Commissioner=s Decision #1317

Décision du Commissaire #1317

TOPICS: A50, O00

SUJETS: A50, O00

Application No: 2,264,559

Demande no: 2,264,559

COMMISSIONER'S DECISION SUMMARY

C.D. 1317 App'n No. 2,264,559

The application relates to a dual balloon catheter which is used to isolate an organ or other area of the body from blood flow. The catheter is insertable into a blood vessel, flow through which is then blocked by inflation of the two spaced apart balloons. The Applicant=s invention includes the provision of a blood bypass through the occluded segment of the catheter, separate inflation of the two balloons, and a lumen passing through the catheter with a plurality of ports opening into the occluded segment for injection and/or evacuation of fluids therethrough.

Jurisdiction to Consider Post-Final Action Defects

The Applicant alleged that because the objections in the Final Action had been overcome by amendment, the Commissioner has no jurisdiction to identify any defects which may arise as a result of the Applicant=s response to the Final Action in accordance with the decisions of the Federal Court of Canada in *Belzberg v Canada (Commissioner of Patents),* 2009 FC 657, 75 CPR (4th) 283 and *Bartley v Canada (Commissioner of Patents)*, 2011 FC 873.

Held: The Commissioner has jurisdiction to raise issues which may arise as a result of the amendments made by an applicant in response to a Final Action. Statements made in the *Belzberg* and *Bartley* decisions concerning the examination process must be considered in light of the facts of that case. Neither the Court nor the drafters of the examination provisions could have intended for applications to be allowed regardless of what defects might be introduced in response to a Final Action.

Obviousness

Claims 1, 2, 4, 9, 10, 12, and 13 in the application were rejected by the Examiner as being obvious in view of a combination of references.

Held: Rejection on these grounds affirmed.

The rejection of claims 1, 2, 4, 9, 10, 12, and 13 of the application based on the combination of references was justified. The Applicant is required under paragraph 31(*c*) of the Rules to amend independent claims 1, 9 and 13 to incorporate the features of dependent claims 3, 11 and 14, respectively, as the addition of these features would place the claims in allowable form. If the above amendments are not made the Commissioner intends to refuse the application.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,264,559 having been rejected under subsection 30(3) of the *Patent Rules*, has consequently been reviewed in accordance with subsection 30(6) of the *Patent Rules* by the Patent Appeal Board and the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

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INTRODUCTION

[1] This recommendation deals with a review by the Commissioner of Patents of patent application no. 2,264,559 entitled ABALLOON CATHETER WITH OCCLUDED SEGMENT BYPASS.@ The Applicant is DELCATH SYSTEMS, INC. The inventor is Morton G. Glickman.

[2] The invention relates to a catheter, particularly a dual balloon catheter which is used to isolate an organ or other area of the body from blood flow in a blood vessel passing through that area. Such a catheter is insertable into the blood vessel, a portion of which is then blocked from blood flow by the inflation of two spaced apart balloons.

[3] As explained by the Applicant, a problem with the known dual balloon catheter is that not only is blood flow through the occluded segment blocked, but blood flow through the blood vessel passing through that area of the body is completely interrupted. Although the body naturally increases blood flow through parallel blood vessels to compensate, this may be undesirable depending on the stress on the affected parallel blood vessels.

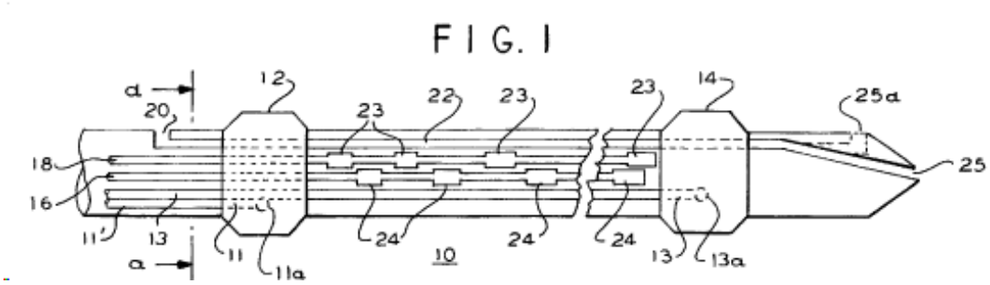
[4] With reference to Figure 1 of the subject application shown below, the applicant proposes a dual balloon (12, 14) catheter which provides for a shunt or bypass (20, 22, 25) through which blood may flow during occlusion of the vessel. In this way alleviation of the necessary increase in blood flow through parallel vessels is achieved. The Applicant also proposes an improvement over the prior art through the provision of separate lumens to inflate/deflate each of the two balloons, achieving advantages such as increased control over blood flow to/from the isolated area of the body. As presently claimed, the Applicant=s alleged invention also provides a lumen connected to a plurality of ports opening into the occluded segment through which fluid may be injected and/or evacuated.

PROSECUTION HISTORY

[5] This application was filed on July 28, 1997 and claims priority based on a US application filed on August 30, 1996, this therefore being the applicable claim date under sections 28.2 and 28.3 of the *Patent Act*.

[6] In a Final Action dated December 2, 2008, the Examiner rejected the application on the basis that then-pending claims 1, 2, 4, 9, 10, 12 and 13 lacked novelty in view of US Patent No. 5,135,484 to Wright. In a response dated June 1, 2009 the Applicant amended the independent claims to include the following limitation (worded slightly differently in claim 1):

> at least one lumen extending to the external end of the catheter and connected to a plurality of ports in a wall portion of said catheter located between said first expandable balloon and said second expandable balloon.



[7] This limitation, although supported by the description of the invention as originally filed, was not present in any of the claims previously. In a Summary of Reasons to the Patent Appeal Board, which was forwarded to the Applicant on April 21, 2010, the Examiner explained that while the amendment to the claims

overcame the anticipation issue, some claims were defective because they would have been obvious. In particular, amended claims 1, 2, 4, 9, 10, 12, and 13 would have been obvious having regard to Wright, in view of Canadian Patent Application No. 2,186,493 to Forman published October 26, 1995, US Patent No. 5,320,604 to Walker et al. [AWalker@] issued June 14, 1994 and US Patent No. 5,059,178 to Ya issued October 22, 1991. The introduction of the above-noted limitation into the claims had necessitated a further search of the prior art, since such a limitation was not previously considered for patentability. Claims 3, 5, 6, 7, 8, 11 and 14 were indicated by the Examiner to be allowable.

[8] The Applicant was given notice of the obviousness issue in the above-noted communication of April 21, 2010. Further to a telephone enquiry by the Board as to the Applicant=s desire to make further submissions, the Applicant was given formal notice of its opportunity to be heard on the obviousness issue in a letter dated February 23, 2011. In a response dated March 17, 2011, the Applicant requested an oral hearing, which took place on May 30, 2011. Written submissions were provided to the Board on May 26, 2011. At the hearing the Applicant was represented by Alex Ross of GOWLING LAFLEUR HENDERSON LLP and the Patent Branch was represented by Megan McTavish, the Examiner in charge of the application, and her Section Head, Jennifer Stickley.

[9] At the hearing, and in the written submissions, the Applicant=s arguments focussed not on the obviousness of the claims, but on the propriety of the consideration of defects under obviousness in response to the amendments made by the Applicant subsequent to the Final Action. The Applicant contended that since all of the objections in the Final Action were overcome by amendment, the Commissioner is required by law to allow the application to proceed to grant, in view of the decision of the Federal Court of Canada in *Belzberg v Canada (Commissioner of Patents)*, 2009 FC 657, 75 CPR (4th) 283 [A*Belzberg*@].

[10] The Applicant made it clear at the hearing that no submissions would be made on the obviousness issue either orally or in writing and that they did not intend to answer any questions

the Board might have in regard to the obviousness issue. The Applicant was given notice at the hearing, and acknowledged, that if the Board could not recommend to the Commissioner that the application be allowed in view of the Applicant=s submissions in relation to *Belzberg*, the Board would then proceed to assess the case for obviousness put forward by the Examiner in the Summary of Reasons.

ISSUES

[11] In view of the Summary of Reasons and the Applicant=s submissions prior to and during the hearing, the issues to be resolved are the following:

(1) Is the Commissioner required by law to allow the present application because the objections in the Final Action were overcome?

(2) If the answer to the first question is no, then would claims 1, 2, 4, 9, 10, 12, and 13 have been obvious in view of Wright when viewed in light of the references to Forman, Walker and Ya, and therefore non-compliant with section 28.3 of the *Patent Act*?

IS THE COMMISSIONER REQUIRED TO ALLOW THE APPLICATION?

Legislative Framework

[12] Subsection 4(2) of the *Patent Act* provides, in part, that the Commissioner:

> ... shall perform and do all acts and things requisite for the granting and issuing of patents of invention...

[13] The Commissioner=s authority to grant patents is outlined in subsection 27(1) of the Act (emphasis added):

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

[14] Once a patent issues, there is a presumption that it is valid,

per subsection 43(2) of the Act.

[15] In order to assess whether the requirements of the Act are met, the Act provides for patent applications to be examined by examiners employed for that purpose, per subsection 35(1) of the Act.

[16] In cases where the Commissioner is satisfied that an applicant is not entitled by law to be granted a patent, the application, per section 40 of the Act, shall be refused. The path which is to be followed during examination, particularly in cases where the result may be refusal under section 40 of the Act, is set out in subsections 30(3) to 30(6) of the Rules. If, in the course of examination, an impasse is reached between the examiner and applicant, a Final Action may be issued, which, per subsection 30(4) of the Rules:

> shall indicate the outstanding defects and shall requisition the applicant to amend the application in order to comply with the Act and these Rules or to provide arguments as to why the application does comply, within the six-month period after the requisition is made or, except in respect of Part V, within any shorter period established by the Commissioner in accordance with paragraph 73(1)(a) of the Act.

[17] If, as a result of the response to the Final Action, the Examiner Ahas reasonable grounds to believe that the application complies with the Act and these Rules@, the Commissioner notifies the applicant that the rejection is withdrawn, and that the application has been found allowable, along with requisitioning payment of the final fee (see subsection 30(5) of the Rules).

[18] If the rejection is not withdrawn, then as per subsection 30(6) of the Rules:

> the rejection shall be reviewed by the Commissioner and the applicant shall be given an opportunity to be heard.

[19] The present issue centres around the interpretation of subsections 30(4) to 30(6) of the Rules, and the effect of the *Belzberg* decision on these provisions.

Analysis

[20] In the written submissions to the Board and at the hearing, the Applicant=s arguments focussed on two aspects of the application process:

> (1) the Final Action, as per the *Belzberg* decision must be Acomprehensive rather than a m Final Action issues)
>
> (2) As a result of the objections in the Final Action being overcome, the Commissioner must allow the application to proceed to grant since there is no authority to decide the fate of the application on the basis of other issues, again per the *Belzberg* decision.

[21] We first point out that the facts of the *Belzberg* case are distinguishable from those of the present case. In *Belzberg* a Commissioner=s Decision was issued based on the outstanding defects, subsequent to which prosecution continued. The continued prosecution was characterized by the Court as Aa problem which had arisen during earlier examinations but which had not been raised in the Final Action report and not considered by the PAB@ (*Belzberg* at para. 26). Justice Simpson also refused to send the application back for further examination since there was Ano evidence that the PAB or any examiner recommended new areas for investigation@ (*Belzberg* at para. 46).

[22] In contrast, in the present case the issue of obviousness arose, not after a Commissioner=s decision, but because of amendments made by the Applicant in response to the Final Action. As noted earlier, when the Examiner notified the Board of the issue, the Applicant was given notice of it and was offered the opportunity to respond before the Board made a recommendation to the Commissioner. This issue is not one which Ahad arisen during earlier examinations@ since the features added by amendment were not previously part of the claims. The issue was clearly indicated by the Examiner and the Board as a Anew area of investigation@ prior to the hearing before the Board.

[23] Per subsection 30(4) of the Rules, in response to a Final Action, an applicant is given six months in which to Aamend the application in order to comply with the Act and these Rules or to provide arguments as to why the application does comply.@ The Patent Office however, has no control over the content of the amendments submitted, other than to later raise any issues that arise as a result of those amendments, as was done in the present case.

[24] The Applicant, in accordance with the first point outlined above, submits that because of the *Belzberg* decision, Athe outstanding defects@ of subsection 30(4) of the Rules, to be included in the Final Action, are exhaustive. According to this interpretation, once a Final Action is written, the Patent Office has no jurisdiction to raise any further issues regardless of what has been submitted in response to the Final Action.

[25] Admittedly, an argument might be made in support of such an interpretation when one looks at the statements made by Justice Simpson, particularly at paras. 41-43 pointed to by the Applicant in their written submissions and at the hearing. At para. 41 Justice Simpson states:

> I do not find that a requirement that final actions detail "all" outstanding defects is unduly onerous or contrary to the spirit and intent of the patent regime. The Canadian patent application process can be quite lengthy and uncertain, as evidenced by the present case. It seems sensible to me in that context to give the word "final" its ordinary meaning. At the point when a requisition is issued that potentially triggers a hearing, it is reasonable to conclude that all outstanding issues would be before the PAB.

[26] Similarly, at para. 43 she states:

> I view the word "outstanding" in the amended provision as indicating that the defects identified in a final action are comprehensive rather than a mere selection. This interpretation is not only harmonious with the object and intention of the scheme, but also gives meaning to the amendment.

[27] The amended provision referred to above is the change from former subsection 47(2) of the Rules to current subsection 30(4).

[28] In the *Belzberg* case, unlike the present one, there were no new issues created by the amendments made in response to the Final Action, and so Justice Simpson had a very different fact situation before her.

[29] Further, we do not understand Justice Simpson to have meant for her statements to be absolute, nor do we believe that the Applicant=s interpretation of these statements reflect what was intended by the drafters in arriving at the examination

provisions. To illustrate why, we would point first to the present case as an example of the consequences of the Applicant=s view.

[30] The Examiner issued a Final Action based on the claims then on file, which were identical to those pending when the previous office action was issued. Based on those claims, the only outstanding defects were related to the novelty of claims 1, 2, 4, 9, 10, 12 and 13, as the Examiner believed that these claims read on a single prior art reference. Examination in relation to novelty and obviousness is focussed on the claims, and not on everything that may have been described in the application. In response, the Applicant amended the claims to add a feature disclosed by the application but not before recited in any claim. As it was not previously claimed, the patentability of the claims in light of this feature had not been assessed. The Examiner, faced with the amended claims, conducted a further search and arrived at the conclusion that, despite being novel, the amended claims were nevertheless obvious.

[31] To adopt the Applicant=s interpretation of *Belzberg*, the Examiner, the Board, and the Commissioner would be required, in light of the fact that the amended claims (presented to the office for the first time) were novel, to allow the application to grant without ever having fully considered the patentability of those claims. The allowance of claimed subject matter which was not previously examined cannot have been what was intended by the drafters of the Rules, nor do we believe this was what was intended by the Court in *Belzberg*. Such an interpretation would conflict with section 27 of the Act, which requires Aall other requirements for the issuance of a patent@ (which includes the requirements under section 28.3) to be met.

[32] Another example of the effect of the Applicant=s interpretation would be a situation where, in response to a Final Action, an applicant overcomes the defects set out therein, but adds new matter not to be reasonably inferred from the specification or drawings, contrary to section 38.2 of the Act. Using the Applicant=s interpretation, such an application would have to be allowed with the defect not being subject to scrutiny by the Examiner, the Board or the Commissioner.

[33] Even if the filter for amendments in response to a Final Action was whether or not the response was in good faith, per paragraph 73(1)(a) of the Act, as suggested by the Applicant at the hearing, this would not prevent the situations noted above from occurring. The fact that an examiner alleges new matter has been added would not by itself provide justification to say that the response was in bad faith. However, it would give an examiner reason to say there were no reasonable grounds to believe that the application complied with the Act and Rules, as required by subsection 30(5) of the Rules in order to withdraw a rejection and prevent review by the Commissioner under subsection 30(6) of the Rules.

[34] The Applicant noted that in *Belzberg* Justice Simpson points to Chapter 21 of the Manual of Patent Office Practice (AMOPOP@) to understand the scope of the Final Action process (*Belzberg* at paras. 11, 24 and 25). The relevant passage from MOPOP reads as follows:

> The final action report must be comprehensive and deal with every grounds for which the application is considered to be defective. The appeal process is restricted to the particular issues discussed in the final action and there is no further opportunity for the examiner to make objections which may have been missed in the final action. Similarly there is no opportunity for the applicant to amend the application other then to make any revisions required by a Commissioner's decision on the patentability of the case.

[35] It is, as quoted above, the general practice of the Patent Office to include all Aoutstanding defects@ in a Final Action report, as occurred in the present case in view of the then-pending claims. The quotation speaks of the duties of an examiner in a Final Action when faced with an established impasse. However, while this section guides an examiner not to raise Aobjections which may have been missed in the final action@ it does not purport to address a situation where, in response to the Final Action, new defects are introduced by the Applicant=s amendments.

[36] At the hearing, the Applicant submitted that it should not have to address an identified defect in the application for the first time before the Board, as its ability to amend the application

is limited to what the Commissioner might require under paragraph 31(*c*) of the *Patent Rules* (The Applicant even suggested that such amendments were not possible in view of *Belzberg*, a point we will address later). It is true that there is no right for the Applicant to, without direction from the Commissioner, amend the application once a case has been forwarded for review by the Commissioner. However, as stated by Justice Simpson in *Belzberg* at para. 25, a Final Action is intended to lead to disposition of the case, and therefore the steps thereafter cannot be equivalent to the normal prosecution of applications. A Final Action is written when an impasse is reached, when the Applicant has already had a chance to address certain defects, as in the present case, where the same defect had been raised on three occasions prior to the Final Action.

[37] The second aspect of the Applicant=s submissions relates to the consequences of the issuance of a Final Action. To reiterate the Applicant`s position, since all of the defects in the Final Action have been overcome (and this is not disputed by the Examiner or the Board), and since these are the only defects which the Examiner, Board or the Commissioner may review, the application must proceed to grant, in accordance with the Applicant`s view of *Belzberg*.

[38] Justice Simpson at para. 44 of *Belzberg* stated:

> In my view, the MOPOP, the language of section 30, the scheme of the Act and the amendment to the provision regarding "Final Actions", make it clear that a final action is to dispose of a patent application. In other words, following a PAB hearing the Commissioner is to make one of two decisions:
>
> i) refuse the patent application under section 40 of the Act if the PAB has found alleged defects to be justified; or
>
> ii) grant the patent application under section 27 of the Act.

[39] The Applicant takes the above passage to mean that since all of the defects in the Final Action have been overcome, then, as per part (ii), the Commissioner must grant the application under section 27 of the Act. The passage, taken on its own, might suggest that the only options for the Commissioner after a hearing are to refuse or to grant, but again, these statements must be considered in light of the facts of the *Belzberg* case.

In *Belzberg*, whether some of the claims were allowable while others were not was not at issue, and so there was no reason for the Commissioner to take any action other than to refuse or grant the application.

[40] According to paragraph 31(*c*) of the Rules, refusal or grant are not the only options following a hearing. This paragraph provides for the possibility that the Commissioner, in a decision, requires certain amendments in order to make the application compliant with the Act and Rules. While this may eventually lead to refusal or grant, depending on the Applicant=s actions in response thereto, it is a third possible outcome following a hearing which leads to a decision by the Commissioner. This third possibility is described in section 21.07 of MOPOP, i.e. where the Commissioner is satisfied that:

> [...]
>
> (*c*) certain amendments are necessary for compliance with the *Patent Act* or the *Patent Rules*, the applicant will be informed of the required amendments and the reasons therefor and will be given a three month period to effect the changes. Should the applicant not amend the application accordingly it will be refused under section 40 of the *Patent Act*.

[41] At the hearing the Applicant suggested that the above-noted outcome was no longer a valid option in light of *Belzberg*. In *Belzberg*, Justice Simpson at paras. 12 and 13 quoted from MOPOP in which paragraph 31(*b*) of the Rules was mentioned. However, she did not mention 31(*c*), and gave no indication that she considered this provision to be no longer applicable. In light of these circumstances, we do not believe that it was her intent to eliminate this possibility.

[42] The present case, unlike the situation in *Belzberg*, is not one where examination is being restarted after a Final Action (*Belzberg* at para. 2). It is a case where the Examiner, per subsection 30(6) of the Rules, could not withdraw the rejection in accordance with subsection 30(5) of the Rules, because she did not believe that the application was compliant with the Act and Rules.

[43] The above considerations lead us to the conclusion that the statements pointed to by the Applicant in the *Belzberg* case must

be taken in the context of the facts of that case, and that the Commissioner has jurisdiction to deal with the obviousness issue in the present case. Further, the Commissioner of Patents has not only the right, but the obligation, to consider the obviousness issue in this case, in view of his statutory duty under subsection 27(1) of the Act.

Post-hearing submissions by Applicant

[44] In a letter dated July 14, 2011, the Applicant provided supplemental written submissions to the Patent Appeal Board, enclosing a copy of the decision of the Federal Court of Canada in *Bartley v Canada (Commissioner of Patents)*, 2011 FC 873, dated July 12, 2011. In particular, the Applicant drew the Board=s attention to para. 80 of the decision, which recites [emphasis added by Applicant]:

> I find, as Justice Simpson did in *Belzberg, supra* that a Final Action is meant to be just that, final. There is an obligation upon the Examiner to put everything on the table that requires the applicants, and, if necessary, the Board and the Commissioner, to deal with. There is no provision to reserve upon or keep certain matters Aoutstanding@.

[45] An answer to this has been provided previously [see in particular paras. 22, 30 and 35], where the facts in the present circumstances were distinguished from those in *Belzberg*, and we see no reason to expound any further on this subject.

[46] The answer to the first issue being no, we proceed to consider the issue of obviousness.

OBVIOUSNESS

The Claims at Issue

[47] For the sake of convenient reference, we set out the problematic claims below:

> 1. A catheter positionable in a blood vessel of a body having a blood flow therethrough, said catheter comprising:

a first expandable balloon expandable beyond a wall of said catheter;

a second expandable balloon expandable beyond a wall of said catheter;

said first balloon and said second balloon spaced along said catheter for generating an occluded segment of said blood vessel between said first balloon and said second balloon when said first balloon and said second balloon are expanded:

at least one fenestration lumen extending to the external end of the catheter and connected to a plurality of ports in said catheter located between said first expandable balloon and said second expandable balloon;

a first port in said wall of said catheter, said first port positioned upstream in the direction of said blood flow from said first balloon;

a second port in said wall of said catheter, said second port positioned downstream, in the direction of said blood flow from said second balloon; and,

a lumen within said catheter and having a first end and a second end, said first end connected to said first port and said second end connected to said second port for defining a bypass for blood in said blood flow for shunting said occluded segment of said blood vessels spaced and positioned for passing a portion of said blood from upstream in the direction of blood flow from said occlusion to downstream in the direction of blood from said occlusion.

2. A catheter according to claim 1 wherein said first balloon is located upstream, in the direction of said blood flow from said second balloon.

4. A catheter according to claim 1 wherein said second port defines a tip of said catheter.

9. A catheter positionable in a blood vessel of a body, said catheter, comprising:

a first balloon and a second balloon spaced from each other;

means for expanding said first balloon and said second balloon to a wall of said blood vessel for generating an occluded segment in said blood vessel between said first balloon and said second balloon when said first balloon and said second balloon are expanded;

a first lumen within said catheter coupled to and opening into an interior of said first balloon for expanding and contracting said first balloon therethrough and independent of said second balloon,

a second lumen within said catheter coupled to and opening into an interior of said second balloon for expanding and contracting said second balloon therethrough and independent of said first balloon, and;

at least one lumen extending to the external end of the catheter and connected to a plurality of ports in a wall portion of said catheter located between said first expandable balloon and said second expandable balloon; and

a bypass for bypassing at least a portion of blood from upstream in the direction of blood flow of said occluded segment to downstream in the direction of blood flow of said occluded segment.

10. A catheter according to claim 9 further comprising:

a first port in a wall of said catheter upstream, in the direction of blood flow through said blood vessel, from said first balloon;

a second port in said wall of said catheter downstream, in the direction of said blood flow through said blood vessel, from said second balloon; and

a third lumen within said wall of said catheter having a first end and a second end and said first port defines said first end of said third lumen and said second port defines said second end of said third lumen.

12. A catheter according to claim 10 wherein said second port defines an

anterior end of said catheter.

13. A catheter positionable in a blood vessel of a body having a blood flow therethrough, said catheter comprising:

a first balloon and a second balloon, spaced from each other longitudinally along said catheter and expandable beyond a wall of said catheter to a wall of said blood vessel, said first balloon and said second balloon for generating an occluded segment in said blood vessel between said first balloon and said second balloon when said first balloon and said second balloon are expanded;

at least one lumen extending to the external end of the catheter and connected to a plurality of ports in a wall portion of said catheter located between said first expandable balloon and said second expandable balloon;

a first port in said catheter, said first port positioned adjacent said first balloon and upstream, in the direction of said blood flow from said first balloon;

a second port in said wall of said catheter, said second port positioned adjacent said second balloon and downstream, in the direction of said blood flow from said second balloon, and,

a lumen within said catheter and having a first end and a second end, said first end connected to said first port and said second end connected to said second port for defining a blood shunt in said catheter for bypassing said occluded segment of said blood vessel spaced and positioned for passing a portion of said blood from upstream in the direction of blood flow from said occlusion to downstream in the direction of blood from said occlusion.

Legal Principles

[48] Section 28.3 of the *Patent Act* sets out the conditions under which a claim may be found to be obvious:

> **28.3** The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
>
> (a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
>
> (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

[49] In *Apotex Inc v Sanofi-Synthelabo Canada Inc,* 2008 SCC 61, [2008] 3 SCR 265 [*Sanofi*], the Supreme Court set out the approach to be followed in the assessment of obviousness, which now involves the following four steps, with the possibility of an obvious to try test at step 4, which is not at issue in this case:

> (1) (a) Identify the notional "person skilled in the art";
> (b) Identify the relevant common general knowledge of that person;
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

[50] In *Sanofi*, Rothstein J., at para. 65, equates obvious with Avery plain.@ This interpretation has been noted by the Federal Court of Appeal in *Pfizer Canada Inc v Apotex Inc*, 2009 FCA 8 at para. 29, [2009] 4 FCR 223.

[51] In a case such as this where an argument is made that the invention would have been obvious in view of a combination of references, the following guidance from Justice Snider in *Laboratoires Servier v Apotex Inc*, 2008 FC 825 at para. 254, 67 CPR (4th) 241; aff=d, 2009 FCA 222, 75 CPR (4th) 443 [A*Servier*@] must be kept in mind:

> As acknowledged by Servier, a mosaic of prior art may be assembled in order to render a claim obvious. Even uninventive skilled technicians would be presumed to read a number of professional journals, attend different conferences and apply the learnings from one source to another setting or even combine the sources. However, in doing so, the party claiming obviousness must be able to demonstrate not only that the prior art exists but how the person of ordinary skill in the art would have been led to combine the relevant components from the mosaic of prior art.

Analysis under the *Sanofi* Four-step Approach

(1)(a) The person skilled in the art

[52] In the Summary of Reasons the Examiner identified the person skilled in the art as Aa person working in the field of balloon catheters ...@ The Applicant did not comment on the Examiner=s identification of the person skilled in the art. While nothing in this case would turn on the exact identification of the skilled person, we would state it less generally as a physician with experience in the use of balloon catheters and the procedures associated with them, since a physician would be the typical user of such a device.

(1)(b) The relevant common general knowledge

[53] In the Summary of Reasons submitted to the Board, the Examiner stated that the person skilled in the art:

> would know that the occluded section of a blood vessel can be treated in a variety of ways, for example by the delivery of drugs or the removal of plaque using a slurry.

[54] While the Examiner has shown that the above features were known (as evidenced by several cited references, to be discussed later), she has not established that these features had become part of the common general knowledge by the claim date. In a usual case, in which an applicant addresses an obviousness objection on its merits, a failure to address an assertion by an examiner may be taken by a reviewing body as an applicant=s acceptance of an examiner=s statements. However, as previously noted, the Applicant in this case did not address the obviousness issue on its merits, based on the belief that the defect should not have been raised, and made it clear at the hearing that they were neither agreeing nor disagreeing with the Examiner=s assertions. This was also the first time this issue was raised, the present case therefore lacking the normal back and forth between the Examiner and the Applicant. In view of these facts and the fact that the basis for the Examiner=s statements as to common general knowledge is not established, the Board will look to the evidence at hand to determine what may be taken to be common general knowledge.

[55] We start with the present application itself. What the Applicant portrays as common general knowledge in their own discussion of the prior art is to be taken as a binding admission (*Merck & Co v Pharmascience Inc*, 2010 FC 510 at para. 8, 85 CPR (4th) 179). At pages 1-2 the Applicant discusses prior art catheters in general. Such devices are known to be used for controlling blood flow and/or isolating an area of the body or an organ in medical procedures. Also well known is a design where body organs and/or body areas are isolated by two spaced balloons on a catheter. The Applicant does not disclose the delivery of drugs to, nor the removal of plaque from, the occluded area as being conventional.

[56] Looking to the prior art applied by the Examiner, Wright, in the background portion, discusses balloon angioplasty in general, but makes no reference to dual balloon catheters nor to the delivery of material to an occluded segment. The removal of plaque using a slurry is part of the invention disclosed by Wright, and therefore we would have no basis to take it to be part of the common general knowledge.

[57] Forman also discusses conventional balloon angioplasty, as well as the delivery of agents to the affected area that may reduce restenosis, such as heparin to prevent clotting and dexamethasone to prevent smooth muscle cell migration and proliferation. Forman reveals that there are various methods known to deliver agents, such as Aweeping@ balloons which are inflated to deliver an agent after an angioplastic procedure. Forman discloses that devices are known which comprise a pair of occlusion balloons with a dilation balloon therebetween. A drug delivery conduit is provided between the balloons as well. However, whether the particular prior art designs pointed to in Forman were part of the common general knowledge is not clear.

[58] In Walker, angioplasty is again discussed in general, including the use of dilation balloons in such a procedure, whether to simply open the artery by dilation or to remove the blockage by withdrawing the dilated balloon past the blockage. Walker discusses various known balloon catheter designs including what are described as conventional dual balloon catheters. These are catheters used subsequent to artery dilation, with the two balloons serving as occlusion balloons, and they comprise an additional lumen communicating with the space between the balloons to supply therapeutic fluids to a lesion. A further balloon may be provided that, when inflated, drives the material into the lesion. This is similar to what was described in the background of the Forman reference. However, in this case it is more clearly portrayed as general background knowledge.

[59] In Ya, the prior art discussion discloses three generally known techniques for treating an arterial blockage, one of which is Percutaneous Transluminal Coronary Recanalization (PTCR) which involves injecting a thrombus (blockage) dissolving agent to

the blockage location. Ya does not discuss any conventionally known catheter designs.

[60] Based on the above, including the Applicant=s own discussion of the prior art, we find that it was common general knowledge at the claim date to use a dual balloon catheter in the treatment of a blockage in a blood vessel. It would also seem that it was common general knowledge to direct treatment agents to the area of the blockage, as stated by the Examiner, both by using a single balloon through which the therapeutic agent flowed and by supplying the agent to the space between two occlusion balloons through a lumen. However, we cannot say that it was common general knowledge to use a slurry, in particular, to remove a plaque deposit.

[61] Before addressing the inventive concepts of the claims, we should add a comment regarding common general knowledge. We do not wish to be taken as concluding that because we were unable to ascertain that certain features of the cited references form part of the common general knowledge, these features cannot be used in an obviousness argument. Even in cases where certain features are found not to form part of the common general knowledge, features appearing in one reference may be combined with those of another reference if, as stated in *Servier*, cited above, it can be demonstrated Ahow the person of ordinary skill in the art would have been led to combine the relevant components from the mosaic of prior art.@

(2) The Inventive Concept(s)

[62] Referring again to the Summary of Reasons, the Examiner identified the inventive concept of the claims as:

> a catheter with two or more inflatable balloons which are individually and separately operated, a blood bypass for retaining blood flow through a vessel while the blood flow to and from a predetermined part or area of the body is shut-off or isolated by the balloons of the catheter, and a lumen, having a plurality of ports, for delivering a substance to the occluded area between the balloons.

[63] The Examiner=s statement appears to be an inventive concept that is a combination of the features of independent claims 1, 9 and

13. While the independent claims, especially claims 1 and 13, are very similar, there are differences. In particular, claim 9 includes first and second lumens for separately expanding and contracting the first and second balloons, but claims 1 and 13 do not include such a limitation. Likewise, claims 1 and 13 claim the bypass in detail, while claim 9 generally claims a bypass. Different claims can, and generally will, have different inventive concepts (see *Eli Lilly & Co v Apotex Inc*, 2009 FC 991 at footnote 190, 80 CPR (4th) 1; see also *Pozzoli SpA v BDMO SA*, [2007] EWCA Civ 588 at para. 17, from which the four-step approach was adopted in *Sanofi*).

[64] We find that the inventive concept of claims 1 and 13, due to their similarity, can be identified in common. We state it as:

> A catheter positionable in a blood vessel of a body having blood flow therethrough, the catheter comprising:
> - first and second expandable balloons spaced along the catheter, which when inflated, form an occluded segment
> - at least one lumen extending to the external end of the catheter connected to a plurality of ports situated between the first and second balloons, and
> - a bypass defined by a lumen and first and second ports upstream and downstream of the first and second balloons, respectively, for shunting the occluded segment to provide blood flow during treatment.

[65] We find the inventive concept of claim 9 is:

> A catheter positionable in a blood vessel of a body comprising:
> - first and second balloons spaced from each other which, when inflated, form an occluded segment, the balloons being separately expandable and controllable through first and second lumens
> - at least one lumen extending to the external end of the catheter and connected to a plurality of ports situated between the first and second balloons, and
> - a bypass allowing for passage of a portion of the blood flow through the occluded segment.

[66] The inventive concepts of the dependent claims would differ by the features added in each of them.

3) Differences between the Astate of the art@ and the inventive concept(s)

[67] In the present case it is not necessary to go into detail as to what is taught by the closest prior art. As noted earlier, prior to the case being referred to the Board, certain claims were defective in that the Examiner contended that they were anticipated by Wright. Reference may be made to the Final Action for a detailed comparison of the then-pending claims with the Wright disclosure. In response to the Final Action the Applicant did not

contend that the claims on file at the time of the Final Action were novel, but sought to distinguish the rejected claims over Wright by the addition of the limitation noted earlier concerning the provision of injecting and/or withdrawing fluids to/from the occluded segment.

[68] In the response of June 1, 2009, the Applicant identified the difference between the amended claims and the Wright reference (emphasis in original):

> Wright does not teach the limitation Aat least one lumen extending to the external end of the catheter and connected to a plurality of ports in a wall portion of said catheter located between said first expandable balloon and said second expandable balloon.@ In contrast, Wright teaches the use of lumens (60 and 62) with single openings to the catheter wall in between two expandable balloons.
> .....
> In contrast, the instant invention utilizes lumens with multiple openings (or fenestrations) to the catheter wall in between two expandable balloons.

[69] As noted earlier, the Applicant made no further submissions with respect to the obviousness defect.

[70] In view of the above, the only difference between claims 1, 2, 4, 9, 10, 12 and 13 and what is disclosed by Wright is that in the present claims the exit of the lumen in connection with the occluded area is defined by a plurality of ports as opposed to a single port.

(4) Do the differences constitute steps which would have been obvious?

[71] Before considering the case for obviousness made by the Examiner, which involves the Wright reference in combination with other references, the Board notes that the Applicant, in the response to the Final Action dated June 1, 2009, took issue with the citation of the Wright reference in light of the amendments made, particularly because of the disclosed use of the lumens supplying the treatment agent in Wright. We will therefore first consider the appropriateness of the Wright reference as a starting point for the present case for obviousness . In the abovementioned response the Applicant stated (emphasis in original):

> Wright teaches the use of lumens (60 and 62) with single openings to the

> catheter wall in between two expandable balloons. This is particularly true in light of Wright=s teaching that slurry should be applied (1) in a localized manner and (2) with relatively high velocity relative to the plaque deposit removed. *See* Wright, col. 3, lines 3-11. In contrast, the instant invention utilizes lumens with multiple openings (or fenestrations) to the catheter wall in between two expandable balloons. Wright teaches away from such an arrangement, as the use of a lumen with multiple openings to the catheter wall would result both (1) in loss of an ability to localize the slurry application to a particular area of vessel stenosis; and (2) in a decreased pressure of the slurry fluid as it emerged from the multiple catheter wall openings. It is therefore submitted that Claims 1, 9, and 13 (and dependent claims thereof), as amended, are not anticipated nor rendered obvious by Wright.

[72] Wright discloses a dual balloon catheter in which lumens are provided for delivering an abrasive slurry to the occluded segment in order to remove a plaque deposit, and for withdrawing a resultant slurry/plaque mixture from the occluded segment (see col. 3, lines 3-11, as cited by the Applicant in the response of June 1, 2009). The inflow and outflow fluids scour out the area of plaque buildup. However, as stated at col. 3, lines 6-11:

> The portion of the vessel with the highest plaque deposit, and hence the narrowest flow section, will be subjected to the maximum liquid flow velocity resulting in the highest scouring or cutting action and plaque removal rate taking place at this site.

[73] The above passage indicates that it is not the direct injection of the abrasive slurry from the exit port towards the deposit that causes the high velocity abrasion, but instead the basic fact that the deposit creates a constriction in the blood vessel. Because of this constriction a pressure drop is created across the area of reduced cross-section and a corresponding increase in velocity occurs. It is, as Wright disclosed, the corresponding higher velocity of the abrasive slurry across the narrowed section that causes increased scouring, and not a localized direction of a jet of slurry towards the plaque deposit, as suggested by the Applicant. Our interpretation is also consistent with Figure 3 of Wright, which shows the inlet ports in the occluded area as ejecting slurry so as to not directly impinge on the plaque deposit. While later, at col. 4, lines 30-34, Wright suggests that slurry is ejected against the stenotic portion, we interpret this taking into account both Figure 3 and the statements at col. 3, lines 6-11.

[74] Since the use of a single port in Wright does not serve a unique

purpose other than to supply the treatment agent to the occluded area, we do not see Wright as teaching away from an embodiment where a plurality of ports are provided. In light of this we will proceed to assess whether the rejected claims would have been obvious in view of the combination of references applied by the Examiner.

[75] In support of her position that amended claims 1, 2, 4, 9, 10, 12 and 13 would have been obvious, the Examiner has cited the supporting references to Forman, Walker and Ya. These references are cited to illustrate that the modification of the Wright device to include a Aplurality of ports@ to deliver a treatment agent to the occluded segment would have been an obvious one, as this would have been a well known variation.

[76] In the Summary of Reasons to the Board the Examiner stated:

> It is well-known in the art of balloon catheters to include multiple ports for delivering a substance between two occlusion balloons, as taught for example by Forman (p. 18 l. 11-21 and Fig. 5, ref. 88), Walker et al. (ref. 54) and Ya (ref. 4, col. 5, l. 34-39)). It is noted that there are many known treatment procedures that can be performed on an occluded section of a vessel using a catheter, for example delivery of medicament or the introduction of a slurry to break up plaque. The specific procedure being performed does not change the structural features of the occlusion balloons and the blood bypass, which are both necessary to maintain blood flow through the vessel during any type of treatment. Therefore, the inclusion of a plurality of ports between the balloons is deemed to be an obvious design variant for one skilled in the art.

[77] Looking to the supporting references cited by the Examiner, Forman discloses a dilation drug delivery catheter which includes a dilation portion 20 for dilating a stenosis, and a drug delivery portion 50, within the dilation portion, for delivery of treatment agents such as antithrombolytic agents (e.g. heparin) and antiproliferative agents (e.g. dexamethasone (see pages 5-6 and Fig. 1). The drug delivery portion is very similar to the catheter of the present application in that it comprises two occlusion balloons (58,60) to isolate a site. A drug delivery lumen (54) supplies the drugs to the occluded segment through a plurality of drug delivery ports (56) (preferably 2-20). As per page 6, a plurality of ports are preferably provided to ensure an adequate supply of the drug to the occluded segment. This does, however, leave the door open to the possibility of a single port sufficing as well. Forman also discloses the provision of perfusion

openings (88) through an inner catheter shaft connected to a central lumen (64) which provides a bypass for blood flow through the occluded site, much like the present application.

[78] The Walker reference also discloses a dual balloon catheter comprising a dilation balloon (46) and an occlusion balloon (58) (see Fig. 1). While this catheter functions in both a dilation mode and an occlusion mode, in its occlusion mode both balloons are inflated to form an occluded segment around a lesion, as in the present application. This catheter also, due to its dual mode operation, allows for separate inflation of the balloons, as in present claim 9. The catheter includes, between the balloons, a perforate infusion section (52) connected to the lumen (56) through which a treatment fluid is delivered to the occluded blood vessel segment. A plurality of perforations (54) are provided in the section (52).

[79] The reference to Ya discloses a method and apparatus for percutaneously removing a thrombus (blockage) from a blood vessel. The apparatus, like Applicant=s claimed invention, comprises a catheter with two balloons (2,7), which, when both are inflated, form an occluded segment. Thereafter, a thrombus dissolving agent is ejected through thrombus dissolving outflow bores (4). As disclosed at col. 5, lines 37-39, it is preferable to provide several such bores, but one may serve the purpose. The outflow bores are located between the two balloons, which balloons are also separately inflatable, as in present claim 9 (see col. 7, lines 28-30).

[80] Each of the Forman, Walker and Ya references show dual balloon catheters forming an occluded segment with a treatment agent injection system provided between the balloons. This injection system includes a lumen supplying the agent to a plurality of openings situated between the inflated balloons to remove a blockage from a blood vessel, whether the agent is an antithrombolytic agent, antiproliferative agent, or some other treatment agent. While only the Forman reference discloses a blood bypass, as in the claimed invention, one must remember that these references were cited not to show a lack of novelty of the claims, but to support the contention that

the difference between the Wright reference and the inventive concepts of the claims, would have been obvious.

[81] All three supporting references illustrate embodiments where, in using a dual balloon catheter to supply a treatment agent to an occluded segment, the agent may be ejected into the occluded portion from a plurality of ports as opposed to a single one as illustrated in Wright. We note that Wright does not specifically discuss the configuration of the ports from which the treatment agent is ejected into the occluded portion. While it would appear to be a single port from the figures included, there is no such limitation discussed, and so as stated earlier we do not see Wright as requiring a single port embodiment in order to properly function.

[82] Given that, as illustrated by the Forman, Walker and Ya references, it was known to use a plurality of ports to supply a treatment agent to the occluded segment of a dual balloon catheter, we find that the choice to do so would have been obvious. All of these references relate to very similar devices of which the skilled person would have been aware, upon performing a diligent search of the relevant prior art (see *Bristol-Myers Squibb Canada Co v Novopharm Ltd*, 2005 FC 1458 at para. 77, 43 CPR (4th) 433). Using one or several ports were known alternatives in view of these references and the Wright reference, as is especially clear in the Forman and Ya references, where a plurality of ports may be preferable, but one may suffice. Forman also discloses a large variation in the number of ports (from 2-20). As noted earlier, we see no specific reason for the use of only one port.

[83] In view of the above, we do not consider the modification of providing a plurality of ports as opposed to a single port for supplying a treatment agent to an occluded segment, without some unexpected advantage flowing from the modification, which we do not see here, to be inventive. In light of the guidance from *Servier*, we consider that the skilled person, in light of the prior art, would have been led to the possibility of one or more ports, the particular number depending on the particular application of the catheter.

[84] We therefore find that claims 1, 2, 4, 9, 10, 12 and 13 would have been obvious.

RECOMMENDATIONS OF THE BOARD

[85] In view of the above findings, the Board recommends that:

(1) the Examiner=s finding that claims 1, 2, 4, 9, 10, 12 and 13 are obvious be upheld, and

(2) the Applicant be informed in accordance with paragraph 31(*c*) of the *Patent Rules*, that the following amendments, and only the following amendments, of the application are necessary for compliance with the *Patent Act* and *Patent Rules*:

incorporation of the features of dependent claims 3, 11, and 14 into independent claims 1, 9 and 13, respectively, with corresponding deletion of claims 3, 11 and 14 and the resultant amendment of claim numbering and references in the remaining dependent claims.

Stephen MacNeil	Paul Fitzner	Andrew Strong
Member	Member	Member

DECISION OF THE COMMISSIONER

[86] I concur with the Patent Appeal Board=s findings and their recommendations. Accordingly, I invite the applicant to make the above amendments, and only the above amendments, within 3 months from the date of this decision, failing which I intend to refuse the application.

Sylvain Laporte
Commissioner of Patents

Dated at Gatineau, Quebec,
this 7th day of September, 2011