INTELLECTUAL PROPERTY INSTITUTE OF CANADA
INSTITUT DE LA PROPRIÉTÉ INTELLECTUELLE DU CANADA
IPIC

Intellectual Property Institute of Canada (IPIC) Submission on Proposed changes to Chapter 17 of the MOPOP

Submission to the
Canadian Intellectual Property Office

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INTRODUCTION

The Intellectual Property Institute of Canada (IPIC) is a professional association of patent agents, trade-mark 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, trade-marks, copyrights and industrial designs) in Canada and elsewhere, and also foreign companies that hold intellectual property rights in Canada.

PROLOGUE

IPIC appreciates that the Commissioner of Patents may change prosecution practice and the procedures in the Manual of Patent Office Practice (henceforth MOPOP) at any time. IPIC also appreciates the intent of CIPO in proposing this new section of MOPOP to provide certainty and consistency in the patent examination process as it pertains to medical kits and packages. However, in view of the important changes being proposed in the Consultation Document: 17.03.04 – Kits and packages (henceforth *Consultation Document*) some reasoning for the proposed changes to Chapter 17.03.04 of the MOPOP would have been appreciated by IPIC.

Canadian patent practice concerning "kits and packages" is well-settled law and has followed the guidance provided in the Supreme Court of Canada's decision *Shell Oil v. Commissioner of Patents* (1982) 67 C.P.R. (2nd) 1 (SCC), which is a leading decision on inventions relating to new uses of known compounds, and the Commissioner's Decision *Re Application for Patent of Wayne State* (1988) 22 C.P.R. (3rd) 407, in which the Patent Appeal Board applied the reasoning of *Shell Oil* to a scenario involving a new medical use for a known compound.

If the applicant is to be *"their own lexicographer"* as stated in the *Consultation Document* (at paragraph 2) then the terms "kit" and "package" can be defined by the applicant, or failing such a definition, can be construed by the skilled practitioner in the art. The terms "kit" and "package" are, and have been used interchangeably, in Canadian Patent Practice at least since *Wayne State*.

IPIC notes that in *Wayne State*, the Patent Appeal Board upheld the following package claim, which has been used as a template/guide for patent agents ever since:

> 4. A commercial package containing as an active pharmaceutical ingredient 3-methyl-1-[2-(2-napthyloxy)-ethyl]-2-pyrazolin-5-one or a pharmaceutically acceptable salt thereof, together with instructions for the use thereof for reducing metastasis and neoplastic growth in a mammal.

This claim structure was later sanctioned by the courts in the well-known AZT decisions. In *Apotex Inc. v. Wellcome Foundation*, [2001] 1 FCR 495 ("*Wellcome*"), the Federal Court of Appeal upheld the validity of claims to a containerized pharmaceutical product because they recited a novel use for the formulation contained therein. The claim language that "associated" instructions with the container provided sufficient limitation of the formulation to the new use:

> 24. A containerized pharmaceutical product comprising a container containing a formulation comprising 3'-azido-3'-deoxythymidine and a pharmaceutically acceptable carrier thereof, and instructions associated with said container directing use of the formulation in the treatment or prophylaxis of AIDS.

The judgment of the Federal Court of Appeal was affirmed by the Supreme Court of Canada [2002] 4 SCR 153.

IPIC notes that Claim 4 of *Wayne State* and claim 24 of *Wellcome* are very similar to claim 2 in the Example found at S.17.03.04c of the *Consultation Document*.

> 2. The kit of claim 1 further comprising instructions for using levetiracetam and carbamazepine to treat pain associated with diabetic neuropathy.

However, the *Consultation Document* reaches the opposite conclusion on the patentability of the latter claim, without any change in jurisprudence that would support this important change in practice.

In this regard, the *Consultation Document* seems to rely on *re Application No. 241,628* (1981) C.D. 811, which predates the *Shell Oil* or *Wayne State* decisions. Surprisingly, the *Consultation Document* makes no mention of either *Shell Oil* or *Wayne State*. IPIC respectfully submits that *re Application No. 241,628* is NOT a precedential authority.

IPIC notes that the *Consultation Document* makes reference to instructions, but may have overlooked a distinction between:

> a) instructions on *how to use the components* of the kit; and
>
> b) instructions defining *what the kit should be used for*.

The former instructions should not constitute a limitation on the scope of the invention since they are directed to the *use of the kit components* to prepare for the intended use of the kit. This would presumably include actions such as mixing components in a given order, preparing a silica chromatographic slide, heating a component, *etc.*

The latter type of instruction is not directed to the use of the components but rather to the *use of the kit itself*. Such (broad) instructions *would* define uses to which the kit should be applied, such as

treating a medical condition, and may be considered an essential element of the claim. Such a claim may have considerable economic value to the patentee. Accordingly, such instructions must be recognized as an actual limitation on the scope of the invention. This was the outcome in *Wellcome*. However, this is not the conclusion supported by the *Consultation Document*. IPIC is not aware of any change in the law that would support and/or mandate a change in policy that would contradict the results of *Wayne State*, much less *Wellcome*.

Claims 2 and 4 (above) are both clearly directed to practical embodiments of a new use for a known thing. While the printed instructions a*lone* might not be patentable, this is not what is being claimed. The instructions in these claims are *executable*, and it is by executing the instructions that one arrives at a new and useful result in accordance with the invention. Thus, the instructions have a *material effect* on the components of the kit (or package), and as such, they are an essential feature of the claim. IPIC submits that this position on *executable* instructions is consistent with S. 16.08.04 MOPOP – that is, in the area of computers, *executable* code is given patentable weight, but *non-executable* code is not.

IPIC submits that the definition of a "kit" in the *Consultation Document* as "*a specific type of package that contains two or more discrete components, and those components work together for a specific purpose, or to achieve a specific result*" finds NO basis in Canadian law. However, this definition will almost certainly be cited by Examiners as grounds for objecting to a claim. IPIC insists that objections in Examiner's Requisitions to claims, including kit claims, should find a solid basis in Canadian law.

The wording of the *Consultation Document* with respect to "Other patentability requirements" also leaves open the possibility that Examiners will increasingly reject kit or package claims under section 2 of the *Patent Act*. Other patentability requirements are covered in other sections of MOPOP and it is unnecessary to specify any particular sections pertaining to kit/package claims. This section of the proposed chapter should be limited to the first paragraph.

IPIC submits that objections in Examiner's Requisitions to claims, including kit claims, must have a solid basis in Canadian law.

Consultation Document **MOPOP Chapter 17.03.04 Kits and Packages –May 2017**

1) IPIC notes that the complete section of this chapter formerly entitled "Office actions relating to utility" has not been rewritten. IPIC would appreciate clarification as to where this subject will be dealt with in the MOPOP.

2) Turning to the text of the *Consultation Document*

The first sentence of the fourth introductory paragraph of Section 17.03.04 reads:

> A "kit" is generally understood as a specific type of package that contains two or more discrete components, and those components work together for a specific purpose, or to achieve a specific result.

IPIC recommends revising this paragraph to read:

> A "kit" ~~is generally~~ may be understood as a specific type of package that contains two or more discrete components~~., and those~~ Those components may work together for a specific purpose, or to achieve a specific result.

As explained in the Prologue above, IPIC submits that the definition of a "kit" in the *Consultation Document* as "*a specific type of package that contains two or more discrete components, and those components work together for a specific purpose, or to achieve a specific result*" finds NO basis in Canadian law. IPIC insists that objections in Examiner's Requisitions to claims, including kit claims, should find a solid basis in Canadian law. Therefore, IPIC proposes that references to a kit which require that the individual components work together for a specific purpose or to achieve a specific result be deleted.

The last two introductory paragraphs of Section 17.03.04 read:

> Conventional packaging material is not included in the above list because such packaging material would not work together with the other components of the kit. Alternatively, the packaging material associated with a package or kit may be unconventional, and in some cases unconventional packaging may be regarded as a component that works together with the other components of a kit. However, for medical kits this is generally the exception, rather than the rule.
>
> Likewise, a set of instructions is not included in the above list because instructions would not generally be considered as a component that works together with the other components of a kit to achieve a specific purpose or result. See 17.03.04c below for a more detailed discussion of instructions.

IPIC recommends deleting these two paragraphs in light of the changes proposed to Subsection 17.03.04b below.

The third paragraph in Subsection 17.03.04a reads:

> A kit would be understood as a specific type of package comprising at least two components that work together for a specific purpose or to achieve a specific result and so a minimum of two components should be defined, at least broadly.

IPIC recommends revising this paragraph to read:

> A kit would be understood as a specific type of package comprising at least two components ~~that work together for a specific purpose or to achieve a specific result~~ and so a minimum of two components should be defined, at least broadly.

The third paragraph following the list of five claims in Subsection 17.03.04a reads:

> Claim 3 is indefinite in this case and does not comply with subsection 27(4) of the Patent Act. The claim is directed to a kit, and so the claim would be understood as any kit comprising two or more components that work together for a specific purpose, or to achieve a specific result, where one of the components is the pharmaceutical composition of claim 1. There is a basis in the description for what the second component may be, but there are no indications in the claim relating to the nature of the second component or the specific purpose or result the components achieve when used together, and so these are not limited. A second component is implicitly present but has not been defined distinctly and in explicit terms, contrary to subsection 27(4) of the Patent Act.

IPIC recommends revising this paragraph to read:

> Claim 3 is indefinite in this case and does not comply with subsection 27(4) of the Patent Act. The claim is directed to a kit, and so the claim would be understood as any kit comprising two or more components ~~that work together for a specific purpose, or to achieve a specific result~~, where one of the components is the pharmaceutical composition of claim 1. There is a basis in the description for what the second component may be, but there are no indications in the claim relating to the nature of the second component ~~or the specific purpose or result the components achieve when used together~~, and so these are not limited. A second component is implicitly present but has not been defined distinctly and in explicit terms, contrary to subsection 27(4) of the Patent Act.

The second paragraph in Subsection 17.03.04b reads:

> A claim to a kit or a package will be non-statutory and fail to satisfy section 2 of the Patent Act where an essential element of the claim is an element that points to a limitation of a physician's skill or judgment (e.g., a dosing schedule encompassing a range), see PN2015-01 – *Revised Examination Practice Respecting Medical Uses.*

IPIC recommends revising this paragraph to read:

> A claim to a kit or a package will be non-statutory and fail to satisfy section 2 of the Patent Act where an essential element of the kit or package claim is an element that points to a limitation of a physician's skill or judgment (e.g., a dosing schedule encompassing a range), see PN2015-01 – *Revised Examination Practice Respecting Medical Uses*.

The last paragraph in Subsection 17.03.04b reads:

> When considering whether a kit or package comprising known components satisfies the patentability requirements of novelty and obviousness, it may be necessary to consider whether packaging known components together as a kit or package is an aggregation, or if there is invention in their combination. See MOPOP 15.01.02 and 15.02.04 for more information on combinations and aggregations.

IPIC recommends revising this paragraph to read:

> Where a use is defined in the preamble or body of a kit or package claim (e.g., a kit for treating disease Y comprising…), such a claim may be construed as a "kit for use" or "package for use", which is distinct from a claim to a kit or package per se. For instance, the recitation of a particular use in the preamble of the claim may bring novelty and/or inventiveness to the claimed kit or package if the components thereof had not been used for that particular purpose prior to the claim date.
>
> When considering whether a kit or package comprising known components satisfies the patentability requirements of novelty and obviousness, it may be necessary to consider whether packaging known components together as a kit or package is an aggregation, or if there is invention in their combination.
>
> For example, conventional packaging material would generally form an obvious and non-patentable aggregation with known components of a package or kit. Alternatively, the packaging material associated with a package or kit may be unconventional, and in some cases unconventional packaging may be regarded as a component that forms a patentable combination with the other components of a package or kit. However, for medical packages or kits this is generally the exception, rather than the rule.

Likewise, a set of instructions to use a known component in a known way would generally form an obvious and non-patentable aggregation with known components of a package or kit. However, claims to a commercial package containing a known compound and instructions for a new use thereof can be patentable (see the Commissioner's Decision *Re Application for Patent of Wayne State University [1988] 22 CPR (3d) 407*).

See MOPOP 15.01.02 and 15.02.04 for more information on combinations and aggregations.

The heading and the first five paragraphs in Subsection 17.03.04c read:

17.03.04c - Instructions

Instructions are generally understood as information printed or displayed on a substrate. In the context of medical inventions, this information often suggests actions or directions that can be taken, such as how an active agent can be administered or used in treatment. The skilled person would understand that the instructions themselves are merely printed matter with solely intellectual or aesthetic significance unless the information printed or displayed on the substrate imparts a new functionality to the substrate itself (see Chapter 12 for a discussion of printed matter).

It is recognized that in most cases instructions would not be considered a discrete component that works together with at least one other component to achieve a specific result. Therefore, instructions that simply provide directions for using the contents of a kit and nothing more would not be considered a component of the kit. For example, in a claim to "a kit comprising drug X and instructions for use" it is clear that one of the components is drug X. Given that the recited instructions do not work together with drug X to achieve a specific result, the instructions are not considered a component in a kit. The claim lacks compliance with subsection 27(4) of the Patent Act because there is no indication in the claim as to the nature of a second component that would work together with drug X to achieve a specific result.

In contrast, it is generally understood that a package is one or more discrete components contained within conventional packaging and there is no requirement that the discrete components work together for a specific purpose. Therefore, instructions may be a second discrete component of a package recognizing that in most cases the instructions would constitute printed matter with solely intellectual or aesthetic significance.

Where a use is defined in the preamble or body of a kit or package claim (e.g., a kit for treating disease Y comprising…), such a claim may be construed as a "kit for use"

> or "package for use", which is distinct from a claim to a kit or package per se. However, a claim is not regarded as a "kit for use" or "package for use" if it is only the instructions that provide information relating to a use (e.g., a kit comprising drug X and instructions for using X to treat disease Y).
>
> The distinction above may become pertinent when assessing the novelty and/or inventiveness of the claimed subject-matter. For instance, the recitation of a particular use in the preamble of the claim may bring novelty and/or inventiveness to the claimed kit or package if the components thereof had not been used for that particular purpose prior to the claim date. In contrast, where only the instructions provide information relating to the use of the claimed kit or package, the claimed kit or package would be anticipated and/or obvious in view of prior art that discloses the use of its components for any purpose. In other words, the recitation of information about a use within the instructions does not pose a limitation on the use of the kit or package.

IPIC recommends deleting these five paragraphs and their heading. As explained in detail in the Prologue above, claims directed to kits which include a known component and instructions reciting a new use of that component have been considered patentable under Canadian law for some time. IPIC again submits that objections in Examiner's Requisitions to claims, including kit claims, must have a solid basis in Canadian law.

The last paragraph in Subsection 17.03.04c reads:

> In regard to the requirement for novelty, both of claims 1 and 2 are anticipated by D1 because D1 discloses and enables a kit comprising levetiracetam, carbamazepine and instructions. It is noted that although claim 2 includes instructions providing information about a use of levetiracetam and carbamazepine that differs from D1; the informational content of the instructions does not pose a limitation on the actual use of the claimed kit and, therefore, does not bestow novelty. In contrast, claim 3 is not anticipated by D1 because claim 3, which defines the use in the preamble, is regarded as a new use of a kit comprising levetiracetam and carbamazepine over D1.

IPIC recommends revising this paragraph to read:

> In regard to the requirement for novelty, ~~both of~~ claim~~s~~ 1 <u>is</u> ~~and 2 are~~ anticipated by D1 because D1 discloses and enables a kit comprising levetiracetam, carbamazepine and instructions. ~~It is noted that although~~ <u>However,</u> claim 2 includes instructions providing information about a use of levetiracetam and carbamazepine that differs from D1 <u>and is not anticipated by D1.</u>~~; the informational content of the instructions does not pose a limitation on the actual use of the claimed kit and, therefore, does not bestow novelty.~~ In ~~contrast~~ <u>addition</u>, claim 3 is not anticipated by D1 because

claim 3~~, which~~ defines the use in the preamble.~~, is~~ Therefore, claims 2 and 3 are regarded as a new use of a kit comprising levetiracetam and carbamazepine over D1.

CONCLUSIONS

CIPO's proposed procedures in *Consultation Document* may be rooted in a concern about "restricting" the activities of a physician. IPIC submits that any such concern is unfounded. A kit/package is a commercial embodiment of the invention. Thus, kit/package claims are intended to protect the patentee from potential infringement by a competing pharmaceutical company making or selling commercial products. Kit/package claims do not impede a physician from prescribing a particular drug for a particular purpose. IPIC submits that this reasoning was recently applied in the Patent Appeal Board decision CD 1418.

IPIC submits that the *Shell Oil* decision provides for a claim to a new use for a known compound, while *Wayne State* building from *Shell Oil* has successfully protected such kit/package inventions since 1988. The Federal Court Judgement in *Wellcome* further confirms the eligibility of kit claims and IPIC respectfully submits that the Commissioner cannot overturn judgement of the Federal Court of Appeal.

IPIC respectfully suggests that CIPO reconsider the proposed changes described in the *Consultation Document.*