



Intellectual Property Institute of Canada
Institut de la propriété intellectuelle du Canada

Intellectual Property Institute of Canada (IPIC) Response to CIPO's *Consultation on changes to MOPOP resulting from "Patentable Subject-Matter under the Patent Act"*

Submission to the
Canadian Intellectual Property Office

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INTRODUCTION

The Intellectual Property Institute of Canada (IPIC) is the professional association of patent agents, trademark agents and lawyers practising in all areas of intellectual property law. Our membership totals over 1700 individuals, consisting of practitioners in law firms and agencies of all sizes, sole practitioners, in-house corporate intellectual property professionals, government personnel, and academics. Our members' clients include virtually all Canadian businesses, universities and other institutions that have an interest in intellectual property (e.g., patents, trademarks, copyrights, and industrial designs) in Canada or elsewhere, as well as foreign companies that hold intellectual property rights in Canada.

IPIC appreciates the opportunity to respond to this consultation on revisions to the *Manual of Patent Office Practice* (MOPOP).

Patent applicants and CIPO face the same challenge with the law on patentable subject matter: simply put, we do not have sufficient worked examples of patentable subject matter analysis in our case law to confidently and consistently apply section 2 and subsection 27(8) of the *Patent Act*, especially in the computing, information technology, and health care fields, where innovations push the boundaries of “physicality”.¹ This is not surprising, considering that Canadian patent jurisprudence is largely driven by the pharmaceutical sector where questions of subject matter eligibility are usually confined to methods of medical treatment.

Consequently, when assessing subject matter eligibility, we start from the basic principles laid out in our jurisprudence and work out for ourselves how those principles apply to thousands of new discoveries in every field of endeavour, every year. It is desirable to have a detailed methodology for patentable subject matter analysis with worked examples to reduce uncertainty for both innovators and users of technology, and to ensure consistent and predictable outcomes in patent examination.

However, consistency and predictability cannot come at the expense of innovators attempting to protect their inventions in Canada. The patent bargain encourages innovators to come forward and disclose their inventions in exchange for a time-limited monopoly. They receive notice of the terms of the bargain from the *Patent Act* and the jurisprudence interpreting the *Act*. Any action contrary to that notice undermines the patent bargain and will, ultimately, disincentivize investment in Canadian research and development.

Unfortunately, CIPO's latest patentable subject matter guidance in *Patentable Subject-Matter under the Patent Act*,² which forms the basis of this consultation, does just that. Respectfully, this guidance is not compliant with our law on patentable subject matter as set out in section 2

¹ *Canada (Attorney General) v. Amazon.com, Inc.*, 2011 FCA 328 (“*Amazon FCA*”) at para 65.

² CIPO, *Patentable Subject-Matter under the Patent Act*, November 3, 2020 (<https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04860.html>).

and subsection 27(8) of the *Act*, as interpreted by the Supreme Court and Federal Court of Appeal in cases such as *Shell Oil*,³ *Tennessee Eastman*,⁴ and *Amazon FCA*, principally for the same reason that prior examination guidance was found to be legally incorrect. IPIC is concerned that if this guidance continues to be enforced, applicants will be compelled to abandon protection for meritorious and patentable inventions, or expend time and resources appealing refusals of applications to demonstrate what should already be clear: this new patentable subject matter guidance is in error, just as CIPO's previous examination guidance from 2009,⁵ 2011,⁶ and 2013⁷ was found to be in error by the Federal Courts.

IPIC does recognize the administrative need for precise and detailed instructions for patent examiners. However, the Commissioner of Patents can only apply the law that exists; they cannot extrapolate new, unsupported legal tests from our case law in the interest of administrative efficiency or policy reasons. In the absence of clear direction from our courts or from Parliament, CIPO must confine itself to the legal guidance that we currently *have*, and not use the guidance they may *want*.

This submission explains why IPIC believes CIPO's latest patentable subject matter guidance is incorrect in law, and proposes an alternate analytical framework that follows the leading jurisprudence while also providing predictable, repeatable outcomes. IPIC strongly recommends that this alternate framework be incorporated into MOPOP in place of *Patentable Subject-Matter under the Patent Act*. This submission concludes with a number of additional comments on the proposed MOPOP chapters presented in this consultation.

³ *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 SCR 536 ("*Shell Oil*").

⁴ *Tennessee Eastman Co. et al. v. Commissioner of Patents*, [1974] SCR 111 ("*Tennessee Eastman*").

⁵ *Amazon Inc. v. Canada (Attorney General)*, 2010 FC 1011 ("*Amazon FC*"), quashing *Re Amazon.com Inc.*, Commissioner's Decision 1290; reversed on the matter of the correct party to carry out claim construction, *Amazon FC*.

⁶ The "actual invention" guidance in PN2011-04, *Practice Subsequent to the Amazon.com Decision* (<https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03122.html>), was advanced in argument to the Federal Court of Appeal in *Amazon FCA*; the Federal Court of Appeal disagreed that the "actual invention", i.e., the inventive concept, could form the sole basis of a patentable subject matter analysis at para 47.

⁷ *Choueifaty v. Canada (Attorney General)*, 2020 FC 837 ("*Choueifaty*"), in respect of PN2013-02, *Examination Practice Respecting Purposive Construction* (<https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03626.html>); PN2013-03, *Examination Practice Respecting Computer-Implemented Inventions* (<https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03627.html>).

THE NEW PATENTABLE SUBJECT MATTER GUIDANCE IS INCORRECT IN LAW

The examination guidance promulgated on November 3, 2020 in response to *Choueifaty v. Canada (Attorney General)* is incorrect in law and should not be incorporated into MOPOP. Instead, the examination guidance should be replaced with new guidance that complies with the law, such as IPIC's proposed framework.

The analytical framework set out in *Patentable Subject-Matter under the Patent Act* and the proposed MOPOP chapters is premised on an identification of the “actual invention” of the claim. In effect, it is no different than the various frameworks that CIPO has imposed since 2009, and that the Federal Courts have found to be legally incorrect. Furthermore, the guidance adds a requirement that the “actual invention” must belong to the “manual or productive arts” which is not a rule in Canadian law, and misrepresents the “physicality” requirement described by the Federal Court of Appeal in *Amazon FCA*.

The current analytical framework is no different than the previous erroneous guidance

Beginning in 2009, as exemplified by *Re Amazon.com Inc.*⁸ CIPO adopted several approaches to determine whether “something” was statutory subject matter. One of these approaches was to determine the “substance of the claim”, or “what has actually been discovered”—based either on the content of the specification in accordance with *Schlumberger Canada Ltd. v. Commissioner of Patents*,⁹ or what new matter the inventor had “really added to human knowledge” as in *Aerotel Ltd v Telco Holdings Ltd & Others*.¹⁰ CIPO's reliance on Canadian and UK case law was misplaced; on appeal the Federal Court found that this “novel legal test” was not supported by Canadian jurisprudence, and an error of law.¹¹

CIPO's subsequent guidance in PN2011-04, *Practice Subsequent to the Amazon.com Decision*, only tweaked this legal test slightly, creating a two-step test and amending “what has actually been discovered” to “actual invention”:

⁸ *Re Amazon.com Inc.*, CD 1290 at para 127.

⁹ *Schlumberger Canada Ltd. v. Commissioner of Patents* (1981), 56 C.P.R. (2d) 204 (“*Schlumberger*”) at 205: “In order to determine whether the application discloses a patentable invention, it is first necessary to determine what, according to the application, has been discovered.”

¹⁰ *Re Amazon.com Inc.*, CD 1290 at paras 127-128, citing *Schlumberger* at 205: “In order to determine whether the application discloses a patentable invention, it is first necessary to determine what, according to the application, has been discovered” (emphasis in CD 1290) and *Aerotel Ltd v Telco Holdings Ltd & Others*, [2006] EWCA Civ 1371 at para 43.

¹¹ *Amazon FC* at paras 43-47.

In examining an application, two things must be identified in the assessment of patentability: 1) what the applicant is claiming as its monopoly, and 2) what the inventors actually invented.

If either the *claimed monopoly* or the *actual invention* is not patentable, the application is defective and is not to be allowed.

• • •

The Office takes the position that the *actual invention* is equivalent to the *inventive concept* of a claim, when the *inventive concept* is identified according to the guidance set forth in the appendix to this document.¹²

The “actual invention” was simply another name for the “inventive concept”, and the “inventive concept” was CIPO’s interpretation of *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*,¹³ that is, “those elements that are required to provide the solution disclosed by the inventors to the problem being confronted” and “those aspects of the solution that define, in practical terms, the new skill or knowledge disclosed by the inventors and which capture the essence of the invention”. The “actual invention” or “inventive concept” was determined from the problem to be solved and its solution as gleaned from the description:

In identifying the problem that the inventors set out to address, and the solution proposed through the invention, guidance should be found in the description, in accordance with paragraph 80(1)(d) of the Patent Rules which provides that the description shall:

describe the invention in terms that allow the understanding of the technical problem, even if not expressly stated as such, and its solution.

Identifying the problem to be solved and its solution can be understood in the context of “achieving the objects of the invention” and “fulfilling the purpose of the invention”.¹⁴

This “actual invention” or “inventive concept” analysis was advanced by CIPO in its argument on appeal from the Federal Court. While the Federal Court of Appeal did acknowledge the relevance of the “actual invention” to various matters of patentability or validity,¹⁵ they clearly stated that this was not the appropriate analysis for patentable subject matter:

In my view, there is nothing in the cases cited by the Attorney General of Canada that casts any doubt on the proposition that the Commissioner’s determination

¹² CIPO, *Practice Subsequent to the Amazon.com Decision*, PN2011-04.

¹³ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61.

¹⁴ CIPO, *Practice Subsequent to the Amazon.com Decision*, PN2011-04, Appendix.

¹⁵ *Amazon FCA* at para 42.

of subject matter must be based on a purposive construction of the patent claims. Therefore, on the question of analytical framework, I agree with Justice Phelan that in determining subject matter solely on the basis of the inventive concept, the Commissioner adopted an analysis that is incorrect in law.¹⁶

The next iteration of CIPO's patentable subject matter guidance was PN2013-02, *Examination Practice Respecting Purposive Construction*, and accompanying guidance for specific types of subject matter. The purposive construction guidance was subsequently modified and incorporated into MOPOP where it remains, although it has since been superseded. In this post-*Amazon FCA* guidance, CIPO latched on to the Federal Court of Appeal's acknowledgement of the "actual invention", and integrated the PN2011-04 "actual invention" guidance into the identification of essential elements, while generally avoiding use of this phrase or "inventive concept". As set out in current MOPOP section 12.02.02e:

12.02.02e Determine which elements of the claim solve the identified problem

One aspect of purposive construction is the identification of the essential elements of the claim. The identification of the essential elements of a claim cannot be performed without having first properly identified the proposed solution to the disclosed problem...

... an element is not necessarily essential merely by the fact that is not found in the prior art. Likewise, an element cannot necessarily be deemed non-essential merely because it is part of the CGK. An element is essential if it is required to provide the solution to the problem, regardless of whether or not it is known.

The problem and solution continued to be identified in a similar manner to that described in PN2011-04.

Once this exercise was completed, only those essential elements that were identified as providing the solution to the identified problem were used to determine whether the claim comprised statutory subject matter. See, for example, current MOPOP section 23.03.04d (a diagnostic claim limited to essential elements that are "disembodied" is defective for non-compliance with section 2 of the *Patent Act*) and PN2013-03, *Examination Practice Respecting Computer-Implemented Inventions* (a claim with essential elements that are "limited to matter excluded from the definition of invention" is not compliant with section 2 of the *Act*).

The Federal Court held that this post-*Amazon FCA* claim construction methodology was also incorrect in law in *Chouiefaty*, finding it "akin to using the 'substance of the invention' approach discredited by the Supreme Court of Canada in *Free World Trust*".¹⁷ The Court moreover found that this methodology neglected the inventor's intention to have a claim element considered

¹⁶ *Amazon FCA* at para 47 (emphasis added).

¹⁷ *Chouiefaty* at para 37.

essential.¹⁸ This decision, of course, led to the post-*Choueifaty* November 2020 practice notice and this consultation.

While the identification of essential elements in the post-*Choueifaty* guidance is now more consistent with *Free World Trust*, the “actual invention” or “inventive concept” analysis of patentable subject matter remains; it simply follows the claim construction instead of being integrated into the claim construction exercise. As illustrated in the table below, the effect is the same as it was in 2011: compliance with the patentable subject matter requirement is determined at the end of the analysis solely on the basis of the “actual invention” or “inventive concept”, defined as those elements that are part of the solution to a technical problem.¹⁹

PN2011-04	Post- <i>Amazon FCA</i> guidance (current MOPOP)	Post- <i>Choueifaty</i> guidance (proposed MOPOP)
Identify the problem and solution to determine the “actual invention”	Identify the person skilled in the art (12.02.02b)	Identify the person skilled in the art (12.02.02b)
Check whether the “actual invention”, i.e., the elements that are part of the solution, is patentable subject matter	Identify the common general knowledge (12.02.02c)	Identify the common general knowledge (12.02.02c)
	Identify the problem and solution (12.02.02d)	[section removed]
	Identify the essential elements of the claim as the elements that are part of the solution (12.02.02e)	Identify the essential elements of the claim, presuming that all the elements are essential (12.02.02d)
	Check whether the essential elements, i.e., the claim elements that are part of the solution, is patentable subject matter (17.02)	Identify the problem and solution to determine the “actual invention” (17.02)
		Identify the elements of the claim that are part of the “actual invention” i.e., the elements that are part of the solution (17.02)
		Check whether the “actual invention”, i.e., the claim elements that are part of the solution, is patentable subject matter (17.02)

All the preliminary steps of claim construction are mere window-dressing for the final step, the actual patentable subject matter determination. It is difficult to understand why CIPO persists in considering the “actual invention” alone for patentable subject matter eligibility when the

¹⁸ *Choueifaty* at para 39. The Federal Court here adopted the “conjunctive” interpretation of paragraph 55 of *Free World Trust v Électro Santé Inc*, 2000 SCC 66 (“*Free World Trust*”) set out in *Shire Canada Inc. v. Apotex Inc.*, 2016 FC 382 in which an inventor’s intention that an element be essential will always be determinative.

¹⁹ This effect was also present in the “what has been discovered” test in 2009, if applied in the manner suggested by *Schlumberger*.

Federal Court of Appeal made it clear that determining subject matter on the basis of inventive concept alone (i.e., what CIPO calls the “actual invention”)²⁰ was incorrect in law.²¹

“Manual or productive arts” has no place in Canadian patentable subject matter guidance

The post-*Choueifaty* guidance also posits that patentable inventions must be limited to the “manual or productive arts”. In proposed section 17.02 of MOPOP:

To be both patentable subject-matter and not be prohibited under subsection 27(8) of the *Patent Act*, the subject-matter defined by a claim must be limited to or narrower than an actual invention that either has physical existence or manifests a discernible physical effect or change and that relates to the manual or productive arts, meaning those arts involving or concerned with applied and industrial sciences as distinguished for example from the fine arts or works of art that are inventive only in an artistic or aesthetic sense. (footnotes omitted)

In footnote 13 of proposed chapter 17:

In addition to satisfying a “physicality requirement” the actual invention must relate to the manual or productive arts and not to a fine art.

In proposed section 22.02:

In order for the subject-matter defined by a claim to be considered patentable subject-matter, it must be limited to or narrower than an actual invention that either has physical existence or manifests a discernible physical effect or change. Said actual invention must also belong to the manual or productive arts, and not be among the excluded categories...

Not only has CIPO continued to restrict the patentable subject matter analysis to the inventive concept alone, in contravention of the Federal Court Appeal’s guidance, but they have also modified the Court’s own language concerning “discernible effect or change” (discussed in further detail below) and added a further requirement that the inventive concept relate to the “manual or productive arts” for no reason.

It is true that *Amazon FCA* confirmed that “fine arts or works of art” are not in themselves patentable subject matter in paragraph 58, the passage cited by CIPO in support of an

²⁰ The Commissioner defined “actual invention”, “what has been discovered”, and “inventive concept” as interchangeable before the Federal Court of Appeal. See for example paragraphs 23, 36, 43 and 48 of the Appellants’ Memorandum of Fact and Law in *Canada (Attorney General) v. Amazon.com, Inc.*, Federal Court of Appeal File No. A-435-10.

²¹ *Amazon FCA* at para 47.

additional “manual or productive arts” step.²² However, the Court did not define the converse of “fine arts or works of art” as “manual or productive arts”, or add a further “must be the right kind of subject matter” step to the patentable subject matter analysis. Rather, *Amazon FCA* is consistent with *Shell Oil* and *Tennessee Eastman* in this regard.

In *Shell Oil*, the Supreme Court confirmed that the discovery of a scientific principle “which is capable of practical application” is an “invention” within the meaning of section 2 of the *Patent Act*.²³ In *Tennessee Eastman*, the Supreme Court observed that the predecessor of subsection 27(8) of the *Patent Act* “circumscribed” the statutory categories in section 2;²⁴ but this was not the *ratio decidendi* that led to the conclusion that the claimed surgical method was unpatentable. The surgical method was unpatentable because it pertained to professional skill.²⁵ The Supreme Court thus drew a distinction between the rule against patenting disembodied ideas, as codified in subsection 27(8),²⁶ and “field-specific” exclusions such as professional skills.²⁷

In *Amazon FCA*, the Federal Court of Appeal interpreted the “practical application” requirement to mean that it is “implicit” that patentable subject matter have some quality of “physicality” — “something with physical existence, or something that manifests a discernible effect or change”.²⁸ Paragraph 58 of the decision confirms that the “well understood classes of patentable subject matter” exclude “fine arts or works of art that are inventive only in an artistic or aesthetic sense”. Like the Supreme Court, the Federal Court of Appeal drew a distinction between the rule against patenting disembodied ideas (i.e., the requirement for a “practical application”) and exclusions.

Neither of these rules—that an invention must involve “practical application” or that an invention must not be subject to a specific exclusion—is equivalent to a positive requirement that an invention “must also belong to the manual or productive arts”. There is a difference between proving that an invention positively belongs to a particular realm of patentable subject matter, and proving that it falls within an exclusion. CIPO’s invented rule places the burden on the applicant or the examiner to establish that the claimed subject matter, already having a “practical application” or “physicality”, and not excluded on a specific basis such as methods of medical treatment, is also blessed as a “manual or productive art”. This new rule has no basis in the statutory requirements of section 2 or subsection 27(8) and forms no part of the

²² Proposed MOPOP chapter 17, footnote 13.

²³ *Shell Oil* at 549, 555.

²⁴ *Tennessee Eastman* at 117.

²⁵ *Shell Oil* at 554.

²⁶ Siebrasse, N., *The Rule Against Abstract Claims: History and Principles*, (2011) Canadian Intellectual Property Review (C.I.P.R.), Vol. 26, No. 2, pp. 205-229 (<https://ssrn.com/abstract=1782712>).

²⁷ Siebrasse, N., *The Structure of the Law of Patentable Subject Matter*, (2011) 23 Intellectual Property Journal 169-204 at 176 (<https://ssrn.com/abstract=1782710>).

²⁸ *Amazon FCA* at para 66.

requirements for issuance of a patent under subsection 27(1) of the Act; nor does it have any clear definition.

CIPO purports to find support for a “manual or productive arts” criterion in our case law. In proposed section 17.02.01:

The manual or productive arts means those arts involving or relating to industrial and applied sciences. These arts have also been called the useful arts.

This passage cites the Exchequer Court decisions *De Forest Phonofilm of Canada Ltd. v. Famous Players Canadian Corp.*²⁹ and *Canadian Gypsum Co. v. Gypsum, Lime & Alabastine Canada Ltd.*,³⁰ as well as the High Court of Australia decision *Re National Research Development Corp’s Patent Application*³¹ and *Shell Oil*. None of these cases support CIPO’s assertion.

De Forest Phonofilm of Canada Ltd. concerns sufficiency of disclosure. The President of the Exchequer Court, in laying down the governing legal principles, stated that the specification of a patent “must be intelligent to ordinary workmen possessing that degree of skill, intelligence and knowledge fairly to be expected of them in respect of that branch of the useful arts to which the invention relates”.³² In *Canadian Gypsum Co.*, a case dealing with obviousness (“want of subject matter”), he observed that patent law is intended to “reward those who make some substantial discovery or invention which adds to our knowledge and makes a step in advance in the useful arts”.³³ Neither of these decisions advance the proposition that “useful arts” is another name for “manual or productive arts” or that it stands as a requirement for subject matter eligibility.

“Useful art” was used in *Shell Oil* in the phrase “new and useful art”—from the definition of “invention” in section 2 of the Act. The Supreme Court did not define “useful arts” as the realm of manual arts. On the contrary, “art” was explained as “a word of very wide connotation and was not to be confined to new processes or products or manufacturing techniques but extended as well to new and innovative methods of applying skill or knowledge provided they produced effects or results commercially useful to the public”.³⁴

NRDC did not define “useful arts” as “manual and productive arts”, either.³⁵ Quite the contrary: *NRDC* rejects both the proposition that “manufacture” is limited to the tangible fruits of manual or machine labour³⁶ and the “vendible product” test.³⁷ The High Court used the term “useful

²⁹ [1931] Ex CR 27.

³⁰ [1931] Ex CR 180.

³¹ [1959] HCA 67 (“*NRDC*”).

³² *De Forest Phonofilm of Canada Ltd. v. Famous Players Canadian Corp.* at para 17.

³³ *Canadian Gypsum Co. v. Gypsum, Lime & Alabastine Canada Ltd.* at para 12.

³⁴ *Shell Oil* at 554.

³⁵ The High Court only differentiated “useful art” from “fine art”, i.e., having an economic rather than merely an aesthetic value: *NRDC* at para 22.

³⁶ *NRDC* at para 14.

³⁷ *NRDC* at para 16, 23.

arts” to distinguish from unpatentable “fine arts”—“useful arts” comprising those processes with economic value.³⁸ Similar principles were later expressed by our Supreme Court in *Shell Oil*.

In short, CIPO has no legal support for this purported “manual or productive arts” requirement. If CIPO’s intention is simply to distinguish fine arts or works of art from subject matter that is patentable, it would be sufficient to simply state that the subject matter tested for eligibility must not be confined to fine arts or works of art. Of course, this fix alone will not correct the problems with CIPO’s post-*Chouiefaty* analytical framework.

The current analytical framework mischaracterizes “discernible effect or change”

Throughout the post-*Chouiefaty* guidance, the phrase “must have physical existence or manifest a discernible physical effect or change” (emphasis added) is used to describe the “physicality” discussed by the Federal Court of Appeal in *Amazon FCA*.

This was not the language of the Federal Court of Appeal in *Amazon FCA*. The Court did not use “physical” to modify “effect or change”.

Footnote 12 in proposed MOPOP chapter 17 explains that because the Court used this phrase in the context of a discussion about “physicality”, CIPO interprets this statement to be intended to refer to a physical effect or change.

There is no reason to put words in the Court’s mouth. It is evident from the record that the Court was aware of the possibility of describing the “effect or change” as “physical” yet chose not to do so. Here, CIPO appears to be recasting *Amazon FCA* to say what they wished the decision had said.

Before the Federal Court of Appeal, the Commissioner had argued for a test for “art” as set out in *Lawson v. Canada (Commissioner of Patents)*,³⁹ characterizing it in argument as “a physical change in a physical object”⁴⁰ and suggesting that Wilson J. agreed with this test in *Shell Oil*.⁴¹ The Federal Court of Appeal disagreed with this interpretation of the case law;⁴² and later, with the Commissioner’s desire for “physical” changes in mind, went on to describe the “physicality requirement” as follows:

³⁸ *NRDC* at para 22.

³⁹ *Lawson v. Canada (Commissioner of Patents)* (1970), 62 C.P.R. 101 (Ex. Ct) (“*Lawson*”).

⁴⁰ Appellants’ Memorandum of Fact and Law in *Canada (Attorney General) v. Amazon.com, Inc.*, Federal Court of Appeal File No. A-435-10, para 64.

⁴¹ Wilson J. simply described *Lawson* as an “effort” to describe the broader definition of “art” now set out in *Shell Oil* at 555. The definition of “art” laid out by the Supreme Court is clearly not restricted to “a physical change in a physical object”.

⁴² *Amazon FCA* at para 50.

Justice Phelan began his discussion of this point, at paragraph 53 of his reasons, where he said that the “practical application” requirement in *Shell Oil* “ensures that something which is a mere idea or discovery is not patented – it must be concrete and tangible. This requires some sort of manifestation or effect or change of character”. Justice Phelan is here acknowledging that because a patent cannot be granted for an abstract idea, it is implicit in the definition of “invention” that patentable subject matter must be something with physical existence, or something that manifests a discernible effect or change. I agree.⁴³

The Court was clearly aware of the option of characterizing a change as “physical” as the Commissioner advocated, yet chose the word “discernible” instead. The fact that this passage follows a quotation of the *Lawson* definition of “art” may suggest that a thing with “physical existence” includes a “physical agent” or “physical object”; but the omission of “physical” from “something that manifests discernible effect or change” suggests that the “something” and/or the “discernible effect or change” need not be “physical”.

CIPO’s insertion of “physical” after “discernible”, in that case, corrupts the Court’s intended meaning. In the absence of further interpretative guidance from the courts, CIPO must not alter this language and present their own idea as the Court’s intention.⁴⁴

⁴³ *Amazon FCA* at para 66. This paragraph follows a discussion of the Commissioner’s argument on a patentable “art”.

⁴⁴ The fact that the Federal Court of Appeal applied the label “physicality requirement” to the Supreme Court’s “practical application” requirement in *Shell Oil* does not mean that inventions must meet the “physical” or “manual or productive arts” requirements as interpreted by CIPO. The Federal Court of Appeal’s label cannot be used to constrain what the Supreme Court of Canada had previously described as sufficient for patentability.

IPIC'S PROPOSED ANALYTICAL FRAMEWORK PROVIDES A WORKABLE AND LEGALLY COMPLIANT SOLUTION

As CIPO is aware, IPIC has proposed a framework for assessing patentability of claimed subject matter in *Benjamin Moore & Co. v. Canada (Attorney General)*, Federal Court File No. T-1340-20:

- (a) Purposively construe the claim;
- (b) Ask whether the construed claim as a whole consists of only a mere scientific principle or abstract theorem, or whether it comprises a practical application that employs a scientific principle or abstract theorem; and
- (c) If the construed claim comprises a practical application, assess the construed claim for the remaining patentability criteria: statutory categories and judicial exclusions, as well as novelty, obviousness, and utility.⁴⁵

Unlike CIPO's post-*Choueifaty* guidance, this framework provides a clear, reproducible method for assessing any type of claim that complies with binding jurisprudence on claim construction and the requirements for patentability or validity.

The analysis begins with a purposive claim construction in step (a) in accordance with the Supreme Court's guidance in *Free World Trust*, and also in compliance with the instructions of the Federal Court of Appeal and the Federal Court that the assessment of patentable subject matter be based on a proper purposive construction of the claim at issue.⁴⁶

Having performed the purposive construction, the assessment of patentable subject matter in step (b) is based on the construed claim as a whole. Here, the rule against patenting disembodied ideas is applied in a manner consistent with the wording of the *Act*. Subsection 27(8) simply states that “[n]o patent shall be granted for any mere scientific principle or abstract theorem”. A patent confers an exclusive right; as set out in subsection 27(4), the exclusive right is defined by the claims. Thus, the question to be answered is whether the exclusive right defined by the claim—not the inventive concept or “actual invention”—consists of only a disembodied idea, or comprises a practical application of the disembodied idea. Since the subject matter under examination in this step is the construed claim as a whole, we expect greater predictability in outcome compared to CIPO's current and previous “actual invention”

⁴⁵ Memorandum of Fact and Law of the Intervener, *Benjamin Moore & Co. v. Canada (Attorney General)*, Federal Court File No. T-1340-20, at para 49.

⁴⁶ *Amazon FCA* at para 47; *Choueifaty* at paras 35-40. As noted earlier, IPIC agrees that the claim construction and identification of essential elements in the current patentable subject matter guidance that CIPO proposes to add to MOPOP is closer to the *Free World Trust* methodology, and believes that this step can be carried out consistently and predictably in examination.

analysis, which created unpredictability as different examiners could read specifications differently to find different problems and solutions.

The assessment in step (b) should be carried out in a manner consistent with governing jurisprudence; in particular, keeping in mind the Supreme Court’s broad characterization of “practical application”: an application of skill or knowledge that produces commercially useful effects or results—i.e., effects or results that have economic value to the public.⁴⁷ In some cases, the practical application can be easily found when subject matter of the construed claim as a whole has a physical existence; in other cases, the practical application requirement is met because the subject matter of the construed claim as a whole manifests a discernible effect or change.⁴⁸ This approach, based on the entire construed claim, avoids the artificial—and legally unjustified—extra “physical” requirement in “manifest a discernible physical effect or change”, or by the need to qualify the claimed subject matter as a “manual or productive art” as in CIPO’s post-*ChouEIFaty* guidance.⁴⁹

In the final step, the claimed subject matter may be allocated to a statutory category—if necessary—and evaluated for any of the field-specific exclusions from patentability such as methods of medical treatment and higher life forms, in accordance with binding jurisprudence. At this stage the other requirements of patentability or validity would then be considered, including the important questions of novelty, non-obviousness, utility, and sufficiency of disclosure. Unlike the patentable subject matter aspect, these are the elements of the patent bargain that ensure the public receives good value from the innovator.

IPIC urges CIPO to adopt this framework for patentable subject matter immediately in place of its post-*ChouEIFaty* guidance.

⁴⁷ *Shell Oil* at 554, 555.

⁴⁸ *Amazon FCA* at para 66.

⁴⁹ CIPO continues to rely on *Schlumberger* as a model for computer-implemented inventions in proposed chapter 22. In *Schlumberger*, the mathematical formula was executed using general purpose computer equipment to yield a computed result. While *Schlumberger* was not discredited by the Federal Court of Appeal in *Amazon FCA*, it must be treated with caution: the *ratio* in *Schlumberger* was that the inventive concept (“what has been discovered”), being a mathematical formula, was solely prohibited matter. While the Federal Court of Appeal in *Amazon FCA* agreed that a mathematical formula was a scientific principle or abstract theorem (para 44), they made it clear that the inventive concept-based approach was not correct (para 47). It cannot be assumed that *Schlumberger* is a model of purposive construction: there is no discussion of how the claims were construed. The references in *Amazon FCA* comparing a possible outcome (with modern purposive construction) to *Schlumberger* are properly considered to be *obiter*: *Schlumberger* is cited as an example where a claim to an art or process was in fact disqualified as being limited to a disembodied idea (paras 44, 62), as a possible outcome in a hypothetical set of possible outcomes depending on the construction of Amazon’s claims (paras 63, 69). It is clear from the remainder of the reasons that *Amazon FCA* did not adopt the analytical process or reasoning of *Schlumberger*.

SPECIFIC COMMENTS ON THE PROPOSED MOPOP CHAPTERS

Leaving aside the significant issues with CIPO's post-*Choueifaty* guidance, IPIC has specific comments concerning the language and examples proposed in the proposed MOPOP chapters in this consultation.

Sections 12.02.04 and 18.01.02: Confusing examples of "non-essential" elements

Section 12.02.04 purports to provide a number of examples in which the element "nails" may be found to be "non-essential".

Example Claim 4 should be deleted.

It is not accurate to say that "nails" is merely non-essential in Claim 4, which recites "A box comprising wooden slats held together by an attachment means where the means does not include nails."

The most likely interpretation of such a claim is that the final clause is a proviso, and nails are specifically excluded as an attachment means. In other words, "the means does not include nails" is an essential element: the use of even one nail as attachment means would cause a box to fall outside the scope of the claim. If a nail were merely "non-essential", it could be substituted,⁵⁰ in which case the use of a nail would not cause the box to fall outside the claim.

Claim 4 is also inconsistent with example Claim 3 in section 18.01.02, which includes the proviso "wherein the protein kinase C inhibitor is not staurosporine". In that example, it is correctly noted that the absence of staurosporine is essential.

Section 18.01.02 also confusingly refers to a "non-essential" element in claim 2:

2. The use of claim 1 wherein the protein kinase C inhibitor is chelerythrine or staurosporine.

In the analysis, claim 2 is correctly described as reciting an alternative, but the staurosporine alternative is described as "the embodiment where chelerythrine is not essential". This is confusing. The discussion of claim 2 would be clearer if it explained that there were effectively two separate claims to be assessed, in accordance with subsection 27(5) of the *Patent Act*; that in one claim, chelerythrine as the kinase C inhibitor was essential and in the other, staurosporine as the kinase C inhibitor was essential.

⁵⁰ *Free World Trust* at para 31.

Section 12.03: Search of the prior art should always be conducted

This section states that examiners are not required to search claimed matter that is determined to be unpatentable subject matter, unless it is evident from the entire specification that a claim on related, patent-eligible subject matter could be made.

This section also states that when the claimed subject matter has already been searched by an International Searching Authority or a foreign patent office, “a further search may be undertaken” if “the examiner deems it appropriate”.

IPIC recommends that examiners be instructed to conduct a search of the claimed subject matter in all cases even if the subject matter appears to be excluded from the statutory categories of section 2 and/or by reason of subsection 27(8) of the *Act*; and to conduct their own searches in all cases, even when they are relying on the work product of another patent office.

Based on its current guidance on the section 2 categories and subsection 27(8), CIPO is excluding subject matter that may very well be patentable. IPIC has also previously pointed out that prolonged examination is caused by examiners who first cite foreign work product, postponing their own searches for additional prior art.⁵¹ Encouraging examiners to conduct their own searches at the start of examination is part of the “shared responsibility” of efficient patent application processing touted in last year’s draft amendments to the *Patent Rules*.⁵²

Section 17.02.02e: No legal basis for prohibition of signals or forms of energy

This entire section should be deleted. No subject matter objections should be raised against claims directed to signals or forms of energy until clear guidance to do so is provided by the courts.

There is no legal support for the conclusion that forms of energy are outside the statutory scope of “invention”—as evidenced by the fact that this section cites absolutely no case law. Rather, CIPO’s reasoning is based on contrived definitions of “art” and “manufacture” in section 2 of the *Patent Act*.

Section 17.02.02e states that an electromagnetic or acoustic signal is not considered to be an “art” because it is “not a method or a use *per se*”—but that is not the meaning of “art” in section 2 of the *Act*, or even the meaning stated earlier in this chapter.

Earlier in chapter 17, section 17.01.01 defines “art”, firstly, as “the application of knowledge to effect a desired result”, and as something that must be “defined in a manner that gives

⁵¹ IPIC, *Intellectual Property Institute of Canada (IPIC) Submission on the Rules Amending the Patent Rules, Canada Gazette, Part I, Volume 155, Number 27, July 3, 2021* at 14 ([https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/IPIC_AmendedPatentRules-submission_Aug3_2021-IPIC.pdf/\\$FILE/IPIC_AmendedPatentRules-submission_Aug3_2021-IPIC.pdf](https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/IPIC_AmendedPatentRules-submission_Aug3_2021-IPIC.pdf/$FILE/IPIC_AmendedPatentRules-submission_Aug3_2021-IPIC.pdf)).

⁵² Canada Gazette, Part I, Volume 155, Number 27: Rules Amending the Patent Rules.

practical effect to the knowledge” which is, by itself, consistent with the Supreme Court’s definition in *Shell Oil*. Based on this, section 17.01.01 states that an “art” is normally claimed as a use or a method. While this may be the case in practice, it does not mean that an “art” *must* be claimed as, or limited to, a use or method.⁵³ Restricting statutory “arts” to subject matter expressed using prescribed claim language invokes the erroneous “form and substance” approach in Commissioner’s Decision 1290 and departs from the “clear direction”⁵⁴ of the Supreme Court to apply purposive construction.

Section 17.02.02e also asserts that an electromagnetic or acoustic signal is not a “manufacture” because it is taken “not to be itself a material product”. This is presumably based on the prior definition of “manufacture” in section 17.01.04, which itself is too constrained: while the Supreme Court did indeed define “manufacture” as a “a non-living mechanistic product or process”,⁵⁵ the Court did not go so far as to define this statutory category as “the process of making (by hand, by machine, industrially, by mass production) technical articles or material (in modern use on a large scale) by the application of physical labour or mechanical power” as asserted in section 17.01.04.⁵⁶ The Supreme Court did not define “mechanistic”, or even “article”, “material”, or “objet technique”, but only stated that these terms did not include a higher life form.⁵⁷

There is no case law that prohibits a signal from being an “art” or a “manufacture”. Rather, a signal shares the same traits as other items that fall within these statutory categories.

Electromagnetic or acoustic signals—or indeed any signal—result from the application of knowledge, and can produce practical effects, consistent with the requirement set out in *Shell Oil*, without requiring further intellectual evaluation. Signals meet the Federal Court of Appeal’s requirement of “something with physical existence”;⁵⁸ they are detectable and measurable. They also meet the requirement of “something that manifests a discernible effect or change”; they are manifestations or results of machines in operation and can create perceivable effects, like any manufactured solid product. Indeed, as observed in *NRDC* the patentable “something” in which a new and useful effect is manifested

... need not be a "thing" in the sense of an article; it may be any physical phenomenon in which the effect, be it creation or merely alteration, may be

⁵³ In fact, “art” is “réalisation” in the French version of the *Patent Act*. The word “réalisation” is not limited to a use or a method, it can also mean an object.

⁵⁴ *Amazon FC* at para 39.

⁵⁵ *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76 (“*Harvard College*”) at para 159.

⁵⁶ This portion of section 17.01.04 appears to be derived from the dictionary definitions quoted in paragraph 159 of *Harvard College* which the Court uses to support its interpretation of the statute; however, the Court did not state that the statutory category should be limited to these definitions.

⁵⁷ *Harvard College* para 159.

⁵⁸ *Amazon FCA* at para 66.

observed: a building (for example), a tract or stratum of land, an explosion, an electrical oscillation.⁵⁹

The fact that signals may not be easily slotted into a single category of “art” or “manufacture”, or even “process” or “composition of matter”, does not matter; they can fit within multiple categories. It is clear from the Supreme Court’s own definitions that the statutory categories overlap, although they are not redundant. “Manufacture” is defined as including a “process”.⁶⁰ A “composition” includes a combination or mixture of ingredients made by an inventor,⁶¹ which falls within the scope of “manufacture”.⁶²

Furthermore, signals and forms of energy cannot be excluded on the basis of subsection 27(8). A signal or form of energy is not a mere “scientific principle” although its existence may be explained by a principle of nature; and it is not a mere “abstract theorem” although its physical characteristics may be defined by an algorithm or equation.

In short, there is no judicial interpretation of the statutory categories of section 2 or the exclusion of subsection 27(8) of the *Act* that supports the conclusion that a signal or form of energy is not patentable subject matter. Therefore, this section of MOPOP is incorrect in law. If CIPO’s interpretation is based on any public policy concern, it is also clearly incorrect.⁶³ The Commissioner has no discretion to refuse a patent based on mere public policy.⁶⁴ Until such time that the *Act* is amended to exclude signals or forms of energy, or our courts provide clear support for such a prohibition, claims to this type of subject matter should not be refused on the basis of unpatentable subject matter.

⁵⁹ *NRDC* at para 23 (emphasis added).

⁶⁰ *Harvard College* at para 159.

⁶¹ *Harvard College* at para 162.

⁶² “Composition of matter” is “somewhat broader” than “manufacture”: *Harvard College* at para 161.

⁶³ Other rationales circulated within CIPO have included the argument that signals are transitory, unlike other subject matter, or that they lack inherent utility because a signal is useless until it has been converted to another form. Both rationales are baseless.

The sometimes-transitory nature of a signal is no bar to patentability. Permanence is not a criterion of any of the statutory categories. In any event, signals are as non-transitory as other subject matter. Waves travelling through a medium necessarily exist for some period of time. Other clearly patentable subject matter is fleeting: chemical compositions decompose; solid articles of manufacture can be destroyed at any time; processes and methods are started and stopped.

The argument that a data-bearing signal lacks utility because it is only an intermediate product, or only has commercial value if it is received, is also contradicted by the treatment of other subject matter. For example, intermediate products in a chemical process are patentable subject matter, although they may have no practical commercial value in and of themselves.

⁶⁴ *Harvard College* at paras 144-145.

Section 17.01.06: Misleading description of subsection 27(8)

The final sentence of this section mischaracterizes the statutory prohibition of subsection 27(8) of the Act and should be deleted:

This statutory prohibition applies when an attempt is made to claim the excluded subject-matter in a general sense.

The notion of a claim to excluded subject matter in a “general sense” has no support in case law. It is also misleading, in that it suggests that any invention that can “generally” be described as incorporating a scientific principle or abstract theorem is unpatentable.

We note that this sentence is a modification of the sentence appearing in current section 17.03.01 of MOPOP, which at least includes a further clarifying clause “but not when a scientific principle, law of nature or mathematical formula is relied upon in operating a practical form of an invention”.

We suggest that this section be limited to the first paragraph, with revision to simply state that subsection 27(8) has been interpreted by the courts as excluding mere mathematical formulae, the only interpretation that is supported by a court decision to date.⁶⁵

Section 22.02: Examples of patentable algorithm-based inventions too restrictive

The introduction of section 22.02⁶⁶ describes two conditions under which an unpatentable algorithm may form part of a patentable claim. However, these conditions are described exhaustively:

A computer program is not, by itself, patentable subject-matter, as it is merely a disembodied algorithm. However, an otherwise non-patentable algorithm may form the basis of a claim reciting patentable subject-matter if any of the following is true:

This language indicates that there are no other possible conditions under which an invention implemented using a computer program may be patentable. These exhaustive conditions are an attempt to explain the operation of subsection 27(8) of the *Patent Act*—in other words, the conditions under which an algorithm ceases to be a “disembodied idea”, in the language of *Shell Oil*.⁶⁷ However, there is no legal basis to limit “not disembodied” to these specific conditions. Neither the Supreme Court in *Shell Oil* nor the Federal Court of Appeal in *Amazon FCA* limited a patentable invention based on a disembodied idea in this fashion.

This guidance should be replaced with a simple restatement of the “practical application” requirement of *Shell Oil* or the “discernible effect” requirement of *Amazon FCA*, with a

⁶⁵ *Schlumberger* at para 5.

⁶⁶ Note that there is no section 22.02.01 in chapter 22.

⁶⁷ *Shell Oil* at 554.

reference to the correct subject matter under examination: that an otherwise non-patentable algorithm may form the basis of a claim reciting patentable subject matter if the subject matter of the construed claim includes a practical application of the algorithm, that is to say, produces a “discernible effect or change.”

Section 22.02: “Well-known manner” of execution and “generic” hardware must be justified by evidence

There are several references in section 22.02 to the processing or execution of an algorithm in a “well-known manner”. This term is not defined anywhere. If this term is intended to mean that the hardware or methodology forms part of the common general knowledge possessed by the person skilled in the art, it should be so defined; but examiners must also be reminded that a conclusion that hardware or methodology is common general knowledge or “well-known” must be supportable by evidence in the event the applicant disputes this finding.

Section 22.02.04 describes hardware elements that are considered to be “generic” devices. Examiners are thus being directed to make blanket factual findings concerning the common general knowledge. Again, such factual findings must be supportable by evidence. If it is necessary to provide these directions to examiners, then it would be helpful for MOPOP to provide citations to references that are considered representative of the common general knowledge, and the specific fields of endeavour in which they are fairly considered to be common general knowledge.

Section 22.02.03: Enhanced disclosure requirement not supported by Canadian law

Section 22.02.03 sets out a list of “non-exhaustive” factors indicating that the algorithm itself is the “actual invention”. This guidance imposes a higher disclosure obligation on the applicant than what is set out in subsection 56(1) of the *Patent Rules* or by the law on sufficiency:

- An “explicit statement” pointing to a problem other than a “computer problem” may suggest that the algorithm is the “actual invention”, implying that the applicant must expressly describe a “computer problem” in the disclosure. Paragraph 56(1)(d) of the *Rules*, however, only requires that the description of the invention “permit the technical problem and its solution to be understood, even if that problem is not expressly stated”.
- The lack of an explicit indication in the specification that a functional limitation of computer operation was overcome may suggest that the algorithm is the “actual invention”, implying that the applicant must specifically describe this advantage in their specification in order to adequately describe a patentable invention. However, an inventor is “not obliged to extol the effect or advantage” of their invention; they are only obligated to describe it sufficiently in accordance with subsection 27(3) of the *Act*.⁶⁸

⁶⁸ *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 SCR 504 (“*Consolboard*”) at 526.

- An absence of technical implementation details concerning execution on a computer may be indicative that the algorithm is the “actual invention”, implying that the applicant must include exhaustive details that may already be known to the person skilled in the art to establish that an invention improves the functioning of a computer. However, the fact that an invention improves the functioning of a computer may be evident to a skilled reader when reading the specification in view of their common general knowledge without such additional detail.

It must be made clear to examiners that these are not requirements to have a complete specification that aptly describes and claims a patent-eligible invention, and that express description of a commercial motivation to provide an invention (e.g., generating revenue through monetization of application development and deployment) must not “trump” the understanding of the person skilled in the art of the technical features of an invention.

This concern arises with Example 3 in section 22.02.05, concerning a hypothetical algorithm for compressing video data. The example mentions that there is an “emphasis” on the “advantages stemming from [the algorithm’s] efficiency improvements”. In accordance with *Consolboard*, there is no need for the applicant to “emphasize” these improvements in their specification, so this stipulation is unwarranted and should be deleted.

We note that when this example was initially published in 2020, it did not mention this “emphasis”.⁶⁹

Section 22.02.05: Insufficient explanation of means-plus-function claims

Example 1, claim 2 recites “means-plus-function” elements but provides no explanation as to how these elements are being construed. On a proper construction it may be possible that these elements are non-generic components, but this possibility is not discussed. For that matter, it is also unclear why the possibility that the “actual invention” is the combination of these elements is not discussed.

This example should be omitted or revised to provide a more thorough explanation.

Sections 22.02.05, 22.08.01, and 23.03.06: Arbitrary “cut-off” for statutory subject matter

Section 22.02.05, Example 2, section 22.08.01, and 23.03.06, Example 2 demonstrate the arbitrary nature of the post-*Choueifaty* guidance: a claim that explicitly recites a sensor for making certain physical measurements or an explicit step of reading or measuring physical values is considered to be patentable subject matter, but a claim that only operates on the

⁶⁹ CIPO, *Examples of Patentable Subject-Matter Analysis*, November 3, 2020, Computer-implemented Example 2 (<https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04861.html>).

physical measurements or values without explicitly including the sensor or an active measurement step is not.

This result is absurd when the nature of the invention is considered. The embodiments covered by the claims in the 22.02.05 and 22.08.01 examples—with and without the sensor—would not operate without a sensor collecting the measurements. On a purposive construction, the values operated on are values acquired using physical devices. The person skilled in the art would understand that a physical acquisition step would be required to obtain those values, and that these values are a manifestation of a physical effect.

The same concern arises with diagnostic method inventions. In claim 5 in Example 2 in section 23.03.06b, the “use of marker Z” necessarily relates to a physical value (presence or absence) obtained through a biochemical test—and a physical test is indeed required to obtain the required information about marker Z to be able to determine whether the patient with Parkinson’s disease will respond to treatment. A fictitious marker Z would not have utility, since it would not pertain to a patient. On a purposive construction, the person skilled in the art would know that marker Z is a value acquired using a physical test, and physical components.

In all these examples, every claim provides the same utility as the other claims in their respective examples. All claims rely on the same inventive concept in their respective examples. By CIPO’s own “actual invention” guidance, if the claims that explicitly recite the sensors or the biological sample are patentable, then the claims that do not explicitly recite the sensors or samples should be patentable as well, because they have the same set of elements providing a solution to the technical problem.

Section 22.07.02: Computer-readable medium claim examples are too restrictive

Agents have found that examiners treat the examples of acceptable computer-readable medium claim language in current examination guidance as absolute rules, occasionally requiring applicants to amend claims to strictly conform to the language provided in the published guidance even when the applicant’s current claim language achieves the same goal (e.g., requiring “when executed by a processor” to be amended to “when executed by a computer”).

It would be helpful if this section, and any other accompanying examination guidance, made it clearer that variations of the language in the example claims are acceptable provided they meet the objective of reciting a physical product limited by a computer program stored thereon.

Section 23.02.03: Typographical errors with respect to human intervention

There are typographical errors in Examples 1 and 3, where the text recites “human invention” rather than “human intervention”.

Section 23.03.02: Not all excisions require professional skill

This passage states that “a method that involves the excision of tissue, organ, or tumour samples from the body is considered to be a form of surgery and is excluded subject-matter”.

IPIC disagrees with this blanket assertion. Professional skill is not always required for these activities, for example in the context of a diagnostic method. Excisions that do not have an immediate object of treatment or providing a therapeutic effect (for example, excisions for the purpose of collecting a sample) should not be considered to be methods of medical treatment. Such excisions should be treated in the same manner as removal of fluids from the body, such as by needle or cannula.

Section 23.03.03b: Patentable claims including dosage ranges should be acknowledged

This section will instruct examiners that a claim encompasses an unpatentable method of medical treatment when a medical professional makes a selection of a dosage from a claimed range:

For example, professional skill and judgment may be involved if a medical professional is expected to monitor or make adjustments to the treatment, or make a selection of a dosage from a claimed range (i.e., in cases where not all dosages in the range will work for all subjects within the treatment group). In such cases, the subject-matter defined by the claim would encompass a method of medical treatment and would not be patentable subject-matter.

This discussion highlights the unpatentable case—where dosages need to be adjusted for each patient—but omits discussion of patentable claims in which a selection within the range does not depend on factors particular to the patient, or the fact that a conversion of a mg/kg dose to a specific dose based on the patient’s weight does not require a professional’s skill or judgment. It would be useful to also refer to the Commissioner’s Decisions that illustrate such patentable claims, e.g., *Re Amgen Research (Munich) GmbH*, 2021 CACP 2 at paras. 29-30, and *Re Genentech, Inc.*, 2021 CACP 8 at para. 36.

Section 23.03.03c: Concrete contradictory evidence must be cited by the examiner

This section discusses evidence that may contradict a claimed dosage, so as to render the claim unpatentable for engaging professional skill or judgment. While the main text observes that contradictory evidence “may become apparent when considering the specification as a whole in light of the relevant common general knowledge of the person skilled in the art”, footnote 28 goes further:

Unlike the courts, examiners do not have the benefit of expert testimony and cross-examination. Therefore, evidence suggesting that further skill and judgment is expected to be exercised may come from a purposive construction.

This is incorrect, as it suggests that purposive construction—that is to say, the construed claim itself—fills the role of evidence. Purposive construction is based on evidence, it does not serve as evidence itself. There must be positive evidence that skill and judgment must be exercised to find a dosage amount that works for a given patient; it cannot be simply assumed.

Put another way, if the drug works for at least one patient, the claimed subject matter has utility.⁷⁰ It is then up to the examiner to establish, based on evidence, that the drug does not work for a particular patient.

Perhaps the intention of the footnote was to refer to documentary evidence, such as the specification as a whole, or other evidence that may be used in the purposive construction exercise such as the common general knowledge (which should also be supportable by documentary evidence) and additional submissions by the applicant.⁷¹ Contradictory evidence must be cited by the examiner.

Section 23.03.04b: Claim in Example 2A not properly construed

Example 2A recites a “cosmetic method”:

1. A cosmetic method for reducing skin ageing in a subject comprising applying formulation X to the subject’s skin, wherein formulation X comprises 7-24% w/w zinc oxide, 5-20% w/w titanium dioxide, and 1-2% w/w vitamin E acetate.

However, this example improperly concludes that the claim recites a method of medical treatment, because “the subject receives a practical therapeutic benefit in preventing a pathological disease (skin cancer) when the steps of the claimed method are implemented”.

We disagree with this example, because the claim was not properly construed. The claim was clearly limited to a cosmetic use, excluding therapeutic uses. The analysis relies on common general knowledge that sunscreens containing zinc oxide and titanium dioxide to protect against skin cancer; but this is relevant for obviousness, not construction. The fact that the person skilled in the art might recognize another benefit for the claimed subject matter does not justify broadening the claim to read in a purpose or utility that the inventor clearly excluded.

⁷⁰ *Monsanto Co. v. Commissioner of Patents*, [1979] 2 SCR 1108.

⁷¹ Assistance concerning the relevant background knowledge when construing claims “comes in the form of submissions from the patent applicant” as well as experienced examiners: *Amazon FCA* at para 73.

Section 23.03.04d: No evidence of the need for professional skill in Example 4C

In Example 4C, it is stated that the titration regime is used only to minimize side effects and ensure patient tolerance; the physician must monitor the patient to determine what adjustments must be made to the dosage for this reason only, and not to ensure an effective dose.

However, claim 2 in this example was found to be unpatentable as requiring the exercise of professional skill and judgment because it “amounts to a titration regime”.

This is not correct. In this example, it is evidently established that the drug is effective across the entire claimed dosage range, as discussed above with respect to section 23.03.03c. There is no concrete contradictory evidence, and the titration and dosage adjustment are directed to managing side effects. Claim 2 in this example should be patentable.

Section 23.05.04: The common general knowledge has advanced

This section requires revision to reflect the state of the art.

This section states:

Given that there is no clear consensus as to what conditions are best used in a given hybridization reaction and that different reaction conditions will capture different nucleic acids, a claim may be held to be indefinite for failing to define the particular parameters to be used during the hybridization reaction and ensuing washings.

This is out of date. Claims should not be found defective because the exact conditions of hybridization are not recited. These conditions would be known by the person skilled in the art.

This section also states:

Where the target itself is solely defined as being any member of a large family of nucleic acids, e.g., a family of degenerate nucleic acids or variants encoding the same amino acid sequence (including nucleic acids defined as having less than 100% identity), the scope of a claim to a nucleic acid molecule that hybridizes to such a target becomes unclear. In such cases, the target is not limited to a single clearly-defined nucleic acid but instead encompasses a vast number of possible combinations of hybridizing and target nucleic acids.

Again, this is out of date. Objections based on the percentage of identity should no longer be made, as long as the activity is maintained. The person skilled in the art knows how to select variants that will work.

While examiners sometimes assert that changing one amino acid will modify the peptide’s activity, the converse can also be true: changing half of the amino acids may not change the

peptide’s activity. It depends which amino acids are changed, how, and where. These parameters are known to the person skilled in the art.

Chapters 22 and 23: More modern examples required

It is surprising that these revised chapters of MOPOP do not provide examples drawn from the forefront of medicine and computing, such as personalized or genomic medicine or machine learning.

The omission of examples of artificial intelligence or machine learning (e.g., data curation and augmentation, neural network design, training, hyperparameter tuning) is particularly surprising, since CIPO published a report highlighting Canadian artificial intelligence innovation in 2020.⁷²

It would be instructive to include several examples drawn to demonstrate how inventions in these fields meet the “discernible effect” or “practical application” requirement. IPIC suggests that joint CIPO-IPIC working groups be established to create these examples for inclusion in MOPOP.

⁷² CIPO, *Processing Artificial Intelligence: Highlighting the Canadian Patent Landscape* (2020) (https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr04776.html).