



2019 Study Question

Submission date: May 28, 2019

Jonathan P. OSHA, Reporter General
Ari LAAKKONEN and Anne Marie VERSCHUUR, Deputy Reporters General
Guillaume HENRY, Ralph NACK and Lena SHEN, Assistants to the Reporter General

Plausibility

Responsible Reporter(s): Ralph NACK

National/Regional Group	Canada
Contributors name(s)	Kevin Shipley, Don MacOdrum, Santosh Chari, Vincent, de Grandpre, Brian Gray, Jonathan Pollack, Graeme Boocock, Jordana Sanft, Norman Siebrass, Charles Boulakia, Richard Naiberg
e-Mail contact	kevin@gilbertslaw.ca

I. Current law and practice

Please answer all questions in Part I on the basis of your Group's current law.

1 Does your law in general provide a plausibility requirement?

Yes

Please Explain

Canadian law does not have a plausibility requirement as such. However, aspects of Canadian law address plausibility-related issues, such as speculative claims, prediction of results, the disclosure required regarding the utility of an invention, and inventions the utility of which is not credible to a skilled person.

2 Is the plausibility requirement if any a stand-alone requirement or is it integrated into another requirement (e.g. inventive step)?

No

Please Explain

As noted above, there is no stand-alone requirement of plausibility in Canadian law. Plausibility-related issues are addressed by the traditional requirements for patentability: that there be an invention comprising patentable subject-matter, that such subject-matter have utility, that this utility be demonstrated or soundly predicted at the time of filing of the application, and that the invention be sufficiently disclosed in the patent application as filed.

3 Are there any statutory provisions that specifically apply to plausibility? If yes, please briefly explain.

No

Please Explain

As stated in our answer to question 1 above, there is no statutory provision specifically addressing plausibility as a separate concept or requirement. However, the Canadian *Patent Act*, RSC 1985, c P-4 [*Patent Act*], as amended, includes provisions for more traditional patentability requirements which may overlap with "plausibility".

The following provisions of the *Patent Act* are relevant to plausibility:

S. 2 In this Act, except as otherwise provided,

"invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;

S. 27

(1) The Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.

(2) The prescribed application fee must be paid and the application must be filed in accordance with the regulations by the inventor or the inventor's legal representative and the application must contain a petition and a specification of the invention.

(3) The specification of an invention must

- (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
- (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
- (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
- (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

(4) The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

(5) For greater certainty, where a claim defines the subject-matter of an invention in the alternative, each alternative is a separate claim for the purposes of divs 2, 28.1 to 28.3, 56 and 78.3.

.....

(8) No patent shall be granted for any mere scientific principle or abstract theorem.

4 Please briefly describe the general patentability requirements in the statutory law of your jurisdiction that are or would be relevant to the issue of plausibility.

The general patentability requirements of Canadian statutory law that are or would be relevant to the issue of plausibility are as set out above in answer to question 3. In addition, aspects of the statutory requirements for novelty and non-obviousness might arguably be relevant to plausibility; but these requirements are generally not considered relevant to plausibility by Canadian practitioners.

5 Under the case law or judicial or administrative practice in your jurisdiction, are there decisions or rules that specifically apply to plausibility? If yes, please briefly explain

No

Please Explain

Plausibility *per se*, as a separate principle, has not been considered by Canadian courts. However, courts have fully canvassed other Canadian requirements for patentability, which are relevant to plausibility, as further explained in response to question 6 below

6 Please briefly describe the general patentability requirements under the case law or judicial or administrative practice of your jurisdiction that are or would be relevant to the issue of plausibility. If there is no explicit or implied plausibility requirement in the law or under the judicial or administrative practice in your jurisdiction, please skip the below questions and proceed directly to question 15.

Utility

Utility is an essential part of the definition of an “invention”; if the subject-matter is not useful, it is not an invention within the meaning of the Act.

The requirement that an invention be useful gives rise to various issues discussed in the divs below. The principal points are the following:

1. An invention must have at least a scintilla of utility. If the claimed invention will not work at all, the claim is invalid.
2. The usefulness of the invention must be related to the nature of the subject-matter claimed.
3. If a claim extends to cover subject-matter which does not work, the claim is invalid.
4. A claim which omits an essential element of a product or process is invalid.
5. The utility of the claimed invention must have been demonstrated or, in the alternative, soundly predicted by the inventor by the filing date.

Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77, [2002] 4 SCR 153 [*Wellcome*], is a leading Canadian decision in relation to these issues. This decision concerned a patent relating to a new use to treat HIV/AIDS of the known drug AZT (3'-azido-3'-deoxythymidine). Justice Binnie for the Supreme Court of Canada stated (*inter alia*):

- The public should not be expected to pay an elevated price in exchange for speculation, or for the statement of “any mere scientific principle or abstract theorem” (s. 27(3)), or for the “discovery” of things that already exist, or are obvious. The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures (*Wellcome* at para 37).
- Glaxo/Wellcome claimed a hitherto unrecognized utility, but if it had not established such utility by tests or sound prediction at the time it applied for its patent, then it was offering nothing to the public but wishful thinking in exchange for locking up potentially valuable research turf ... (*Wellcome* at para 52).
- Where the new use is the gravamen of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available. (*Wellcome* at para 56).
- If a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, there is evidence of lack of utility in respect of some of the area covered. (*Wellcome* at para 56).
- The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In *Monsanto and Burton Parsons*, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may suffice (see *Monsanto Co v Commissioner of Patents*, [1979] 2 SCR 1108; *Burton Parsons Chemicals, Inc v Hewlett-Packard (Canada) Ltd*, [1976] 1 SCR 555). Secondly, the inventor must have at the date of the patent application an articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis. In *Monsanto and Burton Parsons*, the line of reasoning was grounded in the known “architecture of chemical compounds” ..., but other lines of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure. Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practiced: ... It is generally not necessary for an inventor to provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case ... (*Wellcome* at para 70).

In rejecting an “after the fact” validation theory, Justice Binnie wrote:

- The patent claims must be supported by the disclosure. Speculation, even if it afterwards proves justified, does not provide valid consideration (*Wellcome* at para 83).
- In the broader context of the *Patent Act*, as well, there is good reason to reject the proposition that bare speculation, even if it afterwards turns out to be correct, is sufficient. An applicant does not merit a patent on an almost-invention, where the public receives only a promise that a hypothesis might later prove useful; this would permit, and encourage, applicants to put placeholders on intriguing ideas to wait for the science to catch up and make it so. The patentee would enjoy the property right of excluding others from making, selling, using or improving that idea without the public's having derived anything useful in return (*Wellcome* at para 84).

In a recent case, the Supreme Court of Canada has held that the usefulness of an invention must be related to the nature of the subject matter: a proposed invention cannot be saved by an entirely unrelated use. It is not sufficient for a patentee seeking a patent for a machine to assert it is useful as a paperweight. Similarly, it is not sufficient that it is a laboratory curiosity, whose only possible claim to utility is as a starting material for further work (see *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at paras 53, 56 [*AstraZeneca*])

In *AstraZeneca*, Rowe J. for the Supreme Court said (at para 57):

The application of the utility requirement in s. 2, therefore, is to be interpreted in line with its purpose – to prevent the patenting of fanciful, speculative or inoperable inventions.

If an invention has no demonstrated or predictable utility, such as an alleged perpetual motion machine, it is not patentable (*Ottawa v Commissioner of Patents*, (1979) 51 CPR (2d) 134). A claim is invalid if it extends to cover an embodiment which does not work (*Minerals Separation North American Corp v Noranda Mines Ltd*, (1952) 15 CPR 133 (PC)).

Disclosure

As noted above in relation to Question 3, div 27(3) of the *Patent Act* requires that a patent specification correctly and fully describe the invention and its operation or use as contemplated by the inventor.

In general, an inventor is not required to describe in the description or claims in what way the invention is useful (*Consolboard Inc v MacMillan Bloedel (Saskatchewan) Limited*, [1981] 1 SCR 504 at 525-527). There are some exceptions, however.

If the use or utility is necessary to define the invention, as in the case of a new use for a known product, then it is necessary that this utility be referred to in the description and claims.

There is authority that where the invention is a new chemical compound, or a process to produce a new chemical compound, since the utility of such compound or process is not apparent, it must be stated in the description, but not in the claims.

Similarly, it has been held that where the invention is based on a selection of a product from a known class based on some unexpected advantage, such advantage must be disclosed.

Also, as noted above, in *Wellcome*, the Court held that where the utility of an invention is based on a prediction, there must be disclosure of the basis for the prediction. There was *dicta* in a subsequent decision of the Supreme Court (*Teva Canada Limited v Pfizer Canada Inc*, 2012 SCC 60, which indicated that the Court might re-visit this issue—but it did not overrule the prior decision in *Wellcome*).

Other Canadian patent law doctrines are also relevant to understand how Canadian law addresses policy concerns that are the focus of plausibility requirements.

Overbreadth

It is settled law in Canada that a patent claim is invalid if it claims more than was invented by the inventor(s) or more than is described in the specification. This is consistent with the requirements that a patent be for an invention of an inventor and that the specification correctly and fully describe the invention. One way in which a claim may be broader than the invention made or the invention disclosed is if it omits an essential feature of the invention made or the invention as disclosed.

Historical Case Law Relating to Inventorship

Under a previous version of the *Patent Act*, Canadian courts could be called upon to consider *when* a claimed invention had been made, which could be relevant to entitlement to a patent grant and to non-obviousness generally. In this context, Canadian courts concluded that: “It is not enough for a man to say that an idea floated through his brain; he must at least have reduced it to a definite and practical shape before he can be said to have invented a process,” (*Christiani v Rice*, [1930] SCR 443, citing *Permutit Company v Borrowman*, (1926) 43 RPC 356 at 359). In practice, courts were required to determine, as a matter of fact, when the inventor had identified the invention, reduced it to writing, and when the invention was “practical”, in that it will do the job that is claimed (i.e., that it will be useful) (see *Sanofi-Aventis Canada v Apotex Inc*, 2009 FC 676 at para 274). While the date of invention is no longer relevant to the entitlement to or validity of a patent, this jurisprudence influences the view of an “invention” under Canadian law.

7 Can the plausibility requirement be regarded primarily as a “credibility” requirement, i.e., a requirement applying to patent applications that describe a technical effect that appears non-credible, e.g., because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?

No

Please Explain

As noted above, Canadian law does not have a plausibility requirement. However, patentability requirements related to plausibility do partly function as a credibility requirement. Applications claiming inventions that are not credible, e.g. a perpetual motion machine, will be rejected for lack of utility, specifically inoperability, or being incapable of a practical purpose. However, the hurdle for establishing utility (plausibility) is higher than mere credibility.

7.a If yes, is the credibility determined from the perspective of a person having ordinary skill in the art, or from the perspective of an expert in the field?

Yes

Please Explain

The credibility assessment is made from the perspective of a person having ordinary skill in the art.

7.b If the relevant perspective is the person having ordinary skill in the art, why is a “credible” technical effect not also obvious at the same time?

Yes

Please Explain

There are two reasons an invention that is credible may not be obvious. First, the assessment of credibility is made based on the content of the application in light of the common general knowledge, whereas the assessment of obviousness is made based on the content of the applicable prior art, without reference to the content of the application. Second, the date for assessing obviousness is the “claim date,” which is the Canadian filing date or the priority date if priority is properly requested, while plausibility in the sense of utility or sufficiency is considered at the Canadian filing date.

7.c Do all the promises of the patent description have to seem achievable for the person skilled in the art?

No

Please Explain

Until 2017, Canada had what was sometimes called a “promise of the patent doctrine”. Applying it, the courts held that where a patent specification sets out an explicit “promise”, utility was to be measured against that promise: the question was whether the invention does what the patent promises it will do. The doctrine then went on to provide that if any one of the promises was not fulfilled, then the utility requirement in s. 2 of the *Patent Act* was not met and the patent, in its entirety, was invalid (see *AstraZeneca, supra* at paras 28-31).

Applying the promise of the patent doctrine, as the name suggests, involved identifying “promises” in the patent description. This led to many disputes as to whether language in the description was a promise or merely an indication of advantages. Failure to satisfy this “promise of the patent doctrine” led to several patents for inventions which were in fact useful being held invalid.

In *AstraZeneca*, the Supreme Court of Canada held that this promise of the patent doctrine was not good law.

In *AstraZeneca*, Rowe. J. for the Court described the correct approach to utility under Canadian law as follows:

[52] The words in s. 2 of the *Act* ground the type of utility that is pertinent by requiring that it is the subject-matter of an invention or improvement thereof that must be useful. For the subject-matter to function as an inventive solution to a practical problem, the

invention must be capable of an actual relevant use and not be devoid of utility. As stated by Justice Binnie in *AZT [Wellcome, supra]*, a patent “is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time” (para 37 (emphasis added)).

[53] Utility will differ based on the subject-matter of the invention as identified by claims construction. Thus, the scope of potentially acceptable uses to meet the s. 2 requirement is limited — not any use will do. By requiring the usefulness of the proposed invention to be related to the nature of the subject-matter, a proposed invention cannot be saved by an entirely unrelated use. It is not sufficient for an inventor seeking a patent for a machine to assert it is useful as a paperweight.

[54] To determine whether a patent discloses an invention with sufficient utility under s. 2, courts should undertake the following analysis. First, courts must identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e. an actual result)?

[55] The *Act* does not prescribe the degree or quantum of usefulness required, or that every potential use be realized — a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date (*AZT*, at para 56).

[56] The utility requirement serves a clear purpose. To avoid granting patents prematurely, and thereby limiting potentially useful research and development by others, the case law has imposed a requirement that an invention’s usefulness be demonstrated or soundly predicted at the time of application, rather than at some later point. This ensures patents are not granted where the use of the invention is speculative. What matters is that an invention “be useful, in the sense that it carries out some useful known objective” and is not merely a “laboratory curiosity whose only possible claim to utility is as a starting material for further research” (*Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 (Patent Appeal Board and Commissioner of Patents), at p. 91).

[57] The application of the utility requirement in s. 2, therefore, is to be interpreted in line with its purpose — to prevent the patenting of fanciful, speculative or inoperable inventions.

Accordingly, in general, a single use related to the nature of the invention is sufficient if such use is demonstrated or soundly predicted by the filing date (see *AstraZeneca, supra*, at para 55). However, if a specific use is claimed, this claimed utility must have been demonstrated or soundly predicted for the use claim to be valid.

8 Can the plausibility requirement be regarded primarily as a prohibition of “speculative” patent applications which do not (expressly) disclose a technical effect or concrete use, e.g., of a chemical substance (the potential technical effect or concrete use rather remains speculative)?

Yes

Please Explain

Yes, the purpose of the utility requirement is primarily to prevent speculative patents:

The utility requirement serves a clear purpose. To avoid granting patents prematurely, and thereby limiting potentially useful research and development by others, the case law has imposed a requirement that an invention’s usefulness be demonstrated or soundly predicted at the time of application, rather than at some later point. This ensures patents are not granted where the use of the invention is speculative.

AstraZeneca, supra, at para 56.

8.a If yes, which standard does apply to determine a speculative filing? Which requirements does the applicant have to meet in order to reach a non-speculative filing?

The threshold for utility is low: “a scintilla of utility will do.” When utility was demonstrated before the filing date, the evidence supporting utility need not be disclosed in the patent. When utility was established by sound prediction, the specification must disclose a factual basis for the prediction and a sound line of reasoning.

8.b If a technical effect (which is not expressly described in the specification) is nonetheless plausible because the skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification, why was the technical effect not obvious at the priority date?

Similar to the answer in Question 7(b), a technical effect that is not expressly disclosed in the specification may also be obvious, depending on the teaching in the prior art since the bases for the assessments are different.

9 Can the plausibility requirement be regarded primarily as specific prohibition against “prophetic” examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g., the description merely “predicts” that a specific experiment “will” prove a special property of the claimed compound?

No

Please Explain

No, there is no prohibition against “prophetic” examples; however, the claimed invention will still need to meet the utility requirement mentioned above.

9.a If yes, which standard does apply to identify a prophetic example? Must the applicant submit test data etc. to support examples (unless self-evident)?

Not applicable.

9.b Do all examples (or embodiments) need to pass this plausibility test? What is the consequence if only some examples (or embodiments) do not pass the test?

No

Please Explain

Not applicable.

10 Is it possible to make a clear distinction between the above-mentioned aspects (as set out in the questions 7-9 above) or do they merge into each another?

No

Please Explain

Non-credible or wholly inoperable inventions, discussed in Question 7, are considered to be one form of lack of utility. So, at one time applications claiming a method of growing hair on a bald man would be rejected as non-credible or inoperable. Now that effective treatments have been developed for male androgenic alopecia, such claims will no longer be rejected as non-credible; but if utility was not demonstrated or soundly predicted, they will be nonetheless rejected for lack of utility. In either case, the fundamental statutory basis for the rejection is the same: the claimed invention does not work to address male pattern baldness.

11 What is the relevant point in time for the plausibility test?

The relevant time for assessing utility is the Canadian filing date (see *Aventis Pharma Inc v Apotex Inc*, 2006 FCA 64 at para 30, aff'd 2005 FC 1283 at paras 91-96; *Pfizer Canada Inc v Apotex Inc*, 2007 FCA 209 at para 153; *Bristol-Myers Squibb Canada Co v Apotex Inc*, 2017 FCA 190 at para 32). Consequently, post-filing evidence is not admissible to establish utility. However, post-filing evidence is admissible to establish lack of utility. That is, even if utility can be soundly predicted at the time of filing, post-filing evidence is admissible to show that the claimed invention in fact lacks utility, in which case the claim will be held invalid.

What if for example the technical effect of an invention appears plausible at the priority date, but later proves to be wrong, or vice versa?

Consequently, post-filing evidence is not admissible to establish utility. However, post-filing evidence is admissible to establish lack of utility. That is, even if utility can be soundly predicted at the time of filing, post-filing evidence is admissible to show that the claimed invention in fact lacks utility, in which case the claim will be held invalid.

12 Are there different plausibility tests for different types of claims (e.g. pure product/compound claims without a functional feature, product claims including a functional feature, second medical use claims, etc.)?

Yes

Please Explain

As there is no doctrine of "plausibility" as such, there is no test. Rather, the test used is that applicable to the particular doctrine which gives rise to the plausibility consideration, that is, utility, sufficiency, etc., as described in the answer to Question 6. There is no utility distinction based on the type of claim under any of those analyses, but, as noted in the answer to Question 6, the utility or advantage must be disclosed for certain types of inventions.

13 Who has the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?

During prosecution of a patent application, the burden is on the applicant to establish the utility or support in the description for the claimed invention. This issue arises when an examiner challenges the utility or sufficiency of the description of a claimed invention.

Once granted, the patent is presumed to be valid, and so utility is presumed; but, the presumption is weak and applies only in the absence of evidence to the contrary (*Patent Act*, s 43(2)). If evidence of lack of utility or lack of sound prediction is introduced, then the matter is decided on the balance of probabilities.

14 Please comment on any additional issues concerning any aspect of plausibility that is being regulated by your Group's law/practice you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.

*To what extent is data required in the patent itself to establish utility / plausibility (see *Actavis v ICOS*, [2017] EWCA Civ 1671 ("One of the key issues in the law of plausibility is the extent to which experimental data is required in a patent in order to render it plausible."))?*

At present, the law in Canada is that data is not required in the patent if utility is demonstrated, but it is required if utility is based on sound prediction. (Though two trial decisions have suggested that the data need only be in the patent if the claims pertain to a new use of a known compound.) There is also a question as to whether, in sound prediction cases, it is necessary for the data to actually be in the patent, or if it is enough for the data to be referred to in the patent.

What is the extent of proof required to establish lack of utility/plausibility?

In cases where a patent relates to a technical effect that appears non-credible (as in the scenario outlined in Question 7) or speculative (as in the scenario outlined in Question 8), one question that may arise is how many examples are needed, or alternatively, how much support is

needed to establish plausibility. This issue has not been addressed by the courts in Canada.

II. Policy considerations and proposals for improvements of your Group's current law

15 Are there aspects of your Group's current law relating to plausibility that could be improved? If YES, please explain.

No

Please Explain

As noted above, Canadian law does not have a plausibility requirement.

The current Canadian principles of utility and sufficiency, which address similar issues, seem to be fairly balanced.

16 Under your Group's current law, does the availability of patent protection aim to incentivize an early disclosure of technical achievements, or rather the disclosure of "completed" inventions (which may involve a mandatory disclosure of a "best mode")?

Yes

Please Explain

In *Wellcome, supra*, at para 37, Binnie J. for the Supreme Court of Canada said:

A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*. Monopolies are associated in the public mind with higher prices. The public should not be expected to pay an elevated price in exchange for speculation, or for the statement of "any mere scientific principle or abstract theorem" (s. 27(3)), or for the "discovery" of things that already exist, or are obvious. The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures.

The "first to file" regime in Canada would suggest that the availability of patent protection aims to incentivize early disclosure of inventions. However, for patent protection to be obtained, the invention must meet the previously described criteria of utility, among others; and so, an invention must reach a certain level of "completion". As referred to in the answer to Question 6, an invention for which patent protection is available must have been reduced to a definite and practical shape. This does not mean that a physical embodiment must be made if, for example, there is a sufficient description of the invention and its utility is soundly predictable.

17 Under your Group's current law, does the plausibility requirement, if any, interfere with the incentive for an early disclosure provided by the first-to-file system?

No

Please Explain

As noted above, Canadian law does not have a plausibility requirement.

The current Canadian principles of utility and sufficiency, which address similar issues, require that there be an invention before an application is filed, but do not interfere with the incentive for an early disclosure of that invention provided by the first-to-file system.

III. Proposals for harmonization

Please consult with relevant in-house / industry members of your Group in responding to Part III.

18 Do you consider that harmonization regarding plausibility is desirable? If YES, please respond to the following questions without regard to your Group's current law. Even if NO, please address the following questions to the extent your Group considers your Group's current law could be improved.

Yes

Please Explain

The Canadian Group agrees that international harmonization is generally desirable to promote access to patents, promote consistency in the review of patent applications and minimize legal risks across jurisdictions. Supporting harmonization does not necessarily imply embracing plausibility as a distinct patentability requirement, however. International harmonization could also be achieved by eliminating plausibility as a formal requirement in those jurisdictions that currently rely on it as a stand-alone legal condition of patentability.

19 Should there be a plausibility requirement? If no, please briefly explain why and then please also answer the following questions assuming there is a plausibility requirement.

No

Please Explain

The consensus among those who participated in the Canadian Group is that Canada should not adopt a stand-alone plausibility requirement because it is unnecessary and therefore likely to create legal uncertainty without a commensurate benefit.

As a stand-alone requirement, plausibility would not add to Canadian law because the statutory requirements of the *Patent Act* have been interpreted to address the mischiefs that we understand are the purpose of the plausibility requirement in other jurisdictions. Other Canadian legal requirements have evolved to prevent speculative claiming and ensure the sufficient disclosure of inventions in patent applications. We refer specifically to the discussions of Utility and Sufficiency in answer to Question 6, above.

The Canadian Group speculates that a separate plausibility requirement may have evolved in certain jurisdictions (such as Europe) because, unlike Canada, these jurisdictions do not require claimed inventions to have demonstrated or soundly predicted utility at the date of filing.

20 Should plausibility be a "credibility" requirement that excludes patent applications describing a technical effect of the claimed invention which however looks "incredible", e.g. because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?

20.a If yes, which standard should apply to determine the credibility of the invention? Is the credibility determined from the perspective of a person having ordinary skills in the art, or from the perspective of an expert in the field?

As noted in answer to Question 19, from a Canadian standpoint, there is no perceived need for a distinct plausibility requirement, whether it functions as a credibility requirement or otherwise. Other patentability requirements can (and in Canada do) function as a credibility requirement. If a Canadian patent examiner forms the view that a claimed invention is not credible, they will reject the claims at issue for lack of utility, specifically inoperability, or being incapable of a practical purpose.

As explained in answer to Question 7, this assessment is made from the perspective of a person having ordinary skill in the art. The way for an applicant to overcome such an objection is to point to specific elements in the patent disclosure that support the inventor's prediction of the claimed utility of the invention.

20.b Should all the promises of the patent description have to seem achievable for the person skilled in the art?

No

Please Explain

The Canadian Group is of the view that it is not desirable to require that “promises” in a patent’s description that do not directly support a claimed use must seem achievable for the person skilled in the art. The Canadian experience with the “promise of the patent” doctrine suggests that attributing weight to “promises” contained in patent descriptions fosters unreasonable patent construction and uncertainty in the law. See generally, *AstraZeneca, supra* and the discussion in relation to the answer to Question 7(c).

As noted in answer to Question 7, current Canadian law does not require any promise in a patent description to be achieved unless the specific utility promised is claimed, in which case the validity of that claim will require the utility to have been demonstrated or soundly predicted at the Canadian filing date. For example, if a Canadian patent describes and claims a new composition of matter for the treatment of a certain medical condition, the claims to this new substance will be valid if they meet the requirements of the *Patent Act*, without regard to any promises in the patent description relating (for example) to the new substance’s therapeutic use. However, claims directed to the use of the substance to treat the medical condition will be valid only if the claimed utility had been demonstrated or soundly predicted at the Canadian filing date. In the Group’s view, current Canadian law adequately deals with promises contained in patent descriptions, and the Canadian experience offers an alternative model to the plausibility-as-credibility requirement.

21

Should plausibility be a prohibition of “speculative” patent applications which do not (expressly) disclose a technical effect or concrete use e.g. of a chemical substance (the potential technical effect or concrete use rather remains speculative)?

No

Please Explain

The Canadian Group does not believe that there should be a stand-alone plausibility requirement because other patentability requirements can (and in Canada do) function to prohibit speculative claiming. As noted in answer to Questions 6 and 8 above, speculative patent applications are already objectionable under Canadian law as lacking utility, failing to sufficiently describe the invention, or even being obvious:

- In some respects, the Canadian utility requirement is more stringent than plausibility because the utility of a Canadian claim must have been established by its filing date, by demonstration or sound prediction. No post-filing data may establish the utility of a claimed invention.
- In the case of predicted use inventions, Canadian utility may be more granular than plausibility in its requirement: it requires a factual basis, a sound line of reasoning and additional disclosure (see answer to Question 6).
- If the properties of an invention (a novel compound, pharmaceutical formulation, etc.) form part of the invention, then those properties must be described, failing which the claims will fail for lack of disclosure. Moreover, these properties may not be relied upon to establish the inventiveness of the claims if they are not described in the patent.

For these reasons, the Canadian Group does not believe that plausibility is necessarily required to curb speculative claiming in Canada or elsewhere.

21.a

If yes, which standard should apply to determine a speculative filing? Which requirements should the applicant have to meet in order to reach a non-speculative filing?

Not applicable.

21.b

What should be the consequence if a technical effect which is not expressly described in the specification is nonetheless plausible because the skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification?

Not applicable.

22 Should plausibility be a specific prohibition to refer to “prophetic” examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g. the description “predicts” that a specific experiment “will” prove a special property of the claimed compound?

No

Please Explain

From a Canadian standpoint, there is no need for a distinct plausibility requirement to prohibit prophetic examples because, as stated in response to Question 9, the utility of a claimed invention must still be established by the filing date. Prophetic examples can be helpful to someone reading a patent. For example, in a patent for a new compound with a known biological action that is predicted to be useful to treat a certain condition, a prophetic example might explain how the inventor is measuring that therapeutic action in a pending clinical trial. However, such examples can be unhelpful to an applicant, as they create risk that the example will be incorrect or “preclusive” (i.e. the example might disclose or make obvious another use).

22.a If yes, which standard should apply to identify a prophetic examples?

Not applicable.

22.k Should all examples (or embodiments) need to pass this plausibility test? What should be the consequence if only some examples (or embodiments) do not pass the test?

Yes

What should be the consequence if only some examples (or embodiments) do not pass the test?

Not directly applicable, but examples and embodiments in a patent should be truthful and shown to have demonstrated or soundly predicted if they are ever challenged.

23 What should be the relevant point in time for the plausibility test? What if for example the technical effect of an invention appears plausible at the priority date, but later proves to be wrong, or vice versa?

The Canadian Group does not believe that there should be a stand-alone plausibility requirement, as set out above. Canadian law may already address the issue raised by this question by relying on different dates to assess novelty and inventiveness on the one hand (generally, a priority date), and utility on the other (the Canadian filing date).

24 Should there be different plausibility tests for different types of claims (e. g. pure product/compound claims without functional feature, product claims including functional feature, second medical use claims, etc.)?

No

Please Explain

See answer to Question 12. As previously noted, the Canadian Group does not support introduction of a plausibility test. However, we do support a requirement for the disclosure of the utility of a product, such as a bare chemical, with no apparent specific utility or a process to produce such a product, and of the advantage asserted for a selection patent.

25 Who should have the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?

See answer to Question 13. The Canadian Group considers that such an approach is reasonable.

26 Please comment on any additional issues concerning any aspect of plausibility you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.

No comments.

27 Please indicate which industry sector views provided by in-house counsel are included in your Group's answers to Part III.

No in-house counsel participated in the Canadian Group who considered the Study Question.