Proposed Practice Notice on Obviousness

Submission to the
Canadian Intellectual Property Office
by the
Intellectual Property Institute of Canada

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Proposed Practice Notice on Obviousness

Comments from the Intellectual Property Institute of Canada

Conclusion and Recommendations

The Intellectual Property Institute of Canada (IPIC) considers that the Practice Notice (the "Notice") substantially diverges from the law set out by the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 ("*Sanofi*"). Indeed, it appears that the application of the analysis set out in the Notice conceivably would have led, in *Sanofi*, to a different decision than that reached by the Court:

1. The Notice does not follow the orderly approach set out in *Sanofi*, and omits and conflates steps mandated by *Sanofi*. Instead of presenting "obvious to try" as only one factor to be considered in the obviousness inquiry, the Notice presents it as essentially the only factor. The Notice omits threshold questions to determining whether an "obvious to try" test is even appropriate and confuses the preliminary conclusion that a claimed invention was "obvious to try" with a final conclusion that it was ultimately "obvious" (and therefore unpatentable).

Recommendation: The Notice should be amended to directly track the orderly sequence of steps set out in *Sanofi*. This should ensure that the analysis conducted by CIPO is consistent with the approach that will be adopted by the courts.

2. The Notice misstates some obviousness factors and substitutes its own language for terms used by the courts. The Notice misstates the "motivation" test, and introduces its own language to paraphrase clear and unambiguous terms used by the courts. For example, the Notice replaces the Supreme Court's reference to "prolonged and arduous" experimentation with a consideration of "undue burden" and qualifies the Federal Court's reference to "the climate in the relevant field" with references to the qualities of a person "skilled in the art".

Recommendation: The Notice should be amended to track the specific language used in *Sanofi*. Again, this should ensure that the analysis conducted by CIPO is consistent with the analysis to be conducted by the courts.

3. The Notice indicates that evidence of course of conduct, (found directly relevant to obviousness in *Sanofi*) will not be considered during examination by CIPO.

In *Sanofi* the course of conduct of the inventors was found directly relevant to the obviousness inquiry and its analysis constitutes a fourth step in the analysis mandated by the Supreme Court of Canada. The Notice simply omits this step.

Recommendation: The Notice should direct examiners to accept and appropriately consider evidence of the course of conduct of the inventors where this is necessary as a part of the obviousness analysis.

4. The Notice does not provide adequate guidance on how the new criteria will be applied to existing applications.

Recommendation: The Notice should provide additional explanation of whether and how the new standards will be applied procedurally, for example how they may be applied to cases where a Notice of Allowance has already issued, and further explanation of procedures for the proposed "Supplementary Summary of Reasons" after a Final Action.

In summary it is believed that the Notice could be improved by directly quoting and mandating the test set out in *Sanofi* so as to ensure maximum consistency between examination practice and Court decisions.

Introduction

The Notice explains CIPO's approach to examining Canadian patent applications for compliance with Section 28.3 of the *Patent Act* in view of *Sanofi*.

IPIC agrees that CIPO examination practice must be consistent with *Sanofi* as *Sanofi* is the most recent statement by the Supreme Court of Canada on obviousness. However, IPIC is of the view that the Notice is not wholly consistent with *Sanofi*.

In particular, IPIC is of the view that the Notice:

1. departs from the orderly approach to the obviousness inquiry as mandated by *Sanofi*;

2. omits and conflates some of the steps of the approach to the obviousness inquiry mandated by *Sanofi*;

3. misstates some of the obviousness factors discussed in *Sanofi* and previously by the Federal Court of Appeal in *Novopharm Limited v. Janssen-Ortho Inc.* 2007 FCA 217 (*Janssen-Ortho*); and

4. indicates that evidence that the Supreme Court stated in *Sanofi* is specifically relevant to the obviousness inquiry will not be assessed during examination within CIPO.

As is discussed in detail below, in *Sanofi*, the Supreme Court set out a clear and organized structure for the obviousness analysis and then applied that structure.

The Court recognized that, in the obviousness inquiry, overly rigid rules or a "verbal formula" are unhelpful (see paragraph 61-63 of the judgment). Nevertheless, the Court did find it useful to set forth a structure to frame the obviousness inquiry (i.e. the *Windsurfing/Pozzoli* questions) and states at paragraph 67:

> This approach should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis.

IPIC recognizes that it is necessary for CIPO to provide Examiners with guidance as to how examination with respect to obviousness should be conducted and, as recognized in *Sanofi*, there must be flexibility in the factors to be considered. However, this does not mean that there should be departure from the general structure for conducting the obviousness analysis as provided by the Supreme Court.

CIPO should examine patent applications with respect to obviousness using the framework provided by *Sanofi*. Individual issues may, of course, be explored within the *Sanofi* framework but it is problematic if the overall obviousness inquiry is not conducted in a manner consistent with the approach that the Supreme Court clearly took great care

to set out in a clear and orderly fashion. If the *Sanofi* approach is not followed, review of rejections by the Patent Appeal Board and later by the courts will be unnecessarily complex.

The Obviousness Inquiry as Mandated by *Sanofi*

Before discussing the Practice Notice in detail, it is worthwhile first to review the approach to obviousness set out in *Sanofi*. The Supreme Court clearly went to great effort to provide a systematic and organized framework in which to study obviousness, and it is incumbent on CIPO to adhere to the guidance provided by the Court.

Obviousness is discussed in section VI (paragraphs 51-93) of the *Sanofi* decision. Within Section VI, the discussion of obviousness is broken down into the following principal sections:

(a) Relevant Legislation;
(b) Reasons of the Applications Judge;
(c) United Kingdom and United States Approach to Obviousness;
(d) Approach to Obviousness in Canada;
(e) Applications to the Facts of This Case; and
(f) Conclusions on Obviousness

Approach to Obviousness in Canada

Section (d) *"Approach to Obviousness in Canada"* is of primary significance to the CIPO Notice. This section of *Sanofi* provides a clearly ordered approach to the obviousness inquiry as summarized below.

The Court first makes introductory remarks at paragraph 64 of the judgment concerning the "obvious to try" test:

> . . . the "obvious to try" test must be approached cautiously. It is only one factor to assist in the obviousness inquiry. It is not a panacea for alleged infringers. The patent system is intended to provide an economic encouragement for research and development. It is well known that this is particularly important in the field of pharmaceuticals and biotechnology. (emphasis added)

Thus, at the outset, the Supreme Court notes that "obvious to try" is only one factor to assist in the obviousness inquiry.

At paragraph 67, the Court, then restates the approach to the obviousness inquiry as established in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.* [1985] RPC 59 C.A. and modified in *Pozzoli SPA v. BDMO SA* [2007] EWCA Civ 588, involving the following questions:

(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?

The Court concludes paragraph 67 stating:

> It will be at the fourth step of the *Windsurfing/Pozzoli* approach to obviousness that the issue of "obvious to try" will arise.

The *Windsurfing/Pozzoli* questions are therefore presented in *Sanofi* as a series of questions to be considered, in the order presented, and it is clearly explained that the issue of "obvious to try" is possibly relevant at the fourth step.

The Court then further discusses "obvious to try", first setting out a threshold question under subheading (i) *"When is the 'obvious to try' test appropriate?"* The answer is set forth at paragraph 68 of the judgment:

> In areas of endeavour where advances are often won by experimentation, an 'obvious to try' test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an 'obvious to try' test since there may be many chemically similar structures that elicit different biological responses and offer the potential for significant therapeutic advances. (emphasis added)

This threshold question is clearly set out as a predicate to further analysis of "obvious to try". That is, unless the invention is in an area of endeavour "where advances are often won by experimentation" then there is no further inquiry with respect to "obvious to try" considerations.

This is made very clear in *Sanofi* under subheading (ii) *"'Obvious to Try' Considerations"* commencing at paragraph 69 of the judgment:

> **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. (emphasis added)

Three factors are then recited in a list in paragraph 69 of the judgment as follows:

> (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?

The Court immediately goes on to provide a fourth factor to be taken into consideration when addressing "obvious to try" although it is not set out as the fourth item of the above numbered list. This fourth item is the actual course of conduct in making of the invention, and as discussed below, formed an important part of the Court's analysis of obviousness to try in the particular circumstances of the case. This fourth factor is found at paragraph 70 of the judgment, immediately following the three numbered factors mentioned above:

> <u>Another important factor</u> may arise from considering the actual course of conduct which culminated in the making of the invention. It is true that obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art. <u>But this is no reason to exclude evidence of the history of the invention</u>, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person. (emphasis added)

Thus, *Sanofi* is clear as to the form of analysis to be applied:

1. The four *Windsurfing/Pozzoli* questions are to be addressed in order.

2. It is at the fourth step that the issue of "obvious to try" will arise.

3. A threshold question as to whether the "obvious to try" test is even appropriate (areas of endeavour where advances are often won by experimentation) must then be answered.

4. If "obvious to try" is an appropriate test, then four factors are to be considered, with the understanding that the list of four factors is not exhaustive.

5. The over-arching principle then remains that, as explained at the outset, "obvious to try" remains only one factor to assist in the obviousness inquiry (paragraph 64 of the judgment).

<u>Application of the Obviousness Approach to the Facts in *Sanofi*</u>

In Section (e) *"Application to the facts of this case"* the Court then went through the analysis of obviousness in the framework set out above.

Each of the *Windsurfing/Pozzoli* questions or steps is addressed in order.

The fourth step, at which the "obvious to try" test may apply, is discussed in paragraphs 81 through 92 of the judgment. The Court first addresses the threshold question at paragraph 81:

> At this stage, it must be determined whether the nature of the invention in this case is such as to warrant an "obvious to try" test. The discovery of the dextro-rotary isomer and its bisulfate salt came after experimentation. They were interrelated variables with which Mr. Badorc had to experiment.

The Court concluded that an "obvious to try" test was warranted and then went through the above-described factors. In analyzing "obvious to try", the Supreme Court posed and answered five questions as set out in paragraphs 83 through 91 of the judgment:

> (1) Is it more or less self-evident that what is being tried ought to work?
>
> (2) What is the extent, nature and amount of effort required to achieve the invention?
>
> (3) Is there a motive from the prior art to find the solution that the '777 patent addresses?
>
> (4) What is the course of conduct which was followed which culminated in the making of the invention?
>
> (5) Was the invention of the '777 patent "obvious to try"?

It is emphasized that the Court clearly considered all four of the previously described "obvious to try" considerations or factors in making this assessment. Weight was given to all of the factors in the final assessment of whether the invention of the '777 patent was "obvious to try", as is evident from paragraph 92 of the judgment.

> The methods to obtain the invention of the '777 patent were common general knowledge. It can be assumed that there was a motive to find a non-toxic efficacious product to inhibit platelet aggregation in the blood. However, it was not self-evident from the '875 patent or common general knowledge what the properties of the dextro-rotatory isomer of this racemate would be or what the bisulfate salt's beneficial properties would be and therefore that what was being tried ought to work. The course of conduct and the time involved throughout demonstrate that the advantage of the dextro-rotatory isomer was not quickly or easily predictable. Had the dextro-rotatory isomer been "obvious to try", it is difficult to believe that Sanofi would not have opted for it before unnecessary time and investment were spent on the racemate. I conclude that the prior art and common general knowledge of persons skilled in the art at the relevant time were not sufficient for it to be more or less self-evident to try to find the dextro-rotatory isomer.

The Court then concluded in Section (f) that the invention was not obvious.

Comments on the Proposed Notice

IPIC believes that the draft Notice is not wholly consistent with the approach to the analysis of obviousness as mandated by *Sanofi*.

IPIC's comments are set out below. For ease of reference, the entire text of the Notice is set out in bold font, and IPIC's comments and analysis set forth at the appropriate points.

Practice Notice on Obviousness
(for public consultation)

May 14, 2009

Overview

On November 6, 2008, the Supreme Court released its judgement in the case *Apotex Inc. v. Sanofi-Synthelabo Canada, Inc.* [2008 SCC 61].

In its reasons, the Court commented on the approach to obviousness in Canada, concluding that the inquiry into obviousness is not well served by attempting to rigidly apply any one test in all circumstances.

The Court considered recent jurisprudence in both the US and UK, and concluded that the approach known in the UK as *Windsurfing/Pozzoli* will be useful to conducting an obviousness inquiry. [This approach having been introduced in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.* [1985] R.P.C. 59 (C.A.) and refined in *Pozzoli SPA v. BDMO SA* [2007] EWCA Civ 588.]

The four-step approach to obviousness adopted by the Court is as follows:

(1) (a) Identify the notional "person skilled in the art";
(b) Identify the relevant common general knowledge of that person;
(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
(3) Identify what, if any, difference exists 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?

The Court further indicated that, under certain circumstances, the question of obviousness can be considered by asking, in step (4), whether it would

have been "obvious to try" a certain line of inquiry that would inevitably lead to the claimed invention.

The Court provided several factors as being applicable, depending on the nature of the specific case under consideration, in determining whether the matter of a claim would have been "obvious to try". The factors set out by the Court, with the caution that the list is not exhaustive, are:

(A) Is there a motive provided in the prior art to find the solution the patent addresses?
(B) 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 the person skilled in the art?
(C) 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?

Where the questions (A) and (B) can be answered in the affirmative, and the conclusion at item (C) is that the matter of the claim would be arrived at by routine trials that were not prolonged and arduous, it can be concluded that the subject-matter of the claim is obvious since it would have been "obvious to try" to identify the claimed matter from among a finite number of likely solutions one of which more or less self-evidently ought to work.

Incomplete List of Obvious to Try Factors

Only three of the four "obvious to try" factors are mentioned and the fourth factor, which is the course of conduct in making the invention, is not mentioned. Indeed, it is concluded in the Notice that a conclusion on "obvious to try" can be made having regard only to factors 1, 2 and 3 identified by the Supreme Court. Note that the factors are reordered in the Notice — this appears to be an unnecessary complication.

The total exclusion of the fourth factor (course of conduct) is inconsistent with the *Sanofi* approach and is discussed further below.

Equating "Obvious to Try" with "Obviousness"

After setting forth three of the four *Sanofi* "obvious to try" factors, the Notice states that:

> . . . it can be concluded that the subject matter of the claim is obvious since it would have been "obvious to try" to try to identify the claimed matter from among a finite number of likely solutions one of which more or less self-evidently ought to work.

This suggests that "obvious to try" is the same as "obvious" — that is, once it is concluded that an invention is "obvious to try" then the invention is obvious.

Sanofi was clear that the obviousness inquiry is not confined to "obvious to try". An invention could be "obvious to try" but ultimately not obvious in view other factors relevant to the overall obviousness inquiry. As discussed above, it is clear from paragraph 64 of *Sanofi* that obvious to try is only one factor to assist in the overall obviousness inquiry. CIPO must be open to considering other factors of obviousness or unobviousness outside of the "obvious to try" factors.

Impact on examination

A - Framing the obviousness inquiry

In view of this guidance and direction of the Supreme Court, Canadian examiners will henceforth consider whether "obvious to try" is a relevant consideration in determining the obviousness of claimed subject-matter.

Further, in presenting obviousness objections, examiners will be guided by the four-step approach the Supreme Court has indicated will be useful in structuring obviousness inquiries. During examination, however, the steps need not be explicitly addressed unless doing so is relevant to the objection in suit.

Examiners will adhere to the following guidance regarding the steps set out by the Court (the numbering provided refers to the steps in the approach):

(1)(a) Where necessary, examiners will identify the person skilled in the art by reference to the field or fields relevant to the invention, and where applicable by reference to attributes such as their proclivity for engaging in research or experimentation.

The Notice states that the person skilled in the art will be identified "where necessary". *Sanofi* does not describe question (1)(a) in the *Windsurfing/Pozzoli* analysis as being optional.

(1)(b) Examiners, in formulating objections, may refer to information they believe to be common general knowledge. Unless it becomes evident through the applicant's comments that the nature of the common general knowledge is not common ground and is reasonably in dispute, an examiner need not identify documents establishing the common general knowledge.

The Notice explains that examiners may refer to information that they believe to be common general knowledge, and that unless it becomes evident through the applicant's comments that this is reasonably in dispute, an examiner need not identify documents establishing the common general knowledge.

IPIC is of the view that, in all but the clearest cases, this is likely to prove unworkable and prolong examination. Wherever the issue of "common general knowledge" becomes material to a rejection for obviousness, an unsubstantiated assertion by CIPO that something is "common general knowledge" will likely be traversed by the applicant, thus requiring the examiner to cite an appropriate reference in a subsequent Examiner's Report, as should have been done at the outset. It is not the applicant's legal or evidentiary burden to prove under section 28.3 of the *Patent Act* what is <u>not</u> in the prior art, nor is this possible in practical terms. Where examiners believe it is necessary to establish common general knowledge to support a rejection of a claim for obviousness, the examiner should be encouraged to cite an appropriate prior art reference.

(2) The identification of the inventive concept is performed on a claim-by-claim basis, recognising that the specific inventive concept of each claim can (and should) be a refinement of the single general inventive concept that must link the claims as a whole in order to satisfy section 36 of the Patent Rules. The relevant inventive concept is that of the claim under examination, and not a generalised inventive concept derived from the specification as a whole.

The inventive concept of a claim, at this step of the inquiry, is identified without regard to the prior art. It is the essence of the claimed invention and can generally be identified by approaching the matter of the claim as a solution to whatever problem the inventors have set out to address, and relates to those elements of the claim that were described, or which would be recognised by the person skilled in the art, as providing the solution to a given problem. In identifying the problem that the inventors set out to address, and the solution proposed through the invention, guidance will generally be found in the description, in accordance with paragraph 80(1)(d) of the Patent Rules.

The concept of "solving a problem" should be understood in the context of "achieving the objects of the invention" and "fulfilling the purpose of the invention". It is worth reiterating that identifying the problem being addressed is done in the context provided by the description, and not by reference to the closest prior art.

The inventive concept may be clear from the language of the claim itself, where the purpose of the claimed matter is explicitly defined. This would be particularly true in the case of a claim presented in the European or Jepson format. Where it is not clear from the language

of the claim itself what problem is being solved by the claimed matter, the remainder of the specification is consulted to assist in identifying the inventive concept of that claim.

The Notice describes the identification of the inventive concept of a claim as being "…a refinement of the single inventive concept that must link the claims as a whole in order to satisfy section 36 of the *Patent Rules*".

Sanofi does not frame question (2) in the context of the requirement for unity of invention. IPIC does not believe that it is helpful to merge the concept of unity of invention with the identification of the inventive concept of a claim. Neither *Windsurfing* nor *Pozzoli* make reference to unity of invention in the assessment of this issue.

It is not clear what is the basis for the "problem/solution" approach recommended in the Notice. *Sanofi* makes no reference to a problem/solution analysis, which has not historically been the approach to obviousness in Canada. Moreover, a problem/solution analysis may in many cases be entirely inapplicable as the invention may not concern solving a known problem.

Indeed, in *Pozzoli,* on which the *Sanofi* analysis is largely based, the identification of the inventive concept made no reference to unity of invention issues or to a "problem/solution" approach. Rather, *Pozzoli* described the analysis thus at paragraphs 17-22:

> 17. What now becomes stage (2), identifying the inventive concept, also needs some elaboration. As I pointed out in *Unilever Plc v Chefaro Proprietaries Ltd* [1994] R.P.C. 567 at 580:
>
> > "It is the inventive concept of the claim in question which must be considered, not some generalized concept to be derived from the specification as a whole. Different claims can, and generally will, have different inventive concepts. The first stage of identification of the concept is likely to be a question of construction: what does the claim mean? It might be thought there is no second stage--the concept is what the claim covers and that is that. But that is too wooden and not what courts, applying *Windsurfing* stage one, have done. It is too wooden because if one merely construes the claim one does not distinguish between portions which matter and portions which, although limitations on the ambit of the claim, do not. One is trying to identify the essence of the claim in this exercise."
>
> 18. So what one is seeking to do is to strip out unnecessary verbiage, to do what Mummery L.J. described as make a précis.
>
> 19. In some cases the parties cannot agree on what the concept is. If one is not careful such a disagreement can develop into an unnecessary satellite debate. In the end what matters is/are the difference(s) between what is claimed and the prior art. It is those differences which form the "step" to be considered at stage (4). So if a disagreement about the inventive concept of a claim starts getting too involved, the sensible way to proceed is to forget it and simply to work on the features of the claim.

20. In other cases, however, one need not get into finer points of construction--even without them the concept is fairly apparent--in *Windsurfing*, for instance, it was the "free sail" concept. In yet other cases it is not even practical to try to identify a concept--a chemical class claim would often be a good example of this.

21. There is one other point to note. Identification of the concept is not the place where one takes into account the prior art. You are not at this point asking what was new. Of course the claim may identify that which was old (often by a pre-characterising clause) and what the patentee thinks is new (if there is a characterising clause) but that does not matter at this point.

There is no mention here of a "solution" at all, and with respect to the unity issue, it is recognized that different claims can, and generally will, have different inventive concepts.

(3) At this step, the inventive concept (solution) identified in step (2) is compared to the state of the art to determine whether, or to what extent, an equivalent or similar inventive concept (solution) was known at the claim date.

The problem of describing an "inventive solution" rather than "inventive concept" carries on in the analysis of *Windsurfing/Pozzoli* question (3) in the Notice. Neither *Sanofi* nor *Pozzoli* make any reference to a "solution" when answering question 3, which is to 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) Where differences exist between the inventive concept embodied in the claim and the state of the art, it must be determined if these differences would have been obvious as of the claim date. This must be done without presupposing that it was recognized in the art that the problem to be solved formed part of the state of the art. This is important to avoid adopting an improper "hindsight" perspective; where the existence or nature of a problem was unobvious, identifying the problem can contribute to the necessary inventive step.

In reaching a conclusion at step (4) of the approach, the question of obviousness must be framed taking into account the context of the specific case in question. The correct test can be framed in more than one way, and no single expression of this test is likely to apply to all circumstances. The test articulated in *Beloit Canada Ltd. v. Valmet Oy* [(1986), 8 C.P.R. (3rd), 289 (F.C.A.)], for example, is not to be viewed as mandatory.

The Office considers the guidance affirmed by the Federal Court of Appeal in *Novopharm Limited v. Janssen-Ortho Inc. [2007 FCA 217]* to remain

relevant in view of the guidance of the Supreme Court in *Sanofi-Synthelabo*. Particularly, the obviousness inquiry should be framed in the context of:

- **(i) the climate in the relevant field at the time the alleged invention was made, including not only knowledge and information available but also attitudes, trends, prejudices and expectations that would define the person skilled in the art; and**
- **(ii) any motivation in existence at the time of the alleged invention to solve a recognized problem in the field of the invention.**

Point (i) does not accurately reflect what was said by the Federal Court in *Janssen-Ortho* (2006 FC 1234), and summarized by the Federal Court of Appeal. The Federal Court stated:

> 4. What is the climate in the relevant field at the time the alleged invention was made? The general state of the art includes not only knowledge and information but also attitudes, trends, prejudices and expectations. (emphasis in original)

Note there is no mention of "that would define the person skilled in the art". The addition of this language in the Notice confuses factor (4) in *Janssen-Ortho* (climate in the relevant field) with factor (2) (person skilled in the art).

Where it can be reasonably concluded that the person skilled in the art would have been motivated to solve a recognized problem, the criterion set out in item (A) of the *Sanofi-Synthelabo* "obvious to try" considerations is satisfied.

In determining whether, in view of this motivation, the solution defined in the claim lacks invention (i.e. is obvious), relevant considerations are:

(B) Is the person skilled in the art aware, in view of the prior art and their common general knowledge, that a limited number of predictable and identifiable solutions exist to the same or a similar problem, such that they would believe that one of those solutions ought to work to solve the problem being addressed?

(C) Could the person skilled in the art be expected to arrive specifically at the solution claimed, starting from the limited number of solutions conceptually identified in step (B), without inventive step or undue burden? That is, would the solution be arrived at by routine and predictable methods.

Disregarding the Threshold Question of Whether An "Obvious to Try" Inquiry is Appropriate

As discussed above, the Supreme Court was clear in *Sanofi* that before investigating the "obvious to try" factors, it is first necessary to assess whether the "obvious to try" test is even appropriate. It is only if the test is appropriate that the obvious to try factors are considered. The Court said that the obvious to try test might be appropriate "in areas of endeavour where advances are often won by experimentation".

The proposed Notice appears not to recognize that this threshold question should be asked at all.

In the first complete paragraph at page 4 of the Notice it is stated:

> Where it can be reasonably concluded that the person skilled in the art would have been motivated to solve a recognized problem, the criterion set out item (A) of the *Sanofi-Synthelabo* 'obvious to try' considerations is satisfied.

Having renumbered the *Sanofi* obvious to try factors (*Sanofi* factor 3 become A in the Notice), it appears that this means that the "motivation" factor is satisfied. The Notice then directs the Examiner to consider two other "obvious to try factors" which, using the *Sanofi* enumeration would be factors 1 and 2.

The result of this appears to be that the Examiner first looks at whether the person skilled in the art would have been motivated to solve a recognized problem and then look at factors 1 and 2 of the *Sanofi* "obvious to try" factors.

This is not consistent with *Sanofi* for a number of reasons.

First, the threshold question of whether the obvious to try test even applies is not asked or answered. This is contrary to the requirements of *Sanofi*. It appears that, in the Notice, the obvious to try factors (or at least three of the four set out as being important in *Sanofi*) are considered immediately without any determination first of the threshold question.

It may be that the Notice instead intends to replace the *Sanofi* threshold question with the third obviousness to try factor, first asking whether there is a motivation and, if so, then going on to look at the other *Sanofi* factors.

But if this is what is intended and there is still to be a threshold question, then it is the wrong question. "Areas of endeavour where advances are often won by experimentation" is replaced with "would the skilled person have been motivated to solve a recognized problem".

The upshot of this can only be that CIPO proposes to apply obvious to try in any case where there is a recognized problem to be solved. The only inventions in which obvious to try then presumably would not apply would be truly pioneering inventions or those where the existence of a problem had never been recognized in the art.

But this is not at all what *Sanofi* says to do — *Sanofi* says first assess whether the invention is in an area of endeavour where advances are often won by experimentation. This comes before any obvious to try analysis.

This departs from *Sanofi* in two significant respects. The *Sanofi* threshold question is eliminated entirely and the third *Sanofi* factor in the obvious to try test is elevated to become the threshold question.

Misstatement of the "motivation" test

As noted above, in the first complete paragraph at page 4 of the Notice it is stated:

> Where it can be reasonably concluded that the person skilled in the art would have been motivated to solve a recognized problem, the criterion set out item (A) of the *Sanofi-Synthelabo* 'obvious to try' considerations is satisfied.

In addition to the structural problems noted above, this misstates the motivation test.

The test is not "would the person skilled in the art been motivated to solve a recognized problem?". This is purely circular by definition. If something is understood as a "problem" then there is of course motivation to solve the problem — i.e. find some kind of solution to make the problem go away. There would only be no motivation when something is not even recognized as a problem.

Sanofi recognizes this and states the test differently. "Obvious to try" factor 3 is "Is there a motive provided in the art to find the solution the patent addresses" — i.e. not just *any* solution to the problem, *the* solution the patent addresses.

This is exactly how the Supreme Court addressed the issue at paragraph 90 of the judgment:

> It is well known that the pharmaceutical industry is intensely competitive. Market participants are continuously in search of new and improved medications and want to reach the market with them as soon as possible. So demand for an effective and non-toxic product to inhibit platelet aggregation might be assumed to exist. However, nothing in the '875 patent or common general knowledge provided a specific motivation for the skilled person to pursue the '777 invention. The prior patent was a genus patent, and selection might be expected. However, the prior patent did not differentiate between the efficacy and the toxicity of any of the compounds it covered. This suggests that what to select or omit was not then self-evident to the person skilled in the art. (emphasis added)

Of course there was a motivation to find better platelet aggregation inhibitors — but there was no specific motivation to find clopidogrel, the invention claimed in the '777 patent.

The difference between motivation to solve a problem and motivation to pursue the particular solution taught by the patent is explained clearly by the Federal Court of Appeal in *Janssen-Ortho* (which is cited in the Notice) at paragraph 25 of the judgment:

> ***5. The motivation in existence at the time the alleged invention to solve a recognized problem***
>
> "Motivation" in this context may mean the reason why the claimed inventor made the claimed invention, or it may mean the reason why one might reasonably expect the hypothetical person of ordinary skill in the art to combine elements of the prior art to come up with the claimed invention. If within the relevant field there is a specific problem that everyone in the field is trying to solve (a general motivation), it may be more likely that the solution, once found, required inventive ingenuity. On the other hand, if there is a problem that only the claimed inventor is trying to solve (a unique or personal motivation), and no one else has a reason to address that problem, it may be more likely that the solution required inventive ingenuity. However, if commonplace thought and techniques can come up with a solution, there may be a reduced possibility that the solution required inventive ingenuity. (emphasis added)

Indeed, it is recognized in *Janssen-Ortho* that if there was general motivation to solve a problem, the actual solution is less likely to be obvious — with many people presumably interested in finding a solution to the problem, why did they not find the solution taught by the patent?

Hence, IPIC submits that the Practice Note misstates the motivation test. The motivation required for element 3 of the *Sanofi* "obvious to try" test is a motivation from the prior art to find the particular solution that the patent addresses, not simply that something is recognized as a problem for which a solution would be desirable.

It may also be noted that the Federal Court of Appeal, in considering *Sanofi*, has recently confirmed that motivation does not transform a possible solution into an obvious one. See *Pfizer Canada Inc. v. Apotex Inc.* 2009 FCA 8, at paragraphs 43-45:

> 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.
>
> 44 This is no doubt the case. However, the degree of motivation cannot transform a possible solution into an obvious one. Motivation is relevant in determining whether the skilled person has good reason to pursue "predictable" solutions or solutions that provide "a fair expectation of success" (see respectively the passages in *KSR International Co. v. Teleflex Inc.* (2007), 127 S.Ct. 1727 (U.S. S.C. 2007) at page 1742 and *Conor Medsystems Inc. v. Angiotech Pharmaceuticals Inc.*, [2008] UKHL 49 (Eng. H.L.), at paragraph 42, both of which are referred to with approval in *Sanofi-Synthelabo*, *supra*, at paragraphs 58 and 59).

> 45 In contrast, the test applied by Mr. Justice Laddie appears to be met if the prior art indicates that something may work, and the motivation is such as to make this avenue "worthwhile" to pursue (*Pfizer Ltd.* , *supra*, para. 107, as quoted at para. 42 above). As such, a solution may be "worthwhile" to pursue even though it is not "obvious to try" or in the words of Rothstein J. even though it is not "more or less self-evident" (*Sanofi-Synthelabo*, *supra*, para. 66). In my view, this approach which is based on the possibility that something might work, was expressly rejected by the Supreme Court in *Sanofi-Synthelabo*, at paragraph 66. (emphasis added)

It must be noted that many inventions are arrived at by trial and error experimentation, the inventors being motivated by the possibility, or even likelihood, that a solution to some problem might be discovered through these experiments. The Office considers that the "obvious to try" test is not applicable merely because a motivation exists, in the broadest sense, to solve problems through scientific inquiry. Rather, a specific motivation must exist to identify a solution to a specific problem, from among a limited number of possible solutions one of which ought reasonably to work.

This paragraph acknowledges that a broad general motivation is not sufficient and the preceding description of motivation should be brought into conformance.

The Office considers that the "undue burden" aspect of the test must be evaluated objectively by the examiner, taking into account the nature of the person skilled in the art and the knowledge and climate in the relevant field or fields existing at the claim date. The subjective experience of the inventors, generally, will not be determinative during examination, since no practical mechanism exists for an examiner to fully ascertain the appropriateness of the inventors' line of inquiry nor whether the inventor should be treated as the relevant person skilled in the art.

Unnecessary Departure from the *Sanofi* Language

This paragraph, which appears still to relate to the "obvious to try" test, mentions "The 'undue burden' aspect of the test. . . .."

This would seem, on its face, to relate to the second *Sanofi* "obvious to try" factor, which in part states "…are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?"

It is unclear whether "prolonged and arduous" means the same thing as "undue burden" but it does not seem helpful to replace one expression with the other. The Committee recommends that the Notice employ "prolonged and arduous", the language provided by the Supreme Court?

Disregarding the Course of Conduct in Making the Invention

The last paragraph on page 4 of the Notice states in its totality the following:

> The Office considers that the 'undue burden' aspect of the test must be evaluated objectively by the Examiner, taking into account the nature of the person skilled in the art and the knowledge and climate in the relevant field or fields existing at the claim date. The subjective experience of the inventors, generally, will not be determinative during examination, since no practical mechanism exists for an Examiner to fully ascertain the appropriateness of the inventors' line of inquiry nor whether the inventor should be treated as the relevant person skilled in the art.

This proposal appears to depart from *Sanofi* in at least two significant ways.

First, CIPO appears to be addressing in this paragraph the second *Sanofi* "obvious to try" factor which is the extent, nature and amount of effort required to achieve the invention. The Notice states that regard will not be had to the subjective experience of the inventors.

But the subjective experience of the inventors (i.e. how the inventors actually made the invention) is not factor 2 in the *Sanofi* "obvious to try" factors but is rather factor 4.

So CIPO appears to be stating that the relevant considerations for factor 4 will not be taken into account when considering factor 2. But this by itself appears wrong because it incorrectly confuses the two factors. From this, it also can only be assumed that factor 4 will not be considered at all.

IPIC believes that this is wholly inappropriate.

Clearly, if CIPO is in a position to consider "attitudes, trends, prejudices and expectations that would define the person skilled in the art" (see the top of page 4 of the Notice) why cannot CIPO take into account what the inventors actually did? The inventors' course of conduct was clearly of importance in *Sanofi* as discussed above.

It appears that, to apply the law of obviousness as set out in *Sanofi*, CIPO must be prepared to consider the inventors' course of conduct just as the Supreme Court did. Indeed, it would lead to an absurd result if by applying the CIPO approach one could apply the test to the '777 patent in *Sanofi* and perhaps then reach the result that the claimed invention was obvious, contrary to the findings of the Supreme Court.

Surely, the same test must be applied and how evidence of inventor conduct is to be provided and then weighed are simply procedural issues, not issues of what is the appropriate legal inquiry and test.

CIPO's concern about not being equipped to serve as a trier of fact is a surmountable problem. CIPO must weigh evidence all the time, from assessing whether a change in inventorship is permitted under section 31 of the *Patent Act*, to whether an error was a clerical error for the purpose of a section 8 correction, to considering a reissue petition.

CIPO is prepared to investigate the factual circumstances in these situations. CIPO also routinely considers factual matters during examination (affidavits concerning enablement, balancing the weight of different prior art references, etc.). Perhaps the best example is the affidavits about date of inventorship provided in Old Act conflict cases.

There is no reason CIPO could not similarly weigh evidence of course of conduct. Presumably, affidavit evidence would be submitted providing the inventor's CV and explaining the research process, supported by suitable documentation. Such affidavits are submitted routinely for other purposes. They can be used to assess the level of ordinary skill in the art, assess whether the inventor is a skilled person, and to review the course of conduct. Whether this evidence is ultimately convincing is a separate question from whether CIPO can simply refuse to consider it.

B - Impact on cases under prosecution

All examination will henceforth assess obviousness in view of the guidance set forth herein. Applicants may consequently find that claims will be found defective for obviousness where they had not previously been objected to on this ground, or where an earlier obviousness objection had been withdrawn.

Examiners will raise obviousness objections in view of the current guidance where necessary, regardless of the prior prosecution of the application.

Where the present guidance on obviousness applies to an application that has been the subject of a Final Action, the correct obviousness defect may be raised in a "Supplementary Summary of Reasons" to which the applicant will be given an opportunity to respond. The particulars of such cases will be managed by the Patent Appeal Board, such as to introduce the least inconvenience and disruption into the process before the Board.

IPIC believes that this section of the Notice might helpfully provide more detail concerning procedural issues, such as whether rejections may be expected after a Notice of Allowance has issued, and details concerning the procedure for the proposed "Supplementary Summary of Reasons" after a Final Action.