Commissioner's Decision # 1291

Décision du Commissaire # 1291

TOPIC: A20

SUBJECT: A20

Application No : 2,023,636

Demand no : 2,023,636

COMMISSIONER=S DECISION SUMMARY

C.D. 1291 Application No. 2,023,636

The subject application relating to oral sample collection using a hypertonic solution comprises subject matter which overlaps with Applicant=s Canadian Patent 2,076,754. In the Final Action, the Examiner rejected all 19 claims on file for being directed towards the same invention as the 31 claims of Applicant=s issued patent. The Board recommended that the rejection of certain claims be affirmed, and that the rejection of other claims be reversed.

The Commissioner of Patents agreed with the Board, and the application was returned to the Examiner for further prosecution consistent with the recommendation.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 2,023,636 having been rejected under Subsection 30(4) of the *Patent Rules*, the Final Action of the Examiner has been reviewed. The rejection has been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

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INTRODUCTION:

(1) This decision deals with a review of the Examiner's Final Action on patent application number 2,023,636, filed on August 20, 1990, entitled "**Oral Immunoglobulin Collection for Immunoassay**". The Applicant is Orasure Technologies Inc. and the inventors are Andrew Goldstein and Stefan Gavojdea. Examiner Isabelle Gagné issued a Final Action on December 8, 2003 rejecting all of the claims for double patenting.

(2) The subject application allegedly overlaps with Canadian patent 2,076,754 entitled "**Oral Collection for Immunoassays**", which was filed February 27, 1991 and issued on July 25, 2000. The owner is also Orasure Technologies Inc., and the inventors are Andrew Goldstein, Stefan Gavojdea and David Zogg.

(3) The invention in the pending application relates to the use of a hypertonic solution in methods for collecting immunoglobulins from saliva for subsequent use in immunological testing.

BACKGROUND:

Prosecution History

(4) Application 2,023,636 was filed on August 20, 1990, laid open on March 22, 1991, examination was requested on July 22, 1997 and the first Office action was issued on July 23, 2001. The claims on file (claims 1-19) were initially deemed to lack unity since they related to two distinct groups: the first directed towards methods for collecting immunoglobulins using a pad; and, the second directed towards methods for collecting immunoglobulins using a rinse solution. The claims were not significantly amended with Applicant's response (January 23, 2002) and the

Applicant traversed the objection to unity. In the Examiner's subsequent report dated June 14, 2002 the objection to unity was withdrawn as the claims were deemed unified through the feature of a hypertonic solution. However, claims 1-19 were objected to for overlapping with granted claims 1-4, 7, 10, 12, 17, 19-25 and 27-31 of Applicant's patent 2,076,754. The Examiner maintained the objection for overlap in one additional report, this time citing claims 1-19 of application 2,023,636 against claims 1-31 of patent 2,076,754, before issuing a Final Action on December 8, 2003. In response, the Applicant traversed the objection and did not amend the claims.

(5) A Summary of Reasons was prepared by the Examiner and was sent to the Patent Appeal Board on July 19, 2005. In accordance with subsection 30(6) of the *Patent Rules,* the Applicant was given the opportunity to be heard at an oral hearing on December 17, 2008, which was declined. The review of the rejection proceeded on the basis of the documents on record.

Grounds for Rejections (Examiner=s Position)

(6) Although the claims of 2,023,636 were not formally objected to under a section of the *Patent Act and Rules,* in the Final Action the arguments presented by the Examiner related to an implication of double patenting if application 2,023,636 were to issue.

(7) The Examiner objected to the claims on file as overlapping the subject matter of all claims of Applicant=s Canadian Patent 2,076,754 and stated in the Final Action that:

> ...the subject matter of the present application is completely claimed and disclosed in Canadian Patent No. 2,076,754.

(8) The reasoning expressed in the pre-final and Final Action was that only one patent can issue for one invention and the Examiner referred to *Xerox of Canada Ltd. v. IBM Canada Ltd* (1978), 33 C.P.R. (2d) 24 (*Xerox*) as the relevant authority. The Examiner concluded in the Final Action that:

> ...at the stage of patent applications, if 2 applications claim identical subject matter, only one of them can be allowed to proceed to grant.

(9) Further, the Examiner alleged that the Applicant elected to retain the overlapping subject matter in application 2,076,754 since it issued to patent on July 25, 2000, stating in part:

> ...the present application cannot proceed to issuance because if it would be allowed to do so double-patenting would occur, even if the present application has an earlier claim date. The fact no objection was raised in the prosecution of CA 2,076,754 does not change the fact that double-patenting is not allowable and that only one patent may issue for one invention. Applicant has already received protection for the claimed subject-matter, the term of patent CA2,076,754 ending Feb 27, 2011.

(10) In the Final Action claims 1-19 of application 2,023,636 were objected to as overlapping with claims 1-31 of Applicant's patent 2,076,754 since the subject matter of both sets of claims was directed towards methods for collecting immunoglobulins from the oral cavity of a patient for use in immunoassays. The Examiner equated the point of invention, in both cases, to the use of the hypertonic solution and stated in part that:

> ...the manner in which the hypertonic solution is used i.e. in a pad or as a mouth rinse, does not change the point of invention, which is the use of the hypertonic solution.

Applicant's Position

(11) In response to the Final Action the Applicant presented three lines of defence: the Office erred in the prosecution of the two overlapping applications and should have raised the issue of overlap while both applications were pending; the term of application 2,023,636 expired on August 20, 2010 and that there was no extension of patent rights; and that double patenting was not an issue as the claims were not identical nor conterminous.

(12) In Applicant's response dated June 7, 2004, Applicant outlined the prosecution history of patent 2,076,754 and application 2,023,636 stating in part that:

> Clearly these two applications were co-pending in the Canadian Patent Office, both were laid open to public inspection well in advance of the examination of either application and examination of both applications was requested within several months of each other. With respect to each application, the Examiner has stated in each issued Examiner's report that a search of the prior art has revealed no pertinent references.

(13) Further, Applicant traversed the Examiner's assumption that the Applicant choose to prosecute the subject matter in application 2,076,754 over 2,023,636 since no objection was raised against 2,076,754 and the Applicant was not requested to remove overlap. From Applicant's response dated June 7, 2004 Applicant stated in part:

> ...Clearly, the Examiner in each case failed to discharge his or her duties during the pendency

of the two applications to properly search and raise all relevant objections. If the Examiner considered that there was overlap between the two applications when the were both pending, that issue should have been raised at that time. The Applicant cannot now be expected to suffer by having to remove valid subject matter from one application because the Examiner considers that an already issued patent of the same Applicant is directed to the same subject matter. The presently pending application has an earlier priority date and hence an earlier claim date. The Applicant is clearly entitled to the benefit of that earlier date and cannot be disadvantaged by having to give up subject matter in that application because of errors made by the Examiner during the examination process.

(14) The Applicant further contended that the earlier filed application (2,023,636) would expire on August 20, 2010, and that allowing it to proceed to allowance would not extend the monopoly of the application even if the Examiner Atruly considers there to be a double-patenting issue@. Applicant referred to statements made by Collier J. in *Xerox* at paragraph 98 to summarize the Canadian law with respect to double-patenting and extension of monopoly. Applicant concluded that:

> The position outlined in *Xerox v. IBM* that the claims must be identical or conterminous for double patenting to be found has been upheld in subsequent cases. In the decision *Beecham Canada Ltd. et al. v. Proctor & Gamble Co.* 61 C.P.R. 2d 1, the Federal Court of Appeal upheld the position that the prior grant must be identical or conterminous. If this is not the case, the invention is a separate invention.
>
> In the Supreme Court of Canada decision *Camco Inc. et al. v. Whirlpool Corp. et al.* 9 C.P.R. 4th 129 Supreme Court of Canada, the same position is taken.

(15) Lastly, the Applicant contended that Athe claims of the present application are not conterminous or identical with the claims of Canadian Patent No. 2,076,754@ and therefore

Amust be permitted to proceed@ [to allowance].

SUMMARY OF THE RELEVANT CASE LAW:

(16) In view of Applicant=s issued patent 2,076,754 and in view of the fact that only one patent can issue for one invention, the issuance of Applicant=s application 2,023,636 to patent introduces the possibility of double patenting. The prohibition against double patenting is judge-made law which originated under the preB1989 provisions of the *Patent Act* to address the concern of evergreeening and patent term extension in situations where the same parties, such as inventors or Applicants, are involved. Notwithstanding the postB1989 provisions of the *Patent Act* in which patent protection begins at the date of filing rather than the date of issue, the prohibition against double patenting remains: *GlaxoSmithKline Inc. v. Apotex Inc.*, 2003 FCT 687, 27 C.P.R. (4th) 114, at paras. 89-91, (GSK).

(17) *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 (*Whirlpool*) is frequently cited as the leading authority for the prohibition. In *Whirlpool*, the Supreme Court noted that there are two branches to the test for double patenting, each of which may be evaluated in determining whether a second claim-set defines a separate invention from another claim-set. The first branch, termed >same invention double patenting=, applies in situations where the claims are identical or conterminous (*Xerox*; *Beecham Canada Ltd. v. Procter & Gamble Co.* (1982), 61 C.P.R. (2d) 1 at p. 22).

(18) The second branch of the test, outlined in *Whirlpool* at paragraph 66, is termed >obviousness double patenting= and is somewhat broader:

> There is, however, a second branch of the prohibition which is sometimes called

Aobviousness@ double patenting. This is a more flexible and less literal test that prohibits the issuance of a second patent with claims that are not Apatentably distinct@ from those of the earlier patent.

(19) Although there are limitations insofar as what can be considered, obviousness double-patenting is assessed conceptually in the same way as determining obviousness under subsection 28.3 of the *Patent Act*; *viz.*, viewed from the perspective of the person skilled in the art: *Bayer AG v. Novopharm Ltd.*, 2006 FC 379, 48 C.P.R. (4th) 46 at paras. 40B63 (*Bayer*); *Aventis Pharma Inc. v. Pharmascience Inc.*, 2005 FC 340, 38 C.P.R. (4th) 441, aff=d 2006 FCA 229, 53 C.P.R. (4th) 453 at para. 63 (*Aventis*). The assessment is limited in that it is the claims in one patent which are compared against those in another (*Whirlpool* at para. 63). The test may take into account common general knowledge but not particular pieces of prior art.

(20) In *Bayer* and *Aventis* it was the traditional test for obviousness outlined in *Beloit Canada Ltd. v. Valmet Oy* (1986), 8 C.P.R. (3d) 289 at 294 (F.C.A) (*Beloit*) which was considered. Recently, the approach to obviousness has been updated with the decision of the Supreme Court in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, 69 C.P.R. (4th) 251 (*Sanofi*), in which the court stepped away from the strict test defined in *Beloit* and introduced a four-step approach to assessing obviousness. It is this approach that is the current standard for determining obviousness and is likewise the one which can be applied in the conceptual assessment in obviousness double patenting.

(21) A further consideration within the ambit of the obviousness enquiry is whether different claim-types define different inventions or are merely different aspects of the same invention: *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49 (*Hoechst*); *Libbey-Owens-Ford Glass Company v. Ford Motor*

Company of Canada, Ltd., [1970] S.C.R. 833; and *Ciba-Geigy AG v. Commissioner of Patents* 65 C.P.R. (2d) 73). Different categories of invention are not necessarily indicative of distinct inventive concepts; inventive ingenuity is still required to support a second patent (see *GSK* at para. 89). However, claims ostensibly overlapping in scope with claims of another patent may in fact be patentably distinct. For example, claims defining a sub-genus or species are not considered obvious over claims defining the broader genus in a separate patent where the criteria for a proper selection are met (*Sanofi* at para. 113; *Aventis* at paras. 46 and 64).

(22) The foregoing jurisprudence sets forth the requirements to support a second patent in the situation of an application divided from a parent patent and in the case of a copending application filed by the same Applicant. It is clear from the case law that in order for the claims of 2,023,636 to be considered directed towards a second invention the subject-matter must not be conterminous or obvious in view of the claims of 2,076,754.

OVERLAP AND PATENT OFFICE PRACTICE ANALYSIS:

(23) Examination of patent applications proceeds in accordance with section 35(1) of the *Patent Act* once a request is made in the prescribed manner and on the payment of the prescribed fee. Guidance to Examiners with respect to the prosecution of overlapping claimed subject matter is given in the *Manual of Patent Office Practice* (MOPOP), chapter 15, **Requirements for Patentability** (version March 1998), in section 15.06.01.

(24) Although the Examiner referred to MOPOP during the prosecution of application 2,023,626, a specific chapter was not explicitly mentioned in any Office action, but the relevant chapter would appear to be chapter 15 which deals with overlapping subject matter. With respect

to overlap, Applicant alleges that the Office erred in the prosecution of the two applications and should have raised the issue while the two applications were pending in the Office. Further, Applicant contended that they should have been allowed to choose in which application to prosecute the overlapping subject matter and should not be disadvantaged by having to give up subject matter because of errors made by the Office. Nevertheless, though overlap was not raised while both applications were pending in the Office, Applicant elected to expedite examination of application 2,076,754, by requesting special order status on October 2, 1998. Choosing advanced prosecution of 2,076,754 could therefore be perceived as Applicant=s election as it resulted in application 2,076,754 issuing to patent on July 25, 2000 before the issuance of a first Office action for application 2,023,636, on July 23, 2001. Applicant had equal opportunity to request advanced examination of 2,023,636 but choose not to exercise this option.

(25) Nonetheless, despite the fact that overlap was not raised against 2,076,754 while both applications were pending in the Office, nothing in the *Patent Act or Rules* precludes the issuance of such an objection if the Examiner has "reasonable grounds" to conclude that overlapping subject matter exists between the still pending application and the issued patent. Moreover, in accordance with subsection 30(1) of the *Patent Rules*, once an Examiner has Areasonable grounds@ to believe that the application complies with the *Patent Act and Rules*, the Commissioner shall notify the Applicant that the application has been found allowable. Since application 2,076,754 apparently complied with the *Patent Act and Rules* it was therefore allowed.

(26) Notwithstanding the absence of monopoly extension since the term of application 2,023,636 expires on August 20, 2010, the >sin= of double patenting still exists as two inventions are required to support two patents (*GSK, supra*). Whether or not the Applicant

actually elected to prosecute the overlapping subject matter in 2,076,754 is moot since in accordance with judicial precedent, only one patent should issue for one invention.

CLAIM ANALYSIS:

(27) In order to assess whether the issuance of application 2,023,636 to patent introduces the possibility of double patenting, the claims of 2,023,636 must be compared with the claims of Applicant=s patent 2,076,754 which most closely resemble them regardless of claim type. In this respect, claims to kits and claims to pads are grouped together since any reasoning that applies to the pad would also extend to the kits containing them. This claim-by-claim analysis is one that was endorsed by *Whirlpool, supra* for assessing double-patenting. In understanding the language of the claims the whole of the disclosure and the claims should be considered, through the eyes of the skilled technician, to ascertain the nature of the invention claimed. The claims of application 2,023,636 and patent 2,076,754 relate to methods for collecting and testing samples from an oral cavity of a patient, employing a hypertonic solution and a pad for collecting said sample and are grouped in the following table with the relevant claim comparisons indicated:

	Form	Application 2,023,636	Patent 2,076,754
Group A	Method Claims	1-9 and 15-19	1-23
	Claims compared:	1 and 15	1,2 and 6-8

	Methods		
Group B	Product Claims	10-14	24-31
	Claims compared: Pads and Kits	10 and 14	24-26

(28) As indicated in the table above only a subset of the method claims of group A and product claims of group B are used in the claim-by-claim comparison between application 2,023,636 and the 2,076,754 patent. The subject matter of dependent claims 2-5, 9, 11-12 and 16-19 of application 2,023,636 define additional features of salt, preserving agent, blocking agent and salival stimulating agent for the hypertonic solution and the subject matter of claims 6-8 and 13 define additional features of the pad and conditions for storing and preserving the pad after use. These features are also defined in patent 2,076,754 in dependent claims 9-11, 20-22, 27 and 29-31, and claims 3, 4, 12-19, 23 and 28, respectively. As these features are common between both application 2,023,636 and the 2,076,754 patent they are considered non-inventive features and therefore claims containing said features are excluded from the claim comparison. Even though only a subset of the claims within group A and group B are compared in the claim-by-claim analysis, any reasoning applied to these claims would also extend to all claims dependent thereon.

A). In accordance with the first branch of double patenting, are the claims of 2,023,636 and 2,075,754 identical or conterminous ?

(29) In the Final Action, the Examiner alleges that the subject matter of application 2,023,636

was completely claimed and disclosed in 2,076,754 and rejected all of the claims of application 2,023,636 as overlapping with the subject matter of the claims of issued patent 2,076,754 citing *Xerox* as the relevant authority. This objection by the Examiner corresponds to the first branch of the double patenting test noted by *Whirlpool, supra,* termed >same invention double patenting= which applies in situations where the claims are identical or conterminous.

i) Group A claims

(30) Claims 1 and 15 of 2,023,636 used in the method claim comparison read as follows:

1. A method of collecting immunoglobulins for immunological testing comprising the steps of:

(a) dipping a pad into a hypertonic solution wherein the hypertonic solution is in an effective concentration to recover a high concentration of immunoglobulin,

(b) drying the pad,

(c) inserting the dried pad into an oral cavity to collect immunoglobulins within the oral cavity, and

(e) eluting the collected immunoglobulins from the pad for analysis by immunological testing.

15. A method of collection immunoglobulins for immunological testing comprising the steps of:

(a) rinsing the oral cavity of a patient with a pharmaceutically acceptable hypertonic solution, wherein the hypertonic solution is in an effective concentration to recover a high concentration of immunoglobulin, and

(b) collecting a specimen of the hypertonic solution after rinsing for analysis by immunological testing.

(31) Claims 1, 2 and 6 of 2,076,754 used in the method claim comparison are detailed below. Claim 5, on which claim 6 depends defines the analyte of claims 1 or 2 as having a molecular

weight ranging from about 176 D to 950,000 D.

1. A method of collecting an analyte from an oral cavity for testing, said method comprising:

(a) contacting oral mucosa in said oral cavity with an absorbent pad impregnated with a salt whereby said pad absorbs an oral fluid from said oral cavity forming a hypertonic solution in or adjacent to said pad that enhances uptake of said analyte into said absorbent pad;

(b) removing said pad from the oral cavity; and

(c) optionally storing said pad for subsequent testing.

2. A method of immunological testing, said method comprising:

(a) obtaining an oral fluid sample to be tested by:

(i) contacting the oral mucosa with an absorbent pad where said absorbent pad is impregnated with a salt such that when said pad absorbs an oral fluid from said oral cavity a hypertonic solution is formed in or adjacent to said pad that enhances uptake of an analyte in said oral fluid; and

(ii) removing the pad from the oral cavity;

(b) subjecting the sample to at least one immunological test known to reveal the presence or absence of at least one immunologically active analyte; and

(c) analyzing the test results for the presence or absence or quantity of the analyte.

6. The method of claim 5, wherein said analyte is selected from the group consisting of cotinine, glucose, theophylline, cocaine, beta2-microglobulin, hepatitis A antibody, hepatitis B antibody, hepatitis B surface antigen, beta-human chorionic gonadotropin, and an immunoglobulin.

(32) To aid in the analysis of the claims of group A the claim language of relevant claims 1 and 15 of application 2,023,636 and claims 1, 2 and 6 of 2,076,754 is detailed in the table

below, where T indicates the presence of a particular feature and Ξ indicates its absence, and Ig indicates immunoglobulin:

Group A	2,023,636 Claim 1	2,023,636 Claim 15	2,076,754 Claim 1	2,076,754 Claim 2	2,076,754 **Claim 6
Pre-Amble (Purpose)					
collecting Ig	T	T	Ξ	Ξ	T
collecting an analyte	Ξ	Ξ	T	Ξ	Ξ
immunological testing using an analyte	Ξ	Ξ	Ξ	T	Ξ
Analyte					
unspecified	Ξ	Ξ	T	T	Ξ
Ig	T	T	Ξ	Ξ	T
Type of Pad					
Wet or Dry	Ξ	Ξ	T	T	T
Dry	T	Ξ	Ξ	Ξ	Ξ
Hypertonic solution					
effective concentration	T	T	Ξ	Ξ	Ξ
impregnated with salt	Ξ	Ξ	T	T	T
Group A (contd.)	2,023,636 Claim 1	2,023,636 Claim 15	2,076,754 Claim 1	2,076,754 Claim 2	2,076,754 **Claim 6
Method steps					

dipping & drying pad	T	Ξ	Ξ	Ξ	Ξ
rinsing with solution	Ξ	T	Ξ	Ξ	Ξ
hypertonic solution adjacent to pad	Ξ	Ξ	T	T	T
eluting	T	Ξ	Ξ	Ξ	Ξ
storing	Ξ	Ξ	optional	Ξ	*optional/Ξ
test & analyse	done later	done later	done later	T	*now or later

* presence of this feature differs when claim 6 depends on claim 1 or claim 2, respectively.

** claims 7 and 8 are not included in the table but they further define the species and sub-species of the immunoglobulin of claim 6.

(33) Claim 1 of 2,023,636 is directed towards a method of collecting immunoglobulins within the oral cavity for immunological testing by first dipping a pad in a hypertonic solution of >effective concentration=, drying the pad and then taking an oral sample. Alternatively, claim 15 uses an >effective concentration= of hypertonic solution directly as a rinse for collecting immunoglobulins from the oral cavity. Claims 1 and 2 of 2,076,754 are directed towards a method of collecting an analyte from an oral cavity and a method of immunological testing, respectively, where both methods contact the oral mucosa with an absorbent pad impregnated with a salt which absorbs an oral fluid forming a hypertonic solution in or adjacent to said pad. Claim 6 depends on claims 1 and 2 and specifically defines the analyte as an immunoglobulin.

(34) Firstly, since claim 15 uses a hypertonic rinse solution rather than a pad containing a hypertonic solution, the method is clearly distinct from the methods of claims 1 and 2 of 2,076,754 and thus cannot be considered identical or conterminous with any of the claims of 2,076,754. Secondly, claim 1 of 2,023,636 specifies that the method is for immunoglobulin

collection and that the pad is first dipped and dried prior to sample collection, wherein the immunoglobulins are eluted after said collection. By comparison, claims 1 and 2 of 2,076,754 use broader terminology, defining the methods as collecting an analyte and do not specify the state of the absorbent pad impregnated with a salt, nor the steps of preparing said pad. When the analyte is further defined as an immunoglobulin in dependent claim 6, the state of the absorbent pad impregnated with the salt remains unspecified. Further, in 2,076,754, claim 1 includes an optional storage step and claim 2 includes additional steps for testing and analysing the sample.

ii) Group B claims

(35) Claims 10 and 14 of 2,023,636 used in the product claim comparison read as follows:

> 10. An oral immunoglobulin collecting pad comprising an absorbent material and the salts of a hypertonic solution, wherein the salts of the hypertonic solution are in an effective concentration in the pad to recover a high concentration of immunoglobulins.
>
> 14. An immunological testing kit for collecting and storing substances from an oral cavity comprising a pad treated with a hypertonic solution; a pad holder; a container for storing the pad; a pad removal device; and a storage preservation solution.

(36) Claims 24-26 of 2,076,754 used in the product claim comparison read as follows:

> 24. A pad for collecting substances from an oral cavity for testing, said pad comprising an absorbent material impregnated with a salt wherein said salt is in a sufficient quantity in the pad to form a hypertonic solution in or adjacent to said pad when said pad absorbs oral fluid from said oral cavity.

25. The pad of claim 24, wherein said pad is impregnated by said salt by:

(a) dipping the pad into a hypertonic solution; and

(b) drying the pad.

26. The pad of claim 24, wherein said pad is impregnated with said salt by:

(a) spraying the pad with a hypertonic salt solution; and

(b) drying the pad.

(37) To aid in the analysis of the claims of group B the claim language of relevant claims 10 and 14 of application 2,023,636 and claims 24-26 of 2,076,754 is detailed in the table below, where T indicates the presence of a particular feature and Ξ indicates its absence and Ig indicates immunoglobulin:

Group B	2,023,636 Claim 10	2,023,636 Claim 14	2,076,754 Claim 24	2,076,754 Claim 25	2,076,754 Claim 26
Product					
oral Ig collecting pad	T	Ξ	Ξ	Ξ	Ξ
kit for collecting & storing; including pad	Ξ	T	Ξ	Ξ	Ξ
pad for collecting substances	Ξ	Ξ	T	T	T
Analyte					

Analyte (substance)	Ξ	T	T	T	T
Ig	T	Ξ	Ξ	Ξ	Ξ
Type of Pad					
Wet or Dry Pad	Ξ	Ξ	T	Ξ	Ξ
Dry Pad	T	T	Ξ	T	T
Group B (contd.)	2,023,636 Claim 10	2,023,636 Claim 14	2,076,754 Claim 24	2,076,754 Claim 25	2,076,754 Claim 26
Hypertonic solution					
salts of	T	Ξ	Ξ	Ξ	Ξ
treated with	Ξ	T	Ξ	Ξ	Ξ
impregnated with salt	Ξ	Ξ	T	T	T
effective concentration	T	Ξ	Ξ	Ξ	Ξ
sufficient quantity	Ξ	Ξ	T	T	T

(38) The collecting pad of claim 10 of 2,023,636 is defined as an oral immunoglobulin collecting pad, comprising an >effective concentration= of the salts of a hypertonic solution while the collecting pad of claim 24 of 2,076,754 is defined as a pad, impregnated with a salt of a sufficient quantity to form a hypertonic solution in or adjacent to said pad, for collecting substances from an oral cavity. When the collecting pad is specifically defined as a dry pad in

dependent claims 25-26 the analyte remains undefined. Lastly, claim 14 of 2,023,636 defines an immunological testing kit for collecting and storing a substance comprising a pad, treated with a hypertonic solution, while 2,076,754 does not claim an immunological test kit *per se.*

(39) In sum, since the claim language of 2,076,754 is broader than the claim language of 2,023,636, the claims pertaining to Group A (methods) and Group B (products) cannot be considered to be identical or conterminous or directed towards the >same invention=. In this respect, the Board is in agreement with the Applicant=s position. However, double patenting does not require the existence of identical language. When claim language is similar yet not identical the claims must be patentably distinct to warrant issuance of a subsequent patent. This is the second branch of double patenting referred to by *Whirlpool, supra*.

B). In accordance with the second branch of double patenting, are the claims of 2,023,636 patentably distinct over the claims of 2,076,754?

(40) In the Final Action the Examiner did not explicitly address the second branch, >obviousness double-patenting= and thus the Applicant did not provide a response in that regard. The Examiner does, however, refer to the Apoint of invention@ of both applications as being the use of the hypertonic solution to collect a sample and considers the use of the pad and rinse solution equivalent.

(41) Typically, the application which claims the broadest subject matter precedes the application that claims the narrow or specific subject matter. However, in the instant situation application 2,023,636, which claims the narrow subject matter, was filed in August 20, 1990 prior to the filing of application 2,076,754 in February 27, 1991, which claimed and the broad

subject matter. While it is the claims that define and limit the patentee=s breadth of protection, the decision in *Pallmann Maschinenfabrik GmbH Co. KG v. CAE Machinery Ltd.* (1995), 62 C.P.R. (3d) 26, 98 F.T.R. 125, at paragraph 82, states that:

> A[the claims] must be read in light of the specification so that apparently broad language in the claims is to be limited where the specification when fairly read, clearly indicates that a broad interpretation cannot be supported
>
> ...
>
> the fact that some claims maybe narrower does not necessarily permit the court to afford broad protection to claims drafted more broadly for that reason alone@.

(42) Therefore, the narrow claim language of application 2,023,636 cannot be interpreted to encompass broader subject matter. However, the broadening of the method and product claims of application 2,023,636 to the collection of any analyte, in 2,076,754, may be considered to involve ingenuity if the broad significance arose from an unexpected unobvious determination, the nature of which is clearly indicated in the specification of the 2,076,754 patent.

(43) It is worth noting that patent 2,076,754 contains an additional inventor, David Zogg, over the inventors of application 2,023,636. While, the inclusion of an additional inventor does not singularly confirm an inventive contribution, it warrants a factual consideration as this additional inventor may have provided some inventive ingenuity to the group: *Aventis, supra*. Further, with respect to scientific disciplines the decision in *Bayer Ag v. Apotex Inc.* (1995), 60 C.P.R. (3d) 58 at paragraph 79, indicates that the Askilled technician can be a composite of scientists, researchers and technicians bringing their combined expertise to bear on the problem at hand@.

(44) Moreover, application 2,023,636 and patent 2,076,754 both claim priority from US application 486,415 filed February 28, 1990 and have subject matter in common. Subject matter pertaining to the use of a hypertonic solution to collect substances from the oral cavity, including the analytes listed in the table on page 6 and exemplified in examples 3-12, is specific to application 2,076,754 and is supported by US priority application 641,739 filed January 15, 1991, which was filed after the filing date of 2,023,636, August 20, 1990.

(45) However, since the later filed 2,076,754 application containing the broader claims issued to patent on July 25, 2000, the claims of application 2,023,636 can only support the issuance of a second patent if they are deemed unobvious, over the issued claims of 2,076,754.

i) Group A claims

(46) A hypertonic solution is defined in both the 2,023,636 application and the 2,076,754 patent as "a salt solution which has an ionic strength exceeding that found in blood" and the use of said hypertonic solution facilitates the production of immunoglobulins within the oral cavity for sample collection (pages 5-7). It is unknown whether the hypertonic solution facilitates the production of other components of saliva as nothing additional is indicated in the description in the 2,076,754 patent, other than to state that substances other than immunoglobulins were successfully obtained and that there is no limit to the size of the molecules which can be collected (pages 4-6).

(47) In application 2,023,636, Applicant sought to isolate sufficient immunoglobulins from saliva for use in immunological testing. At the filing date, oral samples collected by known methods typically contained about 0.01-0.1% of the immunoglobulins found in blood serum and therefore the testing of salivary specimens had not been extensively developed. Through

Applicant's investigation it was discovered that the use of a hypertonic rinse or dried pad containing the salts of a hypertonic solution resulted in a yield of immunoglobulins from saliva greater than would be expected which was 8-16 times more than that obtained when using distilled water.

(48) The importance of the hypertonic solution in the immunoglobulin collecting methods was further acknowledged by the Applicant in their response dated January 23, 2002, when describing the Acommon inventive thread@ unifying the claims, stating that Athe method is accomplished with the aid of a hypertonic solution@ and that Athere are two ways of doing this and those ways are set out in claims 1 and 15". Considering this response, the Examiner concluded that the point of invention, in both cases (application 2,023,636 and 2,076,754), was the use of the hypertonic solution in sample collection and equated the methods, pad and kit of application 2,023,636 to that of the methods and pads of Applicant=s patent 2,076,754.

(49) The first approach for specimen collection, referred to by the Applicant, uses a hypertonic rinse solution which is placed in the oral cavity and vigorously rinsed. The hypertonic rinse solution was successfully used to obtain total immunoglobulin titres and HIV antibody titres (immunoglobulins) from saliva and is the subject matter of claim 15.

15. A method of collection immunoglobulins for immunological testing comprising the steps of:

(a) rinsing the oral cavity of a patient with a pharmaceutically acceptable hypertonic solution, wherein the hypertonic solution is in an effective concentration to recover a high concentration of immunoglobulin, and

(b) collecting a specimen of the hypertonic solution after rinsing for analysis by immunological testing.

(50) The description of application 2,023,636 defines a preferred oral rinse solution, comprising sodium chloride which is representative of the hypertonic rinse solution used in examples 1-4. The rinse solution is similar to the hypertonic solution used in preparing the pads, however, the solution used to prepare the pads may also contain a blocking agent to prevent nonspecific binding to the pad and the pads are subsequently dried whereby retaining the salts of the hypertonic solution. In example 4, immunoglobulin titres between samples obtained from the oral cavity using a pad, an oral rinse or obtained from blood were compared. Further, example 4 of application 2,023,636 is identical to example 1 of 2,076,754, though the oral rinse solution is not specifically described in 2,076,754 other than by reference to US Patent 5,022,409 (US application, 410,401, filed September 21, 1989; which serves as a priority document for instant application 2,023,636) in the preamble of the example.

(51) Even though the Examiner considered the point of invention of both applications to be the use of a hypertonic solution to collect an oral sample, the means used in each of the respective methods is distinct. This is evident from the description of 2,023,636 which denotes Atwo approaches to collecting a specimen@, the first being the hypertonic rinse solution and the second being a pad containing the salts of the hypertonic solution. While each method uses a hypertonic solution to facilitate the recovery of immunoglobulins from saliva, the free flowing hypertonic rinse solution used in the method of claim 15 of application 2,023,636, and the pad impregnated with a salt, which absorbs oral fluid in the oral cavity forming a hypertonic solution in or adjacent to said pad, of claims 1, 2 and 6 of patent 2,076,754 denote two independent means for collecting said sample. Therefore, each means used in a method for collecting an oral sample, involves ingenuity and thus is considered a separate inventive concept. As such, the method of claim 15, and by extension claims 16 to 19, of application 2,023,636 which use a hypertonic rinse solution

to collect immunoglobulins for immunological testing are patentably distinct from the methods of claims 1, 2 and 6 of Applicant=s patent 2,076,754.

(52) The second approach for specimen collection, referred to by the Applicant, uses a pad containing the salts of the hypertonic solution to absorb saliva and mucosal secretions from the oral cavity and was successfully used to obtain total immunoglobulin titres and HIV antibody titres (immunoglobulins) from saliva and is the subject matter of claim 1.

1. A method of collecting immunoglobulins for immunological testing comprising the steps of:

(a) dipping a pad into a hypertonic solution wherein the hypertonic solution is in an effective concentration to recover a high concentration of immunoglobulin,

(b) drying the pad,

(c) inserting the dried pad into an oral cavity to collect immunoglobulins within the oral cavity, and

(e) eluting the collected immunoglobulins from the pad for analysis by immunological testing.

(53) In preparing the pad for use in said methods the hypertonic solution is applied to the pad by dipping the pad into the hypertonic solution so that the salts of the solution can be absorbed into and onto the pad, removing the pad from the solution and allowing the pad to dry (page 8). These steps of preparing the pad are included as part of the collection method of claim 1 and would therefore be considered essential steps to the method. As such, the method of collecting immunoglobulins of claim 1 can only use one form of the collection pad, the dry form.

(54) In 2,076,754 the claim language differs slightly from that of 2,023,636. Claims 1 and 2 of 2,076,754 define a broader method of collecting any analyte from an oral cavity and the only requirement for the pad used in the methods is that it is impregnated with a salt whereby

said pad absorbs an oral fluid from said oral cavity forming a hypertonic solution in or adjacent to said pad.

(55) Firstly, in order to define the term Aanalyte@ we should look to the description of 2,076,754. The table on page 6 lists a number of analytes which were successfully collected having molecular weights ranging from about 176 (cotinine) to about 950,000 (IgM) daltons. Included in this list are immunoglobulins ranging in molecular weight from 150,000 to 950,000, which encompass both general antibodies (IgG, IgA and IgM) and specific antibodies (HIV-1, hepatitis A, hepatitis B, rubeola, syphilis and non-treponemal). While the term Aanalyte@ encompasses a broad range of substances only the substances that were exemplified in examples 2-12 are specifically claimed which include claims to specific immunoglobulin species and sub-species. Claim 6 of 2,076,754 is reproduced below. Claim 5, on which claim 6 depends defines the analyte of claims 1 or 2 as having a molecular weight ranging from about 176 D to 950,000 D.

> 6. The method of claim 5, wherein said analyte is selected from the group consisting of cotinine, glucose, theophylline, cocaine, beta2-microglobulin, hepatitis A antibody, hepatitis B antibody, hepatitis B surface antigen, beta-human chorionic gonadotropin, and an immunoglobulin. [emphasis added]

(56) Even though patent 2,076,754 additionally claims specific immunoglobulin species and sub-species in dependent claims 7-8, the broad interpretation of immunoglobulin is equivalent for both 2,023,636 and 2,076,754. Thus, when an immunoglobulin is selected as the analyte in claim 6, both claim 1 of application 2,023,636 and claim 6 of 2,076,754 define methods for collecting immunoglobulins.

(57) As noted above, the pads used in the methods of claims 1 and 2 of 2,076,754 are impregnated with a salt whereby said pad absorbs an oral fluid from said oral cavity forming a hypertonic solution in or adjacent to said pad. According to the description of 2,076,754 the pads are impregnated with the hypertonic solution by any known means. One example being that the hypertonic solution could be applied to the pad by dipping the pad into the hypertonic solution so that the salts of the solution can be absorbed into and onto the pad, removing the pad from the solution and allowing the pad to dry (page 8). Even though example 2 of 2,076,754 is identical to example 5 of 2,023,636 and therefore by implication use the dry form of the pad in the sample collection, it is not specified which method was used to prepare the pads used in subsequent examples 3-12. These examples merely state that the "hypertonic solution-impregnated" pad "was prepared using the preferred pad preparation solution of the present invention" which is the same pad preparation solution which was used in the preparation of the dry pads of application 2,023,636. The inclusion of any known means and one example when describing the preparation of the absorbent pad plus the exclusion of steps specifying the preparation of the pad in method claims 1 and 2 suggests that the state of the pad itself is immaterial to its operation. Therefore, the use of the hypertonic solution in the pads of claims 1 and 2 of 2,076,754 and by extension claim 6 of 2,076,754 encompass both the wet and dry forms.

(58) As previously stated, subject matter pertaining to the use of a hypertonic solution to collect substances from the oral cavity, including the analytes listed in the table on page 6 and exemplified in examples 3-12, is specific to application 2,076,754. Applicant=s apparent subsequent discovery, in application 2,076,754, that the form of the pad comprising the salts of a hypertonic solution was immaterial to its operation and that the use of the hypertonic solution in the collection of samples from the oral cavity had broader utility than immunoglobulin collection

from salvia could not have been predicted in view of Applicant=s earlier filed application, 2,023,636. Thus the use of a wet or dry form of the pad in a method of collecting an analyte from an oral cavity is considered a separate, broader, inventive concept.

(59) However, dependent claim 6 of 2,076,754 specifically defines a method of collecting immunoglobulins from an oral cavity comprising the use of a wet or a dry form of the pad. Since the pad used in the method of claim 6 is claimed in the alternative, claim 6 encompasses methods of collecting immunoglobulins using a dry pad. As such, claim 1, and by extension claims 2 to 9, of application 2,023,636 are not patentably distinct from claim 6 of Applicant=s patent 2,076,754.

ii) Group B claims

(60) Next for consideration are the collecting pads themselves, group B. The pad of 2,023,636 is the subject of claim 10 and the pad also forms part of an immunological testing kit which is the subject of claim 14. These are compared to the pad of 2,076,754 which is the subject of claim 24. For clarity, claims 10, 14 of application 2,023,636 and claim 24 of patent 2,076,754 are reproduced below:

>636

10. An oral immunoglobulin collecting pad comprising an absorbent material and the salts of a hypertonic solution, wherein the salts of the hypertonic solution are in an effective concentration in the pad to recover a high concentration of immunoglobulins.

14. An immunological testing kit for collecting and storing substances from an oral cavity comprising a pad treated with a hypertonic solution; a pad holder; a container for storing the pad; a pad removal device; and a storage preservation solution.

>754

24. A pad for collecting substances from an oral cavity for testing, said pad comprising an absorbent material impregnated with a salt wherein said salt is in a sufficient quantity in the pad to form a hypertonic solution in or adjacent to said pad when said pad absorbs oral fluid from said oral cavity.

(61) Even though a patent application comprising claims of differing scope and form may disclose more than one inventive concept, the form of the claims themselves maybe insufficient to establish an inventive concept (*Merck & Co. v. Apotex Inc.* (2006) [53 C.P.R. (4th) 323); inventive ingenuity is still required to support a second patent (*GSK*). The kit of claim 14 of application 2,023,636 merely, lists components of the kit, which include a pad treated with a hypertonic solution and a container for storage. Following the reasoning of *Hoechst*, in which compounds and compositions were deemed to relate to the same inventive concept, the kit of claim 14 merely provides for a commercially available form of the pad. Combining a collecting pad into a kit with other non-inventive components does not constitute a separate invention over the pad itself. In this respect, for the purpose of the claim comparison, claim 14 is considered equivalent to claim 10 which claims the pad itself.

(62) In comparing the pads of group B, claim 10 of application 2,023,636 and claim 24 of 2,076,754 both comprise an absorbent material and salts of a hypertonic solution of effective concentration or sufficient quantity to recover components of saliva and both are capable of analyte collection. Further, as discussed for group A, application 2,023,636 only discloses a pad comprising the salts of a hypertonic solution for use in collecting immunoglobulins from the oral cavity prepared by dipping and drying the pad which is identical to the preferred embodiment of the pads of 2,076,754. Though not explicitly stated in claims 10 and 14 of application

2,023,636, the oral immunoglobulin collecting pad of claims 10 and 14 would be understood by a person skilled in the art, in view of the disclosure and methods of claim 1 as being directed towards said dry form of the pad.

(63) During the prosecution of application 2,076,754, in Applicant=s response dated February 3, 2000, claim 24 was amended to specify the amount of salt in the pad as >a sufficient quantity= capable of forming >a hypertonic solution=. The Applicant reasoned that the above expression was more accurate since the salt in the pad was the solid form and described the method for producing the pad as the impregnation of the pad with a salt solution and subsequent drying in accordance with that disclosed on page 8, lines 22 to 33 of the description. While, these statements by the Applicant suggest that the collecting pad of claim 24 is the dry pad form, as discussed for the use of the pads in the methods of group A, the pad of claim 24 is prepared by any known means. One preferred embodiment is to prepare the pad by dipping and drying the pad, which results in the pads of claims 10 and 14 of application 2,023,636. Claim 24, is therefore expressed in the alternative, providing for either a wet or dry pad form, whereas, claims 25 specifically defines the pad of the preferred embodiment. Claims 25 and 26 read as follows:

> 25. The pad of claim 24, wherein said pad is impregnated by said salt by:
>
> (a) dipping the pad into a hypertonic solution; and
>
> (b) drying the pad.

> 26. The pad of claim 24, wherein said pad is impregnated with said salt by:
>
> (a) spraying the pad with a hypertonic salt solution; and
>
> (b) drying the pad.

(64) Regardless of the steps required to prepare the dry pad, the pads of claims 25 and 26

are equivalent to the pads of claims 10 and 14 of application 2,023,636. Since both the wet and dry forms of the pad fall within the scope of claim 24, the pads of claim 10 and 14 are also equivalent to the pad of claim 24. As such, claims 10 and 14, and by extension claims 11-13, of application 2,023,636, are not patentably distinct in view of claims 24-26 of patent 2,076,754.

SUMMARY:

(65) In sum, in accordance with the first branch of double patenting claims 1-14 are not conterminous in view of the claims of patent 2,076,654. In accordance with the second branch of double patenting claims 1-14 of application 2,023,636 are obvious in view of the claims of patent 2,076,754 and the decision in the Final Action to reject claims 1-14 should be affirmed. In accordance with the first and second branches of double patenting, claims 15-19 of application 2,023,636 are neither conterminous nor obvious in view of the claims of patent 2,076,754 as they are directed towards a second inventive concept. The decision in the Final Action to reject claims 15-19 should therefore be reversed.

RECOMMENDATION OF THE BOARD:

(66) Therefore, the Board recommends that the Commissioner:

1) inform the Applicant that the Examiner=s rejection of claims 15 to 19 is reversed;

2) inform the Applicant in accordance with paragraph 31(c) of the *Patent Rules*,

that the following amendments, and only these amendments, of the application are necessary for compliance with the *Patent Act* and *Patent Rules*:

a) deletion of claims 1 to 14, and

b) renumbering of claims 15 to 19 as claims 1 to 5 respectively, with renumbering of the claim dependencies to the respective claim(s) where appropriate.

Nicole Harris	Ryan Jaecques	Ed MacLaurin
Board member	Board member	Board member

COMMISSIONER=S DECISION

(67) I concur with the findings and the recommendations of the Patent Appeal Board. Accordingly, I invite the Applicant to make the above amendments, and only these amendments, with in three (3) months from the date of this decision, failing which I intend to refuse the application.

Mary Carman

Commissioner of Patents

dated at Gatineau, Quebec,

this 22 day of April, 2009