Citation: Sirtex Medical Limited (Re), 2021 CACP 54
Commissioner's Decision #1607
Décision du Commissaire nº 1607
Date: 2021-12-29

TOPIC:	F00	Novelty
	F20	Novelty – Matters Negating Novelty
	O00	Obviousness

SUJET:	F00	Nouveauté
	F20	Nouveauté – éléments annulant la nouveauté
	O00	Évidence

Application No. : 2,426,602

Demande nº 2 426 602

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,426,602, having been rejected under subsection 30(3) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019, has consequently been reviewed in accordance with paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251). The recommendation of the Patent Appeal Board and the decision of the Commissioner are to withdraw the rejection and allow the application.

Agent for the Applicant:

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INTRODUCTION

[1] This recommendation concerns the review of rejected Canadian patent application number 2,426,602, which is entitled “Polymer based radionuclide containing particulate material” and is owned by Sirtex Medical Limited (the Applicant).

[2] A review of the rejected application has been conducted by the Patent Appeal Board (the Board) pursuant to paragraph 199(3)(c) of the *Patent Rules* (SOR/2019-251) (the *Patent Rules*). As explained in more detail below, our recommendation is that the Commissioner of Patents allow the application.

BACKGROUND

The application

[3] The application has a filing date of October 25, 2001, a claim date of October 25, 2000 and was laid open to public inspection on May 2, 2002.

[4] The application relates to an implantable particulate material comprising yttrium-90 for targeted internal cancer radiation therapy. More specifically, it relates to polymer-based microspheres (herein “SIR-spheres”) comprising an insoluble phosphate salt of yttrium-90 that is stably incorporated within the polymer matrix to prevent it from leaching away and inappropriately radiating other tissues.

[5] The claims under review are claims 1 to 23 on file, dated January 19, 2016 (the claims on file).

Prosecution history

[6] On February 19, 2019, a Final Action (FA) rejecting the claims on file was issued pursuant to subsection 30(4) of the *Patent Rules* (SOR/96–423) as they read immediately before October 30, 2019. The FA stated that claims 1-14 and 16-23 lack novelty, contrary to paragraph 28.2(1)(b) of the *Patent Act*, and that claims 1-23 were further obvious, contrary to section 28.3 of the *Patent Act*.

[7] On August 13, 2019, a response to the FA (RFA) was filed by the Applicant. In the RFA the Applicant submitted a proposed set of claims 1-4 (proposed claims) and argued that the main document cited as prior art for lack of novelty and

obviousness was not “available to the public in Canada or elsewhere” as required by paragraph 28.2(1)(b) and section 28.3 of the *Patent Act*. The RFA further argued that the other cited documents do not provide a prior disclosure and enablement, nor render obvious, the subject-matter of the proposed claims.

[8] The Examiner was not persuaded that the application complied with paragraph 28.2(1)(b) and section 28.3 of the *Patent Act*, and so the application was forwarded to the Board, along with a Summary of Reasons (SOR) for review. The Board forwarded a copy of the SOR to the Applicant on December 4, 2019. In a response dated February 12, 2020, the Applicant expressed its continued interest in having the application reviewed.

[9] This Panel was formed to review the rejected application and make a recommendation to the Commissioner as to its disposition. Our conclusions are set out below.

ISSUES

[10] There are two issues to be considered in this review:

- Whether claims 1-14 and 16-23 on file define subject-matter that lacks novelty, contrary to subsection 28.2(1) of the *Patent Act*; and
- Whether claims 1-23 would have been obvious, contrary to section 28.3 of the *Patent Act*.

LEGAL PRINCIPLES AND OFFICE PRACTICE

Purposive construction

[11] In accordance with *Free World Trust v Électro Santé Inc*, 2000 SCC 66, and *Whirlpool Corp v Camco Inc*, 2000 SCC 67, purposive construction is performed from the point of view of the person skilled in the art in light of the relevant common general knowledge (CGK), considering the whole of the disclosure including the specification and drawings. In addition to interpreting the meaning of the terms of a claim, purposive construction distinguishes the essential elements of the claim from the non-essential elements. Whether or not an element is essential depends on the intent expressed in or inferred from the claim, and on whether it

would have been obvious to the skilled person that a variant has a material effect upon the way the invention works.

[12] "Patentable Subject-Matter under the *Patent Act*" (CIPO, November 2020) [*PN2020–04*] also discusses the application of these principles, pointing out that all elements set out in a claim are presumed essential unless it is established otherwise or such presumption is contrary to the claim language.

Anticipation

[13] Subsection 28.2(1) of the *Patent Act* requires claimed subject-matter to be new:

> The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
>
> (a) before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
>
> (b) before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
>
> […]

[14] Becoming "available" means that the public had an opportunity to access the information that is the invention. It does not require that one actually took advantage of this opportunity: *Wenzel Downhole Tools Ltd v National-Oilwell Canada Ltd*, 2012 FCA 333 at para 68 [*Wenzel Downhole*].

[15] Once the opportunity for the public to access the information is established as fact, the Court applies the legal test for anticipation developed in *Sanofi*, *i.e.*, full disclosure of all the essential elements of the invention and enablement: *Wenzel Downhole* at para 68, citing *Apotex Inc v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 [*Sanofi*].

The "public" and written disclosure of information in a document

[16] For a document to qualify as a “publication” it must have become generally available, without restriction, to members of the public: *Xerox of Canada Ltd v IBM Canada Ltd* [1977] 33 CPR (2d) 24 (FCTD) at page 85 [*Xerox*].

[17] To be categorized as a member of “the public” the person or persons with access to the document must have no special relationship to the author of the publication: *Johnson & Johnson v Boston Scientific*, 2008 FC 552 at para 321-323 [*Johnson & Johnson*], citing *Xerox* at page 85 and *Owens-Illinois Inc v Koehring Waterous Ltd* [1978] 40 CPR (2d) 72 (FCTD) at page 89. The parameters of a “special relationship” are not fully fleshed out in the jurisprudence, although a relationship that “smacks of a joint venture” may be one example: *Johnson & Johnson* at para 323, in reference to *Xerox*.

The “public” and disclosure through the prior use or sale of a product

[18] For a disclosure though the prior use of a product, the “public” has been defined as “a person who [is] free in law and equity to use the information” without “inhibiting fetter” (*Bayer Inc v Cobalt Pharmaceuticals Company*, 2016 FC 1013 at para 144 [*Bayer*]; *Baker Petrolite Corp v Canwell Enviro-Industries Ltd*, 2002 FCA 158 at para 42 [*Baker Petrolite*]; *Lux Traffic Controls Ltd v Pike Signals Ltd* [1993] RPC 107 (Eng Pat Ct) at page 133).

[19] As an exception, the law in Canada has long held that there is no public disclosure for the purposes of anticipation where a prior use is experimental: *Bayer* at para 157, citing *Gibney v Ford Motor Co of Canada Ltd* [1967], 52 CPR 140 (Ex Ct) at pages 157-160 [*Gibney*]. An inventor may use any means of testing available to them, so long as any experimentation is reasonable and necessary, and done in good faith for the purposes of perfecting the invention or testing its merits: *Bayer* at para 157, citing *Gibney*. The experimental use exception applies in particular where, of necessity, the experiment must be conducted in public: *Bayer* at para 159.

[20] With respect to the means taken by an inventor to test their invention, the Court in *Gibney* said the following in regard to a small private inventor as compared to a large corporation (at page 160):

> Indeed, the small man, in my view, is entitled to an invention as well as the large corporation and whether he is or not a dedicated or professional inventor, he should still be entitled to what he invents. He will not have all the advantages of a laboratory or a testing ground and the assistance of a large staff but that should not place him in a position different from those who have such advantages and he should be able to use whatever means of testing are available to him.

[21] Clinical trial experimentation carried out solely or in part to confirm the safety and efficacy of a proposed product before it is offered for sale to the public is inherently experimental in nature and is subject to the experimental use exception for anticipation by prior use: *Bayer* para 162.

ANALYSIS

Purposive construction

The person skilled in the art and their common general knowledge

[22] The FA (page 3) identified the skilled person and their CGK as follows:

> In view of the description, the person skilled in the art to whom the application is directed can be at least characterized as a scientist specializing in radiochemistry, microsphere synthesis including washing steps with appropriate buffers, and cancer treatments.
>
> The person skilled in the art would possess the following CGK: polymer synthesis, radiochemistry and cancer treatment.

[23] The Applicant did not dispute, contest or comment on these characterizations in the RFA.

[24] While this characterization of the skilled person as a team is reasonable, our view is that the CGK relates generally to certain fields without reference to any specific knowledge. Consistent with the background teachings provided on pages 1-4 of the Applicant's description, our view is that the skilled person would be familiar with the alternatives to external beam radiotherapy commonly known at the claim date, including internal radiation therapy using a glass, ceramic and polymeric microspheres encompassing one of the radionuclides associated with cancer therapy. The skilled person would further be familiar with the known and potentially

lethal risk of having a radionuclide leach from the microsphere and radiate non-target tissues.

The essential elements

[25] There are 23 claims on file, including independent claims 1, 9, 10, 11, 16-19 and 22. The independent claims are directed to SIR-spheres which comprise an ion exchange resin and yttrium-90 that is precipitated as an insoluble phosphate salt (claims 1, 9, 16, 17, 22), to processes for producing them (claims 10, 11) and to their use in radiation therapy and treating cancer (claims 18 and 19). Independent claim 1 is reproduced below:

> 1. A particulate material having particles of a diameter in the range of from 5 to 200 microns, comprising a radionuclide stably incorporated within an ion exchange resin polymeric matrix, by precipitating the radionuclide as an insoluble phosphate salt, wherein the radionuclide is yttrium-90, and wherein the radionuclide is incorporated such that there is less than 0.4% unbound or unprecipitated radionuclide.

[26] The dependent claims further define the composition of the ion exchange resin polymeric matrix (claims 2-8); the reactants and reagents used to prepare the SIR-spheres (claims 12-15); and the types of cancer they are used to treat (claims 20, 21 and 23).

[27] As set out above, *PN2020-04* states that all elements set out in a claim are presumed essential unless it is established otherwise or such presumption is contrary to the claim language. In our view, the skilled person reading claims 1-23 in the context of the specification as a whole and the CGK would understand that there is no use of language in the claims indicating that any of the elements are optional, preferred or were otherwise intended as being non-essential. Our view is therefore that all of the elements of claims 1-23 are essential.

Anticipation

[28] On pages 1-3, the FA states that the following document, D7, disclosed the claimed subject-matter before the claim date, contrary to paragraph 28.2(1)(b) of the *Patent Act*:

D7: Self, G.W., "Yttrium-90 microspheres Project – Experimental Procedures and Equipment", Department of Surgery, St. Vincent's Hospital, **1983**
[…]
Document D7 discloses a method of preparation of yttrium-90 microspheres.
[…]
The Self document provides a technique used as of 1984 to make a stable yttrium-90 containing microsphere for selective internal radiation therapy. The stability is achieved by precipitating the radionuclide as the insoluble phosphate salt. Applicant's argument that this document was not publicly available is not persuasive. There is no evidence that the Self document, an instruction booklet for staff within the Department of Surgery at St. Vincent's Hospital, was ever intended to be confidential. From Baker Petrolite v. Canwell Enviro-Ind., (2002) 299 N.R. 247 (FCA) [42], it is a matter of law that the availability of a document within a public institution constitutes a public disclosure for the purposes of paragraph 28.2(1) of the *Patent Act*:

> …if the information has been communicated <u>to a single member of the public without inhibiting fetter</u> that is enough to amount to the making available to the public…
> Further it is settled law that there is no need to prove that anybody actually saw the disclosure provided that the relevant disclosure was in the public. Thus an anticipating description in a book will invalidate a patent if the book is on a shelf of a library open to the public, <u>whether or not anybody read the book</u> and whether or not it was situated in a dark and dusty corner of the library. If the book is available to the public, then the public have the right to make and use the information in the book without hindrance from a monopoly…(emphasis in the original).

The Self document is an instruction booklet that was available to staff within the hospital. In the absence of any non-disclosure agreement with the author, or other indications that the document itself was confidential, it must be considered a public disclosure.

[29] As indicated in the above passage, the Applicant disputed that this document was publicly available in its previous letter of January 19th, 2016, wherein the following was stated (pages 4-5):

> Due to the nature of D7 as an instruction manual for researchers working within a research institution, the Applicant respectfully submits that there was an implied confidentiality requirement related to this document associated with the roles of the various unnamed people involved.
> […]
> The document was related to a particular group of researchers involved in clinical trials of patients with cancer. As can be seen from the other publications cited by the Examiner, said documents are silent as to the methods of preparing the microspheres. Thus, the Applicant respectfully submits that the information presented in D7 was confidential and was not publicly available. Thus, D7 is not citable for purposes of paragraph 28.2(1)(b) or section 28.3 of the *Patent Act* with respect to the novelty or obviousness. (emphasis added)

[30] From the above, it is clear that the availability of the document D7 to the public is central to the issue of anticipation. Before the legal test of disclosure and enablement from *Sanofi* can be applied, it must be established as fact that the public had the opportunity to access the information that is the invention: *Wenzel Downhole* at para 68.

[31] As a preliminary matter, our view is that the FA has overstated the law as expressed in *Baker Petrolite* in the following statement by extending the Court's discussion relating to a published book to any "document" and by extending a library open to the public to any "public institution":

> …it is a matter of law that the availability of a document within a public institution constitutes a public disclosure for the purposes of paragraph 28.2(1) of the *Patent Act*: (emphasis added)

[32] The purpose of a public library is to house information and make it widely available to members of the public and that is the context of the Court's discussion in *Baker Petrolite*. We further disagree that it is a matter of law that any document in any public institution would constitute a public disclosure, irrespective of the existence of any special relationship between the author and those with access to the document.

[33] Further, in our view there has been a conflation in the FA between the test for anticipation by a prior document and the test for anticipation by prior public use of a product. The FA considered D7 as an anticipating document yet applied

principles from *Baker Petrolite* that are specific to anticipation by prior use.

[34] For completeness, we will consider D7 using both tests, first as a prior document disclosing the product and second as evidence of a prior public use of the product.

Document D7

[35] Document D7 was received by the Patent Office as part of a protest and was added to the application file on July 6, 2009.

[36] The FA on page 2 characterizes the document as an instruction booklet for staff within the Department of Surgery at St. Vincent's Hospital. The cover page of D7 has the title of the document and the following information:

> Gregory W. Self,
> Department of Surgery,
> St. Vincent's Hospital,
> Fitzroy, Vic. 3065.
> 1983-84.

[37] The next page is a handwritten statement that "these notes detail the major aspects of techniques which I used during 1983-84", and that the notes appeared satisfactory and correct to him on that date, which he signed and dated as January 31, 1984.

[38] Inside the document, pages 1-4 informally outline logistical information pertaining to scheduling, cost, where to find yttrium-89 within the hospital and who to contact at the Australian Atomic Energy Commission in order to have it converted to radioactive yttrium-90. Specific individuals to contact are named and in one case a person's phone number is provided. The remainder of the document also uses an informal tone where the author refers to themself in the first person and describes how their work in preparing radioactive yttrium-90 microspheres is carried out.

[39] In our view, D7 has the hallmarks of an internal document. Based on the above information, there is no evidence that D7 was a "publication" in terms of having been openly published in a scientific journal or as a book with a named publisher and a verifiable date of publication. Further, there is no evidence of a date wherein the document became available from a library, a publisher's website or any other

publicly accessible database.

Was D7 a "publication" of a written disclosure of information that became generally available, without restriction, to members of the public?

[40] The FA does not purport that D7 was a published document that had been made widely available to the general public. Rather, the position in the FA is that D7 was made available to staff working within the Department of Surgery of St. Vincent's Hospital and that—in the absence of any confidentiality or non-disclosure agreement between the members of the staff and the author—these individuals ought to be regarded as members of the public.

[41] Whether or not a document constitutes a publication of information to members of the public considers whether the specific individuals or groups with access to the document had a special relationship to the author: *Xerox* at page 85; *Johnson & Johnson* at paras 321-323.

[42] In the letter of January 19, 2016, the Applicant disputed that all staff had access to D7, stating on page 5 that the document was related to a particular unnamed group of researchers involved in clinical trials of patients with cancer. The Applicant did not dispute that the document was available at St. Vincent's Hospital as of 1984.

[43] The FA does not name any particular individuals or groups within the Department of Surgery with whom D7 was shared. Further, there is no specific evidence on the record supporting that D7 was available to any specific individual or group, and this cannot be discerned from the document itself. Accordingly, we are unable to assess the relationship of any particular individuals or groups to the author.

[44] However, at a minimum, any persons working within the Department of Surgery at St. Vincent's Hospital would have had a relationship to the author as a colleague, co-worker, collaborator or fellow staff member working within the same department. Dr. Self is identified as a member of the Department of Surgery on the cover page of D7. This is further supported by document D6 which is an undergraduate thesis written on research that was carried out in the St. Vincent's Hospital Department of Surgery and which acknowledges Dr. Self's collaboration in the preface. The details of D6 are provided in the following section.

[45] In view of the above, we are unable to conclude that D7 was a publication that became available to members of the public. Based on the evidence before us, this was an internal document available to people with a special relationship to the author, which removes D7 from the public domain: *Xerox*, page 85.

Is D7 evidence of a disclosure through a prior public use of the product?

[46] The evidence in D7 is that SIR-spheres comprising an ion exchange resin and yttrium-90, precipitated as an insoluble phosphate salt, were prepared at St. Vincent's Hospital as part of the "Yttrium-90 Microspheres Project". As stated above, the Applicant did not dispute that this document existed before the claim date.

[47] For the purposes of assessing anticipation by prior public use of a product, the "public" is defined as "a person who [is] free in law and equity to use the information" without "inhibiting fetter": *Bayer* at para 144; *Baker Petrolite* at para 42.

[48] The FA on pages 2 and 3 point to a lack of any evidence that the information in D7 was confidential.

[49] On page 3, the RFA responded that the information in D7 was considered confidential. The Applicant further submitted in the letter of January 19, 2016 that confidentiality concerning D7 was implied as this was a document for researchers working within a research institution (page 4). On page 5, the Applicant further submitted that the confidentiality of this information is supported by the fact that none of the other publications pertaining to the SIR-spheres cited by the Examiner disclosed their method of preparation.

[50] With respect to the other publications cited by the Examiner, we consider the following documents of record to be of particular relevance to the microspheres that were prepared in the Department of Surgery at St. Vincent's Hospital:

D6: Meade, V. M., "The effect of sphere size on distribution of radioactive microspheres in experimental hepatic tumours", thesis submitted in partial fulfillment of the requirements for the degree of Bachelor of Science with Honors, Australia, Department of Physiology & Department of Surgery, St. Vincent's

Hospital, University of Melbourne, 1984.

D8: Gray et al., “Selective internal radiation (SIR) therapy for treatment of liver metastases: measurement of response rate” (1989) 42:3 J Surgical Oncol pages 192-196.

D9: Burton et al., “Selective internal radiation therapy: distribution of radiation in the liver” (1989) 25:10 Eur J Cancer Clin Oncol pages 1487-1491.

D10: Burton et al., “Selective internal radiation therapy: validation of intraoperative dosimetry” (1990) 175:1 Therapeutic Rad pages 253-255.

[51] D8-D10 are publications by Dr. Bruce Gray’s research group. Importantly, Dr. Gray is the sole named inventor of the present application. These documents disclose the results of early clinical trial experimentation using the claimed SIR-spheres in targeted radiotherapy for treating cancer. We agree with the Applicant that none of these documents disclose the details of the composition or methods of manufacture of the SIR-spheres.

[52] Document D6 is an undergraduate thesis authored by one of Dr. Gray’s students on research carried out under his supervision at St. Vincent’s Hospital in the Department of Surgery. In the preface, Dr. Gray (author of D8), Dr. Burton (author of D9 and D10) and Dr. Self (author of D7) are acknowledged for their involvement which supports that these individuals worked together in collaboration at St. Vincent’s Hospital in the Department of Surgery.

[53] Based on the record as it stands, we agree with the FA that there is no evidence of a confidentiality agreement between Dr. Gray and his collaborators that would constitute inhibiting fetter. However, we also agree that an assumption of implied confidentiality is reasonable given this group worked together collaboratively in the Department of Surgery. The lack of any prior art documents disclosing the composition or methods of manufacture of the SIR-spheres from these or any individuals further supports that the information was kept confidential. We are therefore unable to conclude on the balance of probabilities that Ms. Meade, Dr. Burton or Dr. Self were persons free to use the information without inhibiting fetter.

[54] However, should this position be incorrect, our alternative view is that the prior use

of SIR-spheres that took place at St. Vincent's Hospital would have been subject to the experimental use exception. It is reasonable to conclude that the work was carried out in a hospital out of necessity and for the purposes of testing the merits of SIR-spheres. Further, the work related to clinical research and the generation of early clinical trial data that was reasonable and necessary before the inventor, Dr. Gray, could apply for or obtain marketing approval and before the product could be offered for sale. Clinical trial experimentation carried out, solely or in part, to confirm the safety and efficacy of a proposed product is inherently experimental in nature and is subject to the experimental use exception to anticipation by prior use: *Bayer* para 162.

Conclusion on anticipation

[55] Since we are unable to establish that the public had access to D7 or that D7 constitutes evidence of a prior public use of SIR-spheres at St. Vincent's Hospital, there is no need to consider disclosure and enablement.

[56] D7 is not citable for the purposes of the *Patent Act*. Therefore, our conclusion is that the claims on file comply with subsection 28.2(1) of the *Patent Act*.

Obviousness

[57] On page 3, the FA contends that the subject-matter of claims on file would be obvious having regard to D7, either alone or in combination with other supporting documents or the CGK. None of the supporting documents were cited on their own, independently of D7.

[58] For the same reasons explained above, D7 does not constitute a public disclosure and is therefore not citable as prior art for the purposes of section 28.3 of the *Patent Act*. Accordingly, there is no need to assess the obviousness of the claims on file in view of D7.

[59] Our conclusion is therefore that the claims on file comply with section 28.3 of the *Patent Act*.

RECOMMENDATION OF THE BOARD

[60] In view of the above, the Panel is of the view that the rejection is not justified on the basis of the defects indicated in the Final Action notice and we have reasonable grounds to believe that the application complies with the *Patent Act* and *Patent Rules*. We recommend that the Applicant be notified in accordance with subsection 86(10) of the *Patent Rules* that the rejection of the application is withdrawn and that the application has been found allowable.

Cara Weir	Marcel Brisebois	Philip Brown
Member	Member	Member

DECISION OF THE COMMISSIONER

[61] I concur with the conclusions and recommendation of the Board. In accordance with subsection 86(10) of the *Patent Rules*, I hereby notify the Applicant that the rejection of the instant application is withdrawn, the instant application has been found allowable and I will direct my officials to issue a Notice of Allowance in due course.

Virginie Ethier

Assistant Commissioner of Patents

Dated at Gatineau, Quebec,

This 29th day of December 2021