquiry and the elaboration of a "hard and fast rule" was specifically deemed inappropriate and rejected […] (*Atazanavir* at para. 62).

[105] For an invention to be "obvious to try", there must be evidence establishing, on a balance of probabilities, "that it was more or less self-evident to try to obtain the invention" (*Sanofi* at para. 66). As such, this analysis flows from the identification of the "invention" described by the claim's inventive concept. For example in *Sanofi*, the focus on the properties of the isomers at the obvious to try stage was dictated by the fact that it was the special properties of the selection which made it inventive. The obvious to try test does not broaden the scope of the obviousness inquiry from a claim-by-claim analysis to an invention-overall analysis.

[106] To assess whether it is more or less self-evident to try to obtain an invention, as defined by a claim's identified inventive concept, *Sanofi* enumerated three non-exhaustive factors that should be considered (at paras. 69, 83-92). While they must all be explicitly considered in order to answer the overall question of whether it is "more or less self-evident to try to obtain the invention", they need not all be met (*Hospira* at paras. 89-90):

> (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?

[107] Beyond the enumerated factors, there are contextual factors that should also be considered, depending on the facts of the case. These contextual factors include but are not limited to the history of the invention, how "quickly, easily, directly and relatively inexpensively" it was reached and any "wild goose chases" that were pursued before arriving at the invention, etc. (*Sanofi* at paras. 70-71; *Apotex Inc. v. Pfizer* at paras. 46-48). Although these additional contextual factors may not be, on their own, determinative (see, *e.g.*, *Tearlab* at paras. 68-69), any that arise alongside the factors enumerated in *Sanofi* are to be considered and weighed before coming to a conclusion about whether the invention was obvious.

[108] In this instance, Apotex claims the judge committed the same error as in *Hospira* (at paras. 93, 95) and solely focussed the analysis on only one of the three mandated obvious to try considerations: that it was not obvious that LDX ought to work. However, unlike in *Hospira*, here the judge made determinations of fact that relate directly to the other two obvious to try factors, both of which cement the judge's position, rather than detract from it. As pointed out by Shire, the judge had previously found that the prior art taught away from CA 646, that substantial work preceded CA 646 and that the skilled person would not focus on prodrugs for the purpose of deterring abuse. There was therefore no motivation and the effort expended was substantial (*Decision* at paras. 130-138). The judge's findings at paragraph 137 are dispositive of this argument:

> Nothing in the prior art suggested the properties of LDX, and these properties could not be predicted. The prior art taught away from single amino acid conjugates to extend release, and did not suggest this ought to work. Moreover, the prior art did not suggest the use of prodrugs for the purpose of deterring abuse. The use of prodrugs to achieve sustained release was unpredictable and complex. This is confirmed by the extensive work undertaken by New River researchers that preceded the 646 Patent.

[109] Apotex next takes issue with the judge's reference to the uncertainty about LDX's properties without testing as well as comments in the evidence about the unpredictability of LDX's properties. Apotex is correct that there is no blanket proposition that a compound will not be obvious where a skilled person cannot predict its properties in advance of its making (see, *e.g.*, *Bristol-Myers* at para. 20). Nevertheless, findings on this point may be relevant to the second obvious to try consideration. Regardless, reading the *Decision* shows that the observation about the uncertainty of LDX's properties was but one amongst others that cumulatively led to the conclusion that it was not obvious to try. It is therefore not an error of law to include this consideration in the analysis.

[110] In sum, on the issue of obviousness, the judge applied the *Sanofi* test and identified the single inventive concept linking each claim of CA 646 (*Decision* at paras. 110-113, 117, 122). He then considered the state of the art, the gap between the state of the art and the inventive concept (*Decision* at paras. 123-132), and finally considered whether the differences were obvious based on the enumerated and contextual factors of the obvious to try analysis (*Decision* at paras. 133-145). There was no reviewable error in the legal framework nor in its application to the facts as found.

VI. Conclusion

[111] I would dismiss the appeals with costs.

"Donald J. Rennie"
J.A.

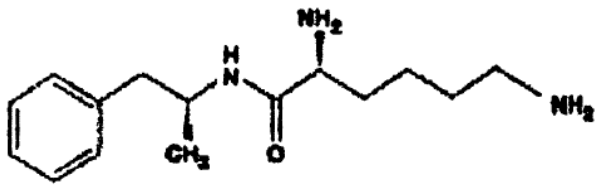
“I agree.
Yves de Montigny J.A.”

“I agree.
Mary J.L. Gleason J.A.”

ANNEX "A"

[34] Claims 1 to 5 describe compounds:

> 1. A compound selected from the group consisting of L-lysine-d-amphetamine and a pharmaceutically acceptable salt thereof.
>
> 2. The compound of claim 1, wherein the compound is L-lysine-d-amphetamine.
>
> 3. The compound of claim 1, wherein the compound is L-lysine-d-amphetamine mesylate.
>
> 4. The compound of claim 1, wherein the compound is L-lysine-d-amphetamine hydrochloride.
>
> 5. The compound of any one of claims 1 to 4 wherein the L-lysine-d-amphetamine is defined by:



[35] Claim 8 describes a composition:

> 8. A pharmaceutical composition comprising L-lysine-d-amphetamine mesylate and one or more pharmaceutically acceptable additives.

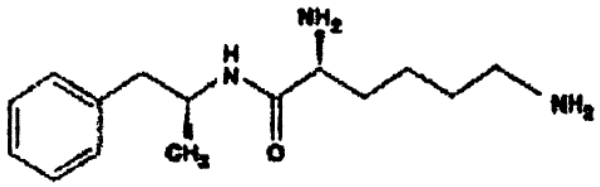
[36] Claims 10 to 12 describe compositions:

> 10. The pharmaceutical composition according to any one of claims 6-9, wherein the composition provides release of amphetamine as an active from the compound following oral administration.
>
> 11. The pharmaceutical composition according to any one of claims 6-9, wherein the L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof provides a therapeutically effective amount of amphetamine.

> 12. The pharmaceutical composition of claim 11, wherein the L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof provides a reduced C_{max} of amphetamine as compared to amphetamine alone.

[37] Claim 22 describes a composition:

> 22. The pharmaceutical composition of any one of claims 7 to 21 wherein the L-lysine-d-amphetamine is defined by:



[38] Claims 24 to 30 describe compositions:

> 24. The pharmaceutical composition of any one of claims 6-15, wherein said compound is present in an amount of from 10 to 250 mg.
>
> 25. The pharmaceutical composition of any one of claims 6-15, wherein said compound is present in an amount of 20 mg.
>
> 26. The pharmaceutical composition of any one of claims 6-21, wherein said compound is present in an amount of 30 mg.
>
> 27. The pharmaceutical composition of any one of claims 6-21, wherein said compound is present in an amount of 40 mg.
>
> 28. The pharmaceutical composition of any one of claims 6-21, wherein said compound is present in an amount of 50 mg.
>
> 29. The pharmaceutical composition of any one of claims 6-21, wherein said compound is present in an amount of 60 mg.
>
> 30. The pharmaceutical composition of any one of claims 6-21, wherein said compound is present in an amount of 70 mg.

[39] Claims 33 to 36 describe uses:

> 33. Use of the compound of any one of claims 1-5 for the preparation of a medicament for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in a subject.
>
> 34. Use of the compound of any one of claims 1-5 for the treatment of ADHD in a subject.
>
> 35. The use according to claim 33 or 34, wherein the subject is an adult.
>
> 36. The use according to claims 33 or 34, wherein the subject is a human.

[40] Claim 43 describes a use:

> 43. The use according to any one of claims 33-42, wherein the compound is for administration once daily.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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