Substitute Form PTO 1390 U.S. Department of Commerce Patent and Trademark Office TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. § 371	Attorney Docket Number: 50245/005001 U.S. Application Number: Not Yet Assigned

INTERNATIONAL APPLICATION NUMBER	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/CA2006/002009	December 11, 2006	December 9, 2005

TITLE OF INVENTION:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
APPLICANTS FOR DO/EO/US:	Muir et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.	☑ This is a FIRST submission of items concerning a filing under 35 U.S.C. § 371.
2.	☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. § 371.
3.	☑ This is an express request to begin national examination procedures (35 U.S.C. § 371(f)).
4.	☑ The U.S. has been elected.
5.	A copy of the International Application (35 U.S.C. § 371(c)(2)). ☑ a. is transmitted herewith (required only if not transmitted by the International Bureau). ☐ b. has been transmitted by the International Bureau. ☐ c. Is not required, as the application was filed with the United States Receiving Office (RO/US).
6.	An English language translation of the International Application into English (35 U.S.C. § 371(c)(2)). ☐ a. is transmitted herewith. ☐ b. has been previously submitted under 35 U.S.C. 154(d)(4).
7.	Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3)). ☐ a. are transmitted herewith (required only if not transmitted by the International Bureau). ☐ b. have been transmitted by the International Bureau. ☐ c. have not been made; however, the time limit for making such amendments has NOT expired. ☑ d. have not been made and will not be made.
8.	☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. § 371(c)(3)).
9.	☐ An oath or declaration of the inventors (35 U.S.C. § 371(c)(4)).
10.	☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. §371 (c)(5).
11.	☐ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98.
12.	☐ An assignment for recording. A separate cover sheet in compliance with 37 C.F.R. §§ 3.28 and 3.31 is included.
13.	☑ A preliminary amendment.
14.	☐ A substitute specification.
15.	☐ A power of attorney and/or change of address letter.
16.	☐ Request for Deferred Examination.
17.	☑ Application Data Sheet.
18.	☑ Other items or information: International Search Report and Written Opinion for PCT/CA2006/002009

ANCESTRY EX. 1002

19.	☑ The following fees are submitted:				
Basic National Stage Fee: $310				$310.00	
National Stage Search Fee If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4): $0 Search fee (37 C.F.R. § 1.445(a)(2)) has been paid on the international application to the USPTO as an International Search Authority: $100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB: $410 All other situations: $510				$410.00	
National Stage Examination Fee If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4): $0 All other situations: $210				$210.00	
Surcharge of $130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 C.F.R. § 1.492(h)).				$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	55 - 20 =	35	x $50	$1750.00	
Independent claims	2 - 3 =	0	x $210	$0.00	
Multiple dependent claims (if applicable)			+ $370	$370.00	
Application Size Fee: Additional fee for specification and drawings in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is $260 for each additional 50 sheets of paper or fraction thereof.					
TOTAL SHEETS	EXTRA SHEETS	Number of each additional 50 sheets or fraction thereof (round up to a whole number)	RATE		
47-100=	0/50=	0	$260	$0.00	
TOTAL OF ABOVE CALCULATIONS =				$3180.00	
Reduction of 1/2 for filing by small entity, if applicable. Applicant claims small entity status under 37 C.F.R. § 1.27*				$	
SUBTOTAL =				$1590.00	
Processing fee of $130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 C.F.R. § 1.492(f)). +				$0.00	
TOTAL NATIONAL FEE =				$1590.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. §§ 3.28, 3.31). $40.00 per property. +				$0.00	
TOTAL FEES ENCLOSED =				$1590.00	
				Amount to be refunded	$
				charged	$

☐ a. Enclosed is a check for $[**AMOUNT**] to cover the total fees.
☐ b. Enclosed is a check for [**$310/$155**] to cover the basic national stage fee; no other fees are being paid at this time.
☑ c. Please charge my Deposit Account No. 03-2095 in the amount of $1590.00 to cover the above fees.
☑ d. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 03-2095.

NOTE: Where an appropriate time limit under 37 C.F.R. §§ 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. § 1.137(a) or (b) must be filed and granted to restore the application to pending status.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Muir et al.	Confirmation No.:	Not Yet Assigned
Serial No.:	Not Yet Assigned	Art Unit:	Not Yet Assigned
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Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination of the above-captioned application, kindly amend the application as follows.

AMENDMENTS TO THE SPECIFICATION

On page 3 (line 3) of PCT/CA2006/002009 (WO 2007/068094 A2; copy enclosed), please amend the specification as follows:

This application is the U.S. National Stage of International Application No. PCT/CA2006/002009, filed December 11, 2006, which, in turn, claims the benefit of ~~This application claims priority to~~ United States Application Serial No. 60/748,977 filed on December 9, 2005, the contents of which are hereby incorporated by reference in its entirety.

AMENDMENTS TO THE CLAIMS

1. (Original) A container system for releasably storing a substance, comprising:

a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member; and

b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir,

wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

2. (Currently amended) The container system ~~according to~~ of claim 1 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir, said wall having a sealing surface for sealingly attaching said pierceable membrane.

3. (Currently amended) The container system ~~accordingly to any one~~ of claim 1~~claims 1~~

~~or 2~~, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

4. (Currently amended) The container system ~~according to any one~~ of claim 1~~claims 1-3~~, wherein said pierceable membrane is inert.

5. (Currently amended) The container system ~~according to any one~~ of claim 1~~claims 1-4~~, wherein said pierceable membrane remains intact and pierceable at temperatures of from about -80°C to about 70°C.

6. (Currently amended) The container system ~~according to any one~~ of claim 1 ~~claims 1-5~~, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

7. (Currently amended) The container system ~~according to~~ of claim 1, wherein the width of said first end is approximately equivalent to the width of said second end.

8. (Currently amended) The container system ~~according to~~ of claim 1, wherein said first end is generally wider than said second end.

9. (Currently amended) The container ~~system according to any one~~ of claim 1 ~~claims 1 – 8~~, wherein said chamber is configured to receive about 1 ml to about 16 ml of said sample.

10. (Currently amended) The container system ~~according to~~ of claim 9, wherein said chamber is configured to receive about 1 ml to about 4 ml of said sample.

11. (Currently amended) The container system ~~according to any one~~ of claim 1~~claims 1 – 10~~, wherein the said piercing member extends from a base surface of said chamber.

12. (Currently amended) The container system ~~according to~~ of claim 11, wherein said piercing member extends approximately perpendicularly from said base.

13. (Currently amended) The container system ~~according to~~ of claim 11, wherein said piercing member is angled inwardly or outwardly toward said first open end of said vial.

14. (Currently amended) The container system ~~according to any one~~ of claim 1 ~~claims 1 – 13~~, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall.

15. (Currently amended) The container system ~~according to~~ of claim 14, wherein said side wall further includes a second cutting edge.

16. (Currently amended) The container system ~~according to any one~~ of claim 1 ~~claims 1 – 15~~, wherein said vial comprises a plurality of piercing members.

17. (Currently amended) The container system ~~according to~~ of claim 16, wherein said vial comprises three piercing members.

18. (Currently amended) The container system ~~according to~~ of claim 16, wherein said vial comprises two piercing members.

19. (Currently amended) The container system ~~according to any one~~ of claim 1 ~~claims 1 – 18~~, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system following movement of said container system to said piercing position.

20. (Currently amended) The container system ~~according to~~ of claim 19, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said vial when the system is said piercing position.

21. (Currently amended) The container system ~~according to any one~~ of claim 1 ~~claims 1 – 20~~, wherein said vial and said lid are sized for shipping in both an unattached state and an attached state.

22. (Original) A container system for releasably storing a substance, comprising:

a) a vial comprising a chamber for retaining a sample

b) a lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir; and

c) a funnel comprising a first open end for receiving said sample, a piercing member and a channel extending from said first open end to a second open end and being in fluid communication with said chamber, said funnel being removably attachable to said lid at said first open end and releasably or permanently attached to said vial at said second end,

wherein, when said system is closed by removable attachment of said lid to said funnel, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir

and said chamber, via said channel, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

23. (Currently amended) The container system ~~according to~~ of claim 22 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir and including a sealing surface for sealingly attaching said pierceable membrane.

24. (Currently amended) The container system ~~accordingly to any one~~ of claim 22~~claims 22 or 23~~, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

25. (Currently amended) The container system ~~according to any one~~ of claim 22 ~~claims 22 – 24~~, wherein said pierceable membrane is inert.

26. (Currently amended) The container system ~~according to any one~~ of claim 22~~claims 22 – 25~~, wherein said pierceable membrane maintains intact and pierceable at temperatures of from about -80°C to about 70°C.

27. (Currently amended) The container system ~~according to any one~~ of claim 22~~claims 22 – 26~~, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

28. (Currently amended) The container system ~~according to any one~~ of claim 22~~claims 22 – 27~~, wherein said piercing member extends from an interior surface of said funnel.

29. (Currently amended) The container system ~~according to~~ of claim 28, wherein said piercing member is angled inwardly or outwardly toward said first open end of said funnel.

30. (Currently amended) The container system ~~according to any one~~ of claim 22~~claims 22 – 29~~, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall.

31. (Currently amended) The container system ~~according to~~ of claim 30, wherein said side wall includes a second cutting edge.

32. (Currently amended) The container system ~~according to any one~~ of claim 22 ~~claims 22 – 31~~, wherein said funnel comprises a plurality of piercing members.

33. (Currently amended) The container system ~~according to~~ of claim 32, wherein said funnel comprises three piercing members.

34. (Currently amended) The container system ~~according to~~ of claim 33, wherein said funnel comprises two piercing members.

35. (Currently amended) The container system ~~according to any one~~ of claim 22 ~~claims 11 – 34~~, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system.

36. (Currently amended) The container system ~~according to~~ of claim 35, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said funnel when the system is in the piercing position.

37. (Currently amended) The container system ~~according to any one~~ of claim 22 ~~claims 22 – 36~~, wherein said vial is releasably attached to said funnel and sized for attachment to a cap when released from said funnel.

38. (Currently amended) The container system ~~according to any one~~ of claim 22~~claims 22 – 37~~, wherein said vial is configured for use in standard laboratory equipment.

39. (Currently amended) The container system ~~according to~~ of claim 38, wherein said vial has dimensions that conforms with industry-standard dimensions for a blood collection tube.

40. (Currently amended) The container system ~~according to~~ of claim 38 ~~or 39~~, wherein said vial is a T501 tube.

41. (Currently amended) The container system ~~according to any one~~ of claim 22 ~~claims 22 – 40~~, wherein said chamber is sized to hold about 1 ml to about 16 ml.

42. (Currently amended) The container system ~~according to any one~~ of claims ~~1 – 41~~1 or 22, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample.

43. (Currently amended) The container system ~~according to~~ of claim 42, wherein said nucleic acid is DNA or RNA.

44. (Currently amended) A method of combining a substance with a biological sample, comprising:

(a) providing ~~a~~ the container system ~~according to any one~~ of claim 1 ~~claims 1-21~~;

(b) providing the sample to the chamber in the vial; and

(c) closing said container system by removably attaching said lid to said vial; and

(d) piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

45. (Currently amended) A method of combining a substance with a biological sample, comprising:

(a) providing ~~a~~ the container system ~~according to any one~~ of claim 22 ~~claims 22 – 41~~;

(b) providing the sample to the chamber in the vial through said funnel; and

(c) closing said container system by removably attaching said lid to said first open end of said funnel; and

(d) piercing said membrane to release said substance into said chamber by moving said system to said piercing position.

46. (Currently amended) The method ~~according to~~ of claim 44 or 45, wherein the substance is a nucleic acid preserving substance.

47. (Currently amended) The method ~~according to any one~~ of claim 44 ~~–46~~or 45, wherein the sample is a biological sample.

48. (Currently amended) The method ~~according to any one~~ of claim 44~~–47~~ or 45, for archiving the sample.

49. (Currently amended) A kit for sample collection and storage, comprising:

a) a container system ~~according to any one~~ of ~~claims 1 to 43~~ claim 1 or 22; and

b) instructions for the use thereof.

50. (Cancelled)

REMARKS

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 6/9/08

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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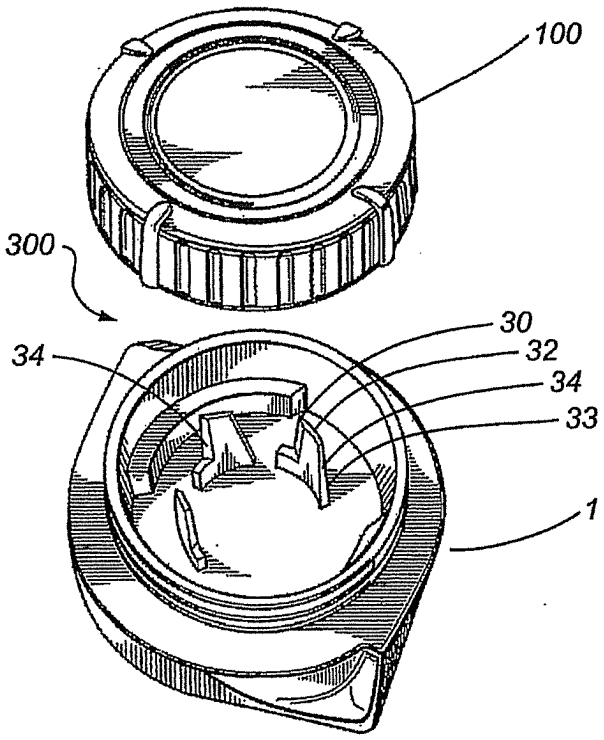

(57) Abstract: The present invention provides a container system for releasably storing a substance. The container system includes a vial having a sample storage chamber and a piercing member for piercing a membrane in the lid, which membrane seals a substance within a reservoir in the lid until the membrane is pierced by the piercing member. The container system optionally includes a funnel. There is also provided a method and kit for use of such a container system.

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GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

RELATED APPLICATION

This application claims priority to United States Application Serial No. 60/748,977 filed on December 9, 2005, the contents of which are hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

The field of the invention generally relates to a container system for releasably storing a substance.

BACKGROUND

It is often desirable to store a substance, such as a liquid, solid, gas, mixtures thereof, or the like, in a container prior to mixing the contents of the container with another material. For example, it may be desirable to package and store a compound, or compounds, in a container for shipping and/or safe storage and handling, prior to combining the compound(s) with another material. It may be desirable to package and store a toxic compound in a container, prior to combining such a toxic compound with a detoxifying material. As well, it is often desirable to keep a concentrated active ingredient separate from a diluent until immediately prior to use.

Moreover, it may be desirable to store and/or ship diagnostic and/or nucleic acid preserving compositions prior to combining such a substance with a biological sample.

Additionally, it may be desirable to keep a substance isolated from a donor until the donor's biological sample has been collected. This will help to prevent the donor from accidentally ingesting or spilling the substance.

It may also be desirable to inactivate pathogens/infectious particles in a biological sample by combining it with a stored substance prior to storage and/or shipping and/or handling of the sample.

It may also be desirable to store and/or ship diagnostic and/or nucleic acid preserving compositions after combining such a substance with a biological sample.

There are a variety of containers for holding substances separately in such a manner that a user may open a closure to combine the substances. Typically these containers are double compartment systems in which substances are stored separately and substances are combined by removal of the container closures by a user.

International PCT application WO 2003/104251 describes a container for collecting a biological sample from a subject, and subsequently mixing the collected sample with a composition intended to stabilize, preserve, or facilitate the recovery of components of the sample. This container has a first region for collecting a biological sample, a second region containing a composition for preserving a nucleic acid, and a barrier between the first region and the second region, which when in a closed position, maintains the sample and composition separate. The exemplified barrier of WO 2003/104251 is a pivoting partition. Attachment of a lid to the container forces the barrier to pivot from its original closed position spanning the container and thereby separating the first region and the second region, to an open position in which both regions are exposed to each other and contact between the composition contained in one region space and the biological sample contained in the other region is allowed. A drawback of this container is that it includes multiple parts (e.g., lid, vial, disk, rod, rod holder), which increases the cost of manufacture of the container. Additionally, because the disk is held in place by friction fit, there must be a high degree of precision for the manufacture of the components of the container.

There remains a need for an improved container system for releasably and reliably storing a substance.

This background information is provided for the purpose of making known information believed by the applicant to be of possible relevance to the present invention. No admission is necessarily intended, nor should be construed, that any of the preceding information constitutes prior art against the present invention.

SUMMARY OF THE INVENTION

The present invention generally relates to a container system for releasably storing a substance.

In accordance with one aspect of the present invention, there is provided a container system for releasably storing a substance, comprising: a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member; and b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir, wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

In accordance with another aspect of the present invention, there is provided a container system for releasably storing a substance, comprising: a) a vial comprising a chamber for retaining a sample b) a lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir; and c) a funnel comprising a first open end for receiving said sample, a piercing member and a channel extending from said first open end to a second open end and being in fluid communication with said chamber, said funnel being removably attachable to said lid at said first open end and releasably or permanently attached to said vial at said second end, wherein, when said system is closed by removable attachment of said lid to said funnel, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, via said channel, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

In accordance with another aspect of the present invention, there is provided a method of combining a substance with a biological sample, comprising: (a) providing a container system as described herein; (b) providing the sample to the chamber in the vial;

and (c) closing said container system by removable attachment of the lid to the vial or funnel; and (d) piercing the membrane to release said substance into said chamber by moving the system to said piercing position.

In accordance with another aspect of the present invention there is provided a kit for releasably storing a substance comprising: a) a container system as described herein; and b) instructions for the use thereof.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a cross-sectional view of a container system in accordance with one embodiment of the present invention, showing the lid and vial attached;

Figure 2 is a perspective view of the interior of the lid of the container system depicted in Figure 1;

Figure 3 is a perspective view of the interior of the vial of the container system depicted in Figure 1;

Figure 4 is a perspective view of a container system in accordance with one embodiment of the present invention;

Figure 5 is a top view of the container system depicted in Figure 4;

Figure 6 is a side view of the container system depicted in Figure 4;

Figure 7 is a side view of the container system depicted in Figure 4;

Figure 8 is a bottom view of the container system depicted in Figure 4;

Figure 9 is a cross-sectional view of the container system of Figure 4 taken along line A-A in Figure 5;

Figure 10 is a top perspective view of the container system depicted in Figure 4 showing the lid and vial separated;

Figure 11 is a bottom perspective view of the container system depicted in Figure 4 showing the lid and vial separated;

Figure 12 is a side perspective view a container system in accordance with one embodiment of the present invention;

Figure 13 is a top view of the container system depicted in Figure 12;

Figure 14 is a bottom view of the container system depicted in Figure 12;

Figure 15 is a side view of the container system depicted in Figure 12;

Figure 16 is a cross-sectional view of the container system of Figure 12 taken along line B-B in Figure 15;

Figure 17 is a side perspective view of the container system depicted in Figure 12;

Figure 18 is a top perspective view of the container system depicted in Figure 12, showing the lid and funnel separated;

Figure 19 is a bottom side perspective view of the container system depicted in Figure 12, showing the lid and funnel separated;

Figure 20 is a side view of the vial and cap of the container system depicted in Figure 9;

Figure 21 is a side view of the container system depicted in Figure 12, showing the lid, funnel, and vial separated;

Figure 22 is a side perspective view a container system in accordance with one embodiment of the present invention;

Figure 23 is a top perspective view of the vial portion of the container system depicted in Figure 22, showing the vial; and

Figure 24 is a cross-sectional view of the lid of the container system depicted in Figure 22.

The numbers in bold face type serve to identify the component parts that are described and referred to in relation to the drawings depicting various embodiments of the present invention. It should be noted that in describing various embodiments of the present invention, the same reference numerals have been used to identify the same or similar elements. Moreover, for the sake of simplicity, parts have been omitted from some figures of the drawings.

DETAILED DESCRIPTION OF THE INVENTION

As will be discussed in more detail below, the present invention provides a container system for releasably storing a substance.

The container system of the present invention has fewer parts and, thus, is less expensive and/or easier to manufacture, than previous containers. Additionally, the manufacturing tolerances can be less precise for the container system of the present invention, as compared to previous containers having separable compartments. Again, this reduces manufacturing cost, and makes accidental disruption of a sealed substance less likely. Additionally, in one example of the present invention, the container system includes a removable vial which is suitable for subsequent processing of samples and/or for use in robotic systems.

The container system of the present invention comprises a vial and a lid. Optionally, the container system additionally comprises a funnel that is permanently or removably attached to the vial and that sealingly engages the lid. The lid is configured to store a substance, and subsequently release the substance from the lid when the lid is sealingly attached to the vial, or the funnel. In use, the substance stored within the lid is released into the vial when the lid is attached to the vial or the funnel, if present.

In accordance with a specific embodiment of the present invention, the lid is suitable to store a substance to stabilize, preserve or facilitate the recovery of nucleic acid from a biological sample. In accordance with a related embodiment, the vial, or the combination of the funnel and vial is suitable for the collection of a biological sample from a subject.

Referring to the Figures 1-11 and 22-24, container system **300** comprises lid **100** and vial **1.**

LID

Lid **100** releasably stores a substance. Lid **100** is generally cylindrically shaped with at least one open end. Lid **100** can be a variety of shapes, as determined by the needs or preferences of the user and/or the intended application of use. The interior of lid **100** includes wall **104** that is positioned within lid **100** and defines reservoir **102** for holding a substance such as a liquid, solid, semi-solid, gas, mixtures thereof and the like. Wall **104** defines all or a portion of the perimeter of reservoir **102.** Wall **104** includes sealing surface **106** which is for sealingly attaching pierceable membrane **160**

Pierceable membrane **160** (depicted in Figure 19) acts as a physical barrier to releasably store a substance within reservoir **102,** when attached to sealing surface **106.** Pierceable membrane **160** is made from material that is inert to the substance to be stored within the reservoir. Pierceable membrane **160** permits little or no diffusion of the substance through pierceable membrane **160** over time. Pierceable membrane **160** is made from a material that is suitable for the intended processing, storage and/or transportation conditions. In a specific embodiment, pierceable membrane **160** is heat and cold resistant such that it remains intact and pierceable at temperatures ranging from about -80°C to about +70°C. In a specific embodiment, pierceable membrane **160** can be attached tightly enough to sealing surface **106** such that pierceable membrane **160** will not be disrupted by vacuum pressures. Pierceable membrane **160** can be made from a variety of materials including polypropylene. Desirably, pierceable membrane **160** is made from the same material as wall **104.** The thickness of pierceable membrane **160** can vary according to application of use, and preference of the user. Desirably, pierceable membrane **160** has a thickness of about two thousandths of an inch. However, the specific thickness of the membrane will be determined by factors such as, nature of the substance, nature of the sample, overall dimensions of the container system and chemical composition of the membrane.

A variety of methods of attaching pierceable membrane **160** to sealing surface **106** can be used, and is dependent on the material used to make lid **100,** the substance stored

within reservoir **102**, and/or the characteristics of membrane **160**. Such methods of attachment include use of adhesive(s), heat-sealing treatment, fasteners, or any combination thereof, and the like. Desirably, heat-sealing is used to attach pierceable membrane **160** to sealing surface **106**. As will be clear to the skilled worker, the type of pierceable membrane, the physical and/or chemical properties of the pierceable membrane will be dependent upon, in part, the composition to be stored. Desirably pierceable membrane **160** is inert with respect to the intended use, stored substance and sample of the container system.

In the specific embodiments depicted in the Figures, lid **100** comprises internal helical threads **108** on the inner surface of outer wall **110**, which are adapted to engage external helical threads **18** on the outer surface of wall **12** on vial **1**. As would be appreciated by a skilled worker, alternative means for releasable attachment of lid **100** to vial **1** can be used in the container system of the present invention, provided that lid **100** and vial **1** are movable to a piercing position, as discussed in greater detail below.

Lid **100** and reservoir **102** can be sized to accommodate a range of volumes of a substance. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, reservoir **102** accommodates about 1 ml to about 4 ml of a substance. The choice of material used to manufacture lid **100** is dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, lid **100** is made from plastics such us polypropylene, medium-density polyethylene (MDPE), high-density polyethylene (HDPE), polyethylene and the like. Desirably, lid **100** is polypropylene. The materials of lid **100** may be opaque, transparent or translucent, depending on the desired application. For example, an opaque material can be used to store a light sensitive composition(s). A transparent or translucent material is desirable if a visual (e.g., colour) indicator is present in the stored substance. Lid **100** and reservoir **102** can be manufactured to include gradations to demarcate the quantity of the substance stored within reservoir **102**. The outer surface of lid **100** can also include a labelling area for a user to identify the contents of the lid. The outer surface of lid **100** may also include a region to affix or emboss a logo and/or other markings.

In accordance with one embodiment of the present invention, wall **104** has a generally cylindrical shape sized to fit within the interior of lid **100**. It will be clear that the shape and size of well **104** is dependent upon the intended use of the container system. Lid **100** may be constructed from a single piece of material that includes wall **104**, or wall **104** may be removably attached to lid **100**. Desirably, lid **100** is formed from a single piece of material.

VIAL

In accordance with one embodiment of the present invention, vial **1** is generally cylindrically shaped with at least one open end. Vial **1** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use. The interior of vial **1** comprises chamber **2** for receiving a sample such as a liquid, solid, semi-solid, mixtures thereof and the like. Desirably, chamber **2** is configured to receive a biological sample, for example a sputum sample, such as saliva.

Vial **1** comprises a first open end for receiving said sample, and a second end comprising chamber **2**. In one example, said second end is a second closed end. In another example, said second end is a second open end.

In one example, the width of the first open end of vial **1** is approximately equivalent to the width of the second end.

In another example, the first open end of vial **1** is generally wider than the second end vial **1**. In this example, the generally wider first open end facilitates sample collection by, for example, acting similar to a funnel.

In accordance with one embodiment, and as shown in Figure 22-24, container system **300** comprises a funnel fixedly attached to, or integral with, vial **1**. In the case in which the funnel is fixedly attached to, or integral with vial **1**, it can also be characterised as a vial having a wide mouth opening for receiving a sample. The wide mouth or funnel characteristics can make it easier for a subject to provide a sample.

Vial **1** and chamber **2** can be sized to accommodate a range of volumes of a sample. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, chamber **2** accommodates about 1 ml to about 4 ml of a sample. In another specific embodiment, chamber **2** accommodates about 1 ml to about 16 ml of a sample.

Vial **1** comprises at least one piercing member **6**. In the specific embodiment depicted in Figures 1-11 piercing member **6** extends from a base surface of chamber **2**. In one example, piercing member **6** extends approximately perpendicular from the base. In another example, piercing member **6** is angled inwardly or outwardly toward the open end of vial **1**. Alternatively, piercing member **6** extends from an interior surface of said vial. In one example, piercing member **6** extends from an interior surface of said vial and is angled inwardly or outwardly toward the open end of vial **1**.

In one example, there is one piercing member **6** within chamber **2**. In an alternative example, there is a plurality of piercing members **6**, for example, two piercing members, three piercing members or more than three piercing members. In one example the piercing members are arranged in a generally semicircular fashion. In a specific example, in the case of three piercing members, the piercing members are arranged in a generally semicircular fashion, as depicted in Figure 9, 10 and 23.

Piercing member **6** can be approximately trapezoidal in shape and includes first cutting edge **33** having pointed end **30** at one corner of the trapezoid and a second end at a second corner of the trapezoid where cutting edge **32** intersects side wall **34**. Optionally, side wall **34** also includes cutting edge **33**, which extends from cutting edge **32**.

Container system **300** further includes a means for sealing attachment of lid **1** to vial **100**. Such sealing means act to ensure that the contents of vial **1** remain sealed with chamber **2** when lid **100** is attached to vial **1**.

In one example, lid **100** and vial **1** are movable between an open position and a piercing position. In a specific example, lid **100** is initially attached to vial **1** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. Initially, lid **100** and vial **1** are threadingly connected, but piercing member **6** does not disrupt pierceable

membrane **160** and end portion **30** of wall **12** engages sealing wall **120.** For example, as depicted in Figure 9, sealing wall **120** extends downwardly and outwardly from the interior of lid **100.** This type of sealing mechanism is similar to a wipe seal that would be well known to the skilled worker. Thus, initially, chamber **2** is maintained out of fluid communication with reservoir **102** by pierceable membrane **160.**

In an alternate example, lid **100** and vial **1** are movable between a first position and a piercing position. In a specific example, lid **100** is initially attached to vial **1** by threadingly engaging internal and external threads **108** and **18** with a twisting motion and thereby moved to the first position. In moving lid **100** and vial **1** to the first position, lid **100** and vial **1** are threadingly connected, but piercing member **6** does not disrupt pierceable membrane **160.** In the first position, end portion **30** of wall **12** sealingly engages sealing wall **120.** For example, as depicted in Figure 9, sealing wall **120** extends downwardly and outwardly from the interior of lid **100.** This type of sealing mechanism is similar to a wipe seal that would be well known to the skilled worker. Thus, in the first position, chamber **2** is sealed against leakage to the outside of the container system by sealing engagement of wall **12** with sealing wall **120** and maintained out of fluid communication with reservoir **102** by pierceable membrane **160.**

A worker skilled in the art will recognize that there are known alternative sealing structures that can be incorporated into the present system for ensuring that chamber **2** is sealed against leakage to the outside of the container system. Such alternatives are considered to be within the scope of the present invention.

Continued twisting moves lid **100** and vial **1** from the open position, or the first position, to the piercing position, in which movement of lid **100** and vial **1** together results in disruption of pierceable membrane **160** by piercing member **6,** and the release of the substance within reservoir **102** into chamber **2.**

In operation, in moving to the piercing position, pointed end **31** of piercing member **6** is brought into contact with pierceable membrane **160** and pierces pierceable membrane **160.** Continued twisting moves cutting edge **32** through pierceable membrane **160,** disrupting pierceable membrane **160,** and thereby producing an opening in the sealing

membrane to enable the substance to enter chamber **2**. It will be clear that if more than one piercing member is present, less twisting of lid **100** and vial **1** is required to generate an opening. When three piercing members are present, a suitable opening is obtainable in about one quarter of a turn. Desirably, pierceable membrane **160** is not completely removed from sealing surface **106**. Thus, in the piercing position, piercing member **6** disrupts pierceable membrane **160** to allow fluid communication between reservoir **102** and chamber **2**.

The distance between piercing member **6** and wall **104** will vary according to the needs and preferences of the user. The distance between piercing member **6** and wall **104** can vary from being generally flush with one another, to being generally separated from one another.

It will be clear to the skilled worker that length, rigidity and the like, of piercing member **6** is selected such that it is sufficient to disrupt pierceable membrane **160** when lid **100** and vial **1** are in the piercing position, and not disrupt the pierceable membrane **160** when lid **100** and vial **1** are in the open or first position.

The choice of the material of vial **1** will be dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. Additionally, the construction material of lid **1** may be same or different as that used to make reservoir **6**. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, vial **1** is made from plastics such us polypropylene, medium-density polyethylene (MDPE), high-density polyethylene (HDPE), polyethylene and the like. Desirably, vial **1** is HDPE.

In accordance with another aspect of the present invention, the container system comprises a lid, a funnel and a vial.

Referring to the Figures 12-21, container system **600** comprises lid **100** and funnel **400** and vial **500**.

LID

Lid **100** releasably stores a substance, as described above.

FUNNEL

Funnel **400** includes a first open end for receiving a sample, a second open end for removable or fixed attachment to vial **500**. In one embodiment, funnel **400** is integral with vial **500**. The interior of funnel **400** comprises interior channel **422** extending therethrough for maintaining the first open end and the second open end in fluid communication and for receiving a sample such as a liquid, solid, semi-solid, mixtures thereof and the like. Funnel **400** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use. Desirably, interior channel **422** is configured to receive a biological sample. For example, the biological sample is a sputum sample, such as saliva. Interior channel **422** can be sized accommodate a range of volumes of sample.

In the specific embodiments depicted in the Figures, lid **100** comprises internal helical threads **108** on the inner surface of outer wall **110**, which are adapted to engage external helical threads **418** on the outer surface of wall **412** on funnel **400**. As would be appreciated by a skilled worker, alternative means for releasable attachment of lid **100** to funnel **400** can be used in the container system of the present invention, provided that lid **100** and funnel **400** are movable to the piercing position, as discussed in greater detail above.

Funnel **400** comprises at least one piercing member **6**. In accordance with the embodiment depicted in Figures 12-21, piercing member **6** extends from an interior surface (interior side wall **420**) of funnel **400**. In one example, piercing member **6** is angled inwardly or outwardly toward pierceable membrane **160**. Other arrangements of piercing member **6** can be used, as would be readily appreciated by the skilled worker.

In one example, there is one piercing member **6** within interior channel **422**. In an alternative example there is a plurality of piercing members, for example, two piercing members, three piercing members or more than three piercing members. In the case of three piercing members, desirably the piercing members are arranged in a generally semicircular fashion, as shown in Figure 18.

As above, piercing member **6** can be approximately trapezoidal in shape and includes first cutting edge **33** having pointed end **30** at one corner of the trapezoid and a second end at a second corner of the trapezoid where cutting edge **32** intersects side wall **34**. Optionally, side wall **34** also includes cutting edge **33**, which extends from cutting edge **32**.

Container system **600** further includes a means for sealing attachment of lid **1** to funnel **400**. Such sealing means act to ensure that the contents of vial **1** remain sealed with chamber **2** when funnel **400** and vial **500** are attached to vial **1**.

Optionally, funnel **400** includes outwardly extending ribs **402** that can used by a user to twist funnel **400** and lid **100**, and/or funnel **400** and vial **500**.

The choice of the material of funnel **400** will be dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. Additionally, the construction material of funnel **400** may be same or different as that used to make lid **100** and collection vial **500**. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, funnel **400** is made from plastics such us polypropylene, high-density polyethylene (HDPE), polyethylene, medium-density polyethylene (MDPE), or any combination thereof, and the like. Desirably, vial **1** is HDPE.

In a specific example, lid **100** is polypropylene, vial **500** is polypropylene and funnel **400** is HDPE.

VIAL

Vial **500** (or collection vial **500**) is generally cylindrically shaped with an open end for removable or fixed attachment to the second end of funnel **400**, and chamber **530** for receiving a sample. Vial **500** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use, and can be specifically manufactured for use in the container system of the present invention or can be a commercially available vial. As noted above, and in one embodiment, funnel **400** is integral with vial **500**. When the container system is used for laboratory purposes, desirably, vial **500** is sized to fit within a standard test tube rack such as that typically used in biological sample processing. In one example, vial **500** conforms with industry-standard dimensions for blood collection tubes

(e.g., 13 mm x 75 mm). Desirably vial **500** is suitable for use with robotic DNA purification systems (e.g., the Beckman BioMek™ FX). Desirably, vial **500** is commercially availably from Simport Plastics Limited (e.g., the T501 tubes).

The open end of vial **500** is also configured for securing attachment with a standard cap **520**, as shown in Figure 21. Cap **520** can be secured by a threaded screw, snap-fit, and the like.

Vial **500** optionally includes surface **502** that is suitable for labelling and/or for providing friction for gripping by a user.

Vial **500** may be removably attached to funnel **400** using a variety of locking mechanisms. In accordance with one embodiment of the present invention, the locking mechanism is a helical threaded screw. Alternatively, the locking mechanism is a snap-fit. Alternatively, vial **500** is fixedly attached to, or integral with, funnel **400**.

In one example, lid **100** and funnel **400** are movable between an open position and a piercing position, as discussed supra with lid **100** and vial **1**. In a specific example, lid **100** is initially attached to funnel **400** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. Initially, lid **100** and funnel **400** are threadingly connected, but piercing member **6** does not disrupt pierceable membrane **160**, and end portion **30** of wall **12** engages sealing wall **120**. As depicted in Figures 9 and 16, sealing wall **120** extends downwardly and outwardly from the inner surface of lid **100**. This type of sealing mechanism is similar to a wipe seal, that would be well known to the skilled worker. Thus, initially, interior channel **422** is maintained out of fluid communication with said reservoir **102** by pierceable membrane **6**.

In an alternate example, lid **100** and funnel **400** are movable between a first position and a piercing position, as discussed supra with lid **100** and vial **1**. Lid **100** is initially attached to funnel **400** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. In moving lid **100** and funnel **400** to the first position, lid **100** and funnel **400** are threadingly connected, but piercing member **6** does not disrupt pierceable membrane **160**. In the first position, end portion **30** of wall **12** sealingly engages sealing

wall **120**. As depicted in Figures 9 and 16, sealing wall **120** extends downwardly and outwardly from the inner surface of lid **100**. This type of sealing mechanism is similar to a wipe seal, that would be well know to the skilled worker. Thus, in the first position, interior channel **422** is sealed against leakage to the outside of the container system and maintained out of fluid communication with said reservoir **102** by pierceable membrane **6**.

Continued twisting moves lid **100** and funnel **400** from either the open position or the first position, to the piercing position, in which moving lid **100** and vial **1** together results in disruption of pierceable membrane **160** by piercing member **6**, and the release of the substance within reservoir **102** into chamber **2** and vial **500**.

In operation, in moving to the piercing position, pointed end **30** is brought into contact with pierceable membrane **160** and subsequently pierces pierceable membrane **160**. Continued twisting moves cutting edge **32** through pierceable membrane **160**, thereby disrupting pierceable membrane **160** and producing an opening in pierceable membrane **160** to permit the substance to enter interior channel **422**. If more than one piercing member is present, less twisting of lid **100** and vial **1** is required to generate an opening. When three piercing members are present, a suitable opening is obtainable in about one quarter of a turn. Thus, in the piercing position, piercing member **6** disrupts pierceable membrane **160** to allow fluid communication between reservoir **102** and interior channel **422**.

The distance between piercing member **6** and wall **104** will vary according to the needs and preferences of the user. The distance between piercing member **6** and wall **104** can vary from being generally flush with one another, to being generally separated from one another.

It will be clear to the skilled worker that length, rigidity and the like, of piercing member **6** is selected such that it sufficient to disrupt pierceable membrane **160** when lid **100** and vial **1** are in the piercing position, and not disrupt the pierceable membrane **160** when lid **100** and vial **1** are in the open or first position.

METHODS

According to one embodiment of the present invention, the container system of the present application is suitable for releasably storing a composition intended to stabilize, preserve, or facilitate the recovery of nucleic acid from a biological sample. A biological sample can include bodily fluids and/or tissues.

Desirably, vial 1 and/or funnel **400** are sized for collecting a biological sample from a subject. Non-limiting examples of biological samples include skin, hair, fecal matter, bodily fluids, tissue, cells and the like.

The term "bodily fluid", as used herein, refers to a naturally occurring fluid from a human or an animal, such as saliva, sputum, serum, plasma, blood, pharyngeal, nasal/nasal pharyngeal and sinus secretions, urine, mucus, gastric juices, pancreatic juices, feces, semen, products of lactation or menstruation, tears, or lymph.

The term "bodily tissue" or "tissue", as used herein, refers to an aggregate of cells usually of a particular kind together with their intercellular substance that form one of the structural materials of a plant or an animal and that in animals include connective tissue, epithelium, muscle tissue, and nerve tissue, and the like.

The term "nucleic acid", as used herein, refers to a chain of nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), typically found in chromosomes, chromatin, mitochondria, ribosomes, cytoplasm, nucleus, microorganisms or viruses.

The term "ribonucleic acid" or "RNA", as used herein, refers to a wide range of RNA species, including, but not limited to high molecular RNA, large and small ribosomal RNAs, messenger RNA, pre-messenger RNA, small regulatory RNAs, RNA viruses (single and double-stranded, positive stranded or negative stranded) and the like. The RNA may be from a variety of sources, including, but not limited to human, non-human, viral, bacterial, fungal, protozoan, parasitic, single-celled, multi-cellular, in vitro, in vivo, natural, and/or synthetic sources.

Optionally the bodily fluid is saliva. The term "saliva", as used herein, refers to the secretion, or combination of secretions, from any of the salivary glands, including the

parotid, submaxillary, and sublingual glands, optionally mixed with the secretions from the numerous small labial, buccal, and palatal glands that line the mouth.

The term "subject", as used herein, refers to an animal or human. Desirably, the subject is a mammal that can produce saliva for the purposes of nucleic acid stabilization and/or detection. Most desirably, the subject is human.

In use, a substance, such as a composition intended to stabilize, preserve, or facilitate the recovery of nucleic acid from a biological sample is sealed within reservoir **102** with a pierceable membrane. Suitable compositions include those described in International PCT application WO 2003/104251; International PCT application PCT/CA2006/000380; United States Application Serial Nos. 60/828,563; or 60/866,985, all of the contents of which are hereby incorporated by reference in their entirety. Desirably the composition is Oragene™ DNA-preserving solution. Other suitable compositions would be well known to the skilled worker.

In use, in one example, a sample of saliva from a subject is placed within chamber **2** of vial **1.** Alternatively, vial **500** is attached to funnel **400**, and a sample of saliva is placed within chamber **2** of funnel **400.**

To collect saliva from a subject, in one example, the subject is instructed to wait for a period of 30 – 60 minutes before last eating. If possible, the subject will brush his teeth (without using toothpaste). If possible, the subject will rinse his/her mouth with 50 ml of water. The subject will be requested to wait for 5-10 minutes to allow the mouth to clear of water. For subjects able to spit, they will be instructed to spit saliva into the special collection vial until the level of saliva reaches the 1 or 2 ml mark. Waiting after last eating and rinsing the mouth is desirable but not essential. Collection of saliva may take several minutes. If the subject finds that he/she is unable to deliver sufficient saliva, he/she will be given a few grains of table sugar to chew, and told not to be concerned if some of the sugar is spit into the vial. For subjects unable to spit (e.g., infants, young children, individuals with limitations/disabilities), an implement (e.g., swab, transfer pipette) may be used for sample collection. Similarly, a subject may be provided a liquid (e.g., mouthwash, water, saline) to

gargle his/her mouth and throat or saline to flush his/her nasal cavity. Samples collected with said liquid would be delivered into the collection vial.

A substance, such as a composition to stabilize, preserve, and/or facilitate the recovery of nucleic acid and saliva is stored within reservoir **102** of lid **100**.

Lid **100** is then attached to vial **1**, moved to the piercing position, and the substance combines with the saliva in chamber **2**.

Alternatively, lid **100** is attached to funnel **400**, moved to the piercing position, and the substance combines with the saliva in interior **530**.

The combination of the composition to stabilize, preserve, or facilitate the recovery of nucleic acid and saliva may then be used in standard nucleic acid testing reactions, for example for detection or quantitation. Alternatively, the combination may be stored within container system **300** or **600** and subsequently used, for example, for detection of nucleic acid contained within the saliva. Alternatively, funnel **400** is removed from vial **500**, and cap **520** is attached to the open end of vial **500**. In this example, the combination may be stored within vial **500** and subsequently used, for example, for detection of nucleic acid contained within the saliva.

In one aspect of the present invention container system **300** and container system **600** are sized for shipping. In one example, vial **1** and lid **100** of container system **300** are sized for shipping when securely attached. In one example lid **1**, funnel **400** and collection vial **500** of container system **600**, are sized for shipping when lid **1**, funnel **400** and collection vial **500** are securely attached. In another example, vial **1** and lid **100** of container system **300** are sized for shipping when vial **1** and lid **100** are separate. In another example, lid **1**, funnel **400** and collection vial **500** of container system **600**, are sized for shipping when lid **1**, funnel **400** and collection vial **500** are separate. It will be appreciated that a variety methods of shipping are contemplated. Non-limiting examples of shipping include shipping by hand, land, air, boat, animal, and the like, or combinations thereof. Desirably, container system **300** or container system **600** fit within a standard mail envelope. In one example, container system **300** or container system **600** fit within an envelope sized to fit within a

standard European mail slot. In a specific example, the standard European mail slot has a width of about 3 cm. Alternatively, container system **300** or container system **600** fit within an envelope sized to fit within a standard Canadian and/or United States of America mail slot.

Another aspect of the present invention provides a method of manufacture of a device for releasably storing a substance. The method of manufacture comprises providing container system in accordance with the present invention.

Another aspect of the present invention provides a method of combining a substance with a biological sample. This method comprises providing a container system in accordance with the present invention, wherein the container system includes the substance, and providing the biological sample.

Another aspect of the present invention provides a method of preserving nucleic acid in a biological sample. This method comprises providing a container system in accordance with the present invention, wherein the container system includes a substance for preserving nucleic acid in a biological sample.

Another aspect of the present invention provides a method of archiving a biological sample for prolonged periods of time. Desirably archiving is at room temperature. This method comprises providing a container system in accordance with the present invention and providing a substance for archiving the biological sample. In one example, prolonged storage is at room temperature for more than about one week, about two weeks, about three weeks, about one month, more than about one month, about one year.

KIT

Another aspect of the present invention provides a kit for collection of a sample and mixing the sample with a substance. The kit includes a container system in accordance with the present invention and instructions for the use thereof, optionally with a substance stored within the lid of the container system.

All publications, patents and patent applications mentioned in this Specification are indicative of the level of skill of those skilled in the art to which this invention pertains and are herein incorporated by reference to the same extent as if each individual publication, patent, or patent applications was specifically and individually indicated to be incorporated by reference.

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A container system for releasably storing a substance, comprising:

a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member; and

b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir,

wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

2. The container system according to claim 1 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir, said wall having a sealing surface for sealingly attaching said pierceable membrane.

3. The container system accordingly to any one of claims 1 or 2, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

4. The container system according to any one of claims 1 - 3, wherein said pierceable membrane is inert.

5. The container system according to any one of claims 1 - 4, wherein said pierceable membrane remains intact and pierceable at temperatures of from about -80°C to about 70°C.

6. The container system according to any one of claims 1 – 5, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

7. The container system according to claim 1, wherein the width of said first end is approximately equivalent to the width of said second end.

8. The container system according to claim 1, wherein said first end is generally wider than said second end.

9. The container system according to any one of claims 1 – 8, wherein said chamber is configured to receive about 1 ml to about 16 ml of said sample.

10. The container system according to claim 9, wherein said chamber is configured to receive about 1 ml to about 4 ml of said sample.

11. The container system according to any one of claims 1 - 10, wherein the said piercing member extends from a base surface of said chamber.

12. The container system according to claim 11, wherein said piercing member extends approximately perpendicularly from said base.

13. The container system according to claim 11, wherein said piercing member is angled inwardly or outwardly toward said first open end of said vial.

14. The container system according to any one of claims 1 - 13, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall.

15. The container system according to claim 14, wherein said side wall further includes a second cutting edge.

16. The container system according to any one of claims 1 - 15, wherein said vial comprises a plurality of piercing members.

17. The container system according to claim 16, wherein said vial comprises three piercing members.

18. The container system according to claim 16, wherein said vial comprises two piercing members.

19. The container system according to any one of claims 1 - 18, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system following movement of said container system to said piercing position.

20. The container system according to claim 19, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said vial when the system is said piercing position.

21. The container system according to any one of claims 1 - 20, wherein said vial and said lid are sized for shipping in both an unattached state and an attached state.

22. A container system for releasably storing a substance, comprising:

a) a vial comprising a chamber for retaining a sample

b) a lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir; and

c) a funnel comprising a first open end for receiving said sample, a piercing member and a channel extending from said first open end to a second open end and being in fluid communication with said chamber, said funnel being removably attachable to said lid at said first open end and releasably or permanently attached to said vial at said second end,

wherein, when said system is closed by removable attachment of said lid to said funnel, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, via said channel, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

23. The container system according to claim 22 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir and including a sealing surface for sealingly attaching said pierceable membrane

24. The container system accordingly to any one of claims 22 or 23, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

25. The container system according to any one of claims 22 - 24, wherein said pierceable membrane is inert.

26. The container system according to any one of claims 22 - 25, wherein said pierceable membrane maintains intact and pierceable at temperatures of from about -80°C to about 70°C.

27. The container system according to any one of claims 22 – 26, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

28. The container system according to any one of claims 22 - 27, wherein said piercing member extends from an interior surface of said funnel.

29. The container system according to claim 28, wherein said piercing member is angled inwardly or outwardly toward said first open end of said funnel.

30. The container system according to any one of claims 22 - 29, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall.

31. The container system according to claim 30, wherein said side wall includes a second cutting edge.

32. The container system according to any one of claims 22 - 31, wherein said funnel comprises a plurality of piercing members.

33. The container system according to claim 32, wherein said funnel comprises three piercing members.

34. The container system according to claim 33, wherein said funnel comprises two piercing members.

35. The container system according to any one of claims 11 - 34, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system.

36. The container system according to claim 35, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said funnel when the system is in the piercing position.

37. The container system according to any one of claims 22 - 36, wherein said vial is releasably attached to said funnel and sized for attachment to a cap when released from said funnel.

38. The container system according to any one of claims 22 - 37, wherein said vial is configured for use in standard laboratory equipment.

39. The container system according to claim 38, wherein said vial has dimensions that conforms with industry-standard dimensions for a blood collection tube.

40. The container system according to claim 38 or 39, wherein said vial is a T501 tube.

41. The container system according to any one of claims 22 – 40, wherein said chamber is sized to hold about 1 ml to about 16 ml.

42. The container system according to any one of claims 1 – 41, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample.

43. The container system according to claim 42, wherein said nucleic acid is DNA or RNA.

44. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 1 – 21;

(b) providing the sample to the chamber in the vial; and

(c) closing said container system by removably attaching said lid to said vial; and

(d) piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

45. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 22 – 41;

(b) providing the sample to the chamber in the vial through said funnel; and

(c) closing said container system by removably attaching said lid to said first open end of said funnel; and

(d) piercing said membrane to release said substance into said chamber by moving said system to said piercing position.

46. The method according to claim 44 or 45, wherein the substance is a nucleic acid preserving substance.

47. The method according to any one of claim 44 – 46, wherein the sample is a biological sample.

48. The method according to any one of claim 44 – 47, for archiving the sample.

49. A kit for sample collection and storage, comprising:

a) a container system according to any one of claims 1 to 43; and

b) instructions for the use thereof.

50. A container system as substantially described herein.

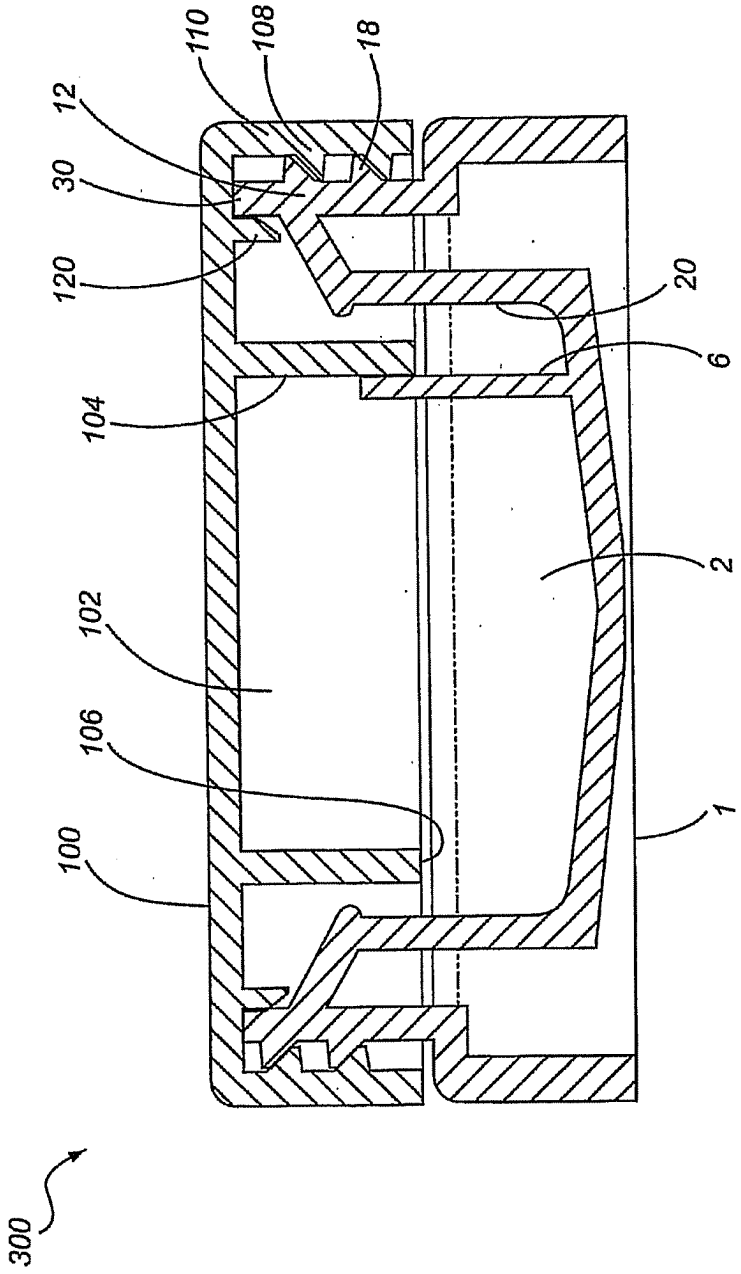

FIG. 1

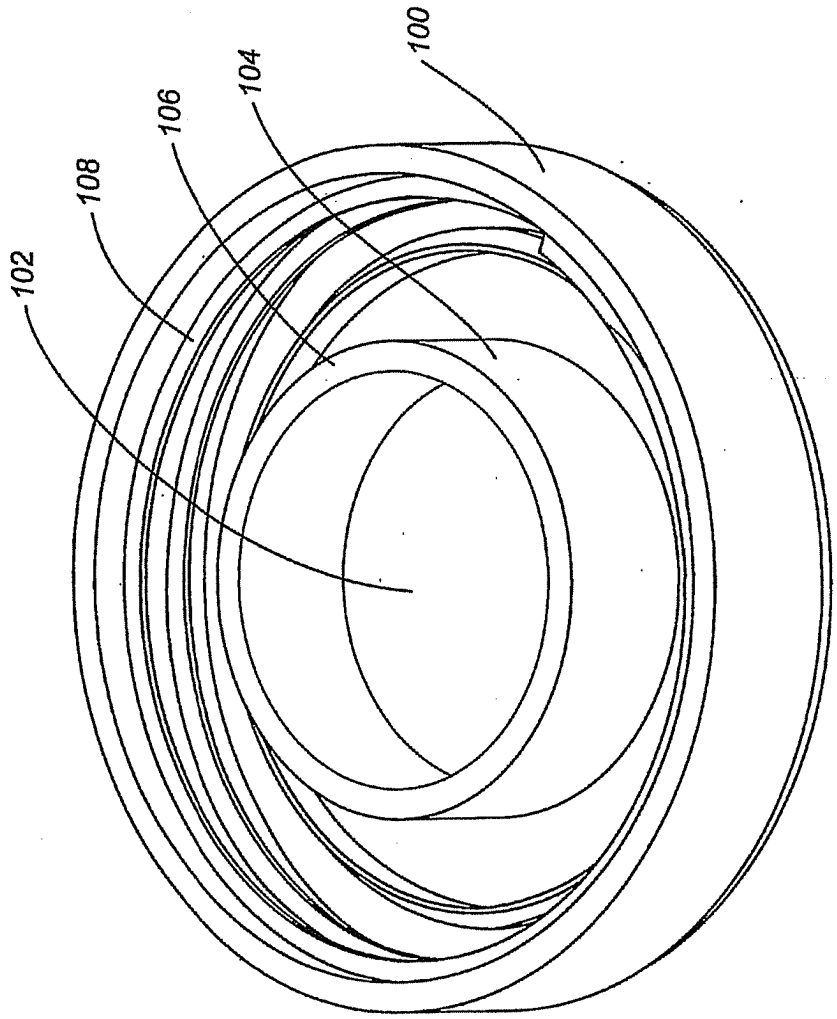

FIG. 2

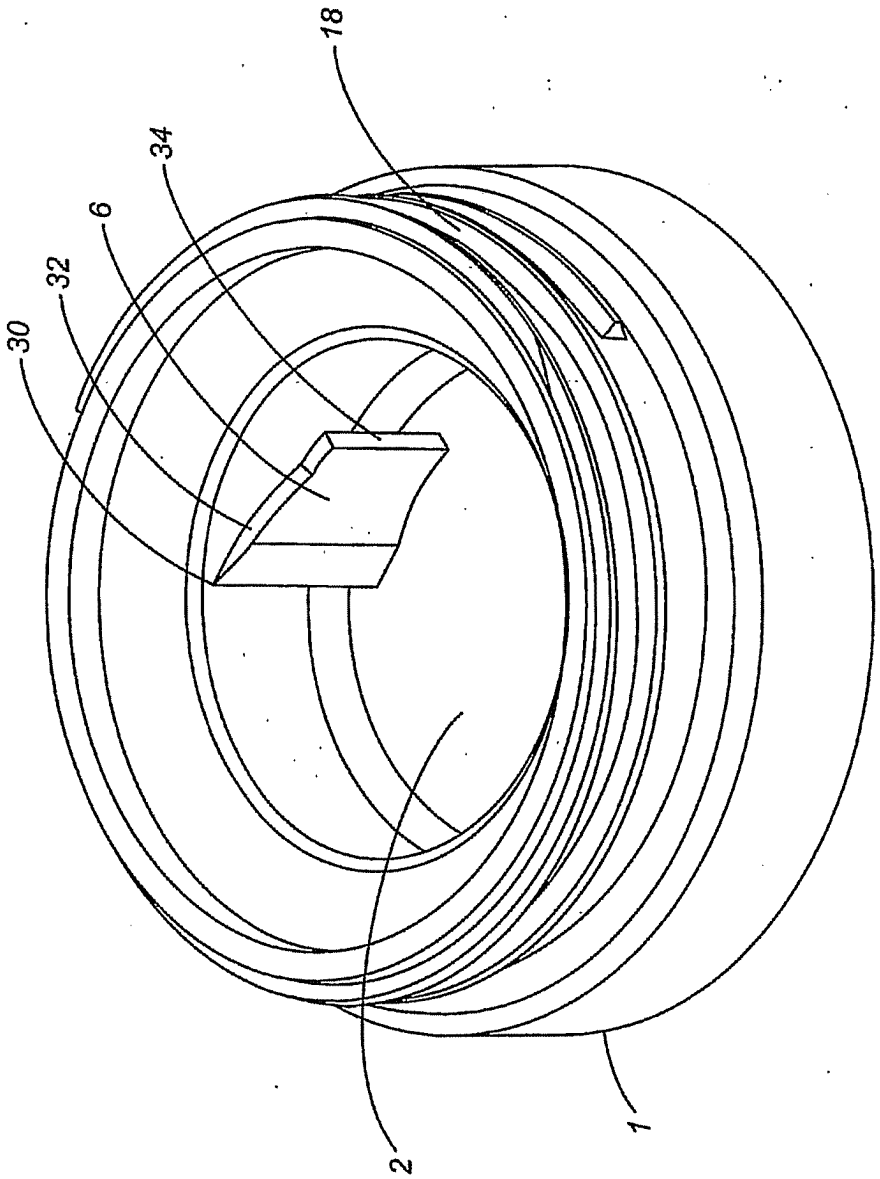

FIG. 3

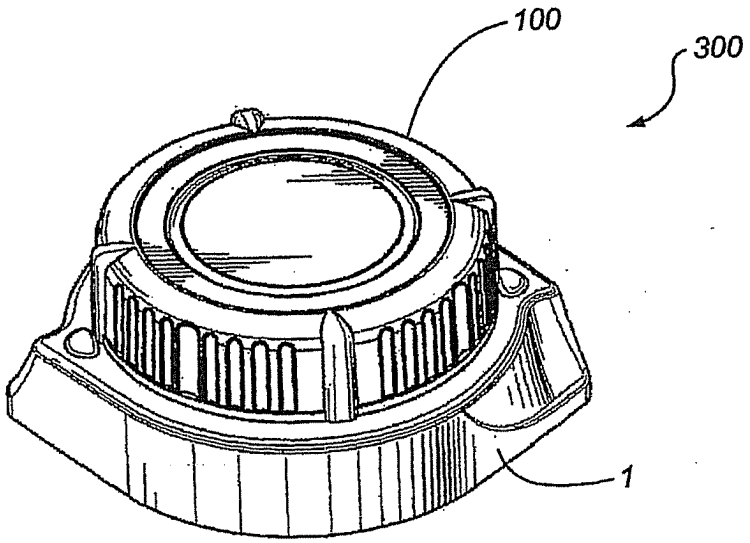

FIG. 4

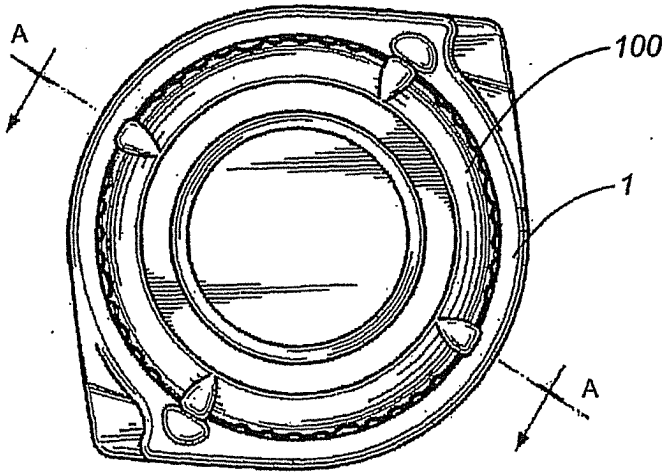

FIG. 5

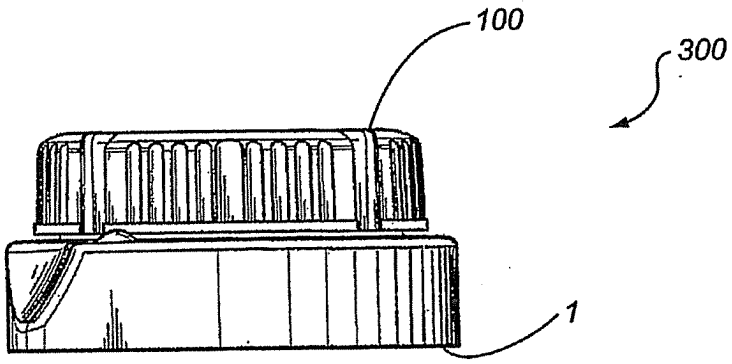

FIG. 6

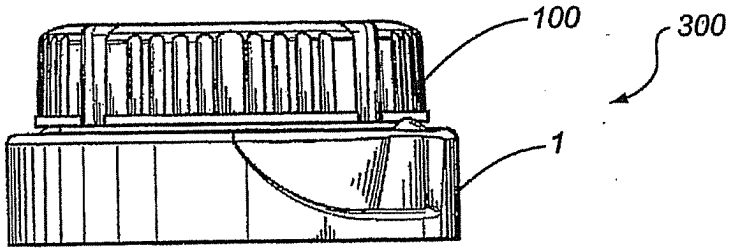

FIG. 7

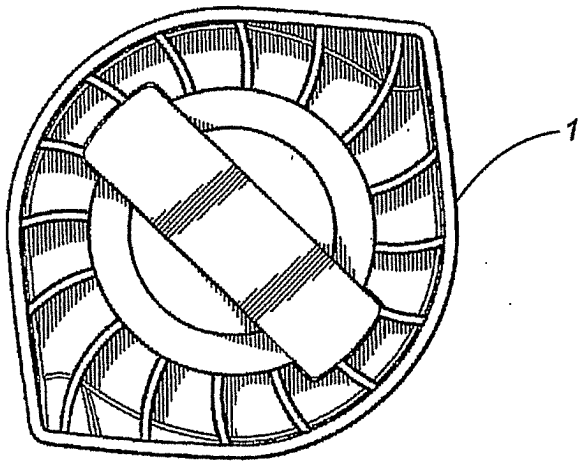

FIG. 8

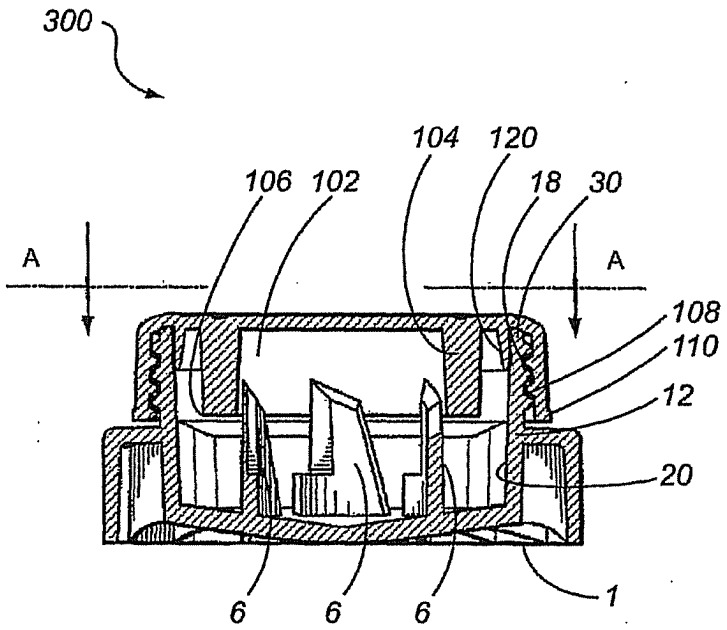

FIG. 9

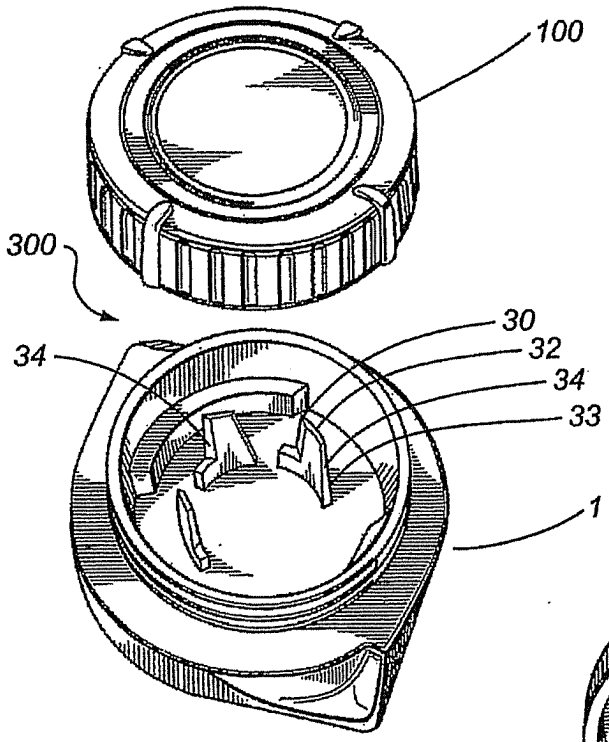

FIG. 10

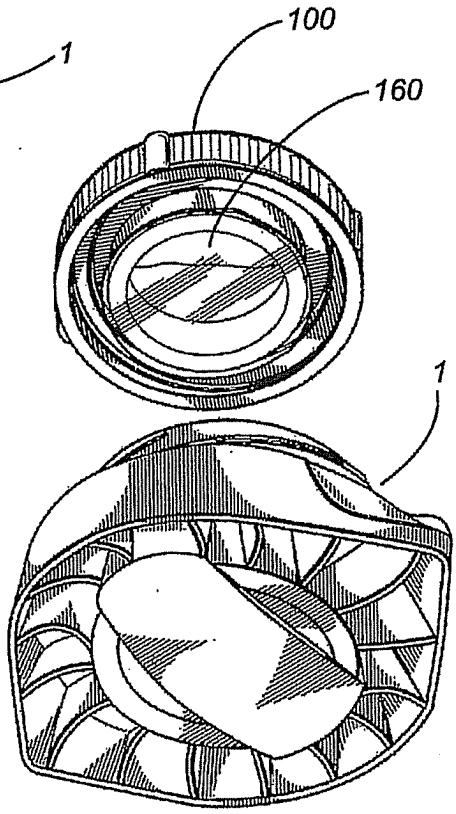

FIG. 11

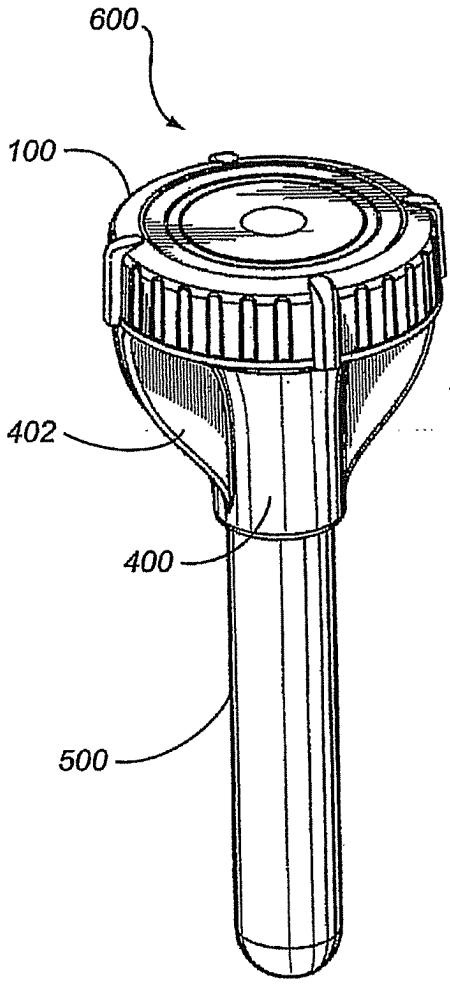

FIG. 12

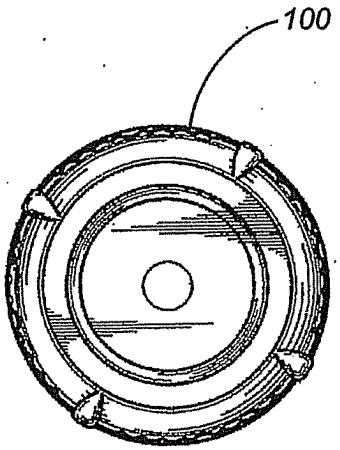

FIG. 13

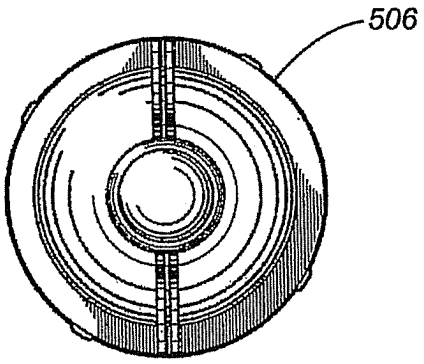

FIG. 14

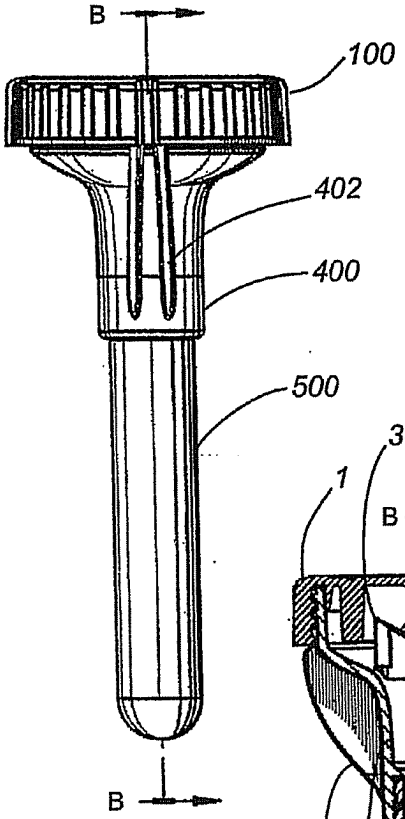

FIG. 15

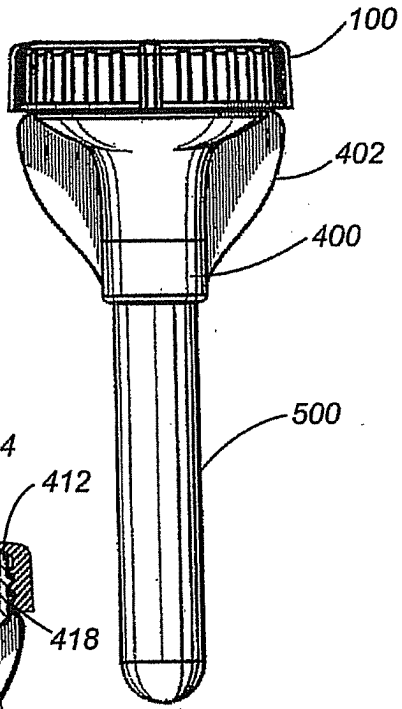

FIG. 17

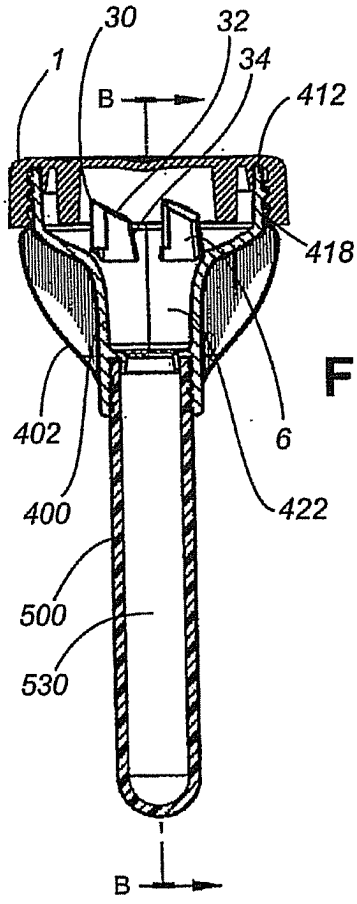

FIG. 16

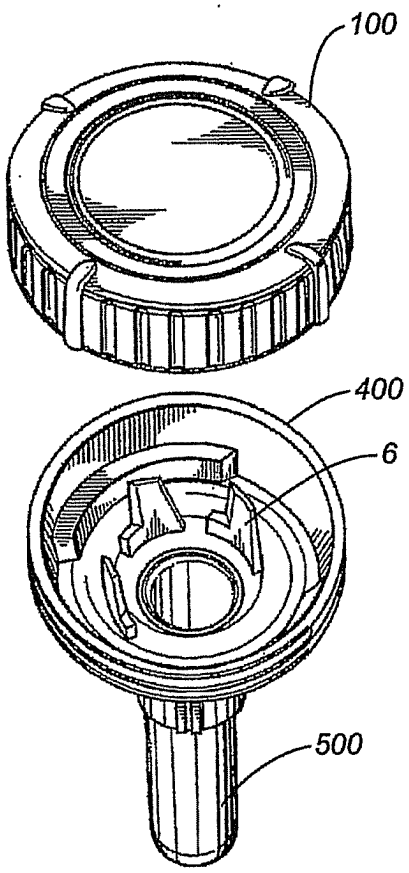

FIG. 18

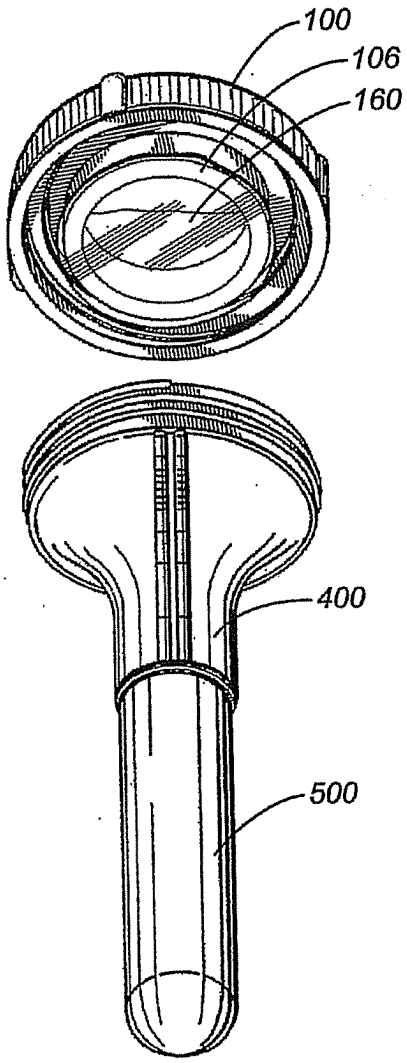

FIG. 19

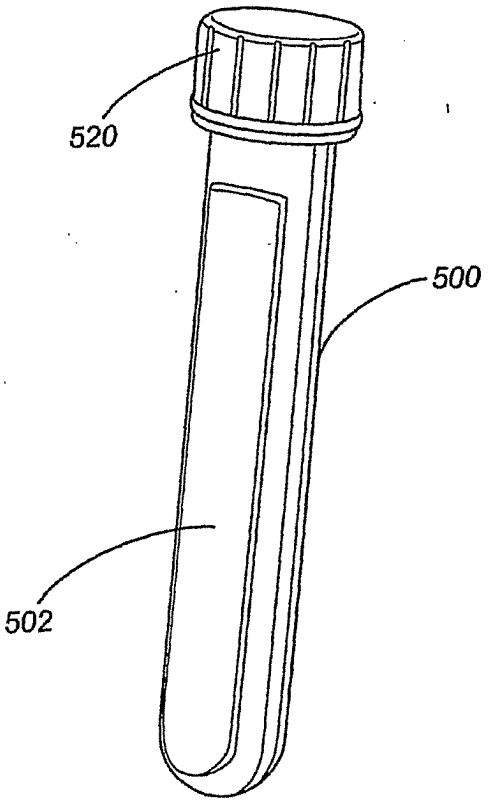

FIG. 20

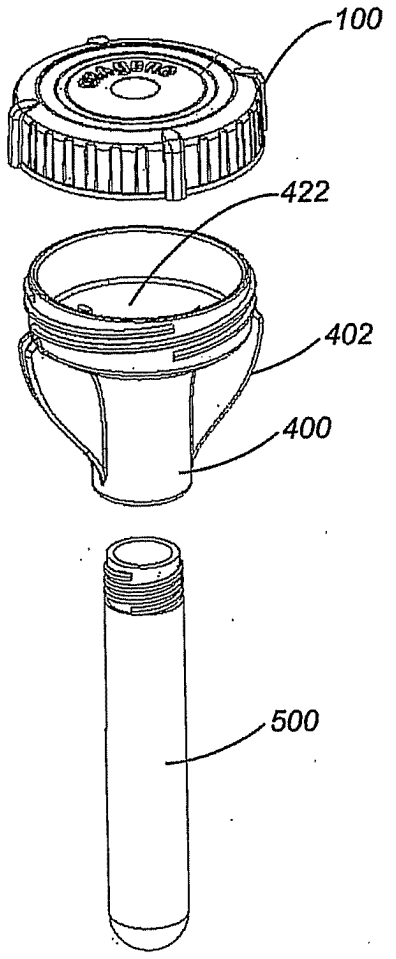

FIG. 21

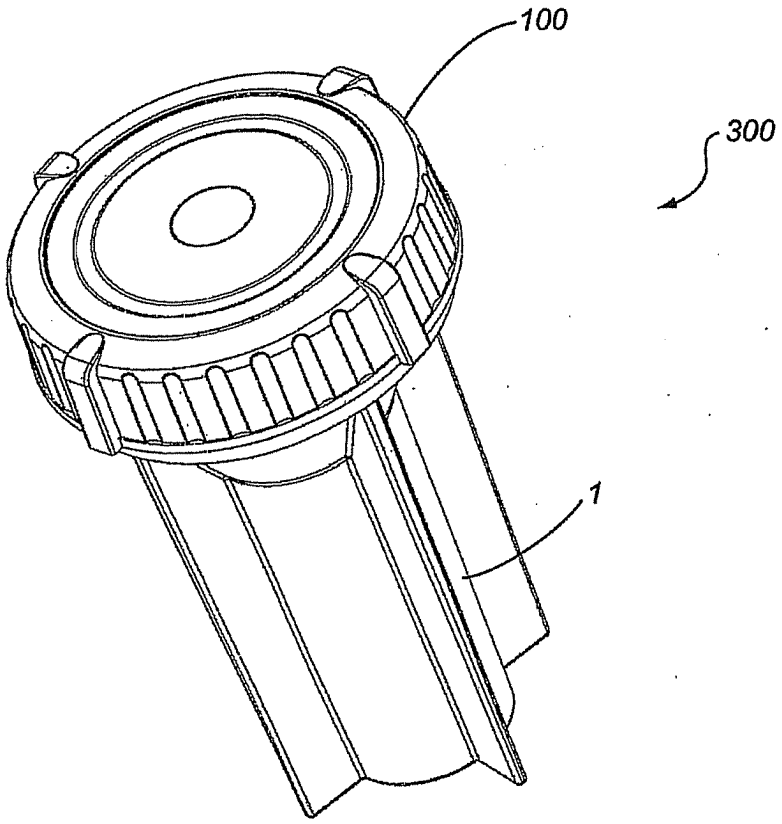

FIG. 22

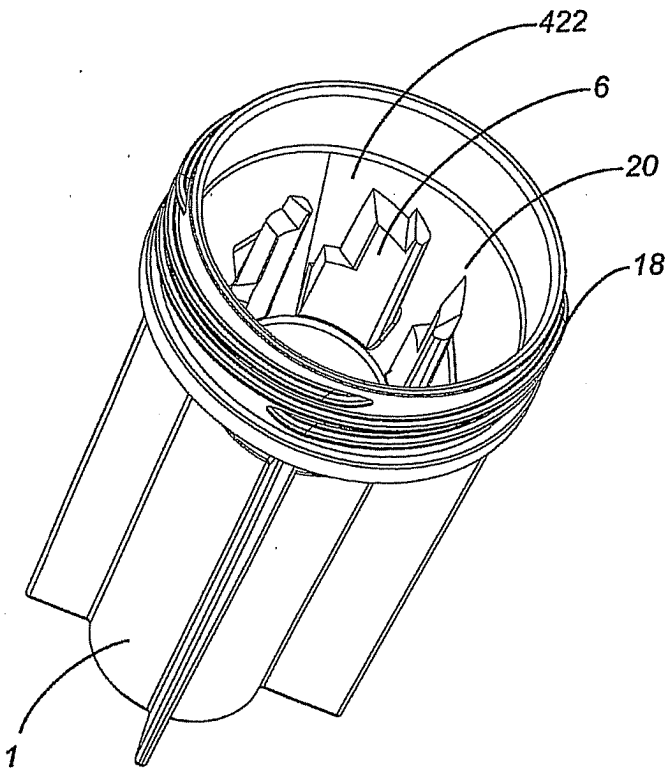

FIG. 23

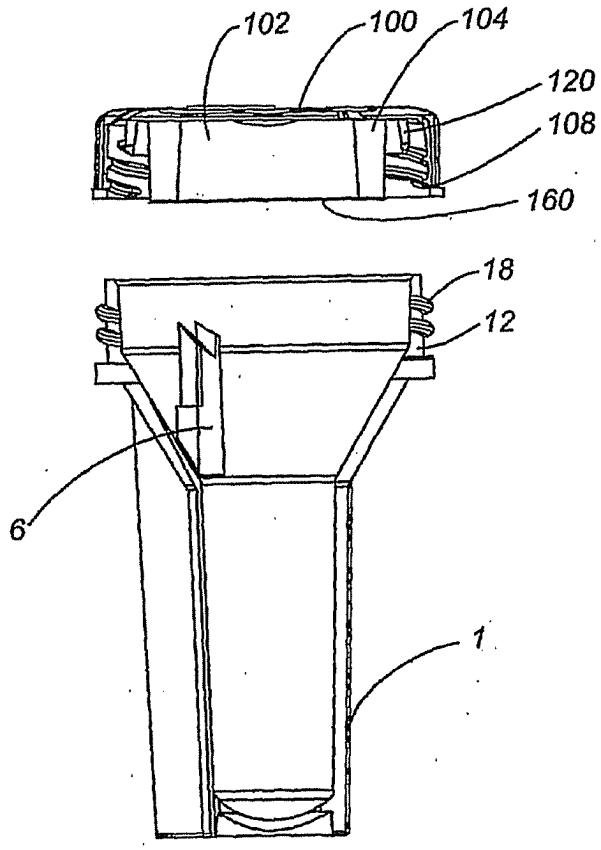

FIG. 24

Application Data Sheet

Application Information

Application number::	
Filing Date::	06/09/08
Application Type::	Regular
Subject Matter::	Utility
Suggested Classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R?::	None
Number of CD disks::	
Number of copies of CDs::	
Sequence submission?::	
Computer Readable Form (CRF)?::	
Number of copies of CRF::	
Title::	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
Attorney Docket Number::	50245/005001
Request of Early Publication?::	No
Request of Non-Publication?::	No
Suggested Drawing Figure::	
Total Drawing Sheets::	15
Small Entity?::	Yes
Petition Included?::	No
Petition Type::	
Licensed US Govt. Agency::	

Contract or Grant Numbers::

Secrecy Order in Parent Appl.?:: No

Applicant Information

Applicant Authority Type:: Inventor

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Status:: Full Capacity

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Name Suffix::

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Country of Residence::	Canada
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City of mailing address::	Kanata
State or Province of mailing address::	Ontario
Country of mailing address::	Canada

Postal or Zip Code of mailing address::	K2K 1X7
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Middle Name::	
Family Name::	Sunstrum
Name Suffix::	
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State or Province of Residence::	Ontario
Country of Residence::	Canada
Street of mailing address::	P.O. Box 1181, 25 Underhill Crescent
City of mailing address::	Richmond
State or Province of mailing address::	Ontario
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	K0A 2Z0
Applicant Authority Type::	Inventor
Primary Citizenship Country::	Canadian
Status::	Full Capacity
Given Name::	Paul
Middle Name::	
Family Name::	Lem
Name Suffix::	

City of Residence::	Ottawa
State or Province of Residence::	Ontario
Country of Residence::	Canada
Street of mailing address::	302-145 York Street
City of mailing address::	Ottawa
State or Province of mailing address::	Ontario
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	K1N 8Y3

Correspondence Information

Correspondence Customer Number:: 21559

Representative Information

Representative Customer Number:: 21559

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	National stage of	PCT/CA2006/002009	12/11/06
PCT/CA2006/002009	An application claiming the benefit under 35 USC 119(e)	60/748,977	12/09/05

Assignee Information

Assignee name::

Street of mailing address::

City of mailing address::

State of Province of mailing address::

Country of mailing address::

Postal or Zip Code of mailing address::

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
OSLER, HOSKIN & HARCOURT LLP
1500 - 50 O'Connor Street
OTTAWA, Ontario
Canada, K1P 6L2

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 30 March 2007 (30-03-2007)
Applicant's or agent's file reference PPCT18678	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/CA2006/002009	International filing date *(day/month/year)* 11 December 2006 (11-12-2006)

Applicant
DNA GENOTEK INC. ET AL

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19 :
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46) :

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
   1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that :

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for the international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Chantal Hébert 819- 953-4957

Form PCT/ISA/220 (October 2005) *(See notes on accompanying sheet)*

NOTES TO FROM PCT/ISA/220

These Notes are intended to give instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide,* Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)) :

The amendments must be submitted with a letter.
The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").
The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;
(ii) the claim is cancelled;
(iii) the claim is new;
(iv) the claim replaces one or more claims as filed;
(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter :

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PPCT18678	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below
International application No. **PCT/CA2006/002009**	International filing date *(day/month/year)* 11 December 2006 (11-12-2006)	(Earliest)Priority date *(day/month/year)* 09 December 2005 (09-12-2005)
Applicant DNA GENOTEK INC. ET AL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

      [X] the international application in the language in which it was filed

      [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

   b. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I

2. [ ] **Certain claims were found unsearchable** (see Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant

   [ ] the text has been established by this Authority to read as follows :

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 10

      [X] as suggested by the applicant

      [ ] as selected by this Authority, because the applicant failed to suggest a figure

      [ ] as selected by this Authority, because this figure better characterizes the invention

   b. [ ] none of the figures is to be published with the abstract

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. [X] Claim Nos. : 50

because they relate to subject matter not required to be searched by this Authority, namely :

Claim 50 is directed to a container system as decribed herein. Such a claim is considered an omnibus claim and thereby no search or opinion is required by this Authority.

2. [ ] Claim Nos. :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

3. [ ] Claim Nos. :

because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2006/002009

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61B 5/00*** (2006.01) , ***A61B 5/15*** (2006.01) , ***A61J 1/05*** (2006.01) , ***B01L 3/14*** (2006.01) , ***B65D 47/36*** (2006.01) , ***B65D 81/32*** (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/00, A61B 5/15, A61J 1/05, B01L 3/14, B65D 47/36, B65D 81/32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Databases: Google, CPD (Canadian Patent Database), Pluspat, Delphion, IEEE Xplore
Keywords: vial, lid, funnel, pierce, container system, store/ing, sample, chamber

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 0273015 (A2) 29 Jun.1988 (29-06-1988), Loretti et al., ** see abstract, Fig, 2,3,5,6**	1, 44 22, 45-49
X	US 6 582 415(B1) 24 June 2003 (24-06-2003), Fowles et al. ** see abstract, col.20-col.21, line 21**	1, 44
Y	US 4 741 346 3 May 1988 (3-05-1988), Wong et al. , ** see abstract, whole document**	22, 45-49
A	US 4 583971 22 Apr. 1986 (22-04-1986), Bocquet et al., ** see whole document**	1-49
A	US 5 980 834 9 Nov. 1999 (9-11-1989), Bruno, ** see whole document**	1-49
A	US 5 567 309 22 Oct. 1996 (22-10-1996), Classon et al., ** see whole document**	1-49

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 March 2007 (29-03-2007)	30 March 2007 (30-03-2007)

Name and mailing address of the ISA/CA	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Karen Oprea 819- 934-2668

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
EP0273015	29-06-1988	EP0273015 A2	29-06-1988
US6582415	24-06-2003	AT283091T T	15-12-2004
		AU760376B B2	15-05-2003
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		BR0009908 A	08-01-2002
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		BR9906945 A	03-10-2000
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		CA2546835 A1	21-07-2005
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		CA1270413 A1	19-06-1990
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		EP0250170 A2	23-12-1987
		ES2028078T T3	01-07-1992
		GR3003996T T3	16-03-1993
		JP2525817B2 B2	21-08-1996
		US4741346 A	03-05-1988
US4583971	22-04-1986	AU580584B B2	19-01-1989
		AU3933085 A	27-08-1985
		CA1234369 A1	22-03-1988
		DE3570594D D1	06-07-1989
		EP0172836 A1	05-03-1986
		ES540177D D0	16-11-1986
		IT1183224 B	15-10-1987
		JP3049262B B	29-07-1991
		US4583971 A	22-04-1986
		WO8503432 A1	15-08-1985
		ZA8500835 A	25-09-1985
US5980834	09-11-1999	US5980834 A	09-11-1999
US5567309	22-10-1996	US5567309 A	22-10-1996

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Filer:	Forrester J. Liddle/Rachel Kamerman
Attorney Docket Number:	50245/005001

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Basic National Stage Fee	2631	1	155	155
Natl Stage Search Fee - Report provided	2642	1	205	205
Natl Stage Exam Fee - all other cases	2633	1	105	105
Pages:				
Claims:				
Claims in excess of 20	2615	35	25	875
Multiple dependent claims	2616	1	185	185
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Oath/decl > 30 mo. from priority date	2617	1	65	65
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1590**

Electronic Acknowledgement Receipt

EFS ID:	3426803
Application Number:	12096767
International Application Number:	PCT/CA06/02009
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Forrester J. Liddle/Rachel Kamerman
Filer Authorized By:	Forrester J. Liddle
Attorney Docket Number:	50245/005001
Receipt Date:	09-JUN-2008
Filing Date:	
Time Stamp:	18:49:12
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1590
RAM confirmation Number	3792
Deposit Account	032095
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	50245_005001_Transmittal_6_9_08.pdf	204398 d6bd1a6834a26708ebaad59c4cecb9d201a15d4b	no	2
Warnings:					
Information:					
2		50245_005001_Preliminary_Amendment_6_9_08.pdf	457103 d956b333a53f3886e83fc780099edb468a788506	yes	14

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	2
Claims	3	13
Applicant Arguments/Remarks Made in an Amendment	14	14

Warnings:					
Information:					
3	Documents submitted with 371 Applications	50245_005001_Specification_6_9_08.pdf	2015882 8082a7a942980152e71b5621235717828063a9bf	no	44
Warnings:					
Information:					
4	Application Data Sheet	50245_005001_ADS_6_9_08.pdf	136418 d1e32cd978c3c61a1e3b28146553534eb464c69b	no	6
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
5	Miscellaneous Incoming Letter	50245_005001_ISR_and_Written_Opinion_6_9_08.pdf	1118170 fe15096bac6f2d0e3fb7e44d45ca23927e9d1a7a	no	13
Warnings:					
Information:					

6	Fee Worksheet (PTO-06)	fee-info.pdf	8792 870e20790955974098d7594af5c594bec0ebd852	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	3940763

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	3426803
Application Number:	12096767
International Application Number:	PCT/CA06/02009
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Forrester J. Liddle/Rachel Kamerman
Filer Authorized By:	Forrester J. Liddle
Attorney Docket Number:	50245/005001
Receipt Date:	09-JUN-2008
Filing Date:	
Time Stamp:	18:49:12
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1590
RAM confirmation Number	3792
Deposit Account	032095
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	50245_005001_Transmittal_6_9_08.pdf	204398 d6bd1a6834a26708ebaad59c4cecb9d201a15d4b	no	2
Warnings:					
Information:					
2		50245_005001_Preliminary_Amendment_6_9_08.pdf	457103 d956b333a53f3886e83fc780099edb468a788506	yes	14

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	2
Claims	3	13
Applicant Arguments/Remarks Made in an Amendment	14	14

Warnings:					
Information:					
3	Documents submitted with 371 Applications	50245_005001_Specification_6_9_08.pdf	2015882 8082a7a942980152e71b5621235717828063a9bf	no	44
Warnings:					
Information:					
4	Application Data Sheet	50245_005001_ADS_6_9_08.pdf	136418 d1e32cd978c3c61a1e3b28146553534eb464c69b	no	6
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
5	Miscellaneous Incoming Letter	50245_005001_ISR_and_Written_Opinion_6_9_08.pdf	1118170 fe15096bac6f2d0e3fb7e44d45ca23927e9d1a7a	no	13
Warnings:					
Information:					

6	Fee Worksheet (PTO-06)	fee-info.pdf	8792 870e20790955974098d7594af5c594bec0ebd852	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	3940763

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 June 2007 (21.06.2007)

PCT

(10) International Publication Number
WO 2007/068094 A1

(51) International Patent Classification:
A61B 5/00 (2006.01) *B01L 3/14* (2006.01)
A61B 5/15 (2006.01) *B65D 47/36* (2006.01)
A61J 1/05 (2006.01) *B65D 81/32* (2006.01)

(21) International Application Number:
PCT/CA2006/002009

(22) International Filing Date:
11 December 2006 (11.12.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/748,977 9 December 2005 (09.12.2005) US

(71) Applicant *(for all designated States except US)*: **DNA GENOTEK INC.** [CA/CA]; 29 Camelot Dr., Unit 200, Ottawa, Ontario K2G 5W6 (CA).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **MUIR, Rod** [CA/CA]; Box 303, 10361 Country Road 3, South Mountain, Ontario K0E 1W0 (CA). **KIRKLAND, Derek** [CA/CA]; 57 Muskoka Road, Chelsea, Quebec J9B 2E8 (CA). **CURRY, Ian** [CA/CA]; 8 Wildacre Lane, Kanata, Ontario K2K 1X7 (CA). **SUNSTRUM, Roy** [CA/CA]; P.O. Box 1181, 25 Underhill Crescent, Richmond, Ontario K0A 2Z0 (CA). **LEM, Paul** [CA/CA]; 302-145 York Street, Ottawa, Ontario K1N 8Y3 (CA).

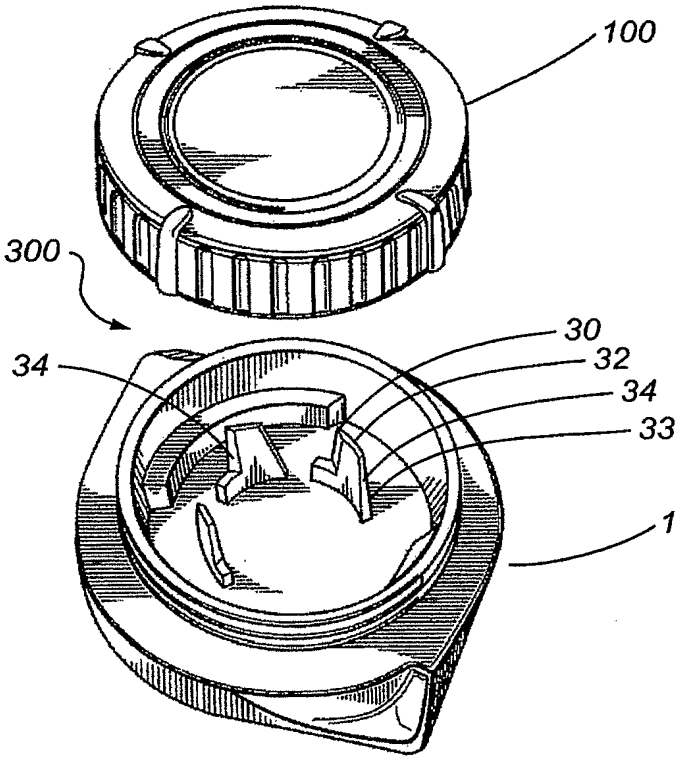
(74) Agents: **OSLER, HOSKIN & HARCOURT LLP** et al.; Suite 1500, 50 O'Connor Street, Ottawa, Ontario K1P 6L2 (CA).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH,

[Continued on next page]

(54) Title: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE



(57) Abstract: The present invention provides a container system for releasably storing a substance. The container system includes a vial having a sample storage chamber and a piercing member for piercing a membrane in the lid, which membrane seals a substance within a reservoir in the lid until the membrane is pierced by the piercing member. The container system optionally includes a funnel. There is also provided a method and kit for use of such a container system.

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CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

RELATED APPLICATION

This application claims priority to United States Application Serial No. 60/748,977 filed on December 9, 2005, the contents of which are hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

The field of the invention generally relates to a container system for releasably storing a substance.

BACKGROUND

It is often desirable to store a substance, such as a liquid, solid, gas, mixtures thereof, or the like, in a container prior to mixing the contents of the container with another material. For example, it may be desirable to package and store a compound, or compounds, in a container for shipping and/or safe storage and handling, prior to combining the compound(s) with another material. It may be desirable to package and store a toxic compound in a container, prior to combining such a toxic compound with a detoxifying material. As well, it is often desirable to keep a concentrated active ingredient separate from a diluent until immediately prior to use.

Moreover, it may be desirable to store and/or ship diagnostic and/or nucleic acid preserving compositions prior to combining such a substance with a biological sample.

Additionally, it may be desirable to keep a substance isolated from a donor until the donor's biological sample has been collected. This will help to prevent the donor from accidentally ingesting or spilling the substance.

It may also be desirable to inactivate pathogens/infectious particles in a biological sample by combining it with a stored substance prior to storage and/or shipping and/or handling of the sample.

It may also be desirable to store and/or ship diagnostic and/or nucleic acid preserving compositions after combining such a substance with a biological sample.

There are a variety of containers for holding substances separately in such a manner that a user may open a closure to combine the substances. Typically these containers are double compartment systems in which substances are stored separately and substances are combined by removal of the container closures by a user.

International PCT application WO 2003/104251 describes a container for collecting a biological sample from a subject, and subsequently mixing the collected sample with a composition intended to stabilize, preserve, or facilitate the recovery of components of the sample. This container has a first region for collecting a biological sample, a second region containing a composition for preserving a nucleic acid, and a barrier between the first region and the second region, which when in a closed position, maintains the sample and composition separate. The exemplified barrier of WO 2003/104251 is a pivoting partition. Attachment of a lid to the container forces the barrier to pivot from its original closed position spanning the container and thereby separating the first region and the second region, to an open position in which both regions are exposed to each other and contact between the composition contained in one region space and the biological sample contained in the other region is allowed. A drawback of this container is that it includes multiple parts (e.g., lid, vial, disk, rod, rod holder), which increases the cost of manufacture of the container. Additionally, because the disk is held in place by friction fit, there must be a high degree of precision for the manufacture of the components of the container.

There remains a need for an improved container system for releasably and reliably storing a substance.

This background information is provided for the purpose of making known information believed by the applicant to be of possible relevance to the present invention. No admission is necessarily intended, nor should be construed, that any of the preceding information constitutes prior art against the present invention.

SUMMARY OF THE INVENTION

The present invention generally relates to a container system for releasably storing a substance.

In accordance with one aspect of the present invention, there is provided a container system for releasably storing a substance, comprising: a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member; and b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir, wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

In accordance with another aspect of the present invention, there is provided a container system for releasably storing a substance, comprising: a) a vial comprising a chamber for retaining a sample b) a lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir; and c) a funnel comprising a first open end for receiving said sample, a piercing member and a channel extending from said first open end to a second open end and being in fluid communication with said chamber, said funnel being removably attachable to said lid at said first open end and releasably or permanently attached to said vial at said second end, wherein, when said system is closed by removable attachment of said lid to said funnel, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, via said channel, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

In accordance with another aspect of the present invention, there is provided a method of combining a substance with a biological sample, comprising: (a) providing a container system as described herein; (b) providing the sample to the chamber in the vial;

and (c) closing said container system by removable attachment of the lid to the vial or funnel; and (d) piercing the membrane to release said substance into said chamber by moving the system to said piercing position.

In accordance with another aspect of the present invention there is provided a kit for releasably storing a substance comprising: a) a container system as described herein; and b) instructions for the use thereof.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a cross-sectional view of a container system in accordance with one embodiment of the present invention, showing the lid and vial attached;

Figure 2 is a perspective view of the interior of the lid of the container system depicted in Figure 1;

Figure 3 is a perspective view of the interior of the vial of the container system depicted in Figure 1;

Figure 4 is a perspective view of a container system in accordance with one embodiment of the present invention;

Figure 5 is a top view of the container system depicted in Figure 4;

Figure 6 is a side view of the container system depicted in Figure 4;

Figure 7 is a side view of the container system depicted in Figure 4;

Figure 8 is a bottom view of the container system depicted in Figure 4;

Figure 9 is a cross-sectional view of the container system of Figure 4 taken along line A-A in Figure 5;

Figure 10 is a top perspective view of the container system depicted in Figure 4 showing the lid and vial separated;

Figure 11 is a bottom perspective view of the container system depicted in Figure 4 showing the lid and vial separated;

Figure 12 is a side perspective view a container system in accordance with one embodiment of the present invention;

Figure 13 is a top view of the container system depicted in Figure 12;

Figure 14 is a bottom view of the container system depicted in Figure 12;

Figure 15 is a side view of the container system depicted in Figure 12;

Figure 16 is a cross-sectional view of the container system of Figure 12 taken along line B-B in Figure 15;

Figure 17 is a side perspective view of the container system depicted in Figure 12;

Figure 18 is a top perspective view of the container system depicted in Figure 12, showing the lid and funnel separated;

Figure 19 is a bottom side perspective view of the container system depicted in Figure 12, showing the lid and funnel separated;

Figure 20 is a side view of the vial and cap of the container system depicted in Figure 9;

Figure 21 is a side view of the container system depicted in Figure 12, showing the lid, funnel, and vial separated;

Figure 22 is a side perspective view a container system in accordance with one embodiment of the present invention;

Figure 23 is a top perspective view of the vial portion of the container system depicted in Figure 22, showing the vial; and

Figure 24 is a cross-sectional view of the lid of the container system depicted in Figure 22.

The numbers in bold face type serve to identify the component parts that are described and referred to in relation to the drawings depicting various embodiments of the present invention. It should be noted that in describing various embodiments of the present invention, the same reference numerals have been used to identify the same or similar elements. Moreover, for the sake of simplicity, parts have been omitted from some figures of the drawings.

DETAILED DESCRIPTION OF THE INVENTION

As will be discussed in more detail below, the present invention provides a container system for releasably storing a substance.

The container system of the present invention has fewer parts and, thus, is less expensive and/or easier to manufacture, than previous containers. Additionally, the manufacturing tolerances can be less precise for the container system of the present invention, as compared to previous containers having separable compartments. Again, this reduces manufacturing cost, and makes accidental disruption of a sealed substance less likely. Additionally, in one example of the present invention, the container system includes a removable vial which is suitable for subsequent processing of samples and/or for use in robotic systems.

The container system of the present invention comprises a vial and a lid. Optionally, the container system additionally comprises a funnel that is permanently or removably attached to the vial and that sealingly engages the lid. The lid is configured to store a substance, and subsequently release the substance from the lid when the lid is sealingly attached to the vial, or the funnel. In use, the substance stored within the lid is released into the vial when the lid is attached to the vial or the funnel, if present.

In accordance with a specific embodiment of the present invention, the lid is suitable to store a substance to stabilize, preserve or facilitate the recovery of nucleic acid from a biological sample. In accordance with a related embodiment, the vial, or the combination of the funnel and vial is suitable for the collection of a biological sample from a subject.

Referring to the Figures 1-11 and 22-24, container system **300** comprises lid **100** and vial **1**.

LID

Lid **100** releasably stores a substance. Lid **100** is generally cylindrically shaped with at least one open end. Lid **100** can be a variety of shapes, as determined by the needs or preferences of the user and/or the intended application of use. The interior of lid **100** includes wall **104** that is positioned within lid **100** and defines reservoir **102** for holding a substance such as a liquid, solid, semi-solid, gas, mixtures thereof and the like. Wall **104** defines all or a portion of the perimeter of reservoir **102**. Wall **104** includes sealing surface **106** which is for sealingly attaching pierceable membrane **160**

Pierceable membrane **160** (depicted in Figure 19) acts as a physical barrier to releasably store a substance within reservoir **102**, when attached to sealing surface **106**. Pierceable membrane **160** is made from material that is inert to the substance to be stored within the reservoir. Pierceable membrane **160** permits little or no diffusion of the substance through pierceable membrane **160** over time. Pierceable membrane **160** is made from a material that is suitable for the intended processing, storage and/or transportation conditions. In a specific embodiment, pierceable membrane **160** is heat and cold resistant such that it remains intact and pierceable at temperatures ranging from about -80°C to about +70°C. In a specific embodiment, pierceable membrane **160** can be attached tightly enough to sealing surface **106** such that pierceable membrane **160** will not be disrupted by vacuum pressures. Pierceable membrane **160** can be made from a variety of materials including polypropylene. Desirably, pierceable membrane **160** is made from the same material as wall **104**. The thickness of pierceable membrane **160** can vary according to application of use, and preference of the user. Desirably, pierceable membrane **160** has a thickness of about two thousandths of an inch. However, the specific thickness of the membrane will be determined by factors such as, nature of the substance, nature of the sample, overall dimensions of the container system and chemical composition of the membrane.

A variety of methods of attaching pierceable membrane **160** to sealing surface **106** can be used, and is dependent on the material used to make lid **100**, the substance stored

within reservoir **102**, and/or the characteristics of membrane **160**. Such methods of attachment include use of adhesive(s), heat-sealing treatment, fasteners, or any combination thereof, and the like. Desirably, heat-sealing is used to attach pierceable membrane **160** to sealing surface **106**. As will be clear to the skilled worker, the type of pierceable membrane, the physical and/or chemical properties of the pierceable membrane will be dependent upon, in part, the composition to be stored. Desirably pierceable membrane **160** is inert with respect to the intended use, stored substance and sample of the container system.

In the specific embodiments depicted in the Figures, lid **100** comprises internal helical threads **108** on the inner surface of outer wall **110**, which are adapted to engage external helical threads **18** on the outer surface of wall **12** on vial **1**. As would be appreciated by a skilled worker, alternative means for releasable attachment of lid **100** to vial **1** can be used in the container system of the present invention, provided that lid **100** and vial **1** are movable to a piercing position, as discussed in greater detail below.

Lid **100** and reservoir **102** can be sized to accommodate a range of volumes of a substance. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, reservoir **102** accommodates about 1 ml to about 4 ml of a substance. The choice of material used to manufacture lid **100** is dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, lid **100** is made from plastics such us polypropylene, medium-density polyethylene (MDPE), high-density polyethylene (HDPE), polyethylene and the like. Desirably, lid **100** is polypropylene. The materials of lid **100** may be opaque, transparent or translucent, depending on the desired application. For example, an opaque material can be used to store a light sensitive composition(s). A transparent or translucent material is desirable if a visual (e.g., colour) indicator is present in the stored substance. Lid **100** and reservoir **102** can be manufactured to include gradations to demarcate the quantity of the substance stored within reservoir **102**. The outer surface of lid **100** can also include a labelling area for a user to identify the contents of the lid. The outer surface of lid **100** may also include a region to affix or emboss a logo and/or other markings.

In accordance with one embodiment of the present invention, wall **104** has a generally cylindrical shape sized to fit within the interior of lid **100**. It will be clear that the shape and size of well **104** is dependent upon the intended use of the container system. Lid **100** may be constructed from a single piece of material that includes wall **104**, or wall **104** may be removably attached to lid **100**. Desirably, lid **100** is formed from a single piece of material.

VIAL

In accordance with one embodiment of the present invention, vial **1** is generally cylindrically shaped with at least one open end. Vial **1** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use. The interior of vial **1** comprises chamber **2** for receiving a sample such as a liquid, solid, semi-solid, mixtures thereof and the like. Desirably, chamber **2** is configured to receive a biological sample, for example a sputum sample, such as saliva.

Vial **1** comprises a first open end for receiving said sample, and a second end comprising chamber **2**. In one example, said second end is a second closed end. In another example, said second end is a second open end.

In one example, the width of the first open end of vial **1** is approximately equivalent to the width of the second end.

In another example, the first open end of vial **1** is generally wider than the second end vial **1**. In this example, the generally wider first open end facilitates sample collection by, for example, acting similar to a funnel.

In accordance with one embodiment, and as shown in Figure 22-24, container system **300** comprises a funnel fixedly attached to, or integral with, vial **1**. In the case in which the funnel is fixedly attached to, or integral with vial **1**, it can also be characterised as a vial having a wide mouth opening for receiving a sample. The wide mouth or funnel characteristics can make it easier for a subject to provide a sample.

Vial **1** and chamber **2** can be sized to accommodate a range of volumes of a sample. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, chamber **2** accommodates about 1 ml to about 4 ml of a sample. In another specific embodiment, chamber **2** accommodates about 1 ml to about 16 ml of a sample.

Vial **1** comprises at least one piercing member **6**. In the specific embodiment depicted in Figures 1-11 piercing member **6** extends from a base surface of chamber **2**. In one example, piercing member **6** extends approximately perpendicular from the base. In another example, piercing member **6** is angled inwardly or outwardly toward the open end of vial **1**. Alternatively, piercing member **6** extends from an interior surface of said vial. In one example, piercing member **6** extends from an interior surface of said vial and is angled inwardly or outwardly toward the open end of vial **1**.

In one example, there is one piercing member **6** within chamber **2**. In an alternative example, there is a plurality of piercing members **6**, for example, two piercing members, three piercing members or more than three piercing members. In one example the piercing members are arranged in a generally semicircular fashion. In a specific example, in the case of three piercing members, the piercing members are arranged in a generally semicircular fashion, as depicted in Figure 9, 10 and 23.

Piercing member **6** can be approximately trapezoidal in shape and includes first cutting edge **33** having pointed end **30** at one corner of the trapezoid and a second end at a second corner of the trapezoid where cutting edge **32** intersects side wall **34**. Optionally, side wall **34** also includes cutting edge **33**, which extends from cutting edge **32**.

Container system **300** further includes a means for sealing attachment of lid **1** to vial **100**. Such sealing means act to ensure that the contents of vial **1** remain sealed with chamber **2** when lid **100** is attached to vial **1**.

In one example, lid **100** and vial **1** are movable between an open position and a piercing position. In a specific example, lid **100** is initially attached to vial **1** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. Initially, lid **100** and vial **1** are threadingly connected, but piercing member **6** does not disrupt pierceable

membrane **160** and end portion **30** of wall **12** engages sealing wall **120**. For example, as depicted in Figure 9, sealing wall **120** extends downwardly and outwardly from the interior of lid **100**. This type of sealing mechanism is similar to a wipe seal that would be well known to the skilled worker. Thus, initially, chamber **2** is maintained out of fluid communication with reservoir **102** by pierceable membrane **160**.

In an alternate example, lid **100** and vial **1** are movable between a first position and a piercing position. In a specific example, lid **100** is initially attached to vial **1** by threadingly engaging internal and external threads **108** and **18** with a twisting motion and thereby moved to the first position. In moving lid **100** and vial **1** to the first position, lid **100** and vial **1** are threadingly connected, but piercing member **6** does not disrupt pierceable membrane **160**. In the first position, end portion **30** of wall **12** sealingly engages sealing wall **120**. For example, as depicted in Figure 9, sealing wall **120** extends downwardly and outwardly from the interior of lid **100**. This type of sealing mechanism is similar to a wipe seal that would be well known to the skilled worker. Thus, in the first position, chamber **2** is sealed against leakage to the outside of the container system by sealing engagement of wall **12** with sealing wall **120** and maintained out of fluid communication with reservoir **102** by pierceable membrane **160**.

A worker skilled in the art will recognize that there are known alternative sealing structures that can be incorporated into the present system for ensuring that chamber **2** is sealed against leakage to the outside of the container system. Such alternatives are considered to be within the scope of the present invention.

Continued twisting moves lid **100** and vial **1** from the open position, or the first position, to the piercing position, in which movement of lid **100** and vial **1** together results in disruption of pierceable membrane **160** by piercing member **6**, and the release of the substance within reservoir **102** into chamber **2**.

In operation, in moving to the piercing position, pointed end **31** of piercing member **6** is brought into contact with pierceable membrane **160** and pierces pierceable membrane **160**. Continued twisting moves cutting edge **32** through pierceable membrane **160**, disrupting pierceable membrane **160**, and thereby producing an opening in the sealing

membrane to enable the substance to enter chamber **2**. It will be clear that if more than one piercing member is present, less twisting of lid **100** and vial **1** is required to generate an opening. When three piercing members are present, a suitable opening is obtainable in about one quarter of a turn. Desirably, pierceable membrane **160** is not completely removed from sealing surface **106**. Thus, in the piercing position, piercing member **6** disrupts pierceable membrane **160** to allow fluid communication between reservoir **102** and chamber **2**.

The distance between piercing member **6** and wall **104** will vary according to the needs and preferences of the user. The distance between piercing member **6** and wall **104** can vary from being generally flush with one another, to being generally separated from one another.

It will be clear to the skilled worker that length, rigidity and the like, of piercing member **6** is selected such that it is sufficient to disrupt pierceable membrane **160** when lid **100** and vial **1** are in the piercing position, and not disrupt the pierceable membrane **160** when lid **100** and vial **1** are in the open or first position.

The choice of the material of vial **1** will be dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. Additionally, the construction material of lid **1** may be same or different as that used to make reservoir **6**. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, vial **1** is made from plastics such us polypropylene, medium-density polyethylene (MDPE), high-density polyethylene (HDPE), polyethylene and the like. Desirably, vial **1** is HDPE.

In accordance with another aspect of the present invention, the container system comprises a lid, a funnel and a vial.

Referring to the Figures 12-21, container system **600** comprises lid **100** and funnel **400** and vial **500**.

LID

Lid **100** releasably stores a substance, as described above.

FUNNEL

Funnel **400** includes a first open end for receiving a sample, a second open end for removable or fixed attachment to vial **500**. In one embodiment, funnel **400** is integral with vial **500**. The interior of funnel **400** comprises interior channel **422** extending therethrough for maintaining the first open end and the second open end in fluid communication and for receiving a sample such as a liquid, solid, semi-solid, mixtures thereof and the like. Funnel **400** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use. Desirably, interior channel **422** is configured to receive a biological sample. For example, the biological sample is a sputum sample, such as saliva. Interior channel **422** can be sized accommodate a range of volumes of sample.

In the specific embodiments depicted in the Figures, lid **100** comprises internal helical threads **108** on the inner surface of outer wall **110**, which are adapted to engage external helical threads **418** on the outer surface of wall **412** on funnel **400**. As would be appreciated by a skilled worker, alternative means for releasable attachment of lid **100** to funnel **400** can be used in the container system of the present invention, provided that lid **100** and funnel **400** are movable to the piercing position, as discussed in greater detail above.

Funnel **400** comprises at least one piercing member **6**. In accordance with the embodiment depicted in Figures 12-21, piercing member **6** extends from an interior surface (interior side wall **420**) of funnel **400**. In one example, piercing member **6** is angled inwardly or outwardly toward pierceable membrane **160**. Other arrangements of piercing member **6** can be used, as would be readily appreciated by the skilled worker.

In one example, there is one piercing member **6** within interior channel **422**. In an alternative example there is a plurality of piercing members, for example, two piercing members, three piercing members or more than three piercing members. In the case of three piercing members, desirably the piercing members are arranged in a generally semicircular fashion, as shown in Figure 18.

As above, piercing member **6** can be approximately trapezoidal in shape and includes first cutting edge **33** having pointed end **30** at one corner of the trapezoid and a second end at a second corner of the trapezoid where cutting edge **32** intersects side wall **34**. Optionally, side wall **34** also includes cutting edge **33**, which extends from cutting edge **32**.

Container system **600** further includes a means for sealing attachment of lid **1** to funnel **400**. Such sealing means act to ensure that the contents of vial **1** remain sealed with chamber **2** when funnel **400** and vial **500** are attached to vial **1**.

Optionally, funnel **400** includes outwardly extending ribs **402** that can used by a user to twist funnel **400** and lid **100**, and/or funnel **400** and vial **500**.

The choice of the material of funnel **400** will be dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. Additionally, the construction material of funnel **400** may be same or different as that used to make lid **100** and collection vial **500**. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, funnel **400** is made from plastics such us polypropylene, high-density polyethylene (HDPE), polyethylene, medium-density polyethylene (MDPE), or any combination thereof, and the like. Desirably, vial **1** is HDPE.

In a specific example, lid **100** is polypropylene, vial **500** is polypropylene and funnel **400** is HDPE.

VIAL

Vial **500** (or collection vial **500**) is generally cylindrically shaped with an open end for removable or fixed attachment to the second end of funnel **400**, and chamber **530** for receiving a sample. Vial **500** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use, and can be specifically manufactured for use in the container system of the present invention or can be a commercially available vial. As noted above, and in one embodiment, funnel **400** is integral with vial **500**. When the container system is used for laboratory purposes, desirably, vial **500** is sized to fit within a standard test tube rack such as that typically used in biological sample processing. In one example, vial **500** conforms with industry-standard dimensions for blood collection tubes

(e.g., 13 mm x 75 mm). Desirably vial **500** is suitable for use with robotic DNA purification systems (e.g., the Beckman BioMek™ FX). Desirably, vial **500** is commercially availably from Simport Plastics Limited (e.g., the T501 tubes).

The open end of vial **500** is also configured for securing attachment with a standard cap **520**, as shown in Figure 21. Cap **520** can be secured by a threaded screw, snap-fit, and the like.

Vial **500** optionally includes surface **502** that is suitable for labelling and/or for providing friction for gripping by a user.

Vial **500** may be removably attached to funnel **400** using a variety of locking mechanisms. In accordance with one embodiment of the present invention, the locking mechanism is a helical threaded screw. Alternatively, the locking mechanism is a snap-fit. Alternatively, vial **500** is fixedly attached to, or integral with, funnel **400**.

In one example, lid **100** and funnel **400** are movable between an open position and a piercing position, as discussed supra with lid **100** and vial **1**. In a specific example, lid **100** is initially attached to funnel **400** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. Initially, lid **100** and funnel **400** are threadingly connected, but piercing member **6** does not disrupt pierceable membrane **160**, and end portion **30** of wall **12** engages sealing wall **120**. As depicted in Figures 9 and 16, sealing wall **120** extends downwardly and outwardly from the inner surface of lid **100**. This type of sealing mechanism is similar to a wipe seal, that would be well known to the skilled worker. Thus, initially, interior channel **422** is maintained out of fluid communication with said reservoir **102** by pierceable membrane **6**.

In an alternate example, lid **100** and funnel **400** are movable between a first position and a piercing position, as discussed supra with lid **100** and vial **1**. Lid **100** is initially attached to funnel **400** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. In moving lid **100** and funnel **400** to the first position, lid **100** and funnel **400** are threadingly connected, but piercing member **6** does not disrupt pierceable membrane **160**. In the first position, end portion **30** of wall **12** sealingly engages sealing

wall **120**. As depicted in Figures 9 and 16, sealing wall **120** extends downwardly and outwardly from the inner surface of lid **100**. This type of sealing mechanism is similar to a wipe seal, that would be well know to the skilled worker. Thus, in the first position, interior channel **422** is sealed against leakage to the outside of the container system and maintained out of fluid communication with said reservoir **102** by pierceable membrane **6**.

Continued twisting moves lid **100** and funnel **400** from either the open position or the first position, to the piercing position, in which moving lid **100** and vial **1** together results in disruption of pierceable membrane **160** by piercing member **6**, and the release of the substance within reservoir **102** into chamber **2** and vial **500**.

In operation, in moving to the piercing position, pointed end **30** is brought into contact with pierceable membrane **160** and subsequently pierces pierceable membrane **160**. Continued twisting moves cutting edge **32** through pierceable membrane **160**, thereby disrupting pierceable membrane **160** and producing an opening in pierceable membrane **160** to permit the substance to enter interior channel **422**. If more than one piercing member is present, less twisting of lid **100** and vial **1** is required to generate an opening. When three piercing members are present, a suitable opening is obtainable in about one quarter of a turn. Thus, in the piercing position, piercing member **6** disrupts pierceable membrane **160** to allow fluid communication between reservoir **102** and interior channel **422**.

The distance between piercing member **6** and wall **104** will vary according to the needs and preferences of the user. The distance between piercing member **6** and wall **104** can vary from being generally flush with one another, to being generally separated from one another.

It will be clear to the skilled worker that length, rigidity and the like, of piercing member **6** is selected such that it sufficient to disrupt pierceable membrane **160** when lid **100** and vial **1** are in the piercing position, and not disrupt the pierceable membrane **160** when lid **100** and vial **1** are in the open or first position.

METHODS

According to one embodiment of the present invention, the container system of the present application is suitable for releasably storing a composition intended to stabilize, preserve, or facilitate the recovery of nucleic acid from a biological sample. A biological sample can include bodily fluids and/or tissues.

Desirably, vial **1** and/or funnel **400** are sized for collecting a biological sample from a subject. Non-limiting examples of biological samples include skin, hair, fecal matter, bodily fluids, tissue, cells and the like.

The term "bodily fluid", as used herein, refers to a naturally occurring fluid from a human or an animal, such as saliva, sputum, serum, plasma, blood, pharyngeal, nasal/nasal pharyngeal and sinus secretions, urine, mucus, gastric juices, pancreatic juices, feces, semen, products of lactation or menstruation, tears, or lymph.

The term "bodily tissue" or "tissue", as used herein, refers to an aggregate of cells usually of a particular kind together with their intercellular substance that form one of the structural materials of a plant or an animal and that in animals include connective tissue, epithelium, muscle tissue, and nerve tissue, and the like.

The term "nucleic acid", as used herein, refers to a chain of nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), typically found in chromosomes, chromatin, mitochondria, ribosomes, cytoplasm, nucleus, microorganisms or viruses.

The term "ribonucleic acid" or "RNA", as used herein, refers to a wide range of RNA species, including, but not limited to high molecular RNA, large and small ribosomal RNAs, messenger RNA, pre-messenger RNA, small regulatory RNAs, RNA viruses (single and double-stranded, positive stranded or negative stranded) and the like. The RNA may be from a variety of sources, including, but not limited to human, non-human, viral, bacterial, fungal, protozoan, parasitic, single-celled, multi-cellular, in vitro, in vivo, natural, and/or synthetic sources.

Optionally the bodily fluid is saliva. The term "saliva", as used herein, refers to the secretion, or combination of secretions, from any of the salivary glands, including the

parotid, submaxillary, and sublingual glands, optionally mixed with the secretions from the numerous small labial, buccal, and palatal glands that line the mouth.

The term "subject", as used herein, refers to an animal or human. Desirably, the subject is a mammal that can produce saliva for the purposes of nucleic acid stabilization and/or detection. Most desirably, the subject is human.

In use, a substance, such as a composition intended to stabilize, preserve, or facilitate the recovery of nucleic acid from a biological sample is sealed within reservoir **102** with a pierceable membrane. Suitable compositions include those described in International PCT application WO 2003/104251; International PCT application PCT/CA2006/000380; United States Application Serial Nos. 60/828,563; or 60/866,985, all of the contents of which are hereby incorporated by reference in their entirety. Desirably the composition is Oragene™ DNA-preserving solution. Other suitable compositions would be well known to the skilled worker.

In use, in one example, a sample of saliva from a subject is placed within chamber **2** of vial **1.** Alternatively, vial **500** is attached to funnel **400**, and a sample of saliva is placed within chamber **2** of funnel **400.**

To collect saliva from a subject, in one example, the subject is instructed to wait for a period of 30 – 60 minutes before last eating. If possible, the subject will brush his teeth (without using toothpaste). If possible, the subject will rinse his/her mouth with 50 ml of water. The subject will be requested to wait for 5-10 minutes to allow the mouth to clear of water. For subjects able to spit, they will be instructed to spit saliva into the special collection vial until the level of saliva reaches the 1 or 2 ml mark. Waiting after last eating and rinsing the mouth is desirable but not essential. Collection of saliva may take several minutes. If the subject finds that he/she is unable to deliver sufficient saliva, he/she will be given a few grains of table sugar to chew, and told not to be concerned if some of the sugar is spit into the vial. For subjects unable to spit (e.g., infants, young children, individuals with limitations/disabilities), an implement (e.g., swab, transfer pipette) may be used for sample collection. Similarly, a subject may be provided a liquid (e.g., mouthwash, water, saline) to

gargle his/her mouth and throat or saline to flush his/her nasal cavity. Samples collected with said liquid would be delivered into the collection vial.

A substance, such as a composition to stabilize, preserve, and/or facilitate the recovery of nucleic acid and saliva is stored within reservoir **102** of lid **100**.

Lid **100** is then attached to vial **1**, moved to the piercing position, and the substance combines with the saliva in chamber **2**.

Alternatively, lid **100** is attached to funnel **400**, moved to the piercing position, and the substance combines with the saliva in interior **530**.

The combination of the composition to stabilize, preserve, or facilitate the recovery of nucleic acid and saliva may then be used in standard nucleic acid testing reactions, for example for detection or quantitation. Alternatively, the combination may be stored within container system **300** or **600** and subsequently used, for example, for detection of nucleic acid contained within the saliva. Alternatively, funnel **400** is removed from vial **500**, and cap **520** is attached to the open end of vial **500**. In this example, the combination may be stored within vial **500** and subsequently used, for example, for detection of nucleic acid contained within the saliva.

In one aspect of the present invention container system **300** and container system **600** are sized for shipping. In one example, vial **1** and lid **100** of container system **300** are sized for shipping when securely attached. In one example lid **1**, funnel **400** and collection vial **500** of container system **600**, are sized for shipping when lid **1**, funnel **400** and collection vial **500** are securely attached. In another example, vial **1** and lid **100** of container system **300** are sized for shipping when vial **1** and lid **100** are separate. In another example, lid **1**, funnel **400** and collection vial **500** of container system **600**, are sized for shipping when lid **1**, funnel **400** and collection vial **500** are separate. It will be appreciated that a variety methods of shipping are contemplated. Non-limiting examples of shipping include shipping by hand, land, air, boat, animal, and the like, or combinations thereof. Desirably, container system **300** or container system **600** fit within a standard mail envelope. In one example, container system **300** or container system **600** fit within an envelope sized to fit within a

standard European mail slot. In a specific example, the standard European mail slot has a width of about 3 cm. Alternatively, container system **300** or container system **600** fit within an envelope sized to fit within a standard Canadian and/or United States of America mail slot.

Another aspect of the present invention provides a method of manufacture of a device for releasably storing a substance. The method of manufacture comprises providing container system in accordance with the present invention.

Another aspect of the present invention provides a method of combining a substance with a biological sample. This method comprises providing a container system in accordance with the present invention, wherein the container system includes the substance, and providing the biological sample.

Another aspect of the present invention provides a method of preserving nucleic acid in a biological sample. This method comprises providing a container system in accordance with the present invention, wherein the container system includes a substance for preserving nucleic acid in a biological sample.

Another aspect of the present invention provides a method of archiving a biological sample for prolonged periods of time. Desirably archiving is at room temperature. This method comprises providing a container system in accordance with the present invention and providing a substance for archiving the biological sample. In one example, prolonged storage is at room temperature for more than about one week, about two weeks, about three weeks, about one month, more than about one month, about one year.

KIT

Another aspect of the present invention provides a kit for collection of a sample and mixing the sample with a substance. The kit includes a container system in accordance with the present invention and instructions for the use thereof, optionally with a substance stored within the lid of the container system.

All publications, patents and patent applications mentioned in this Specification are indicative of the level of skill of those skilled in the art to which this invention pertains and are herein incorporated by reference to the same extent as if each individual publication, patent, or patent applications was specifically and individually indicated to be incorporated by reference.

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A container system for releasably storing a substance, comprising:

a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member; and

b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir,

wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

2. The container system according to claim 1 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir, said wall having a sealing surface for sealingly attaching said pierceable membrane.

3. The container system accordingly to any one of claims 1 or 2, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

4. The container system according to any one of claims 1 - 3, wherein said pierceable membrane is inert.

5. The container system according to any one of claims 1 - 4, wherein said pierceable membrane remains intact and pierceable at temperatures of from about -80°C to about 70°C.

6. The container system according to any one of claims 1 – 5, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

7. The container system according to claim 1, wherein the width of said first end is approximately equivalent to the width of said second end.

8. The container system according to claim 1, wherein said first end is generally wider than said second end.

9. The container system according to any one of claims 1 – 8, wherein said chamber is configured to receive about 1 ml to about 16 ml of said sample.

10. The container system according to claim 9, wherein said chamber is configured to receive about 1 ml to about 4 ml of said sample.

11. The container system according to any one of claims 1 - 10, wherein the said piercing member extends from a base surface of said chamber.

12. The container system according to claim 11, wherein said piercing member extends approximately perpendicularly from said base.

13. The container system according to claim 11, wherein said piercing member is angled inwardly or outwardly toward said first open end of said vial.

14. The container system according to any one of claims 1 - 13, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall.

15. The container system according to claim 14, wherein said side wall further includes a second cutting edge.

16. The container system according to any one of claims 1 - 15, wherein said vial comprises a plurality of piercing members.

17. The container system according to claim 16, wherein said vial comprises three piercing members.

18. The container system according to claim 16, wherein said vial comprises two piercing members.

19. The container system according to any one of claims 1 - 18, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system following movement of said container system to said piercing position.

20. The container system according to claim 19, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said vial when the system is said piercing position.

21. The container system according to any one of claims 1 - 20, wherein said vial and said lid are sized for shipping in both an unattached state and an attached state.

22. A container system for releasably storing a substance, comprising:

a) a vial comprising a chamber for retaining a sample

b) a lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir; and

c) a funnel comprising a first open end for receiving said sample, a piercing member and a channel extending from said first open end to a second open end and being in fluid communication with said chamber, said funnel being removably attachable to said lid at said first open end and releasably or permanently attached to said vial at said second end,

wherein, when said system is closed by removable attachment of said lid to said funnel, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, via said channel, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

23. The container system according to claim 22 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir and including a sealing surface for sealingly attaching said pierceable membrane

24. The container system accordingly to any one of claims 22 or 23, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

25. The container system according to any one of claims 22 - 24, wherein said pierceable membrane is inert.

26. The container system according to any one of claims 22 - 25, wherein said pierceable membrane maintains intact and pierceable at temperatures of from about -80°C to about 70°C.

27. The container system according to any one of claims 22 – 26, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

28. The container system according to any one of claims 22 - 27, wherein said piercing member extends from an interior surface of said funnel.

29. The container system according to claim 28, wherein said piercing member is angled inwardly or outwardly toward said first open end of said funnel.

30. The container system according to any one of claims 22 - 29, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall.

31. The container system according to claim 30, wherein said side wall includes a second cutting edge.

32. The container system according to any one of claims 22 - 31, wherein said funnel comprises a plurality of piercing members.

33. The container system according to claim 32, wherein said funnel comprises three piercing members.

34. The container system according to claim 33, wherein said funnel comprises two piercing members.

35. The container system according to any one of claims 11 - 34, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system.

36. The container system according to claim 35, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said funnel when the system is in the piercing position.

37. The container system according to any one of claims 22 - 36, wherein said vial is releasably attached to said funnel and sized for attachment to a cap when released from said funnel.

38. The container system according to any one of claims 22 - 37, wherein said vial is configured for use in standard laboratory equipment.

39. The container system according to claim 38, wherein said vial has dimensions that conforms with industry-standard dimensions for a blood collection tube.

40. The container system according to claim 38 or 39, wherein said vial is a T501 tube.

41. The container system according to any one of claims 22 – 40, wherein said chamber is sized to hold about 1 ml to about 16 ml.

42. The container system according to any one of claims 1 – 41, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample.

43. The container system according to claim 42, wherein said nucleic acid is DNA or RNA.

44. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 1 – 21;

(b) providing the sample to the chamber in the vial; and

(c) closing said container system by removably attaching said lid to said vial; and

(d) piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

45. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 22 – 41;

(b) providing the sample to the chamber in the vial through said funnel; and

(c) closing said container system by removably attaching said lid to said first open end of said funnel; and

(d) piercing said membrane to release said substance into said chamber by moving said system to said piercing position.

46. The method according to claim 44 or 45, wherein the substance is a nucleic acid preserving substance.

47. The method according to any one of claim 44 – 46, wherein the sample is a biological sample.

48. The method according to any one of claim 44 – 47, for archiving the sample.

49. A kit for sample collection and storage, comprising:

a) a container system according to any one of claims 1 to 43; and

b) instructions for the use thereof.

50. A container system as substantially described herein.

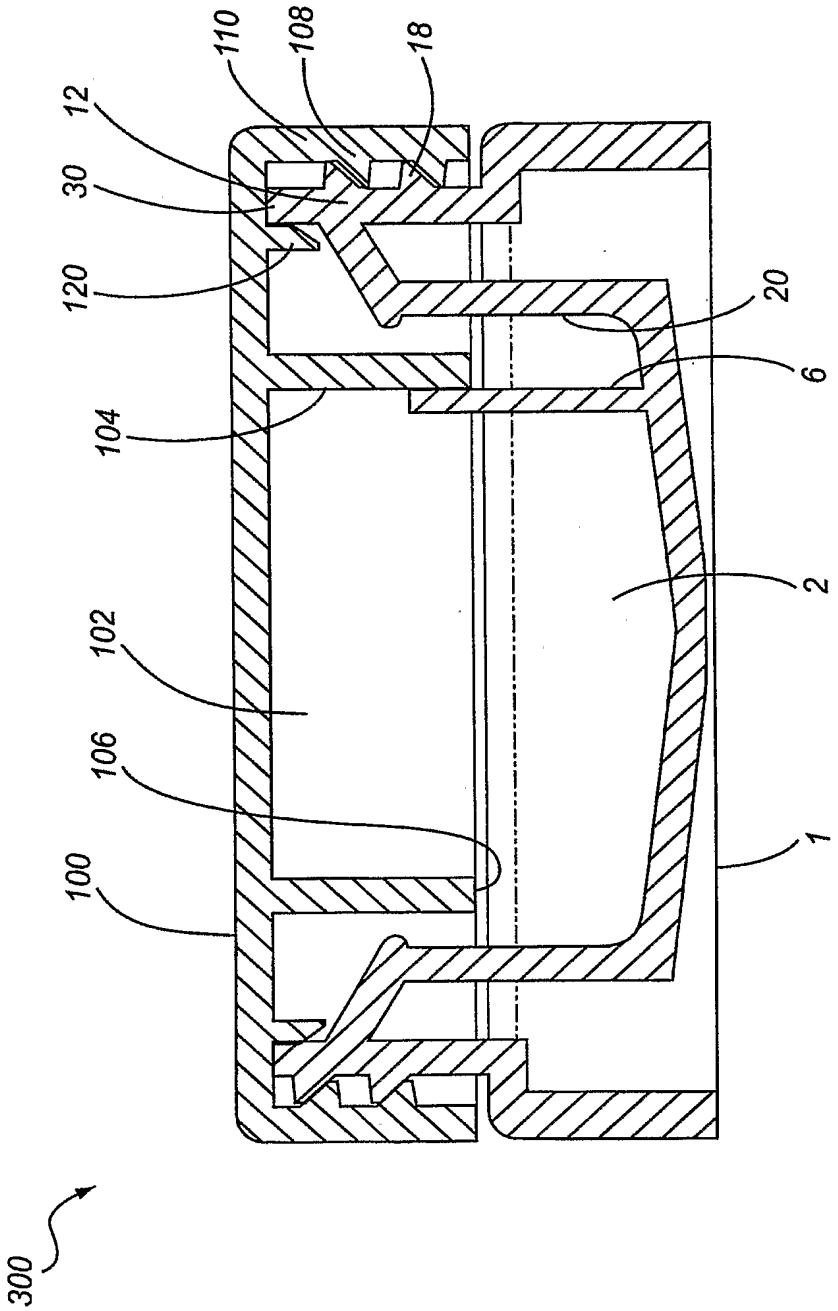

FIG. 1

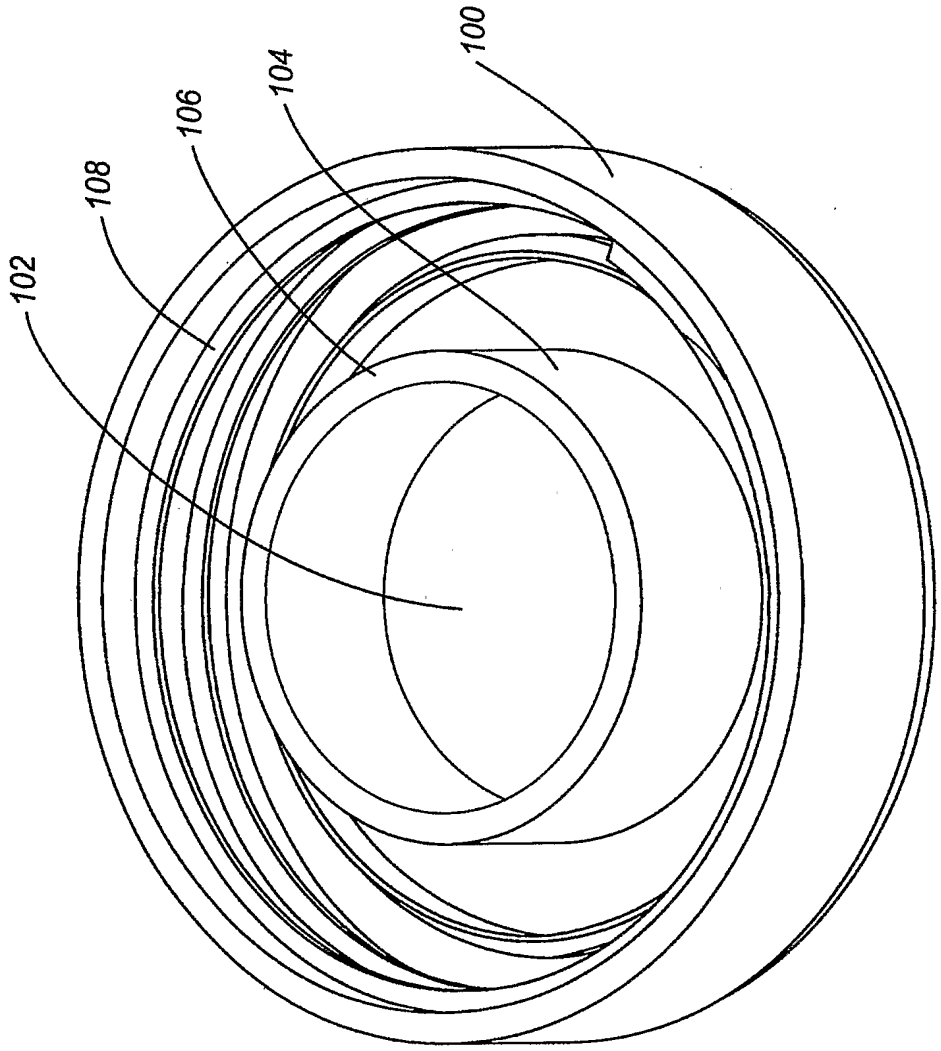

FIG. 2

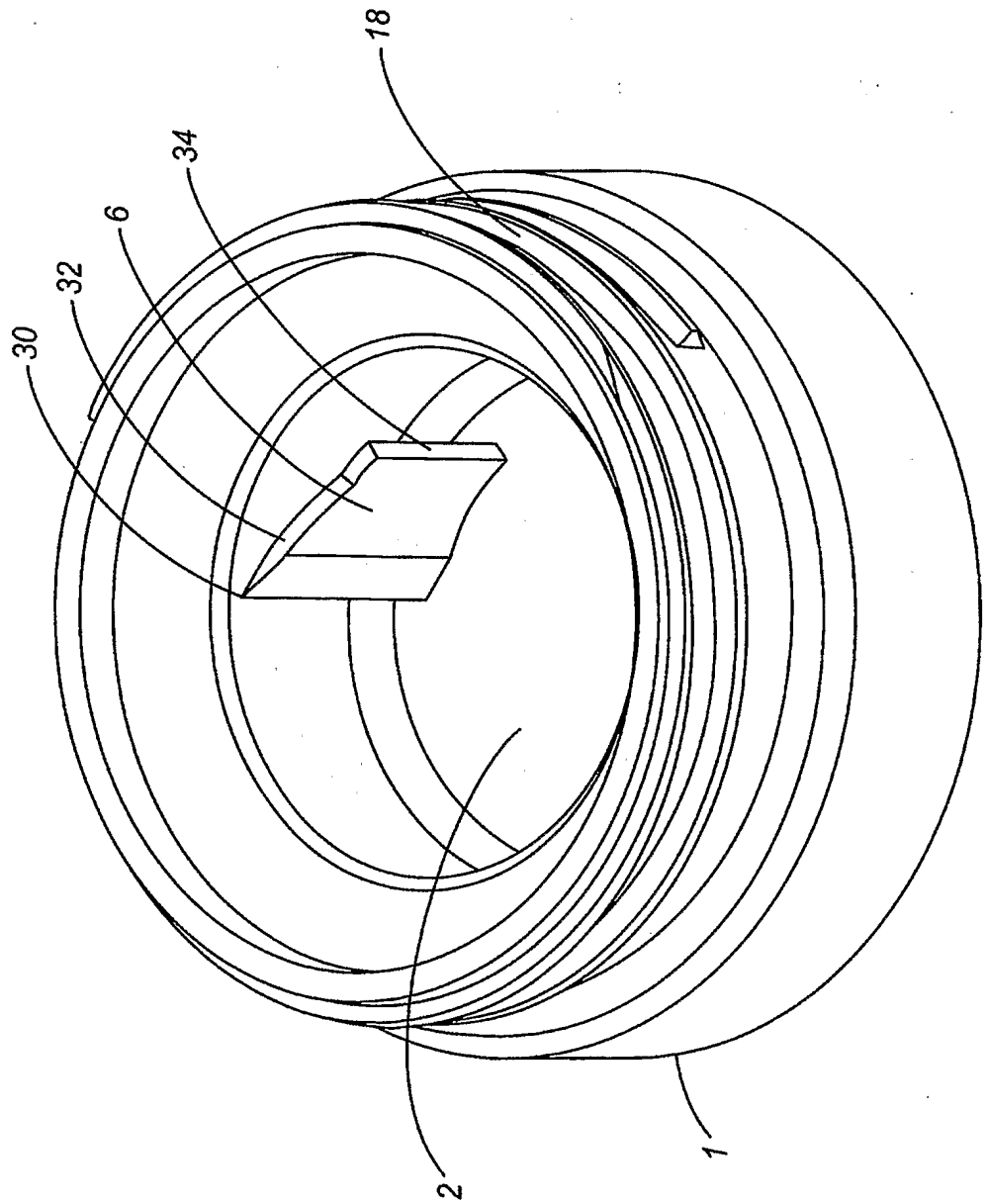

FIG. 3

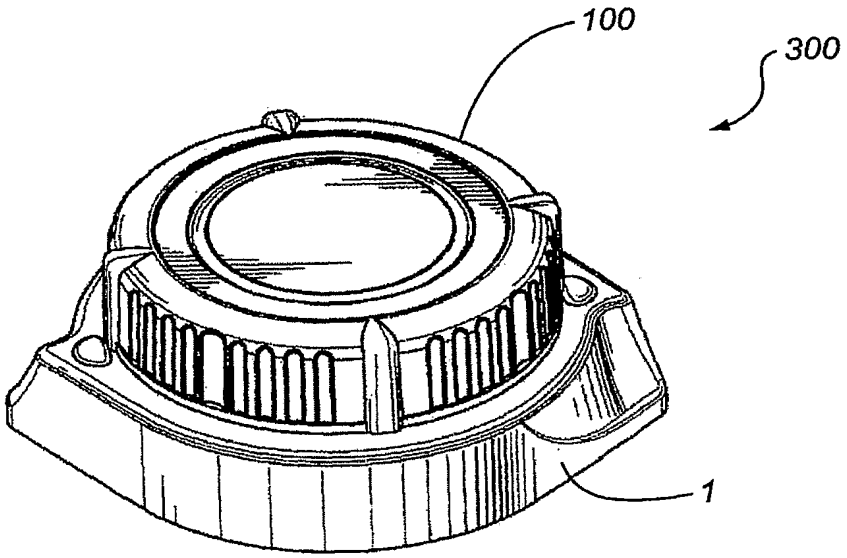

FIG. 4

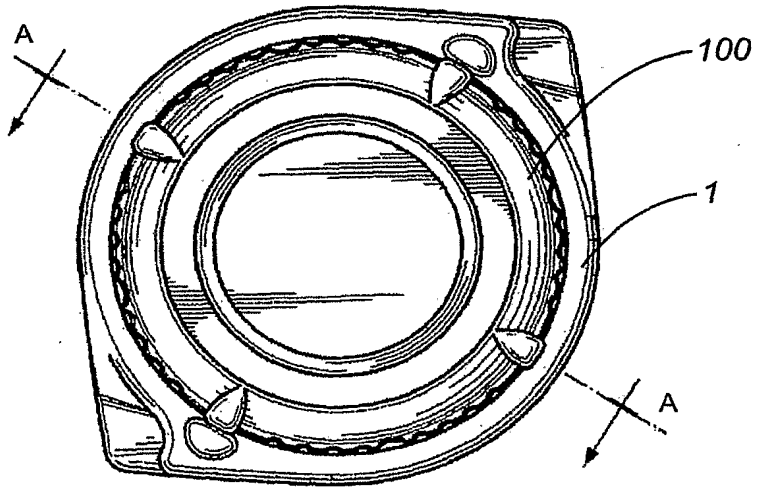

FIG. 5

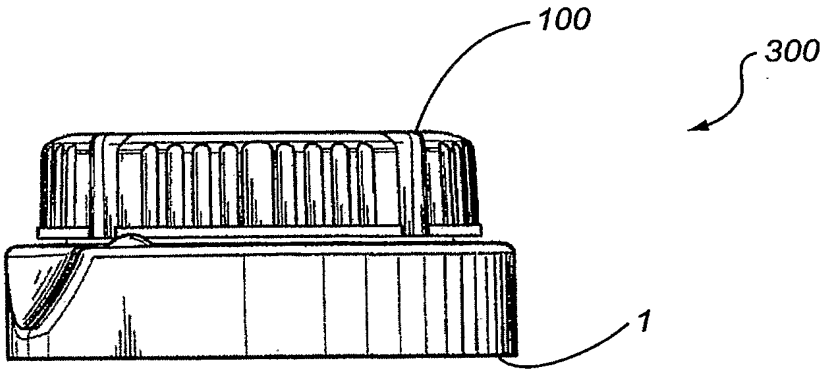

FIG. 6

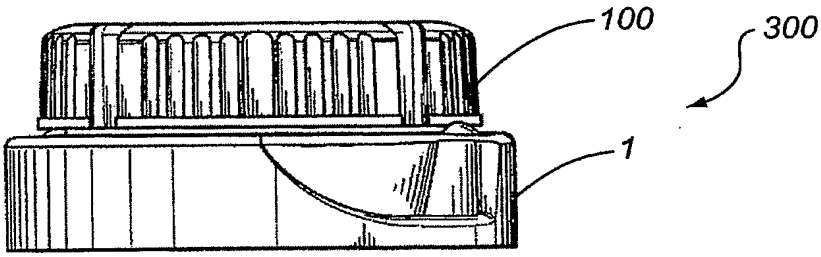

FIG. 7

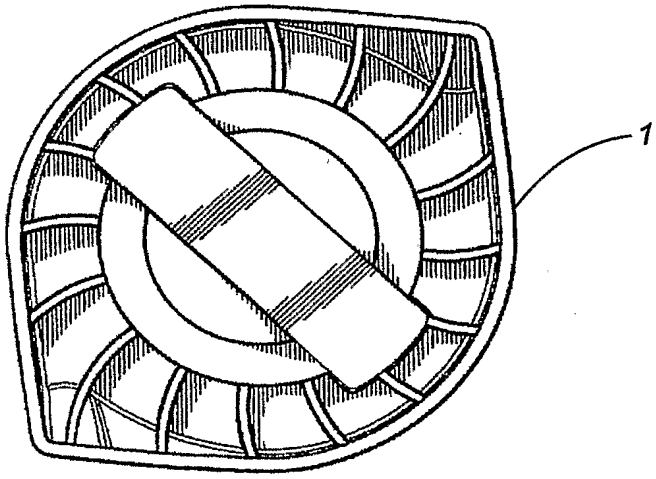

FIG. 8

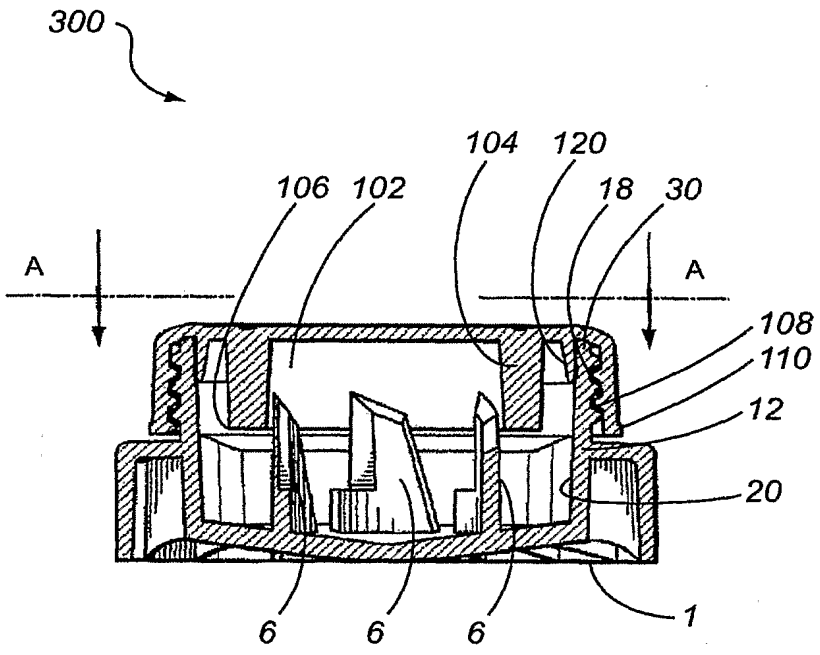

FIG. 9

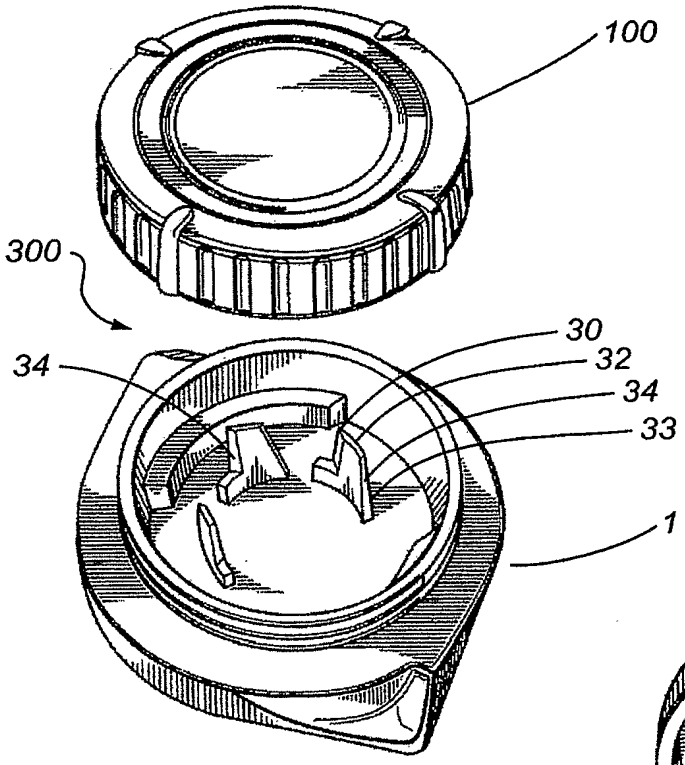

FIG. 10

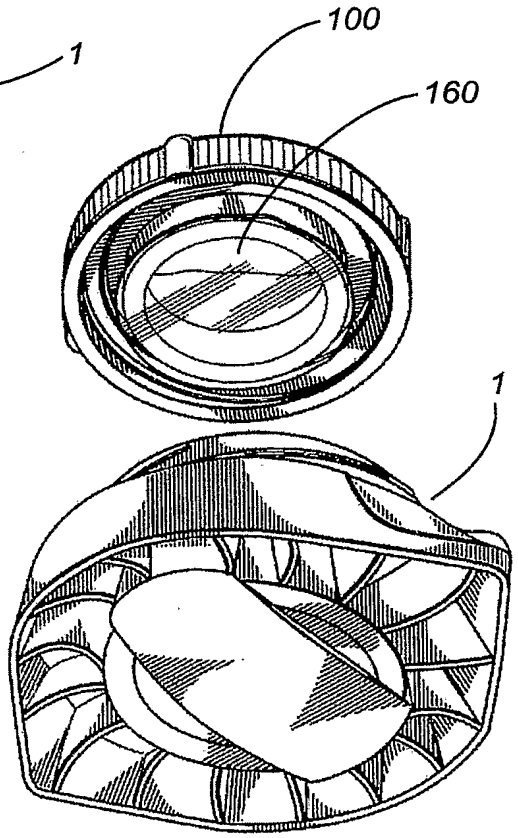

FIG. 11

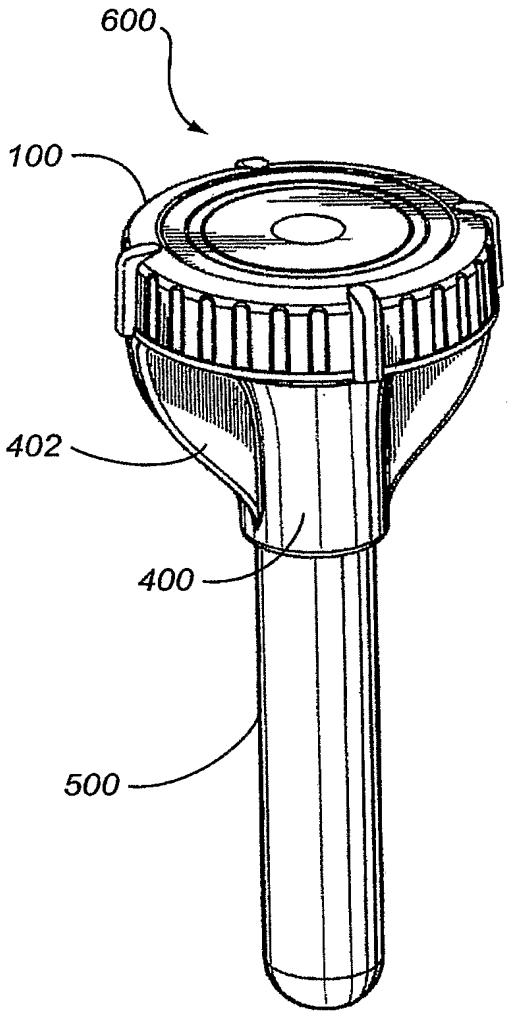

FIG. 12

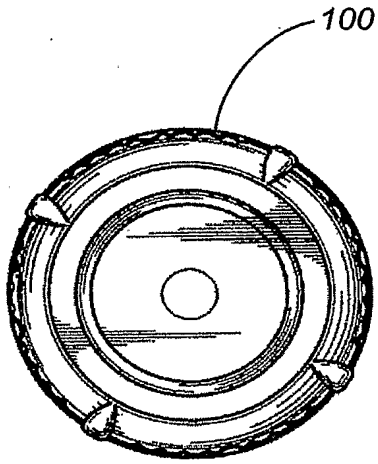

FIG. 13

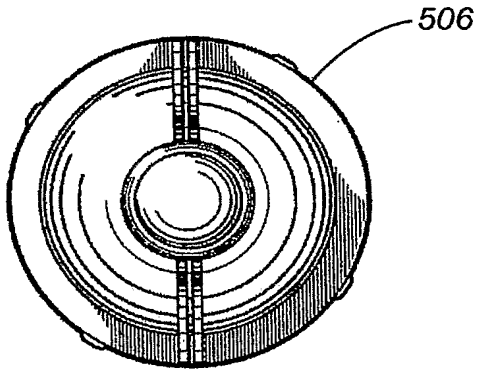

FIG. 14

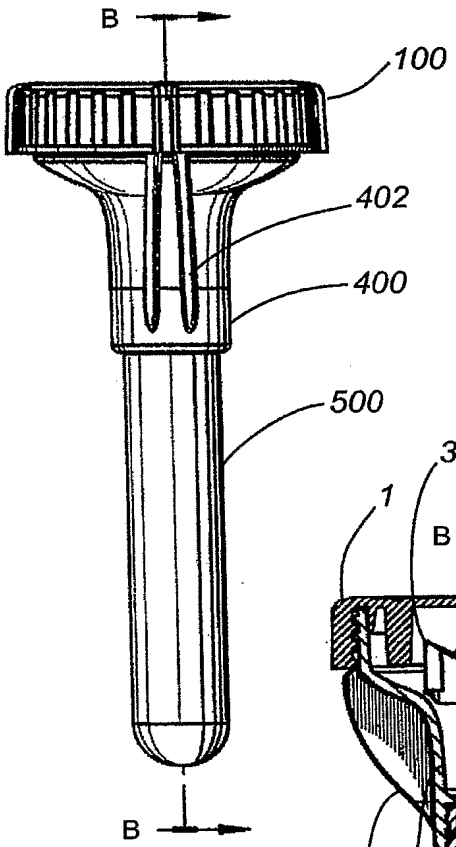

FIG. 15

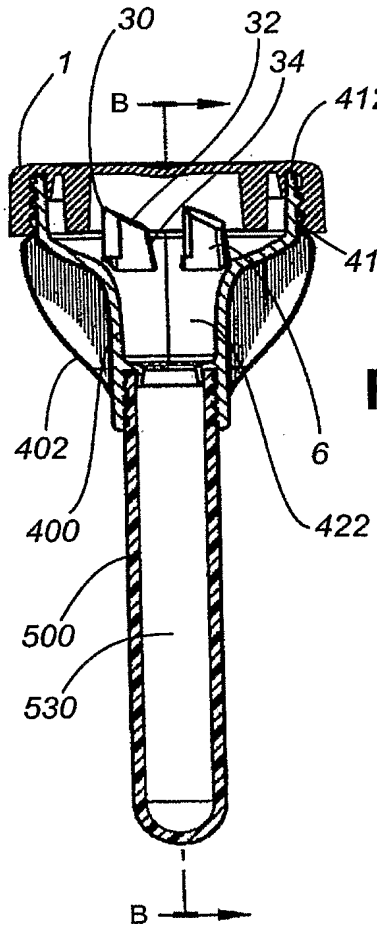

FIG. 16

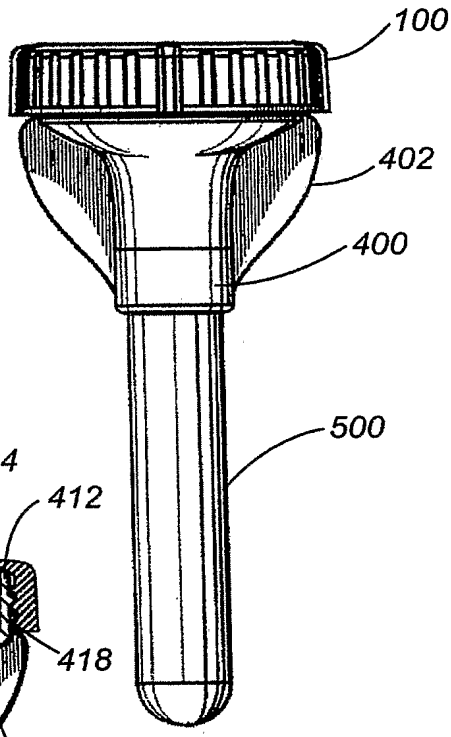

FIG. 17

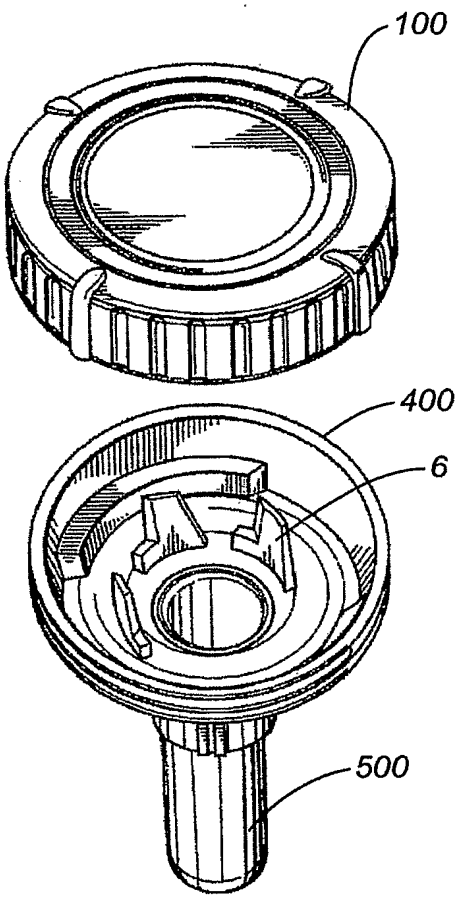

FIG. 18

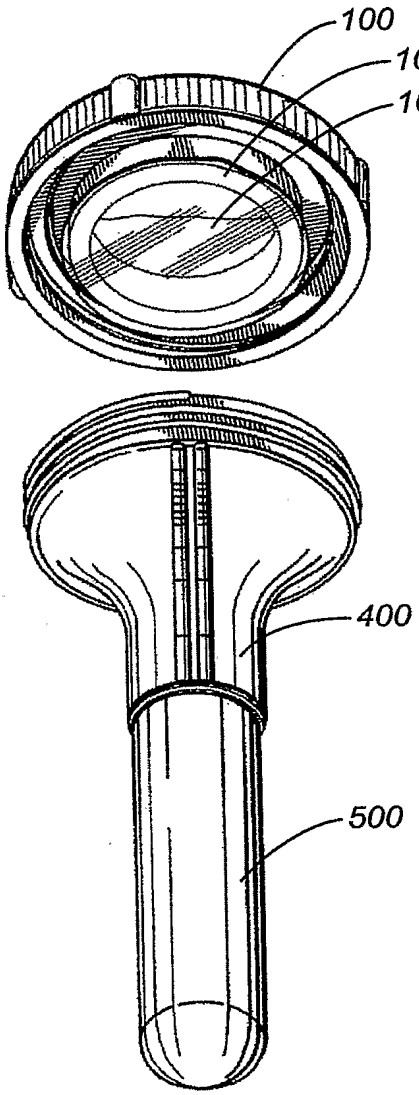

FIG. 19

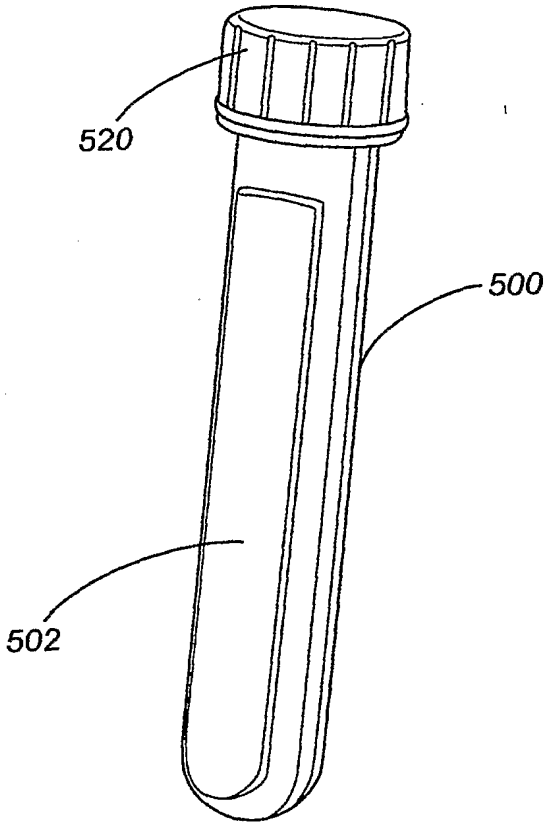

FIG. 20

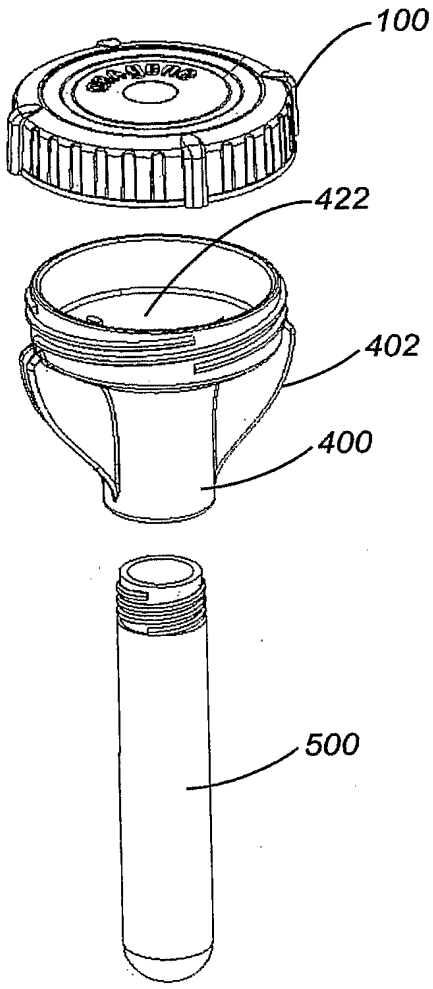

FIG. 21

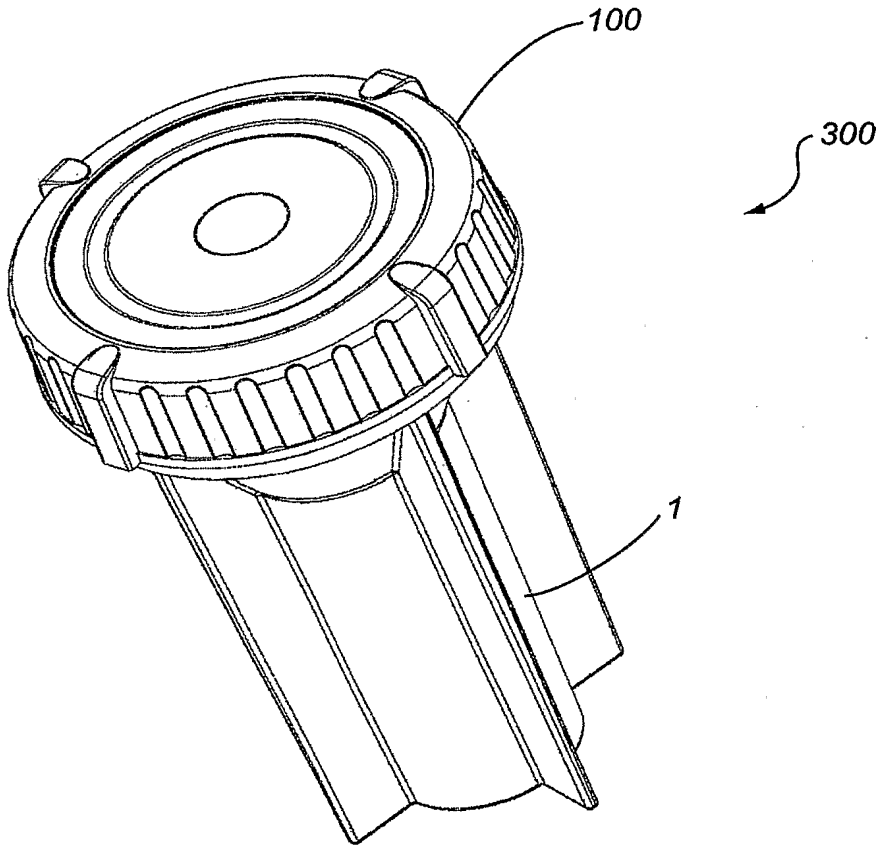

FIG. 22

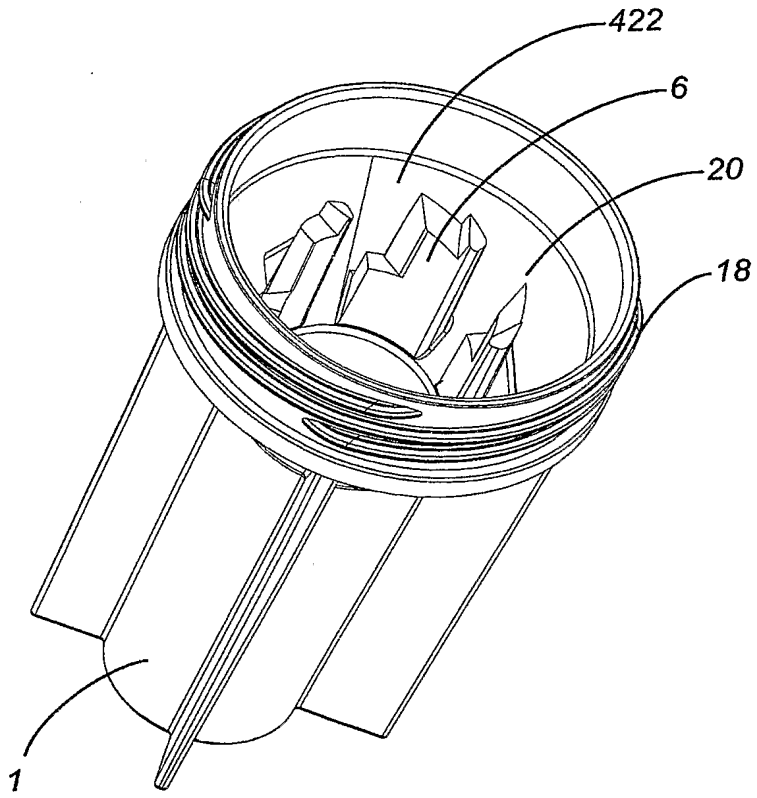

FIG. 23

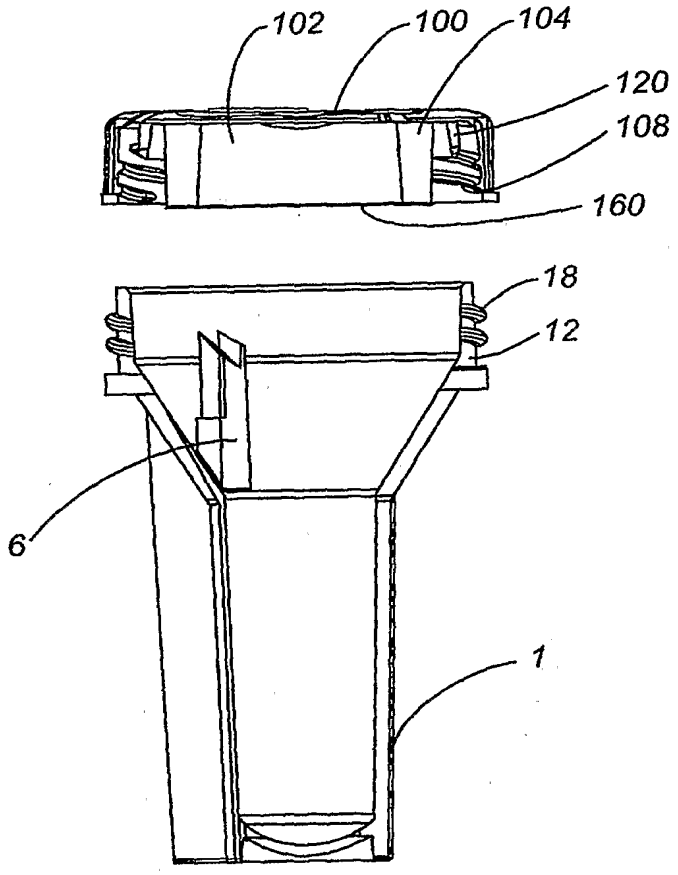

FIG. 24

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/CA2006/002009

International filing date: 11 December 2006 (11.12.2006)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/748,977
Filing date: 09 December 2005 (09.12.2005)

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December 08, 2006

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APPLICATION NUMBER: *60/748,977*
FILING DATE: *December 09, 2005*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US60/748,977*

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

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Certifying Officer

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PTO/SB/16 (04-04)
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. ER 478207644 US

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Rod	Muir	South Mountain, Ontario, Canada

Additional inventors are being named on the 1 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

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ENCLOSED APPLICATION PARTS (*check all that apply*)

☑ Specification *Number of Pages* 17
☑ Drawing(s) *Number of Sheets* 12
☑ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees.
☐ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:
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FILING FEE Amount ($): $100.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

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Date December 9, 2005

REGISTRATION NO. 22,386 *(if appropriate)*

Docket Number: OHH-P-40

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PROVISIONAL APPLICATION COVER SHEET
Additional Page

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Docket Number OHH-P-40

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Number 2 of 2

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PATENT
ATTORNEYS FILE: OHH-P-40

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Jon Carl Gealow

Dear Sir:

Transmitted herewith for filing is the Provisional Patent Application of:

Inventors: **Rod Muir, Derek Kirkland, Ian Curry, Roy Sunstrum and Dr. Paul Lem**

For: **CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE.**

Attorney Case No: **OHH-P-40**

Enclosed are the following:

1. Provisional Application Cover Sheet. (2 Sheet)
2. Application Data Sheet
3. **17** - page specification.
4. **12** Sheets of Figures
5. Form PTO-2038 in payment of the Provision Application Filing Fee 37 CFR

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OHH-P-40.TRS

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APPLICATION DATA SHEET

Initial Information Data Sheet

Application Information

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Attorney Docket Number::	OHH-P-40
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FIELD OF THE INVENTION

The field of the invention generally relates to a container system for releasably storing a substance.

BACKGROUND

It is often desirable to store a substance, such as a liquid, solid, gas, mixtures thereof, or the like, in a container prior to mixing the contents of the container with another material. For example, it may be desirable to package and store a compound, or compounds, in a container for shipping and/or safe storage and handling, prior to combining the compound(s) with another material. It may be desirable to package and store a toxic compound in a container for shipping, prior to combining such a toxic compound with a detoxifying material. As well, it is often desirable to keep a concentrated active ingredient separate from a diluent until immediately prior to use.

Moreover, it may be desirable to store and/or ship diagnostic and/or nucleic acid preserving compositions prior to combining such a substance with a biological sample.

Additionally, it may be desirable to keep a substance isolated from a donor until the donor's biological sample has been collected. This will help to prevent the donor from accidentally ingesting of spilling the substance.

It may also be desirable to store and/or ship diagnostic and/or nucleic acid preserving compositions after combining such a substance with a biological sample.

There are a variety of containers for holding substances separately, in such a manner that a user may open a closure to combine the substances. Typically these containers are double compartment systems in which substances are stored separately and in order to combine the substances, the container closures are removed by a user.

International PCT application WO 2003/104251 describes a container for collecting a biological sample from a subject, and subsequently mixing the collected sample with a composition intended to stabilize, preserve, or facilitate the recovery of components of the sample. This container has a first region for collecting a biological sample, a second region

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containing a composition for preserving a nucleic acid, and a barrier between the first region and the second region that keeps the sample and composition separate. The exemplified barrier of WO 2003/104251 is a pivoting partition. Attachment of the lid to the container forces the partition to pivot from its original closed position spanning the container and thereby separating the first region and the second region, to an open position in which both regions are exposed to each other and contact between the composition contained in one region space and the bodily fluid contained in the other region is allowed. A drawback of this container is that it includes multiple parts (e.g., lid, vial, disk, rod, rod holder), which increases the cost of manufacture of the container. Additionally, because the disk is held in place by friction fit, there must be a high degree of precision for the manufacture of the components of the container.

There remains a need for an improved container system for releasably and reliably storing a substance.

This background information is provided for the purpose of making known information believed by the applicant to be of possible relevance to the present invention. No admission is necessarily intended, nor should be construed, that any of the preceding information constitutes prior art against the present invention.

SUMMARY OF THE INVENTION

The present invention generally relates to a container system for releasably storing a substance.

In accordance with one aspect of the present invention, the container system comprises: a) a lid comprising a reservoir for holding a substance, and a piercable membrane sealing the substance within said reservoir; and b) a vial comprising a piercing member and a chamber for receiving a sample, said lid and vial being (i) attachable in a first position in which the chamber is sealed against leakage to the outside of the container system and maintained out of fluid communication with said reservoir by said piercable membrane; and (ii) movable to a piercing position in which the piercing member disrupts the piercable membrane to allow fluid communication between said reservoir and said chamber.

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In accordance with another aspect of the present invention the container system comprises: a) a lid comprising a reservoir for holding a substance, and a piercable membrane sealing the substance within said reservoir; b) a funnel comprising a piercing member and a chamber for receiving a sample; and c) a collection tube for releasable attachment to a first end of said funnel, and having an interior in fluid communication with said chamber when attached to said funnel, said lid and funnel being (i) attachable in a first position in which the chamber is sealed against leakage to the outside of the container system and maintained out of fluid communication with said reservoir by said piercable membrane; and (ii) movable to a piercing position in which the piercing member disrupts the piercable membrane to allow fluid communication between said reservoir and said chamber.

In accordance with another aspect of the present invention there is provided a kit for releasably storing a substance comprising: a) a container system as described herein; and b) instructions for the use thereof.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a cross-sectional view of a container system in accordance with one embodiment of the present invention;

Figure 2 is a perspective view of the interior of the lid of the container system depicted in Figure 1;

Figure 3 is a perspective view of the interior of the vial of the container system depicted in Figure 1;

Figure 4 is a perspective view a container system in accordance with one embodiment of the present invention;

Figure 5 is a top view of the container system depicted in figure 4;

Figure 6 is a side view of the container system depicted in figure 4;

Figure 7 is a side view of the container system depicted in figure 4;

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Figure 8 is a bottom view of the container system depicted in figure 4;

Figure 9 is a cross-sectional view of the container system taken along line A-A in Figure 5;

Figure 10 is a top perspective view of the container system depicted in Figure 4 showing the lid and vial separated;

Figure 11 is a bottom perspective view of the container system depicted in Figure 4 showing the lid and vial separated;

Figure 12 is a side perspective view a container system in accordance with one embodiment of the present invention;

Figure 13 is a top view of the container system depicted in figure 12;

Figure 14 is a bottom view of the container system depicted in Figure 12;

Figure 15 is a side view of the container system depicted in Figure 12;

Figure 16 is a cross-sectional view of the container system taken along line B-B in Figure 15;

Figure 17 is a side perspective view of the container system depicted in Figure 12;

Figure 18 is a top perspective view of the container system depicted in Figure 12, showing the lid and funnel separated;

Figure 19 is a bottom side perspective view of the container system depicted in Figure 12, showing the lid and funnel separated;

Figure 20 is a side view of the tube and cap of the container system depicted in Figure 9; and

Figure 21 is a side view of the container system depicted in Figure 12, showing the lid, funnel, and tube separated.

The numbers in bold face type serve to identify the component parts that are described and referred to in relation to the drawings depicting various embodiments of the

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present invention. It should be noted that in describing various embodiments of the present invention, the same reference numerals have been used to identify the same or similar elements. Moreover, for the sake of simplicity, parts have been omitted from some figures of the drawings.

DETAILED DESCRIPTION OF THE INVENTION

As will be discussed in more detail below, the present invention provides a container system for releasably storing a substance.

Advantageously, the container system of the present invention has fewer parts, and thus is less expensive and easier to manufacture, than previous containers. Additionally, the manufacturing tolerances can be less precise for the container system of the present invention, as compared to previous containers. Again, this reduces manufacturing cost, and makes accidental disruption of the sealed fluid less likely. Additionally, in one example of the present invention, the container system includes a removable tube which is suitable for subsequent processing of samples, and for use in robotic systems.

In accordance with one aspect of the present invention, the container system comprises a vial and a lid. The lid is configured to store a substance, and subsequently release the substance from the lid when it is sealingly attached to the vial.

In accordance with another aspect of the present invention, the container system comprises a lid, a funnel and a tube. The lid is configured to store a substance, and subsequently release the substance from the lid into the tube when the lid is sealingly attached to the funnel.

Desirably, the lid is suitable to store a substance to stabilize, preserve or facilitate the recovery of nucleic acid from a biological sample. Desirably the vial, or the combination of the funnel and tube is suitable for the collection of a biological sample from a subject. In use, in accordance with one aspect of the present invention, the substance stored within the lid is released into the vial when the lid is attached to the vial. In accordance with another aspect of the present invention, the substance stored within the lid is released into the funnel,

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and subsequently into the tube, when the funnel is attached to the tube and the lid is attached to the funnel.

Referring to the Figures 1-11 , container system **300** comprises lid **100** and vial **1**.

LID

Lid **100** releasably stores a substance. Lid **100** is generally cylindrically shaped with at least one open end. Lid **100** can be a variety of shapes, as determined by the needs or preferences of the user and/or the intended application of use. The interior of lid **100** includes wall **104** that is positioned within lid **100** and defines reservoir **102** for holding a substance such as a liquid, solid, semi-solid, gas, mixtures thereof and the like. Wall **104** includes sealing surface **106** which is suitable for attachment of piercable membrane **160**

Piercable membrane **160** (depicted in Figure 19) acts as a physical barrier to releasably store a substance within reservoir **102**, when attached to sealing surface **106**. Piercable membrane **160** is made from material that is inert to the substance to be stored within the reservoir. Advantageously, piercable membrane **160** permits little or no diffusion of the substance through piercable membrane **160** over time. Advantageously, piercable membrane **160** is made from a material that is suitable for the intended processing, storage and/or transportation conditions. In a specific embodiment, piercable membrane **160** is heat and cold resistance for temperatures ranging from about -80°C to about +50°C. In a specific embodiment, piercable membrane **160** can be attached tightly enough to sealing surface **106** such that piercable membrane **160** will not be disrupted by vacuum pressures. Piercable membrane **160** can be made from a variety of materials including polypropylene. Desirably, piercable membrane **160** is made from the same material as wall **104**. The thickness of piercable membrane **160** can vary according to application of use, and preference of the user. Desirably, piercable membrane **160** has a thickness of about two thousandths of an inch. A variety of methods of attaching piercable membrane **160** to sealing surface **106** may be used, and will be dependent on the material used to make lid **100** and membrane **160**. Such methods of attachment include adhesives, heat-sealing, fasteners, combinations thereof, and the like. Desirably, heat-sealing is used to attach piercable membrane **160** to sealing surface **106**. As will be clear to the skilled worker, the type of piercable membrane,

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the physical and/or chemical properties of the piercable membrane will be dependent upon, in part, the composition to be stored. Desirably piercable membrane **160** is inert with respect to the intended use, stored substance and sample of the container system.

Container system **300** further includes a closure for sealing attachment of lid **1** to vial **100**. In the specific embodiments depicted in the Figures, the closure comprises internal helical threads **108** on the inner surface of outer wall **110** of lid **100,** which are adapted to engage external helical threads **18** on the outer surface of wall **12** on vial **1**. As would be appreciated by a skilled worker, alternative means for releasable attachment of lid **100** to vial **1** can be used in the container system of the present invention, provided that lid **100** and vial **1** are movable between a first position and a piercing position, as discussed in greater detail below.

Lid **100** and reservoir **102** can be sized to accommodate a range of volumes of a substance. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, reservoir **102** accommodates about 1 ml to about 4 ml of a substance. The choice of material used to manufacture lid **100** is dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, lid **100** is made from plastics such us polypropylene, high-density polyethylene (HDPE), polyethylene and the like. Desirably, lid **100** is polyethylene. The materials of lid **100** may be opaque, transparent or translucent, depending on the desired application. For example, an opaque material can be used to store a light sensitive compositions. A transparent or translucent material is desirable if a visual (e.g., colour) indicator is present in the stored substance. Lid **100** and reservoir **102** can be manufactured to include gradations to demarcate the quantity of the substance stored within reservoir **102**. The outer surface of lid **100** can also include a labelling area for a user to identify the contents of the lid. The outer surface of lid **100** may also include a region to affix or emboss a logo and/or other markings.

In accordance with one embodiment of the present invention, wall **104** has a generally cylindrical shape sized to fit within the interior of lid **100**. It will be clear that the

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shape and size of well **104** is dependent upon the intended use of the container system. Lid **100** may be constructed from a single piece of material that includes wall **104**, or wall **104** may be removably attached to lid **100**. Desirably, lid **100** is formed from a single piece of material.

VIAL

In accordance with one embodiment of the present invention, vial **1** is generally cylindrically shaped with at least one open end. Vial **1** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use. The interior of lid **1** comprises chamber **2** for receiving a sample such as a liquid, solid, semi-solid, mixtures thereof and the like. Desirably, chamber **2** is configured to receive a biological sample, for example a sputum sample, such as saliva. Vial **1** and chamber **2** can be sized accommodate a range of volumes of a sample. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, chamber **2** accommodates about 1 ml to about 4 ml of a sample.

Vial **1** comprises at least one piercing member **6**. In the specific embodiment depicted in Figures 1-6 piercing member **6** extends upwardly from chamber **2**. Alternatively, piercing member **6** extends laterally inward from interior side wall **20** of chamber **2**.

In one example, there is one piercing member **6** within chamber **2**. In another example there are two piercing members. In another example, there are three piercing members. In yet another example there are more than three piercing members. In the case of three piercing members, desirably the piercing members are arranged in a generally semicircular fashion, as seen in Figure 9.

The piercing member comprises pointed end **30**, at least one cutting edge **32**, and side walls **34**. Optionally, side walls **34** also include cutting edge **32**.

As noted above, lid **100** and vial **1** are movable between a first position and a piercing position. Lid **100** is initially attached to vial **1** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. In moving lid **100** and vial **1** to the first

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position, lid **100** and vial **1** are threadingly connected, but piercing member **6** does not disrupt piercable membrane **160**. In the first position, end portion **30** of wall **12** sealingly engages sealing wall **120**. For example, as depicted in Figure 6, sealing wall **120** extends downwardly and outwardly from the interior of lid **100**. This type of sealing mechanism is similar to a wipe seal that would be well known to the skilled worker. Thus, in the first position, chamber **2** is sealed against leakage to the outside of the container system and maintained out of fluid communication with reservoir **102** by piercable membrane **160.**

Continued twisting moves lid **100** and vial **1** from the first position to the piercing position, in which movement of lid **100** and vial **1** together results in disruption of piercable membrane **160** by piercing member **6**, and the release of the substance within reservoir **102** into chamber **2**.

In operation, in moving to the piercing position, pointed end **30** of piercing member **6** is brought into contact with piercable membrane **160** and pierces piercable membrane **160**. Continued twisting moves cutting edge **32** through piercable membrane **160**, and disrupting piercable membrane **160**, and thereby producing an opening in the sealing membrane to enable the substance to enter chamber **2**. It will be clear that if more than one piercing member is present, less twisting of lid **100** and vial **1** is required to generate an opening. When three piercing members are present, a suitable opening is obtainable in about one quarter of a turn. Desirably, piercable membrane **160** is not completely removed from sealing surface **106**. Thus, in the piercing position, piercing member **6** disrupts piercable membrane **160** to allow fluid communication between reservoir **102** and chamber **2**.

The distance between piercing member **6** and wall **104** will vary according to the needs and preferences of the user. The distance between piercing member **6** and wall **104** can vary from being generally flush with one another, to being generally separated from one another.

It will be clear to the skilled worker that length, rigidity and the like, of piercing member **6** is selected such that it is sufficient to disrupt piercable membrane **160** when lid **100** and vial **1** are in the piercing position, and not disrupt the piercable membrane **160** when lid **100** and vial **1** are in the first position.

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The choice of the material of vial **1** will be dependent upon a number of factors including manufacturing constraints, chemical suitability, and the like. Additionally, the construction material of lid **1** may be same or different as that used to make reservoir **6**. In the specific embodiment in which the substance is a nucleic acid preservative for use with a saliva sample, vial **1** is made from plastics such us polypropylene, high-density polyethylene (HDPE), polyethylene and the like. Desirably, vial **1** is polypropylene.

In accordance with another aspect of the present invention, the container system comprises a lid, a funnel and a tube.

Referring to the Figures 12-21, container system **600** comprises lid **100** and funnel **400** and tube **500**.

LID

Lid **100** releasably stores a substance, as described above.

FUNNEL

Funnel **400** includes a first open end for receiving a sample, a second open end for removable attachment to tube **500**. The interior of funnel **400** comprises chamber **2** for maintaining the first open end and the second open end in fluid communication and for receiving a sample such as a liquid, solid, semi-solid, mixtures thereof and the like. Funnel **400** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use. Desirably, chamber **2** is configured to receive a biological sample. For example, the biological sample is a sputum sample, such as saliva. Chamber **2** can be sized accommodate a range of volumes of sample.

Funnel **400** comprises at least one piercing member **6**. In accordance with the embodiment depicted in Figures 12-21, piercing member **6** extends laterally inward from interior side wall **20** of chamber **2**. Other arrangements of piercing member **6** can be used, as would be readily appreciated by the skilled worker.

In one example, there is one piercing member **6** within chamber **2**. In another example there are two piercing members. In another example, there are three piercing

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members. In yet another example there are more than three piercing members. In the case of three piercing members, desirably the piercing members are arranged in a generally semicircular fashion, as shown in Figure 18.

As above, the piercing member comprises a pointed end **30**, at least one cutting edge **32**, and side walls **34**. Optionally, side walls **34** also include cutting edge **32**.

Optionally, funnel **400** includes outwardly extending ribs **402** that can used by a user to twist funnel **400** and lid **100**, and/or funnel **400** and tube **500**.

TUBE

Tube **500** is generally cylindrically shaped with an open end for removable attachment to the second end of funnel **400**, and an interior **530** for receiving a sample. Tube **500** can be a variety of shapes, as determined by the needs or preferences of the user and/or application of use, and can be specifically manufactured for use in the container system of the present invention or can be a commercially available tube. When the container system is used for laboratory purposes, desirably, tube **500** is sized to fit within a standard test tube rack such as that typically used in biological sample processing. In one example, tube **500** conforms with industry-standard dimensions for blood collection tubes (e.g., 13 mm x 75 mm). Desirably tube **500** is suitable for use with robotic DNA purification systems (e.g., the Beckman BioMek™ FX). Desirably, tube **500** is commercially availably from Simport Plastics Limited (e.g., the T501 tubes).

The open end of tube **500** is also configured for securing attachment with a standard cap **520**, as shown in Figure 21. Cap **520** can be secured by a threaded screw, snap-fit, and the like.

Tube **500** optionally includes surface **502** that is suitable for labeling and/or for providing friction for gripping by a user.

Tube **500** may be removably attached to funnel **500** using a variety of locking mechanisms. In accordance with one embodiment of the present invention, the locking mechanism is a helical threaded screw. Alternatively, the locking mechanism is a snap-fit.

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Lid **100** and funnel **400** are movable between a first position and a piercing position. Lid **100** is initially attached to funnel **400** by threadingly engaging internal and external threads **108** and **18** with a twisting motion. In moving lid **100** and funnel **400** to the first position, lid **100** and funnel **400** are threadingly connected, but piercing member **6** does not disrupt piercable membrane **160**. In the first position, end portion **30** of wall **12** sealingly engages sealing wall **120**. As depicted in Figures 9 and 16, sealing wall **120** extends downwardly and outwardly from the inner surface of lid **100**. This type of sealing mechanism is similar to a wipe seal, that would be well know to the skilled worker. Thus, in the first position, chamber **2** is sealed against leakage to the outside of the container system and maintained out of fluid communication with said reservoir **102** by piercable membrane **6**.

Continued twisting moves lid **100** and funnel **400** from the first position to the piercing position, in which moving lid **100** and vial **1** together results in disruption of piercable membrane **160** by piercing member **6**, and the release of the substance within reservoir **102** into chamber **2** and tube **500**.

In operation, in moving to the piercing position, pointed end **30** is brought into contact with piercable membrane **160** and subsequently pierces piercable membrane **160**. Continued twisting moves cutting edge **32** though piercable membrane **160**, thereby disrupting piercable membrane **160** and producing an opening in piercable membrane **160** to permit the substance to enter chamber **2**. If more than one piercing member is present, less twisting of lid **100** and vial **1** is required to generate an opening. When three piercing members are present, a suitable opening is obtainable in about one quarter of a turn. Thus, in the piercing position, piercing member **6** disrupts piercable membrane **160** to allow fluid communication between reservoir **102** and said chamber **2**.

The distance between piercing member **6** and wall **104** will vary according to the needs and preferences of the user. The distance between piercing member **6** and wall **104** can vary from being generally flush with one another, to being generally separated from one another.

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It will be clear to the skilled worker that length, rigidity and the like, of piercing member **6** is selected such that it sufficient to disrupt piercable membrane **160** when lid **100** and vial **1** are in the piercing position, and not disrupt the piercable membrane **160** when lid **100** and vial **1** are in the first position.

METHODS

According to one embodiment of the present invention, the container system of the present application is suitable for releasably storing a composition intended to stabilize, preserve, or facilitate the recovery of nucleic acid from a biological sample. The term "nucleic acid", as used herein, refers to a chain of nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), typically found in chromosomes, chromatin, mitochondria, ribosomes, bacteria or viruses.

Desirably, vial **1** and/or funnel **500** are sized for collecting a biological sample from a subject. Non-limiting examples of biological samples include skin, hair, fecal matter, bodily fluids, tissue, cells and the like.

The term "bodily fluid", as used herein, refers to a naturally occurring fluid from an animal or human, such as saliva, sputum, serum, plasma, blood, urine, mucus, gastric juices, pancreatic juices, semen, products of lactation or menstruation, tears, or lymph.

Optionally the bodily fluid is saliva. The term "saliva", as used herein, refers to the secretion, or combination of secretions, from any of the salivary glands, including the parotid, submaxillary, and sublingual glands, optionally mixed with the secretions from the numerous small labial, buccal, and palatal glands that line the mouth.

The term "subject", as used herein, refers to an animal or human. Desirably, the subject is a mammal that can produce saliva for the purposes of nucleic acid stabilization and/or detection. Most desirably, the subject is human.

In use, a substance, such as a composition intended to stabilize, preserve, or facilitate the recovery of nucleic acid from a biological sample is sealed within reservoir **102** with a piercable membrane. Suitable compositions include those described in International PCT

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application WO 2003/104251 or United States Application Serial No. 60/662,510. Desirably the composition is Oragene™ DNA-preserving solution. Other suitable compositions would be well known to the skilled worker.

In use, a sample of saliva from a subject is placed within chamber **2** of vial **1.** Alternatively, tube **400** is attached to funnel **500,** and a sample of saliva is placed within chamber **2** of funnel **500.**

To collect saliva from a subject it is preferred that the mouth be rinsed before sampling. Food particles can introduce foreign DNA and saliva transferred by kissing can be a source of foreign human DNA. The mouth can be rinsed with about 50 ml of tepid water by vigorous swishing or by brushing with a toothbrush without toothpaste. Unstimulated saliva is usually of the mucinous type and is secreted at a slow rate. Stimulated saliva (anticipation of tasty food, sweet or sour candy) is of the serous (watery) type and secreted at a faster rate. It has been found that there is more DNA in 2 ml of unstimulated saliva than in 2 ml of stimulated saliva. After rinsing of the mouth and waiting about two or three minutes for the mouth to clear of water, the donor may spit a volume (for example, about 1 ml) of "unstimulated" saliva into the receiving tube. If this proves to be difficult, saliva flow can conveniently be stimulated with a few grains of table sugar, or any other such saliva-stimulatory substance that does not interfere with DNA stability or subsequent amplification.

A substance, such as a composition to stabilize, preserve, and/or facilitate the recovery of nucleic acid and saliva is stored within reservoir **102** of lid **100.**

Lid **100** is then attached to vial **1,** moved to the piercing position, and the substance combines with the saliva in chamber **2.**

Alternatively, lid **100** is attached to funnel **500,** moved to the piercing position, and the substance combines with the saliva in interior **530.**

The combination of the composition to stabilize, preserve, or facilitate the recovery of nucleic acid and saliva may then be used in standard nucleic acid testing reactions, for example for detection or quantitation. Alternatively, the combination may be stored within

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container system **300** or **600** and subsequently used, for example, for detection of nucleic acid contained within the saliva. Alternatively, funnel **500** is removed from tube **400**, and cap **520** is attached to the open end of tube 400. In this example, the combination may be stored within tube **400** and subsequently used, for example, for detection of nucleic acid contained within the saliva.

KIT

Another aspect of the present invention provides a kit for collection of a sample and mixing the sample with a substance. The kit includes a container system in accordance with the present invention and instructions for the use thereof, optionally with a substance stored within the lid of the container system.

All publications, patents and patent applications mentioned in this Specification are indicative of the level of skill of those skilled in the art to which this invention pertains and are herein incorporated by reference to the same extent as if each individual publication, patent, or patent applications was specifically and individually indicated to be incorporated by reference.

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

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THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A container system for releasably storing a substance, comprising:

a) a lid comprising a reservoir for holding the substance, and a piercable membrane sealing the substance within said reservoir; and

b) a vial comprising a piercing member and a chamber for receiving a sample,

said lid and vial being (i) attachable in a first position in which the chamber is sealed against leakage to the outside of the container system and maintained out of fluid communication with said reservoir by said piercable membrane; and (ii) movable to a piercing position in which the piercing member disrupts the piercable membrane to allow fluid communication between said reservoir and said chamber.

2. A container system for releasably storing a substance, comprising:

a) a lid comprising a reservoir for holding the substance, and a piercable membrane sealing the substance within said reservoir; and

b) a funnel comprising a piercable member and a chamber for receiving a sample; and

c) a collection tube for releasable attachment to said funnel, and having an interior in fluid communication with said chamber,

said lid and funnel being (i) attachable in a first position in which the chamber is sealed against leakage to the outside of the container system and maintained out of fluid communication with said reservoir by said piercable membrane; and (ii) movable to a piercing position in which the piercing member disrupts the piercable membrane to allow fluid communication between said reservoir and said chamber.

3. A kit for sample collection and storage, comprising:

a) a container system according to claims 1 or 2; and

b) instructions for the use thereof.

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CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE.

ABSTRACT

The present invention provides a container system for releasably storing a substance. There is also provided a method and kit for use of such a container system.

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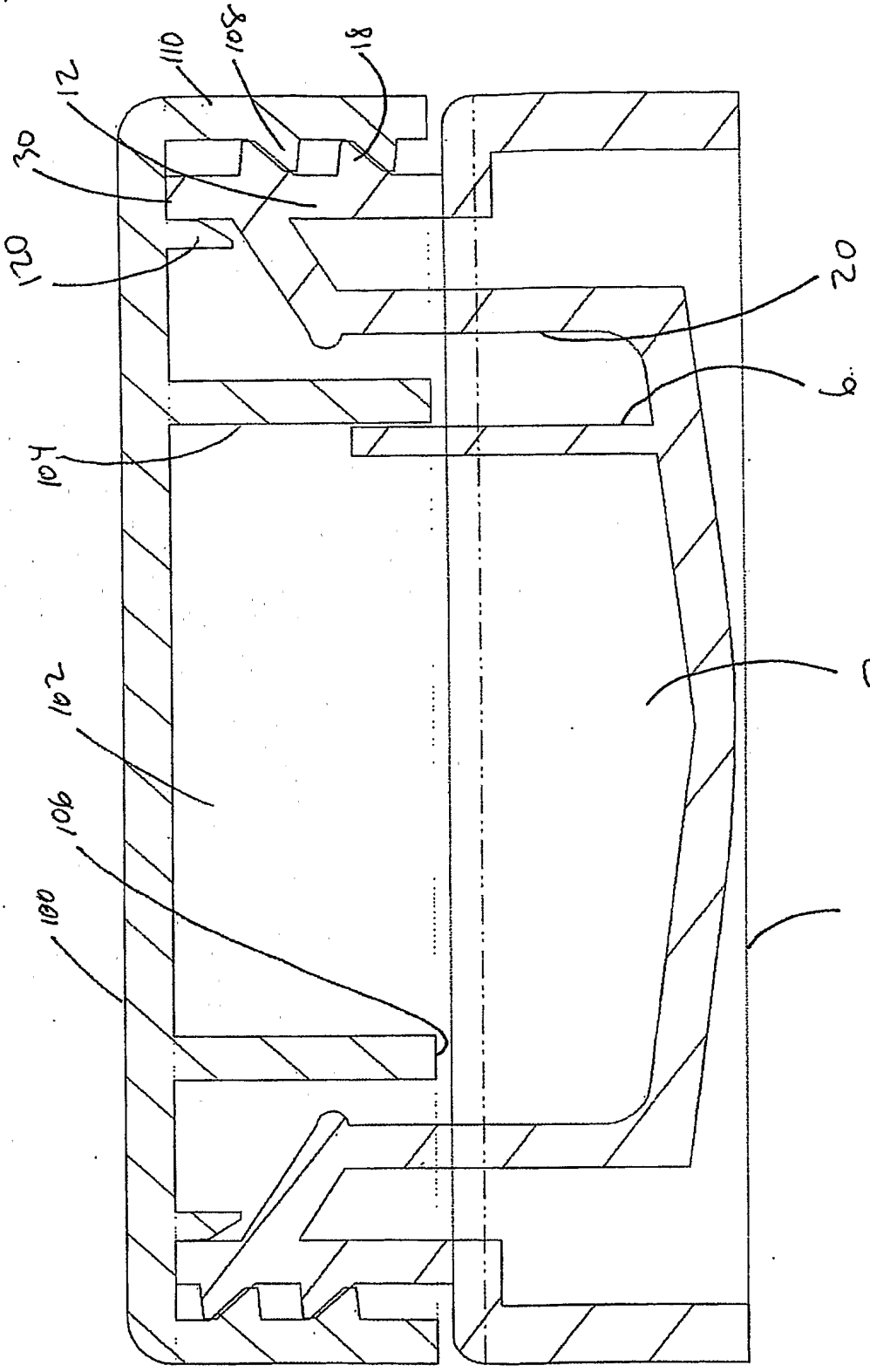

Figure 1

1/2

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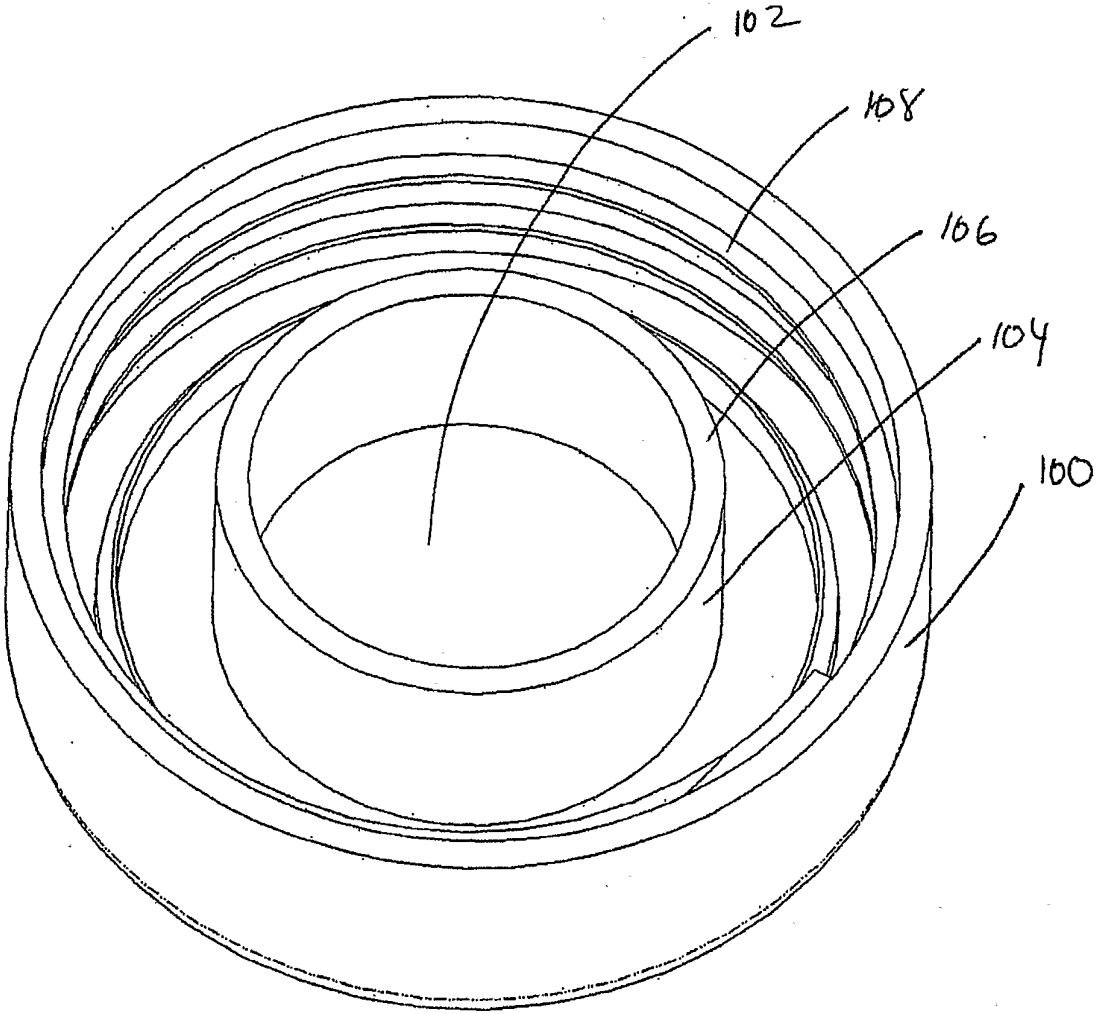
Figure 2



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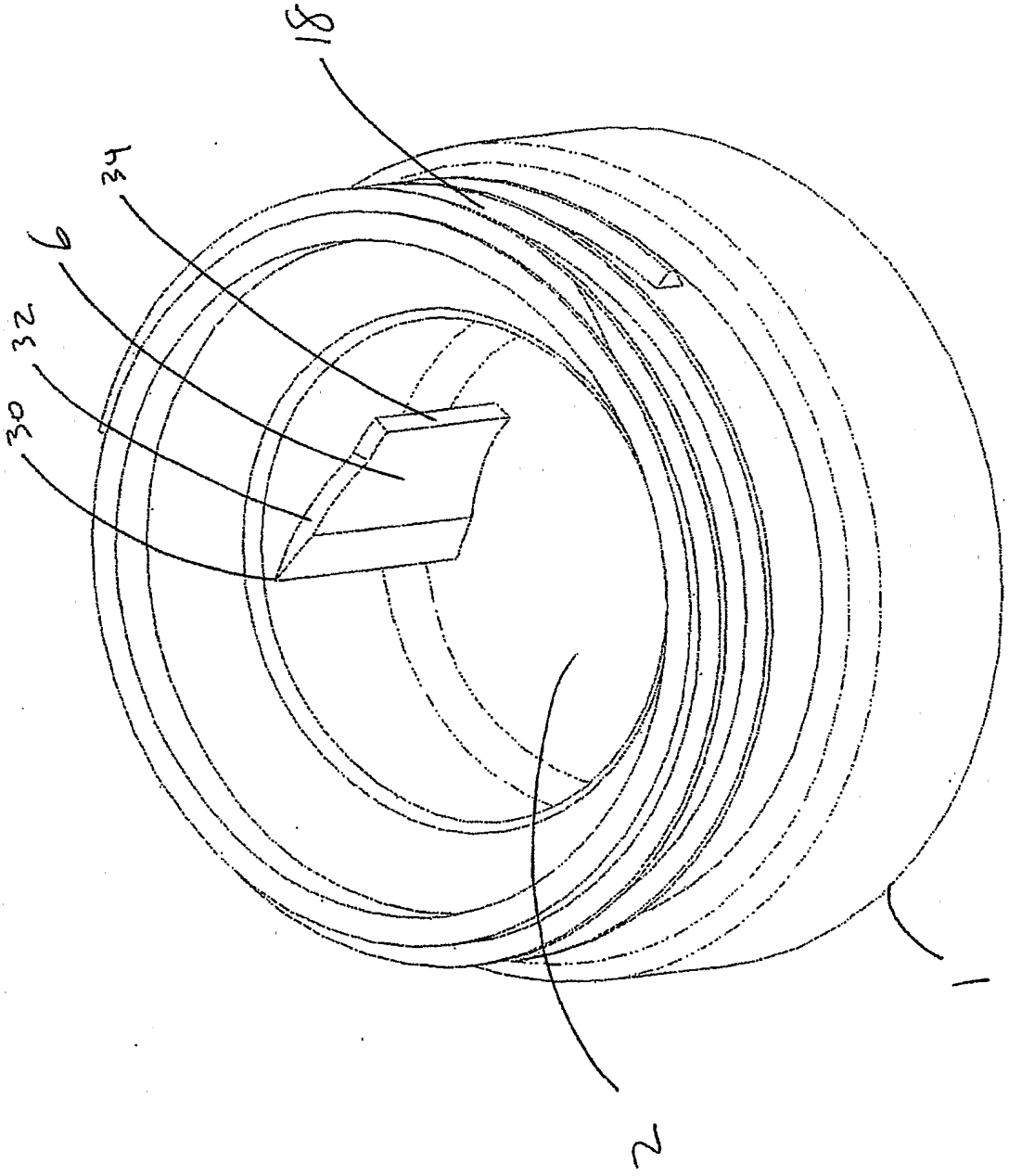

Figure 3

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Figure 4

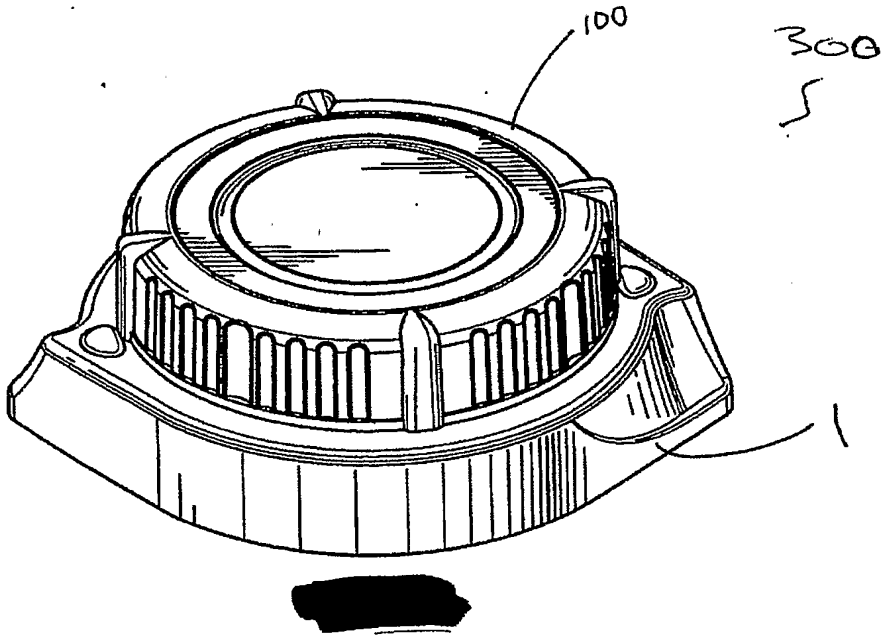

Figure 5

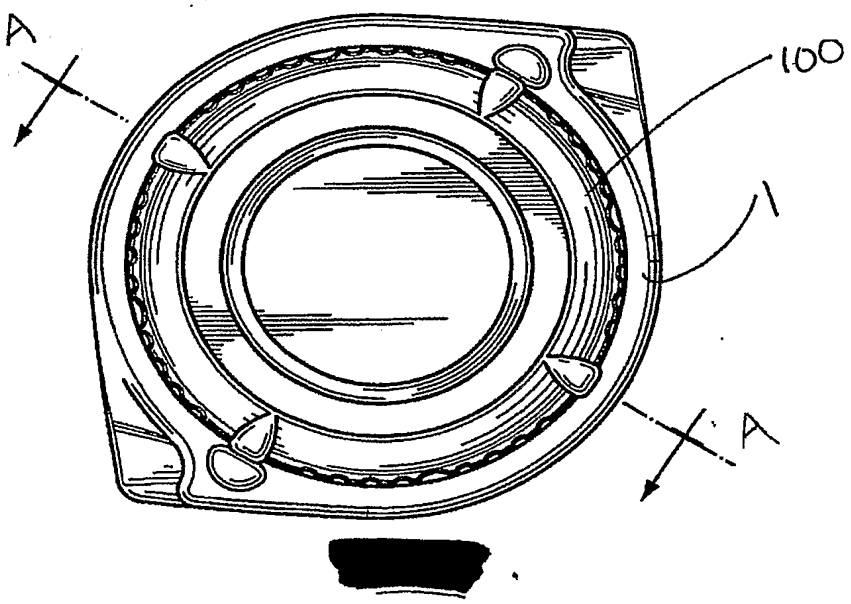

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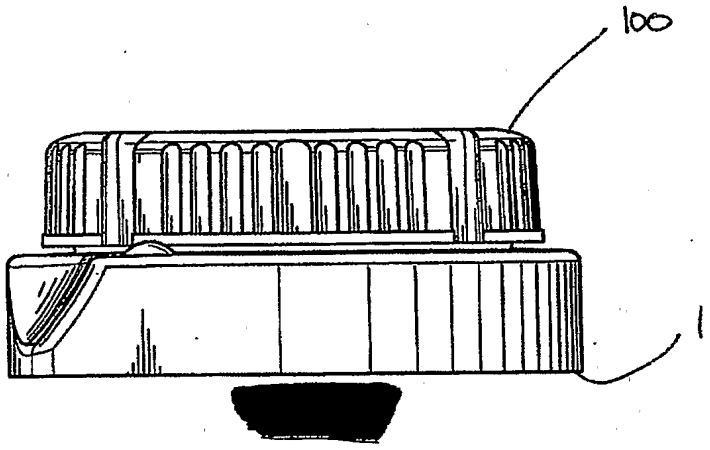
Figure 6



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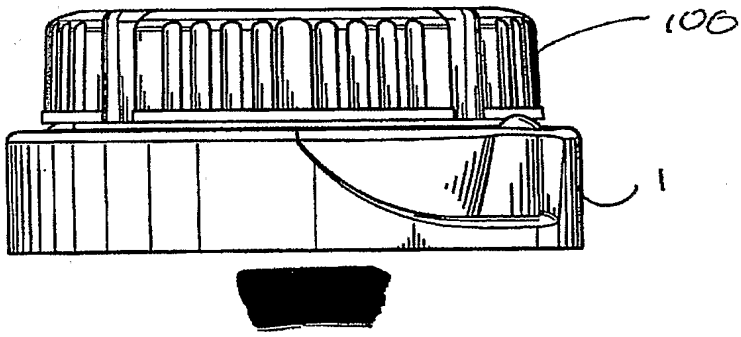

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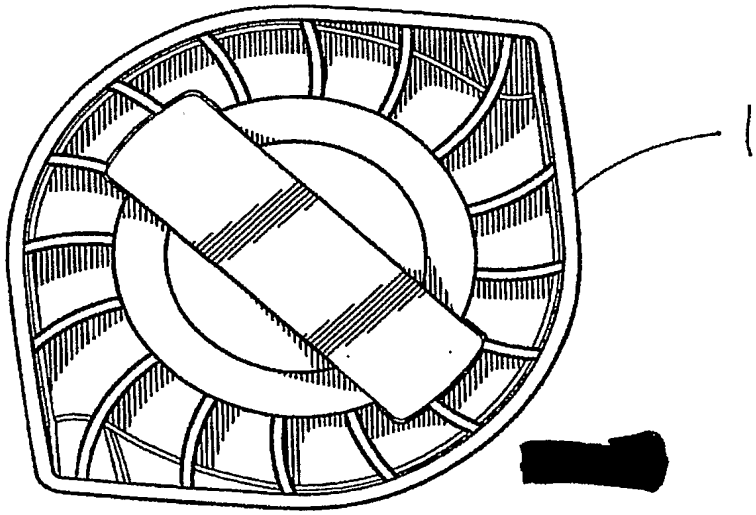

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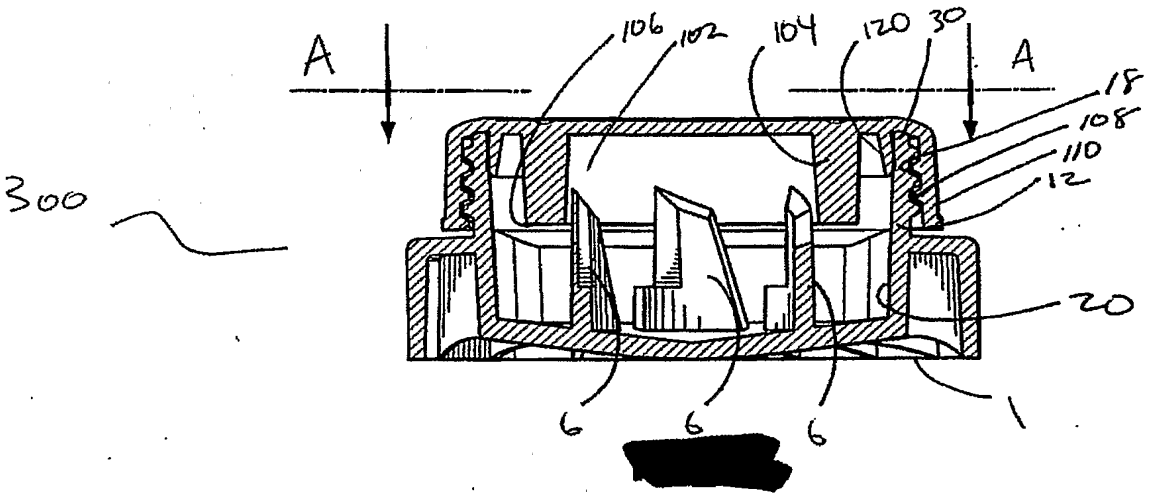

Figure 9

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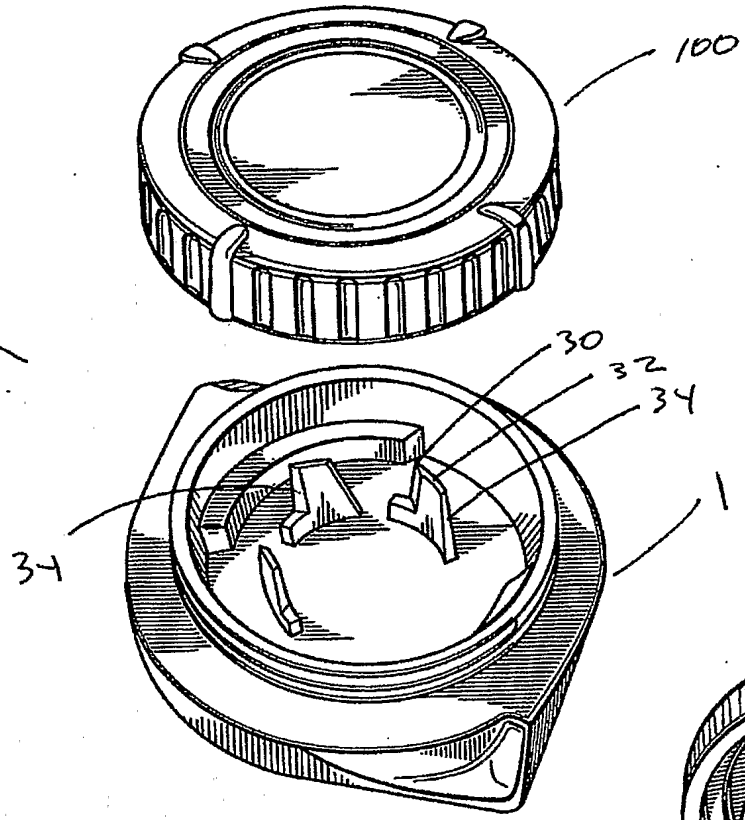
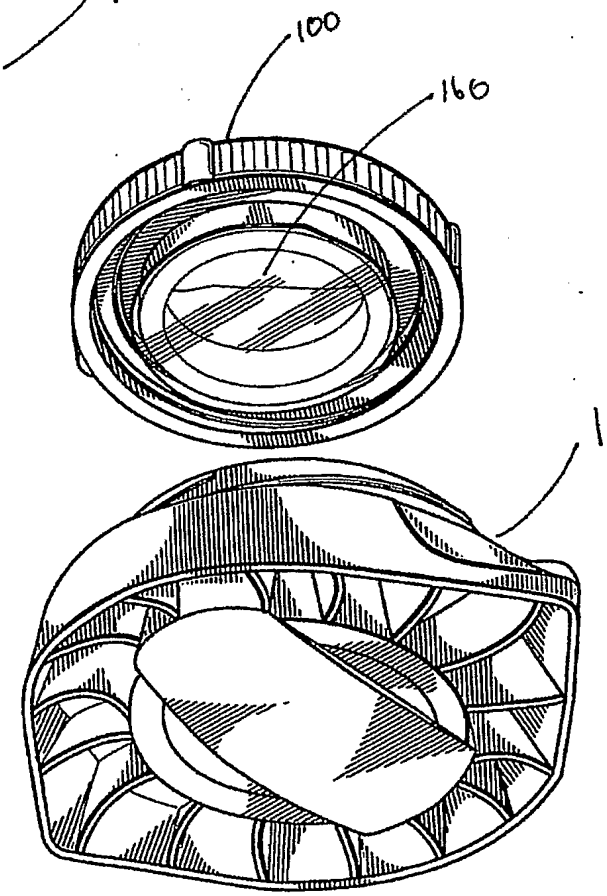


Figure 10



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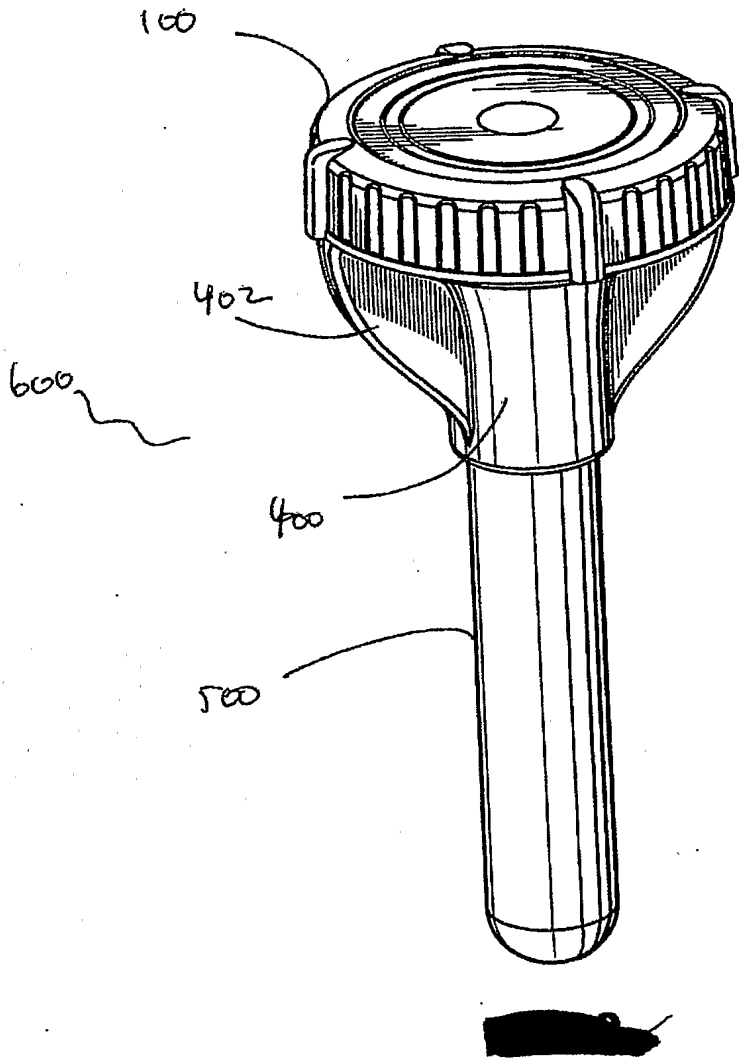

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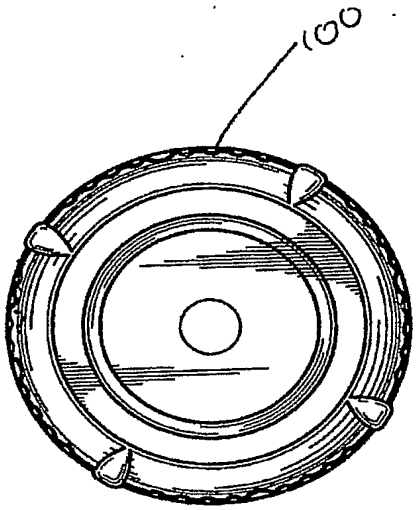

Figure 13

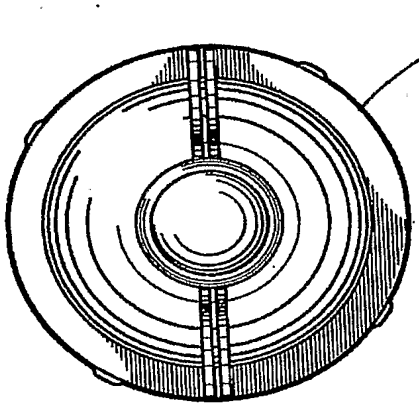

Figure 14

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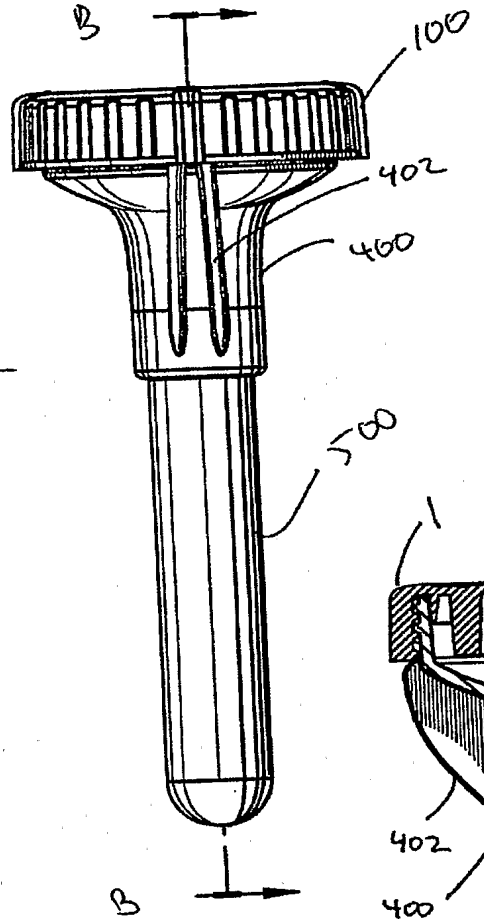
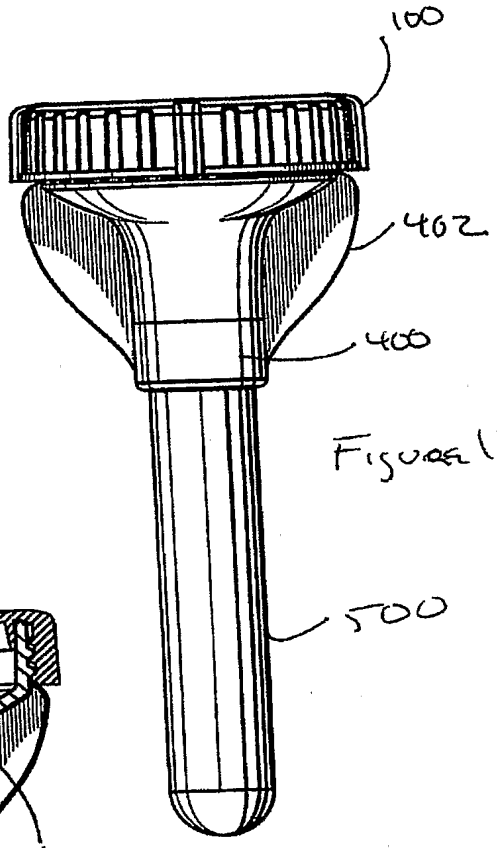


Figure 15



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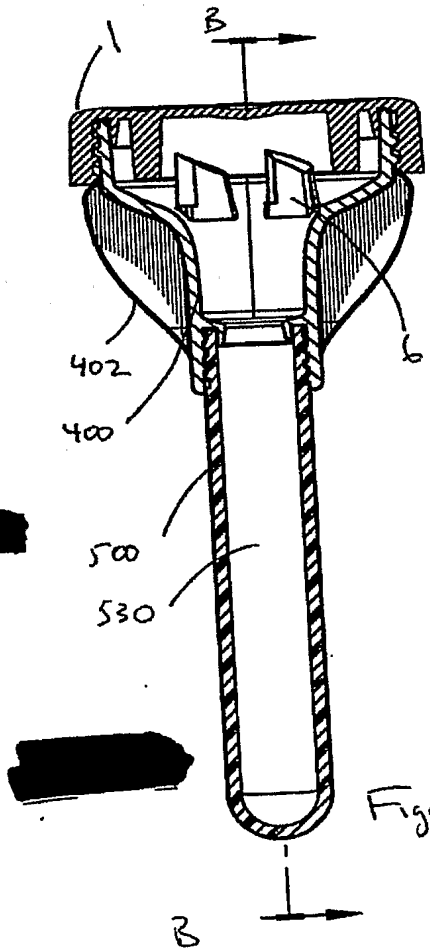

Figure 16

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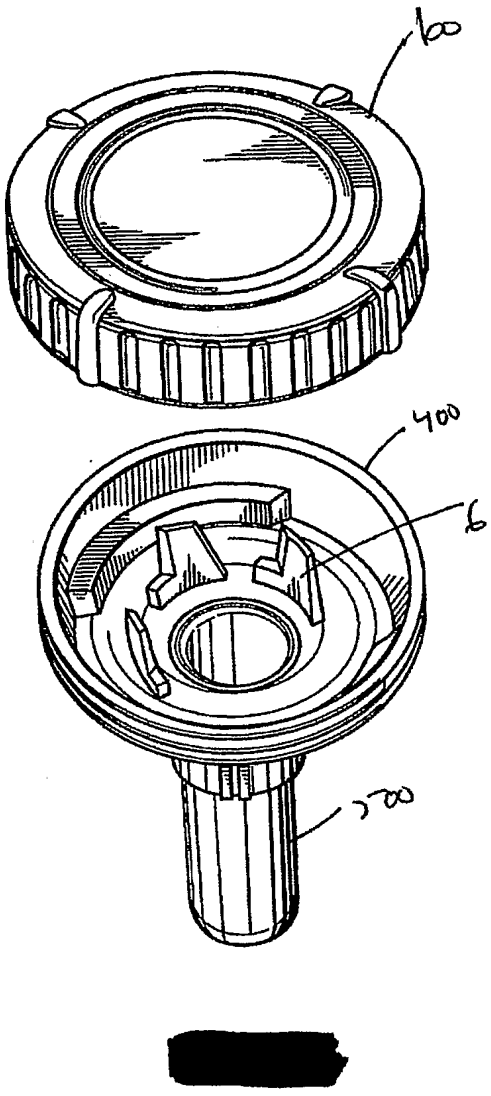

Figure 1B

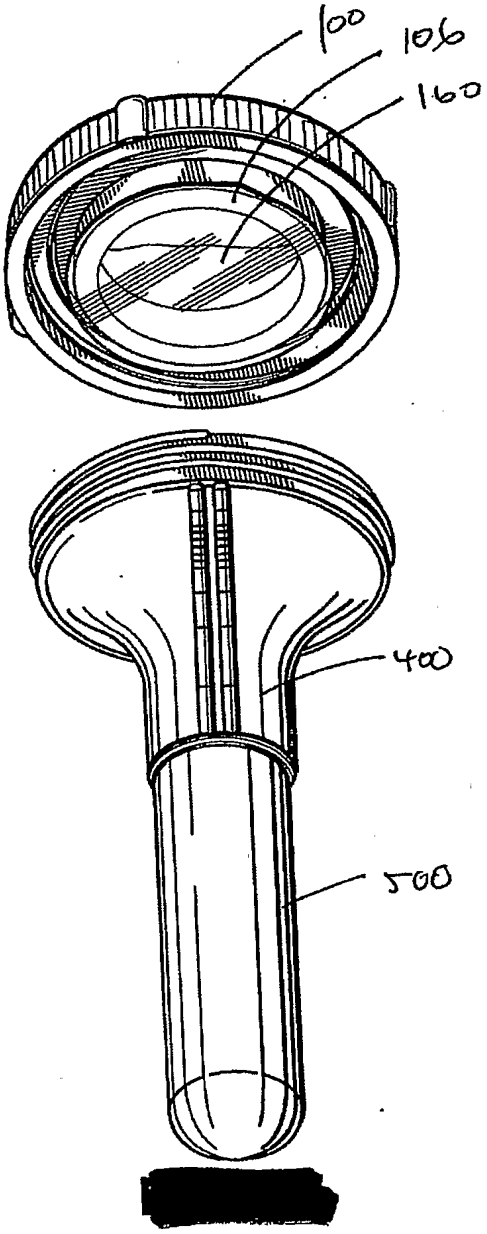

Figure 1C

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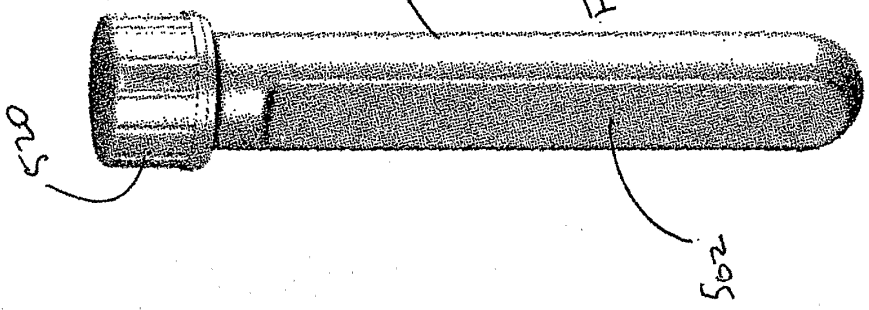

Figure 20

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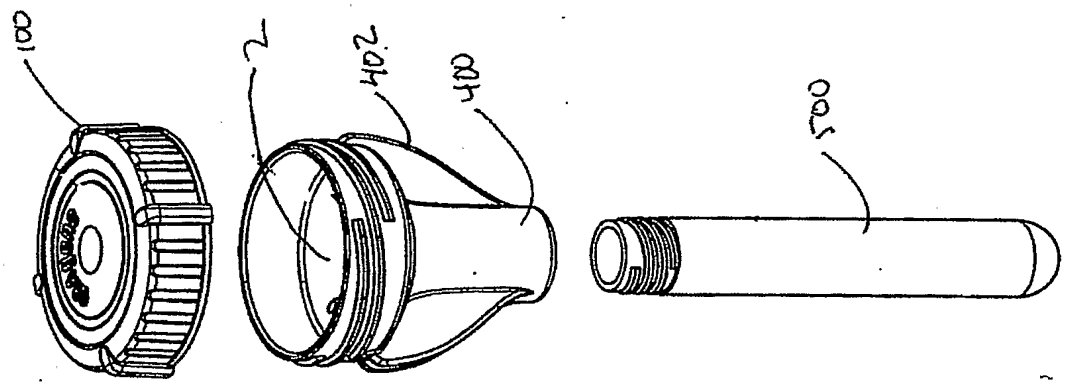

Figure 21

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PPCT18678	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/CA2006/002009	International filing date *(day/month/year)* 11 December 2006 (11-12-2006)	Priority date *(day/month/year)* 09 December 2005 (09-12-2005)

International Patent Classification (IPC) or national classification and IPC
IPC: ***A61B 5/00*** (2006.01) , ***A61B 5/15*** (2006.01) , ***A61J 1/05*** (2006.01) , ***B01L 3/14*** (2006.01) , ***B65D 47/36*** (2006.01) , ***B65D 81/32*** (2006.01)

Applicant
DNA GENOTEK INC. ET AL

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      [X] sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.
   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] Box No. II Priority
   - [X] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09 October 2007 (09-10-2007)	23 April 2008 (23-04-2008)
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Karen Oprea 819- 934-2668

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2006/002009

Box No. I Basis of the report

1. With regard to the **language,** this report is based on:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (Rules 12.3(a) and 23.1(b))

[ ] publication of the international application (Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

[ ] the international application as originally filed/furnished

[X] the description:

[X] pages 1-21 as originally filed/furnished

[ ] pages* received by this Authority on

[ ] pages* received by this Authority on

[X] the claims:

[X] pages 22-25 as originally filed/furnished

[ ] pages* as amended (together with any statement) under Article 19

[X] pages* 26 and 27 received by this Authority on 9 Oct. 2007 (09-10-2007)

[ ] pages* received by this Authority on

[X] the drawings:

[X] pages 1/15-15/15 as originally filed/furnished

[ ] pages* received by this Authority on

[ ] pages* received by this Authority on

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

5. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 66.1(d-*bis*))

**If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

[ ] the entire international application

[X] claims Nos. 51

because:

[X] the said international application, or the said claims Nos.
relate to the following subject matter which does not require an international preliminary examination *(specify):*

More specifically, claim 51 is directed to a container system as substantially described herein. Such a claim is considered an omnibus claim and thereby no search or opinion is requried by this Authority.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify):*

[ ] the claims, or said claims Nos. are so inadequately supported
by the description that no meaningful opinion could be formed *(specify):*

[X] no international search report has been established for said claims Nos. 51

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-50	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-50	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-50	YES
	Claims	None	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: EP 0273015 (A2) 29 June 1988 (29-06-1988) by Loretti et al.
D2: US 6 582 415 (B1) 24 June 2003 (24-06-2003) by Fowles et al.
D3: US 4 741 346 3 May 1988 (03-05-1988) by Wong et al.

D1 teaches a device comprises the following: a cartridge and a lid delimiting between them a cavity intended for the vial; the lid is arranged removably on the cartridge, and a seal which ensures the leakproofness between the cartridge and the lid. The neck of the vial is intended to be placed towards the bottom of the cartridge opposite the lid; the bottom of the cartridge is equipped with an opening for the passage of the fluid, which opening is extended in the direction of the lid by a trocar which is intended to pierce the stopper sealing the vial and the direction away from the lid by a conduit sealed by a breakable seal. This conduit is placed in a passage for introduction towards the inside of the container. The cartridge is preferably provided with a cylindrical inner part for holding the outer surface of the standardised, crimped neck of the vial and for guiding it during its introduction into the device.

D2 teaches a container device for establishing fluid communication between a liquid container having sidewalls and a vial, the device comprising : a piercing member having first and second end and a central fluid pathway, the piercing member being mounted to the liquid container and having fluid accessing portions sealed from an outside environment; a vial receiving member associated with said piercing member and means for connecting the vial receiving chamber to connect to the liquid container.

D3 teaches a biological fluid specimen collector e.g. for medical apparatuses including gripping walls upstanding from the base to hold a specimen vial in an upright position.

D1, even though it teaches a container with a receiving device for a vial, it fails to disclose a container system which releasably stores a substance, comprising a vial and a lid which is so configured as to removably engage said vial comprising a reservoir for holding the substance as well as a funnel and a piercing member as claimed in claims 1-50. With regard to D2 and D3, even though they teach a container device system for releasably storing a substance comprising a vial, the system of D2 does not include a lid as recited in the present claims. Furthermore, there is nothing within the cited reference that teaches or even suggests a method of combining a substance using a container system as disclosed in claims 1-50 in view of D1 or D2 , alone or in combination with D3.

Conclusions

Article 33(2) PCT- Novelty (N)
The subject matter of claims 1-50 is deemed to be novel in view of D1-D3, thereby fulfilling the requirements of Article 33(2) PCT.

Article 33(3) PCT-Inventive Step (IS)
The subject matter of claim 1-50 is considered to be inventive in view of D1-D3, hence fulfilling the requirements of Article 33(3) PCT.

Article 33(4) PCT-Industrial Applicability (IA)
The subject matter of claims 1-50 is considered to be industrially applicable, hence fulfilling the requirements of Article 33(4) PCT.

37. The container system according to any one of claims 22 - 36, wherein said vial is releasably attached to said funnel and sized for attachment to a cap when released from said funnel.

38. The container system according to any one of claims 22 - 37, wherein said vial is configured for use in standard laboratory equipment.

39. The container system according to claim 38, wherein said vial has dimensions that conforms with industry-standard dimensions for a blood collection tube.

40. The container system according to claim 38 or 39, wherein said vial is a T501 tube.

41. The container system according to any one of claims 22 – 40, wherein said chamber is sized to hold about 1 ml to about 16 ml.

42. The container system according to any one of claims 1 – 41, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample.

43. The container system according to claim 42, wherein said nucleic acid is DNA or RNA.

44. The container system according to any one of claims 1 – 43, additionally comprising a solid or semi-solid material within said vial and maintained separate from the substance in the reservoir of said lid until said pierceable membrane is disrupted.

45. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 1 – 21;

(b) providing the sample to the chamber in the vial; and

(c) closing said container system by removably attaching said lid to said vial; and

(d) piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

46. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 22 – 41;

(b) providing the sample to the chamber in the vial through said funnel; and

(c) closing said container system by removably attaching said lid to said first open end of said funnel; and

(d) piercing said membrane to release said substance into said chamber by moving said system to said piercing position.

47. The method according to claim 45 or 46, wherein the substance is a nucleic acid preserving substance.

48. The method according to any one of claim 45 – 47, wherein the sample is a biological sample.

49. The method according to any one of claim 45 – 48, for archiving the sample.

50. A kit for sample collection and storage, comprising:

a) a container system according to any one of claims 1 to 44; and

b) instructions for the use thereof.

51. A container system as substantially described herein.

DO/ EO WORKSHEET

Patent Application Specialist/ National Stage Division

U.S. Appl. No. 12/096,767 International Appl. No. PCT/CA2006/002005

WIPO PUBLICATION INFORMATION :

Publication No.: WO200 7068054 Publication Language : ☑ English (IA used as specification) ☐ German ☐ Japanese ☐ Chinese ☐ Korean ☐ French ☐ Spanish ☐ Russian ☐ Other : ___

Publication Date : 14 Jun 2007 Not Published : ☐ U.S. only ☐ Early Pub. Request Published : ☐ Early Pub.

INTERNATIONAL APPLICATION PAPERS IN THE APPLICATION FILE :

- ☑ International Application *(RECORD COPY)*
- ☐ Article 19 Amendments
- ☑ PCT/IPEA/409 - IPER (check Examination Authority) : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☑ CA ☐ KR ☐ ___
- ☐ Annexes to 409
- ☑ PCT/ISA/237 (check Searching Authority) : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☑ CA ☐ KR ☐ ___
- ☐ Other : _____
- ☐ PCT/IB/306
- ☐ Request form PCT/RO/101
- ☑ PCT/ISA/210 - Search Report (check Searching Authority) : ☐ EP ☐ JP ☐ SE ☑ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☑ CA ☐ KR ☐ ___ ☐ NONE
- ☐ Search Report References
- ☑ Priority Document (s) No. 1 ☐ N/A ☐ Priority Document was NOT AVAILABLE at the time of paralegal review
- ☐ Other : _____

RECEIPTS FROM THE APPLICANT *(filed with the application unless noted otherwise) :*

- ☐ Basic National Fee (*or authorization to charge*)
- ☑ Description 64 ☑ Claims ☑ Abstract
- ☑ Number of Drawing Sheets : 15
- ☐ Translation of Article 19 Amendments ☐ entered ☐ not entered : ☐ not a page for page substitution ☐ replaced by Article 34 Amendment
- ☐ Annexes to 409 ☐ entered ☐ not entered : ☐ not a page for page substitution ☐ no translation ☐ other : _____
- ☑ Application Data Sheet
- ☐ Power of Attorney
- ☐ Change of Address
- ☐ PG Pub Early Publication Request
- ☑ Express Request to Begin Nat'l Examination Procedures
- ☑ Preliminary Amendment(s) Filed on : 1. ☑ same as 371 request date 2. _____ 3. _____
- ☐ Information Disclosure Statement(s) Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____
- ☐ Assignee Statement Under 37 CFR 3.73(b)
- ☐ Assignee PG Publication Notice
- ☐ Substitute Specification Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____
- ☐ Verified Small Status Statement
- ☐ Oath/ Declaration (executed)
- ☐ Defective Oath/ Declaration ☐ unsigned ☐ no citizenship ☐ other
- ☐ DNA Diskette ☐ Sequence Listing
- ☐ Other : _____
- ☐ Other : _____

NOTES :

35 U.S.C. 371 - Receipt of Request (PTO-1390)	6/5/08
Date Acceptable Oath/ Declaration Received	
Date of Completion of requirements under 35 U.S.C. 371	
Date of Completion of DO/ EO 903 - Notification of Acceptance	
Date of Completion of DO/ EO 905 - Notification of Missing Requirements	9/26/08
Date of Completion of DO/ EO 909 - Notification of Abandonment	
Date of Completion of DO/ EO 916 - Notification of Defective Response	
Date of Completion of DO/ EO 922 - Notification to Comply w/ Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures	
Date of Completion of DO/ EO 923	

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

(FOR USE WITH FORM PTO-875)

SERIAL NO. 12/056,767

FILING DATE

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1	1		1			
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49		1		2		
50	1					
TOTAL IND.	3		2			
TOTAL DEP.	51		53			
TOTAL CLAIMS	54		55			

	AS FILED		AFTER 1st AMENDMENT		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
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TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS						

PTO - 1360 (REV. 04/2007)

U.S. DEPARTMENT of COMMERCE
Patent and Trademark Office

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

Application or Docket Number: 10/856,767

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
U.S. NATIONAL STAGE FEES		
BASIC FEE		
EXAMINATION FEE		
SEARCH FEE		
FEE FOR EXTRA SPEC. PGS.	minus 100 =	/ 50 =
TOTAL CHARGEABLE CLAIMS	55 minus 20 =	35
INDEPENDENT CLAIMS	2 minus 3 =	—
MULTIPLE DEPENDENT CLAIM PRESENT		X

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY		OR	LARGE ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	150	OR	BASIC FEE	
EXAM. FEE	180		EXAM. FEE	
SEARCH FEE	200		SEARCH FEE	
X $ 125 =			X $ 250 =	
X $ 25 =	875	OR	X $ 50 =	
X $ 100 =		OR	X $ 200 =	
+ $ 180 =	180	OR	+ $ 360 =	
TOTAL		OR	TOTAL	

CLAIMS AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT A	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X $ 25 =		OR	X $ 50 =	
X $ 100 =		OR	X $ 200 =	
+ $ 180 =		OR	+ $ 360 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
AMENDMENT B	Total	*	Minus	**	=
	Independent	*	Minus	***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDITIONAL FEE		RATE	ADDITIONAL FEE
X $ 25 =		OR	X $ 50 =	
X $ 100 =		OR	X $ 200 =	
+ $ 180 =		OR	+ $ 360 =	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than '20', enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than '3', enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92*bis*.1 and Administrative Instructions, Section 422)

To:

OSLER, HOSKIN & HARCOURT LLP
Suite 1900
340 Albert Street
Ottawa, Ontario K1R 7Y6
CANADA

Date of mailing *(day/month/year)*
03 July 2008 (03.07.2008)

Applicant's or agent's file reference
PPCT18678

IMPORTANT NOTIFICATION

International application No.
PCT/CA2006/002009

International filing date *(day/month/year)*
11 December 2006 (11.12.2006)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address	State of Nationality	State of Residence
BIRNBOIM, H., Chaim 1552 Featherston Drive Ottawa, Ontario K1H 6P2 Canada		CA
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:
The person identified in Box 2 should be added to the record as applicant for the United States of America only and inventor for all designated States. The request for recording of the above change was received by the International Bureau between 20 and 30 months from the priority date.

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☐ the International Preliminary Examining Authority
☐ the designated Offices concerned
☒ the elected Offices concerned
☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 89 95	Authorized officer Tholle Peter e-mail pt04.pct@wipo.int Telephone No. +41 22 338 74 04

Form PCT/IB/306 (October 2005) I/DPK7GUFQ0

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
12/096,767	11/24/2008	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 06/09/2008	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 49	Minus	** 55	= 0	X $25 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $105 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/ROSALIND BALL/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
12/096,767	Rod Muir	50245/005001

21559
CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

INTERNATIONAL APPLICATION NO.	
PCT/CA2006/002009	
I.A. FILING DATE	PRIORITY DATE
12/11/2006	12/09/2005

CONFIRMATION NO. 4566
371 FORMALITIES LETTER

OC000000032202262

Date Mailed: 09/23/2008

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Indication of Small Entity Status
- Priority Document
- Copy of the International Application filed on 06/09/2008
- Copy of the International Search Report filed on 06/09/2008
- Copy of IPE Report filed on 06/09/2008
- Preliminary Amendments filed on 06/09/2008
- Request for Immediate Examination filed on 06/09/2008
- U.S. Basic National Fees filed on 06/09/2008
- Priority Documents filed on 06/09/2008
- Specification filed on 06/09/2008
- Claims filed on 06/09/2008
- Abstracts filed on 06/09/2008
- Drawings filed on 06/09/2008

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

FORM PCT/DO/EO/905 (371 Formalities Notice)

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

RODERICK M JONES

Telephone: (703) 308-9140 EXT 181

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
Filed:	June 9, 2008	Examiner:	Not Yet Assigned
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO NOTIFICATION OF MISSING REQUIREMENTS

In reply to the Notification of Missing Requirements that was mailed in connection with the above-captioned application on September 23, 2008, Applicants, as a small entity, submit the following:

A Combined Declaration and Power of Attorney in compliance with 37 C.F.R. § 1.497(a) and (b), identifying the application by the international application number and international filing date; and a Supplemental Application Data Sheet.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Todd Armstrong, Ph.D.
Reg. No. 54,590

Date: 24 November 2008

for Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

Electronic Acknowledgement Receipt

EFS ID:	4342534
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Richard Todd Armstrong/Claire Yotts
Filer Authorized By:	Richard Todd Armstrong
Attorney Docket Number:	50245/005001
Receipt Date:	24-NOV-2008
Filing Date:	
Time Stamp:	18:07:25
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	50245_005001_Supplemental_Application_Data_Sheet.PDF	144768 e586a8a44c882f7bf9d3290fc75d6a9e20a9b673	no	6

Warnings:	
Information:	

This is not an USPTO supplied ADS fillable form					
2	Oath or Declaration filed	50245_005001_Combined_Declaration_and_Power_of_Attorney.PDF	145274 2e8dd1acf7e05f9963f071ae271734131310 90fd	no	4
Warnings:					
Information:					
3	Applicant Response to Pre-Exam Formalities Notice	50245_005001_Reply_to_Notification_of_Missing_Requirements.PDF	102906 3312c99eb7b96fbbdf846f23bc6c132f8d7c a4d8	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	392948		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Supplemental Application Data Sheet

Application Information

Application number::	12/096,767
Filing Date::	06/09/08
Application Type::	Regular
Subject Matter::	Utility
Suggested Classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R?::	None
Number of CD disks::	
Number of copies of CDs::	
Sequence submission?::	
Computer Readable Form (CRF)?::	
Number of copies of CRF::	
Title::	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
Attorney Docket Number::	50245/005001
Request of Early Publication?::	No
Request of Non-Publication?::	No
Suggested Drawing Figure::	
Total Drawing Sheets::	15
Small Entity?::	Yes
Petition Included?::	No
Petition Type::	
Licensed US Govt. Agency::	

Contract or Grant Numbers::

Secrecy Order in Parent Appl.?:: No

Applicant Information

Applicant Authority Type:: Inventor

Primary Citizenship Country:: Canadian

Status:: Full Capacity

Given Name:: Rod

Middle Name::

Family Name:: Muir

Name Suffix::

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State or Province of Residence:: Ontario

Country of Residence:: Canada

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City of mailing address:: South Mountain

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Country of mailing address:: Canada

Postal or Zip Code of mailing address:: K0E 1W0

Applicant Authority Type:: Inventor

Primary Citizenship Country:: Canadian

Status:: Full Capacity

Given Name:: Derek

Middle Name::

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City of mailing address::	Chelsea
State or Province of mailing address::	Quebec
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	J9B 2E8

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Middle Name::	
Family Name::	Curry
Name Suffix::	
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State or Province of Residence::	Ontario
Country of Residence::	Canada
Street of mailing address::	8 Wildacre Lane
City of mailing address::	Kanata
State or Province of mailing address::	Ontario
Country of mailing address::	Canada

Postal or Zip Code of mailing address::	K2K 1X7
Applicant Authority Type::	Inventor
Primary Citizenship Country::	Canadian
Status::	Full Capacity
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Middle Name::	
Family Name::	Sunstrum
Name Suffix::	
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State or Province of Residence::	Ontario
Country of Residence::	Canada
Street of mailing address::	P.O. Box 1181, 25 Underhill Crescent
City of mailing address::	Richmond
State or Province of mailing address::	Ontario
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	K0A 2Z0
Applicant Authority Type::	Inventor
Primary Citizenship Country::	Canadian
Status::	Full Capacity
Given Name::	Paul
Middle Name::	
Family Name::	Lem
Name Suffix::	

City of Residence::	Ottawa
State or Province of Residence::	Ontario
Country of Residence::	Canada
Street of mailing address::	302-145 York Street
City of mailing address::	Ottawa
State or Province of mailing address::	Ontario
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	K1N 8Y3

Applicant Authority Type::	Inventor
Primary Citizenship Country::	Canadian
Status::	Full Capacity
Given Name::	H.
Middle Name::	Chaim
Family Name::	Birnboim
Name Suffix::	
City of Residence::	Ottawa
State or Province of Residence::	Ontario
Country of Residence::	Canada
Street of mailing address::	1552 Featherston Drive
City of mailing address::	Ottawa
State or Province of mailing address::	Ontario
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	K1H 6P2

Correspondence Information

Correspondence Customer Number:: 21559

Representative Information

Representative Customer Number:: 21559

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	National stage of	PCT/CA2006/002009	12/11/06
PCT/CA2006/002009	An application claiming the benefit under 35 USC 119(e)	60/748,977	12/09/05

Assignee Information

Assignee name::	DNA GENOTEK INC.
Street of mailing address::	29 Camelot Drive, Unit 200
City of mailing address::	Ottawa
State of Province of mailing address::	Ontario
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	K2G 5W6

PATENT
ATTORNEY DOCKET NO. 50245/005001

COMBINED DECLARATION AND POWER OF ATTORNEY FOR UTILITY APPLICATION USING AN APPLICATION DATA SHEET

Title: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

As the below named inventors, we declare that:

This declaration is directed to:

☐ The attached application, or

☑ Application No. 12/096,767, filed on June 9, 2008;

we believe that we are the original and first inventors of the subject matter which is claimed and for which a patent is sought;

we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

we hereby appoint the attorneys and/or agents associated with customer number **21559** to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all correspondence relating to this application to the address associated with customer number **21559**.

Address all telephone calls to: Kristina Bieker-Brady, Ph.D. at 617-428-0200.

All statements made herein of my/our knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Rod Muir	
Signature: July 18/2008	Citizen of: Canada

Derek Kirkland	
Signature: July 18/2008	Citizen of: Canada

Ian Curry	
Signature: July 18, 2008	Citizen of: Canada

Roy Sunstrum	
Signature: July 18, 2008	Citizen of: Canada

Paul Lem	
Signature:	Citizen of: Canada

H. Chaim Birnboim	
Signature: 2008 July 18	YES. Citizen of: Canada

COMBINED DECLARATION AND POWER OF ATTORNEY FOR UTILITY APPLICATION USING AN APPLICATION DATA SHEET

Title: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

As the below named inventors, we declare that:

This declaration is directed to:

☐ The attached application, or

☑ Application No. 12/096,767, filed on June 9, 2008;

we believe that we are the original and first inventors of the subject matter which is claimed and for which a patent is sought;

we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

we hereby appoint the attorneys and/or agents associated with customer number **21559** to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all correspondence relating to this application to the address associated with customer number **21559**.

Address all telephone calls to: Kristina Bieker-Brady, Ph.D. at 617-428-0200.

All statements made herein of my/our knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Rod Muir	
Signature:	Citizen of: Canada

Derek Kirkland	
Signature:	Citizen of: Canada

Ian Curry	
Signature:	Citizen of: Canada

Roy Sunstrum	
Signature:	Citizen of: Canada

Paul Lem	
Signature: July 18/08	Citizen of: Canada

H. Chaim Birnboim	
Signature:	Citizen of: Canada

DO/ EO WORKSHEET

Patent Application Specialist/ National Stage Division

U.S. Appl. No. 10/056,767 International Appl. No. PCT/CA2004/000805

WIPO PUBLICATION INFORMATION :

Publication No.: WO2005/066054 Publication Language : ☑ English (IA used as specification) ☐ German ☐ Japanese ☐ Chinese ☐ Korean ☐ French ☐ Spanish ☐ Russian ☐ Other : ___

Publication Date : 14 Jul 2005 Not Published : ☐ U.S. only ☐ Early Pub. Request Published : ☐ Early Pub.

INTERNATIONAL APPLICATION PAPERS IN THE APPLICATION FILE :

- ☑ International Application *(RECORD COPY)*
- ☐ Article 19 Amendments
- ☑ PCT/IPEA/409 - IPER (check Examination Authority) : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☑ CA ☐ KR ☐ ___
- ☐ Annexes to 409
- ☑ PCT/ISA/237 (check Searching Authority) : ☐ EP ☐ JP ☐ SE ☐ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☑ CA ☐ KR ☐ ___
- ☐ Other : _____
- ☒ PCT/IB/306
- ☐ Request form PCT/RO/101
- ☑ PCT/ISA/210 - Search Report (check Searching Authority) : ☐ EP ☐ JP ☐ SE ☑ AU ☐ US ☐ FR ☐ CN ☐ ES ☐ RU ☐ AT ☑ CA ☐ KR ☐ ___ ☐ NONE
- ☐ Search Report References
- ☑ Priority Document (s) No. 1 ☐ N/A ☐ Priority Document was NOT AVAILABLE at the time of paralegal review
- ☐ Other : _____

RECEIPTS FROM THE APPLICANT *(filed with the application unless noted otherwise) :*

- ☐ Basic National Fee *(or authorization to charge)*
- ☑ Description ☑ Claims ☑ Abstract
- ☑ Number of Drawing Sheets : 15
- ☐ Translation of Article 19 Amendments ☐ entered ☐ not entered : ☐ not a page for page substitution ☐ replaced by Article 34 Amendment
- ☐ Annexes to 409 ☐ entered ☐ not entered : ☐ not a page for page substitution ☐ no translation ☐ other : _____
- ☑ Application Data Sheet
- ☐ Power of Attorney
- ☐ Change of Address
- ☐ PG Pub Early Publication Request
- ☒ Express Request to Begin Nat'l Examination Procedures
- ☑ Preliminary Amendment(s) Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____
- ☐ Information Disclosure Statement(s) Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____
- ☐ Assignee Statement Under 37 CFR 3.73(b)
- ☐ Assignee PG Publication Notice
- ☐ Substitute Specification Filed on : 1. ☐ same as 371 request date 2. _____ 3. _____
- ☐ Verified Small Status Statement
- ☒ Oath/ Declaration (executed)
- ☐ Defective Oath/ Declaration ☐ unsigned ☐ no citizenship ☐ other
- ☐ DNA Diskette ☐ Sequence Listing
- ☐ Other : _____
- ☐ Other : _____

NOTES :

35 U.S.C. 371 - Receipt of Request (PTO-1390)	6/5/05
Date Acceptable Oath/ Declaration Received	11/04/05
Date of Completion of requirements under 35 U.S.C. 371	11/04/05
Date of Completion of DO/ EO 903 - Notification of Acceptance	8/15/05
Date of Completion of DO/ EO 905 - Notification of Missing Requirements	
Date of Completion of DO/ EO 909 - Notification of Abandonment	
Date of Completion of DO/ EO 916 - Notification of Defective Response	
Date of Completion of DO/ EO 922 - Notification to Comply w/ Requirements for Patent Applications Containing Nucleotide and/or Amino Acid Sequence Disclosures	
Date of Completion of DO/ EO 923	

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
12/096,767	11/24/2008	3761	1590	50245/005001	49	2

CONFIRMATION NO. 4566

21559
CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

FILING RECEIPT

OC000000036016887

Date Mailed: 05/22/2009

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Rod Muir, South Mountain, ON, CANADA;
Derek Kirkland, Chelsea, QC, CANADA;
Ian Curry, Kanata, ON, CANADA;
Roy Sunstrum, Richmond, ON, CANADA;
Paul Lem, Ottawa, ON, CANADA;
H. Chaim Birnboim, Ottawa, ON, CANADA;

Assignment For Published Patent Application

DNA GENOTEK INC., Ottawa, ON, CANADA

Power of Attorney: The patent practitioners associated with Customer Number 21559

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/CA2006/002009 12/11/2006
which claims benefit of 60/748,977 12/09/2005

Foreign Applications

If Required, Foreign Filing License Granted: 05/15/2009

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/096,767**

Projected Publication Date: 08/27/2009

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **

Title

CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

Preliminary Class

604

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
12/096,767	Rod Muir	50245/005001

21559
CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

INTERNATIONAL APPLICATION NO.	
PCT/CA2006/002009	
I.A. FILING DATE	PRIORITY DATE
12/11/2006	12/09/2005

CONFIRMATION NO. 4566
371 ACCEPTANCE LETTER

OC000000036016888

Date Mailed: 05/22/2009

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

11/24/2008	11/24/2008
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Indication of Small Entity Status
- Copy of the International Application filed on 06/09/2008
- Copy of the International Search Report filed on 06/09/2008
- Copy of IPE Report filed on 06/09/2008
- Preliminary Amendments filed on 06/09/2008
- Oath or Declaration filed on 11/24/2008
- Request for Immediate Examination filed on 06/09/2008
- U.S. Basic National Fees filed on 06/09/2008
- Priority Documents filed on 06/09/2008
- Specification filed on 06/09/2008
- Claims filed on 06/09/2008
- Abstracts filed on 06/09/2008
- Drawings filed on 06/09/2008

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

RODERICK M JONES

Telephone: (703) 756-1460

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/096,767	11/24/2008	Rod Muir	50245/005001

CONFIRMATION NO. 4566

21559
CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

PUBLICATION NOTICE

OC00000037543614

Title:CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

Publication No.US-2009-0216213-A1
Publication Date:08/27/2009

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	371(c) Date	November 24, 2008
	Group	3761
	IDS Filed	January 13, 2010

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant
	4,583,971	April 22, 1986	Bocquet et al.
	4,741,346	May 3, 1988	Wong et al.
	5,140,043	August 18, 1992	Darr et al.
	5,364,763	November 15, 1994	Kacian
	5,496,562	March 5, 1996	Burgoyne
	5,567,309	October 22, 1996	Classon et al.
	5,807,527	September 15, 1998	Burgoyne
	5,817,630	October 6, 1998	Hofmann et al.
	5,980,834	November 9, 1999	Bruno
	6,176,836	January 23, 2001	Trudil et al.
	6,242,188	June 5, 2001	Dattagupta et al.
	6,291,178	September 18, 2001	Schneider
	6,309,827	October 30, 2001	Goldstein et al.
	6,503,716	January 7, 2003	Lai et al.
	6,551,777	April 22, 2003	Shuber et al.
	6,582,415	June 24, 2003	Fowles et al.
	6,617,170	September 9, 2003	Augello et al.
	6,716,392	April 6, 2004	Putcha et al.
	6,869,769	March 22, 2005	Burgoyne
	7,482,116	January 27, 2009	Birnboim
	2001/0008614	July 19, 2001	Aronowitz

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	371(c) Date	November 24, 2008
	Group	3761
	IDS Filed	January 13, 2010

U.S. PATENT DOCUMENTS			
	2002/0026046	February 28, 2002	Pasloske et al.
	2002/0081575	June 27, 2002	Small et al.
	2004/0038269	February 26, 2004	Birnboim

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
	CA 2072331	December 26, 1992	Canada	
	CA 2236240	October 29, 1999	Canada	
	EP 0273015	June 29, 1988	Europe	English Abstract
	EP 0586024	March 9, 1994	Europe	
	EP 0734684	October 2, 1996	Europe	
	EP 1207208	May 22, 2002	Europe	
	WO 89/06704	July 27, 1989	W.I.P.O.	
	WO 91/02740	March 7, 1991	W.I.P.O.	
	WO 97/05248	February 13, 1997	W.I.P.O.	
	WO 98/44158	October 8, 1998	W.I.P.O.	
	WO 99/29904	June 17, 1999	W.I.P.O.	
	WO 01/34844	May 17, 2001	W.I.P.O.	
	WO 01/60517	August 23, 2001	W.I.P.O.	English Abstract
	WO 02/44691	June 6, 2002	W.I.P.O.	
	WO 03/104251	December 18, 2003	W.I.P.O.	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	371(c) Date	November 24, 2008
	Group	3761
	IDS Filed	January 13, 2010

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Birnboim, "Effect of Lipophilic Chelators on Oxyradical-Induced DNA Strand Breaks in Human Granulocytes: Paradoxical Effect of 1,10-Phenanthroline," *Archives of Biochemistry and Biophysics* 294(1):17-21 (1992).
	Birnboim, "Extraction of High Molecular Weight RNA and DNA from Cultured Mammalian Cells," *Methods in Enzymology* 216:154-160 (1993).
	Birnboim and Doly, "A Rapid Alkaline Extraction Procedure for Screening Recombinant Plasmid DNA," *Nucleic Acids Research* 7(6):1513-1524 (1979).
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	Clarke and Martell, "Stabilities of the Alkaline Earth and Divalent Transition Metal Complexes of the Tetraazamacrocyclic Tetraacetic Acid Ligands," *Inorganica Chimica Acta* 190:27-36 (1991).
	French et al., "Ultra-Rapid DNA Analysis Using HyBeacon™ Probes and Direct PR Amplification from Saliva," *Molecular and Cellular Probes* 16:319-326 (2002).
	Garcia-Closas et al., "Collection of Genomic DNA From Adults in Epidemiological Studies by Buccal Cytobrush and Mouthwash," *Cancer Epidemiology, Biomarkers & Prevention* 10:687-696 (2001).
	Heath et al. "Use of Buccal Cells Collected in Mouthwash as a Source of DNA for Clinical Testing," *Archives of Pathology and Laboratory Medicine* 125:127-133 (2001).
	Hiraide et al., "Speciation of Iron in River Water," *Analytical Sciences* 4:605-609 (1988).
	Loens et al., "Detection of *Mycoplasma Pneumoniae* in Spiked Clinical Samples by Nucleic Acid Sequence-Based Amplification," *Journal of Clinical Microbiology* 40(4):1339-1345 (2002).
	Lum and Marchand, "A Simple Mouthwash Method for Obtaining Genomic DNA in Molecular Epidemiological Studies," *Cancer Epidemiology, Biomarkers & Prevention* 7:719-724 (1998).
	Nilsson et al., "Real-Time Monitoring of DNA Manipulations Using Biosensor Technology," *Analytical Biochemistry* 224:400-408 (1995).
	Pershadsingh and McDonald, "A High Affinity Calcium-Stimulated Magnesium-Dependent Adenosine Triphosphatase in Rat Adipocyte Plasma Membranes," *Journal of Biological Chemistry* 255(9):4087-4093 (1980).
	Roberts et al., "UV Laser Machined Polymer Substrates for the Development of Microdiagnostic Systems," *Analytical Chemistry* 69:2035-2042 (1997).
	Rymaszewski et al., "Estimation of Cellular DNA Content in Cell Lysates Suitable for RNA Isolation," *Analytical Biochemistry* 188:91-96 (1990).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	371(c) Date	November 24, 2008
	Group	3761
	IDS Filed	January 13, 2010

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Seutin et al., "Preservation of Avian Blood and Tissue Samples for DNA Analyses," *Canadian Journal of Zoology* 69:82-90 (1991).
	Terasaki et al., "Saliva as DNA Source for HLA Typing," *Human Immunology* 59:597-598 (1998).
	van Schie and Wilson, "Saliva: A Convenient Source of DNA for Analysis of Bi-Allelic Polymorphisms of Fcγ Receptor IIA (CD32) and Fcγ Receptor IIIB (CD16)," *Journal Immunological Methods* 208:91-101 (1997).
	Videira and Werner, "Assembly Kinetics and Identification of Precursor Proteins of Complex I from *Neurospora Crassa*," *European Journal of Biochemistry* 181:493-502 (1989).
	International Preliminary Report on Patentability for PCT/CA2006/002009 dated April 23, 2008.
	Transmittal of the International Search Report and Written Opinion of the International Searching Authority for PCT/CA2006/002009 dated March 30, 2007.
	Transmittal of The International Search Report and The Written Opinion of the International Searching Authority for PCT/CA06/000380 dated July 6, 2006.
	Communication from European Patent Office regarding EP 03729743 dated October 1, 2007.
	Transmittal of the International Search Report for PCT/CA03/00869 dated March 30, 2004.
	Written Opinion for PCT/CA03/00869 dated July 20, 2004.
	Applicant's Letter in Response to the Written Opinion for PCT/CA03/00869 dated June 3, 2004.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
371(c) Date:	November 24, 2008	Examiner:	Not yet assigned
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449, copies of which are enclosed, with the exception of U.S. patents and U.S. patent application publications. Copies of correspondence from a corresponding international application are also enclosed.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed before the receipt of a first Office Action on the merits.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: January 12, 2010

Kristina Bicker Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

Electronic Acknowledgement Receipt

EFS ID:	6791335
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Richard Todd Armstrong/Claire Yotts
Filer Authorized By:	Richard Todd Armstrong
Attorney Docket Number:	50245/005001
Receipt Date:	13-JAN-2010
Filing Date:	24-NOV-2008
Time Stamp:	14:51:53
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	EP0273015.PDF	610546 b16138b6abaeb6dc1842ee3b56230d63fb346607	no	9

Warnings:	
Information:	

2	Foreign Reference	EP0586024.pdf	797246 35be0868631e689bfd0bee7231e500cb91f72019	no	11
Warnings:					
Information:					
3	Foreign Reference	EP0734684.pdf	675766 681e75d93a2dfe50e6f1e3738a51bc87fd539b7a	no	16
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Information:					
4	Foreign Reference	EP1207208.pdf	538460 1fa3dab6f655fd4ea2fa181aa187c3829aa93fc8	no	10
Warnings:					
Information:					
5	Foreign Reference	WO8906704.pdf	2506943 3a464d39a051edcfa090d26afceb6e5a21ef06f1	no	54
Warnings:					
Information:					
6	Foreign Reference	WO9102740.pdf	1482377 0f23fbd07b157383279db79e9fa92c92fcae4e95	no	37
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Information:					
7	Foreign Reference	WO9705248.pdf	1101295 98544acb0d6f22b68a33c084c78897f44429e111	no	34
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Information:					
8	Foreign Reference	WO9844158.pdf	2977054 fed88cc5e9390d82760c70b4552df525c603eb66	no	71
Warnings:					
Information:					
9	Foreign Reference	WO9929904.pdf	1537599 fd22fe873ee2518d5dd3262be2a1848437574204	no	39
Warnings:					
Information:					
10	Foreign Reference	WO0134844.pdf	2679061 df76f5e3b71c0df43b03f01e9f865f35bbb952e9	no	66
Warnings:					
Information:					

11	Foreign Reference	WO0160517.pdf	1106478 ef90d05196bbf26736be45960930d9f16fb0a589	no	29
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Information:					
12	Foreign Reference	WO0244691.pdf	1500088 0b1a9953c1b29b26af0503a6751c1ea58b28b4c0	no	38
Warnings:					
Information:					
13	Foreign Reference	WO03104251.pdf	2104989 cfbc321a385a5cb765d10f497a542a32c3667bf7	no	50
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Information:					
14	NPL Documents	Birnboim_1993.pdf	278643 6d8ba52a0528e923ef85afcd83fe7e54b240a544	no	4
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15	NPL Documents	Birnboim_1979.pdf	596382 79d3d7c4f724140e3706a16204b76e4f594f0634	no	12
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Information:					
16	NPL Documents	Birnboim_1981.pdf	314519 fcf6b5a8511a3702c07c6d3f0008e9ae9caaf3d6	no	4
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Information:					
17	NPL Documents	Clarke_1991.pdf	636753 f36b5b7d0fbb2122cdda6ec79f64359134369b5d	no	10
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18	NPL Documents	French_2002.pdf	538096 16e608a500ce907e0754612ca55b08eff8724471	no	8
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19	NPL Documents	Garcia_Closas_2001.pdf	951065 a9931ca3379f831de145c9e20c477cefe9b98c6a	no	10
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Information:					

20	NPL Documents	Heath_2001.pdf	616109 56997d7f094d5502bf26b2f7bff9c12f2ca55361	no	7
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21	NPL Documents	Hiraide_1988.pdf	410349 f87a49d9b1ea49238be7de4130caa1e526a5ddcb	no	5
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Information:					
22	NPL Documents	Loens_2002.pdf	669846 ce979e55b67c6f473649367eb95616b0ffddd95b	no	7
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Information:					
23	NPL Documents	Lum_1998.pdf	507012 6f28c0fdf06f3b43985fac596451b7eb8b7201c2	no	6
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Information:					
24	NPL Documents	Nilsson_1995.pdf	780096 ffc0605386728e026dfea9046ea9e8e58213ce61	no	9
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Information:					
25	NPL Documents	Pershadsingh_1980.pdf	722978 3523105b0e953e8a04f407c3e0d01ab30a8d15e7	no	7
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Information:					
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Information:					
27	NPL Documents	Rymaszewski_1990.pdf	484006 c2a50494eb80893fea51ef8e46340b418a7e74fc	no	6
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28	NPL Documents	Seutin_1991.pdf	810678 65cfc281d260f47cfe364c60b2f6b7cbfe37d65b	no	9
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29	NPL Documents	Terasaki_1998.pdf	90724 7acfb1d7041ee9ccb717711ee80bae8fac00c729	no	2
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Information:					
30	NPL Documents	van_Schie_1997.pdf	754796 2631206294f6160e19d7eeac3d6034cfb8c34d76	no	11
Warnings:					
Information:					
31	NPL Documents	Videira_1989.pdf	987672 583943398bf4972b11e7013cb7f1be968492b0b2	no	10
Warnings:					
Information:					
32	NPL Documents	IPRP_CA06002009_4_23_2008.pdf	282380 4e12b0ccf4b9519cb661cf2574ca1006cbf8252b	no	6
Warnings:					
Information:					
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Information:					
34	NPL Documents	ISR_WO_PCTCA06000380_7_6_2006.pdf	797420 e4ac2537ff242787ae5bfce5c7acc8ede7954d57	no	15
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Information:					
35	NPL Documents	EPO_Comm_EP03729743_10_1_2007.pdf	331350 b1a394479e8f73af1d4857745bf4fc6b4457f2fd	no	7
Warnings:					
Information:					
36	NPL Documents	Trans_ISR_PCTCA0300869_3_30_2004.pdf	497900 89038e5db5f4570bc4a640e333d0e4b4554048cd	no	11
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Information:					
37	NPL Documents	WrittenOP_PCTCA0300869_7_20_2004.pdf	569420 d4a87200b7cde5bc5c1345d6d4c673962e8bdcf7	no	12
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Information:					

38	NPL Documents	Response_to_Written_Opinion_PCTCA0300869_6_3_2004.pdf	158950 9a13b59ae3dc649a9776ba23a749c43375f91069	no	4
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39	NPL Documents	Birnboim_1992.PDF	523003 a3a9732629ff39e056116f3791090afcf936dd77	no	5
Warnings:					
Information:					
40	Information Disclosure Statement (IDS) Filed (SB/08)	IDS.PDF	247448 4d7117b6a52af57eb14dea834168554eb29f7b71	no	4
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
41	Transmittal Letter	Transmittal_Letter.PDF	60565 6da943795ff01def0a00fd38dbce81f5c7dc5f42	no	2
Warnings:					
Information:					
42	Foreign Reference	CA2236240.pdf	456433 bc747921618a33f765c180002967097a4e404efb	no	17
Warnings:					
Information:					
43	Foreign Reference	CA2072331.pdf	2007844 3d5febfd9b20957e0a3a69b3eca4c8f169d44344	no	51
Warnings:					
Information:					
		Total Files Size (in bytes):	37523539		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PPCT18678	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/CA2006/002009	International filing date *(day/month/year)* 11 December 2006 (11-12-2006)	Priority date *(day/month/year)* 09 December 2005 (09-12-2005)

International Patent Classification (IPC) or national classification and IPC
IPC: ***A61B 5/00*** (2006.01), ***A61B 5/15*** (2006.01), ***A61J 1/05*** (2006.01), ***B01L 3/14*** (2006.01), ***B65D 47/36*** (2006.01), ***B65D 81/32*** (2006.01)

Applicant
DNA GENOTEK INC. ET AL

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. [X] *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:

      [X] sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   [X] Box No. I Basis of the report
   [ ] Box No. II Priority
   [X] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   [ ] Box No. IV Lack of unity of invention
   [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   [ ] Box No. VI Certain documents cited
   [ ] Box No. VII Certain defects in the international application
   [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand 09 October 2007 (09-10-2007)	Date of completion of this report 23 April 2008 (23-04-2008)
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Karen Oprea 819- 934-2668

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (Rules 12.3(a) and 23.1(b))

[ ] publication of the international application (Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

[ ] the international application as originally filed/furnished

[X] the description:

[X] pages 1-21 as originally filed/furnished

[ ] pages* received by this Authority on

[ ] pages* received by this Authority on

[X] the claims:

[X] pages 22-25 as originally filed/furnished

[ ] pages* as amended (together with any statement) under Article 19

[X] pages* 26 and 27 received by this Authority on 9 Oct. 2007 (09-10-2007)

[ ] pages* received by this Authority on

[X] the drawings:

[X] pages 1/15-15/15 as originally filed/furnished

[ ] pages* received by this Authority on

[ ] pages* received by this Authority on

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

5. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 66.1(d-*bis*))

**If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

[ ] the entire international application

[X] claims Nos. 51

because:

[X] the said international application, or the said claims Nos.
relate to the following subject matter which does not require an international preliminary examination *(specify):*

More specifically, claim 51 is directed to a container system as substantially described herein. Such a claim is considered an omnibus claim and thereby no search or opinion is requried by this Authority.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify):*

[ ] the claims, or said claims Nos. are so inadequately supported
by the description that no meaningful opinion could be formed *(specify):*

[X] no international search report has been established for said claims Nos. 51

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-50	YES
	Claims	None	NO
Inventive step (IS)	Claims	1-50	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1-50	YES
	Claims	None	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: EP 0273015 (A2) 29 June 1988 (29-06-1988) by Loretti et al.
D2: US 6 582 415 (B1) 24 June 2003 (24-06-2003) by Fowles et al.
D3: US 4 741 346 3 May 1988 (03-05-1988) by Wong et al.

D1 teaches a device comprises the following: a cartridge and a lid delimiting between them a cavity intended for the vial; the lid is arranged removably on the cartridge, and a seal which ensures the leakproofness between the cartridge and the lid. The neck of the vial is intended to be placed towards the bottom of the cartridge opposite the lid; the bottom of the cartridge is equipped with an opening for the passage of the fluid, which opening is extended in the direction of the lid by a trocar which is intended to pierce the stopper sealing the vial and the direction away from the lid by a conduit sealed by a breakable seal. This conduit is placed in a passage for introduction towards the inside of the container. The cartridge is preferably provided with a cylindrical inner part for holding the outer surface of the standardised, crimped neck of the vial and for guiding it during its introduction into the device.

D2 teaches a container device for establishing fluid communication between a liquid container having sidewalls and a vial, the device comprising : a piercing member having first and second end and a central fluid pathway, the piercing member being mounted to the liquid container and having fluid accessing portions sealed from an outside environment; a vial receiving member associated with said piercing member and means for connecting the vial receiving chamber to connect to the liquid container.

D3 teaches a biological fluid specimen collector e.g. for medical apparatuses including gripping walls upstanding from the base to hold a specimen vial in an upright position.

D1, even though it teaches a container with a receiving device for a vial, it fails to disclose a container system which releasably stores a substance, comprising a vial and a lid which is so configured as to removably engage said vial comprising a reservoir for holding the substance as well as a funnel and a piercing member as claimed in claims 1-50. With regard to D2 and D3, even though they teach a container device system for releasably storing a substance comprising a vial, the system of D2 does not include a lid as recited in the present claims. Furthermore, there is nothing within the cited reference that teaches or even suggests a method of combining a substance using a container system as disclosed in claims 1-50 in view of D1 or D2 , alone or in combination with D3.

Conclusions

Article 33(2) PCT- Novelty (N)
The subject matter of claims 1-50 is deemed to be novel in view of D1-D3, thereby fulfilling the requirements of Article 33(2) PCT.

Article 33(3) PCT-Inventive Step (IS)
The subject matter of claim 1-50 is considered to be inventive in view of D1-D3, hence fulfilling the requirements of Article 33(3) PCT.

Article 33(4) PCT-Industrial Applicability (IA)
The subject matter of claims 1-50 is considered to be industrially applicable, hence fulfilling the requirements of Article 33(4) PCT.

37. The container system according to any one of claims 22 - 36, wherein said vial is releasably attached to said funnel and sized for attachment to a cap when released from said funnel.

38. The container system according to any one of claims 22 - 37, wherein said vial is configured for use in standard laboratory equipment.

39. The container system according to claim 38, wherein said vial has dimensions that conforms with industry-standard dimensions for a blood collection tube.

40. The container system according to claim 38 or 39, wherein said vial is a T501 tube.

41. The container system according to any one of claims 22 – 40, wherein said chamber is sized to hold about 1 ml to about 16 ml.

42. The container system according to any one of claims 1 – 41, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample.

43. The container system according to claim 42, wherein said nucleic acid is DNA or RNA.

44. The container system according to any one of claims 1 – 43, additionally comprising a solid or semi-solid material within said vial and maintained separate from the substance in the reservoir of said lid until said pierceable membrane is disrupted.

45. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 1 – 21;

(b) providing the sample to the chamber in the vial; and

(c) closing said container system by removably attaching said lid to said vial; and

(d) piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

46. A method of combining a substance with a biological sample, comprising:

(a) providing a container system according to any one of claims 22 – 41;

(b) providing the sample to the chamber in the vial through said funnel; and

(c) closing said container system by removably attaching said lid to said first open end of said funnel; and

(d) piercing said membrane to release said substance into said chamber by moving said system to said piercing position.

47. The method according to claim 45 or 46, wherein the substance is a nucleic acid preserving substance.

48. The method according to any one of claim 45 – 47, wherein the sample is a biological sample.

49. The method according to any one of claim 45 – 48, for archiving the sample.

50. A kit for sample collection and storage, comprising:

a) a container system according to any one of claims 1 to 44; and

b) instructions for the use thereof.

51. A container system as substantially described herein.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
OSLER, HOSKIN & HARCOURT LLP
1500 - 50 O'Connor Street
OTTAWA, Ontario
Canada, K1P 6L2

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 30 March 2007 (30-03-2007)
Applicant's or agent's file reference PPCT18678	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/CA2006/002009	International filing date *(day/month/year)* 11 December 2006 (11-12-2006)

Applicant
DNA GENOTEK INC. ET AL

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19 :
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46) :

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that :

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for the international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Chantal Hébert 819- 953-4957

Form PCT/ISA/220 (October 2005) *(See notes on accompanying sheet)*

NOTES TO FROM PCT/ISA/220

These Notes are intended to give instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)) :

The amendments must be submitted with a letter.
The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").
The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;
(ii) the claim is cancelled;
(iii) the claim is new;
(iv) the claim replaces one or more claims as filed;
(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter :

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

P ENT COOPERATION TREAT

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PPCT18678	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below
International application No. **PCT/CA2006/002009**	International filing date *(day/month/year)* 11 December 2006 (11-12-2006)	(Earliest)Priority date *(day/month/year)* 09 December 2005 (09-12-2005)
Applicant DNA GENOTEK INC. ET AL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

      [X] the international application in the language in which it was filed

      [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

   b. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I

2. [ ] **Certain claims were found unsearchable** (see Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant

   [ ] the text has been established by this Authority to read as follows :

5. With regard to the **abstract**,

   [X] the text is approved as submitted by the applicant

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 10

      [X] as suggested by the applicant

      [ ] as selected by this Authority, because the applicant failed to suggest a figure

      [ ] as selected by this Authority, because this figure better characterizes the invention

   b. [ ] none of the figures is to be published with the abstract

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. [X] Claim Nos. : 50

because they relate to subject matter not required to be searched by this Authority, namely :

Claim 50 is directed to a container system as decribed herein. Such a claim is considered an omnibus claim and thereby no search or opinion is required by this Authority.

2. [ ] Claim Nos. :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

3. [ ] Claim Nos. :

because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2006/002009

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61B 5/00*** (2006.01) , ***A61B 5/15*** (2006.01) , ***A61J 1/05*** (2006.01) , ***B01L 3/14*** (2006.01) , ***B65D 47/36*** (2006.01) , ***B65D 81/32*** (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/00, A61B 5/15, A61J 1/05, B01L 3/14, B65D 47/36, B65D 81/32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Databases: Google, CPD (Canadian Patent Database), Pluspat, Delphion, IEEE Xplore
Keywords: vial, lid, funnel, pierce, container system, store/ing, sample, chamber

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 0273015 (A2) 29 Jun.1988 (29-06-1988), Loretti et al., ** see abstract, Fig, 2,3,5,6**	1, 44 22, 45-49
X	US 6 582 415(B1) 24 June 2003 (24-06-2003), Fowles et al. ** see abstract, col.20-col.21, line 21**	1, 44
Y	US 4 741 346 3 May 1988 (3-05-1988), Wong et al. , ** see abstract, whole document**	22, 45-49
A	US 4 583971 22 Apr. 1986 (22-04-1986), Bocquet et al., ** see whole document**	1-49
A	US 5 980 834 9 Nov. 1999 (9-11-1989), Bruno, ** see whole document**	1-49
A	US 5 567 309 22 Oct. 1996 (22-10-1996), Classon et al., ** see whole document**	1-49

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 March 2007 (29-03-2007)	30 March 2007 (30-03-2007)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	Authorized officer Karen Oprea 819- 934-2668

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
EP0273015	29-06-1988	EP0273015 A2	29-06-1988
US6582415	24-06-2003	AT283091T T	15-12-2004
		AU760376B B2	15-05-2003
		AU762850B B2	10-07-2003
		AU1090600 A	03-04-2000
		AU4455600 A	02-11-2000
		AU2003226002 A1	13-10-2003
		AU2004311928 A1	21-07-2005
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		BR0009908 A	08-01-2002
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		BR9906945 A	03-10-2000
		CA2309730 A1	23-03-2000
		CA2365557 A1	26-10-2000
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		CA2546835 A1	21-07-2005
US4741346	03-05-1988	AT70178T T	15-12-1991
		CA1270413 A1	19-06-1990
		DE3775119D D1	23-01-1992
		EP0250170 A2	23-12-1987
		ES2028078T T3	01-07-1992
		GR3003996T T3	16-03-1993
		JP2525817B2 B2	21-08-1996
		US4741346 A	03-05-1988
US4583971	22-04-1986	AU580584B B2	19-01-1989
		AU3933085 A	27-08-1985
		CA1234369 A1	22-03-1988
		DE3570594D D1	06-07-1989
		EP0172836 A1	05-03-1986
		ES540177D D0	16-11-1986
		IT1183224 B	15-10-1987
		JP3049262B B	29-07-1991
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		ZA8500835 A	25-09-1985
US5980834	09-11-1999	US5980834 A	09-11-1999
US5567309	22-10-1996	US5567309 A	22-10-1996

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
OSLER, HOSKIN & HARCOURT LLP
1500 - 50 O'Connor Street
OTTAWA, Ontario
Canada, K1P 6L2

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	30 March 2007 (30-03-2007)
Applicant's or agent's file reference PPCT18678	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA2006/002009	11 December 2006 (11-12-2006)	09 December 2005 (09-12-2005)

International Patent Classification (IPC) or both national classification and IPC
IPC: ***A61B 5/00*** (2006.01), ***A61B 5/15*** (2006.01), ***A61J 1/05*** (2006.01), ***B01L 3/14*** (2006.01), ***B65D 47/36*** (2006.01), ***B65D 81/32*** (2006.01)

Applicant
DNA GENOTEK INC. ET AL

1. This opinion contains indications relating to the following items :

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA	Date of completion of this opinion	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476	29 March 2007 (29-03-2007)	Karen Oprea 819- 934-2668

WP[illegible]TI)PINION OF THE
INTERNA[illegible]AL SEARCHING AUTHORITY

International application No.
PCT/CA2006/002009

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed

   [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :

   a. type of material

      [ ] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed.

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search.

3 [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statement that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments :

WP[illegible]TI [illegible]PINION OF THE
INTERNA[illegible]AL SEARCHING AUTHORITY

International application No.
PCT/CA2006/002009

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

[ ] the entire international application

[X] claim Nos. 50

because:

[X] the said international application, or the said claim Nos. 50 relate to the following subject matter which does not require an international search *(specify)*:

More specifically, claim 50 is directed to a container system as substantially described herein . Such a claim is considered an omnibus claim and thereby no search or opinion is required by this Authority.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claim Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

[ ] the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify):*

[X] no international search report has been established for said claims Nos. 50

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-43,45-49	YES
	Claims	1, 44	NO
Inventive step (IS)	Claims	2-21,23-43	YES
	Claims	1, 22, 44-49	NO
Industrial applicability (IA)	Claims	1-49	YES
	Claims	50	NO

2. Citations and explanations :

D1: EP 0273015 (A2) 29 Jun. 1988 (29-06-1988) Loretti et al.
D2: US 6 582 415 (B1) 24 June 2003 (24-06-2003) Fowles et al.
D3: US 4741346 3 May 1988 (3-05-1988) Wong et al.

D1 discloses by means of a flexible container equipped with the device, that the contents of a vial can be transferred into the container in a sterile manner. The device comprises the following: a cartridge and a lid delimiting between them a cavity intended for the vial; the lid is arranged removably on the cartridge, and a seal which ensures the leakproofness between the cartridge and the lid . The neck of the vial is intended to be placed towards the bottom of the cartridge opposite the lid; the bottom of the cartridge is equipped with an opening for the passage of fluid, which opening is extended in the direction of the lid by a trocar which is intended to pierce the stopper sealing the vial and in the direction away from the lid by a conduit sealed by a breakable seal. This conduit is placed in a passage for introduction towards the inside of the container.

D2 discloses a container device for establishing fluid communication between a liquid container having sidewalls and a vial, the device comprising: a piercing member having first and second end and a central fluid pathway, the piercing member being mounted to the liquid container and having fluid accessing portions sealed from an outside environment; a vial receiving chamber associated with said piercing member and means for connecting the vial receiving chamber to connect to the liquid container.

D3 discloses a biological fluid specimen collector e.g. for medical apparatuses including gripping walls upstanding from base to hold a specimen vial in an upright position. The apparatus for collecting biological fluids includes a specimen vial, in which a funnel is inserted, held in a substantially upright position in a base which has a detachable wall that houses and holds a vial cap and which lid is grippable to be used to secure and/or unsecure the cap to and/or from the vial.

1.0. Novelty (N)
The subject matter of claims 1,44 lacks novelty in view of D1 or D2 and hence does not fulfill the requirements Article 33(2) PCT.
RE: Claim 1
D1 disclose a flexible container system for storing a substance comprising the following:
-a vial (3) comprising first end (12) for receiving a sample, and second end (11) comprising a sample storage chamber and a piercing member (13)
-a lid (8) which is so configured as to engage the vial, said lid comprising a reservoir (7) for holding the substance and a pierceable membrane (13) sealing the substance within said reservoir
- wherein said system is closed by removable engagement of said vial with said lid, said vial and lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between the reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position. (see abstract and col.4, line 45 to col. 5, line 7)

D2 also discloses a container device system for releasably storing a substance comprising a vial, comprising a first open end comprising a sample storage and a piercing member (see col.20, line 64 to col. 21, line 21), a lid which is configured to hold the substance and a pierceable membrane sealing the substance in said reservoir which allows the fluid communication between the reservoir and said chamber.

....continued in Supplemental Box.....

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

1.0. Description

The description does not comply with Article 5 of the PCT. The statement found on page1, line(s) 3-5, page 18, lines 9-11 and page 21, lines 1-5 which incorporates by reference another document, does not comply with Article 5 of the PCT. The description should be complete in and of itself. A person skilled in the art should be able to understand the patent specification without reference to any other document.

The description does not comply with Article 5 of the PCT. All documents referred to in the description of an application must be available to the public. Reference to the document on page 1, line 4 and page 18, line 10 must be deleted or replaced by its corresponding patent number or publication number.

2.0. Claims

Claims 2,7,12, 28 do not comply with Article 6 PCT for the following reasons:

RE: claim 2
the expression " ....all or a portion" on lines 1-2 of the claim is vague and ambiguous within the context of the claim

RE: claims 7 and 12
the term "approximately" within these claims is vague

Clerical Errors
The following clerical error is noted on page 27 of the claims (claim 48) "..for archiving..." should read –...for achieving..–.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

RE: Claim 44:
D1 or D2 disclose a method of combining a substance within a biological sample comprising (see D1, abstract, D2, col. 21, line 1 to col. 22, line 43).
- a container according to the system of claim 1
- providing the sample to the chamber in the vial
- closing said container system by removably attaching said lid to said vial;
- piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

2.0. Inventive Step (IS)
Claims 1, 22, 44-49 are not considered to be inventive in view of documents D1 or D2 in view of D3 and therefore do not fulfill the requirements for Article 33(3) PCT.
RE: Claims 1, 44
Given the above objection, claims 1,44 are also considered to lack an inventive step in light of the described prior art and thus fail to comply with Article 33(3) of the PCT.

RE: Claim 22
D1 discloses a container system for releasably storing a substance comprising:
- a vial (3) comprising a chamber for retaining a sample
- a lid (8) comprising a reservoir for holding a substance and a pierceable membrane sealing that substance within said reservoir
D3 on the other hand discloses an apparatus for collecting biological fluids including a specimen vial in which a funnel is inserted in a base which has a detachable wall which houses and holds a vial lid that is grippable to be used to secure and unsecure the cap from the lid (see abstract and col.2, lines 19 to line 58). Thereby the container system of claim 22 lacks and inventive step and would have been obvious to one skilled in the art at the time of invention given the disclosure of D1 in view of D3.

RE: Claims 45:
D1 discloses the container of claim 1 (lid, vial and pierceable member) which is provided with a biological sample in the chamber of said vial (see abstract, whole document). D3 discloses providing of the sample to the chamber in the vial through said funnel (32) (see also abstract and col. 5, lines 1-35), closing said container system by removably attaching said lid to said first open end of said funnel (col. 5 - col.6, line 34). D1 further discloses piercing said chamber to allow for fluid communication thereof.

RE: Claim 46-48:
D1, D2 in view of D3 (see abstracts) disclose that the substance which is generally stored within their device is either a nucleic acid or a biological sample

RE: Claim 49
The use of a kit for sample collection and storage comprising a container system as disclosed in claims 1-43 including instructions thereof simply provides an implementation detail without adding to the independent claims any subject matter which is distinguishable over the prior art.

Given the above objections, claims 1, 22, 44-49 are considered to lack an inventive step in light of the described prior art (D1,D2 in view of D3) and thus fail to comply with Article 33(3) of the PCT.

3.0. Industrial Applicability (IA)
Claims 1-49 fulfill the requirements of Industrial Applicability and thereby comply with the requirements of Article 33(4) PCT.
For the assessment of present claim 50, which is directed to an omonibus claim, under Rule 43bis.1(a)(i) and Article 33(4) PCT on whether it is industrially applicable, no unified criteria exisits.

Conclusions
Article 33(2) PCT-Novelty(N)
The subject matter of claims 1, 44 is not considered to be novel in view of the prior art on record, hence not fulfilling the requirements of Article 33(2) PCT.
Article 33(3) PCT- Inventive Step (IS)
The subject matter of claims 1,22,44-49 is not considered to be inventive in view of D1-D3 and hence does not comply with the requirements of Article 33(3) PCT.
Article 33(4) PCT-Industrial Applicability (IA)
The subject matter of claims 1-49 is deemed to be industrially applicable and compliant with Article 33(4) PCT. For the assessment of present claim 50, which is directed to an omonibus claim, under Rule 43bis.1(a)(i) and Article 33(4) PCT on whether it is industrially applicable, no unified criteria exisits.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
OSLER, HOSKIN & HARCOURT LLP
1500 - 50 O'Connor Street
OTTAWA, Ontario
Canada, K1P 6L2

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 6 July 2006 (06-07-2006)
Applicant's or agent's file reference 18058	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/CA2006/000380	International filing date *(day/month/year)* 14 March 2006 (14-03-2006)
Applicant DNA GENOTEK INC. ET AL	

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19 :
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46) :

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that :

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for the international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Authorized officer Lucille Leonard (819) 953-1737

Form PCT/ISA/220 (October 2005) *(See notes on accompanying sheet)*

NOTES TO FROM PCT/ISA/220

These Notes are intended to give instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide,* Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)) :

The amendments must be submitted with a letter.
The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").
The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;
(ii) the claim is cancelled;
(iii) the claim is new;
(iv) the claim replaces one or more claims as filed;
(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter :

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 18058	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below
International application No. **PCT/CA2006/000380**	International filing date *(day/month/year)* 14 March 2006 (14-03-2006)	(Earliest)Priority date *(day/month/year)* 16 March 2005 (16-03-2005)
Applicant DNA GENOTEK INC. ET AL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

      [X] the international application in the language in which it was filed

      [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

   b. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I

2. [X] **Certain claims were found unsearchable** (see Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

   [X] the text is approved as submitted by the applicant

   [ ] the text has been established by this Authority to read as follows :

5. With regard to the **abstract**,

   [ ] the text is approved as submitted by the applicant

   [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No.

      [ ] as suggested by the applicant

      [ ] as selected by this Authority, because the applicant failed to suggest a figure

      [ ] as selected by this Authority, because this figure better characterizes the invention

   b. [X] none of the figures is to be published with the abstract

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. [ ] Claim Nos. :
because they relate to subject matter not required to be searched by this Authority, namely :

2. [X] Claim Nos. : 1-3, 6 and 15-21
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

See extra sheet (Continuation of Box No. II)

3. [ ] Claim Nos. :
because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Box No. IV **Text of the abstract (Continuation of item 5 of the first sheet)**

The present invention provides an aqueous composition comprising SDS, Cyclohexanediamine tetraacetate, Tris-HCl and proteinase K for the extraction of nucleic acid from a sample of bodily fluid, such a saliva, wherein the extracted nucleic acid is stable for at least fourteen days at room temperature. The composition permits direct use of the extracted and stored DNA in an amplification reaction without further processing.

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***C12N 15/10*** (2006.01) , ***C12P 19/34*** (2006.01) , ***C07H 1/06*** (2006.01) , ***C12N 9/50*** (2006.01) , ***C07H 21/04*** (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: ***C12N 15/10*** (2006.01), ***C12P 19/34*** (2006.01) , ***C07H 1/06*** (2006.01) , ***C12N 9/50*** (2006.01) , ***C07H 21/04*** (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
Databases: PubMed, Delphion, Canadian Patent Database, STN (CAPlus, BIOSIS)
Keywords: nucleic acid, storage, preservation, forensic, archive, room temperature, CTDA, cyclohexanediamine tetraacetate, saliva, extraction, Birnboim

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/104251 A2 (BIRNBOIM, C.) December 18, 2003. see whole document	4 and 14
A	SEUTIN, G. *et al.* Preservation of avian blood and tissue samples for DNA analyses. Can. J. Zool. 1991. Vol. 69, No. 1, pages 82-90. see whole document.	4, 5 and 7-14
A	EP 1207208 A2 (McMILLIAN, R.) May 22, 2002. see whole document	4, 5 and 7-14

[ ] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 June 2006 (06-06-2006)	6 July 2006 (06-07-2006)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Authorized officer Robin Green (819) 997-3077

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO03104251 A2	18-12-2003	AU2003240327 A1	22-12-2003
		AU2003240327 A1	22-12-2003
		CA2488769 A1	18-12-2003
		EP1513952 A2	16-03-2005
		US2004038269 A1	26-02-2004
		WO03104251 A3	15-07-2004
		WO03104251 A9	11-03-2004
EP1207208 A2	22-05-2002	CA2437473 A1	20-02-2004
		EP1207208 A3	10-12-2003
		JP2002199899 A	16-07-2002
		JP2004159648 A	10-06-2004
		US7029840 B2	18-04-2006
		US2003113705 A1	19-06-2003

Continuation of Box II

Claims 1-3, 6 and 15-21 do not comply with Article 6 and Rule 6.3(a) of the PCT. The aqueous composition of claim 1 lacks clarity and is defined in terms of the desired result and not in terms of technical features that would allow one skilled in the art to ascertain what are the components of said aqueous composition. As such, claims dependent thereon (claims 2-3, 6 and 15-21) are also not sufficiently defined in terms of technical features. Further, the "basic agent" of claim 6 is indefinite and not fully supported over the full breadth of the meaning of term. For instance, a basic agent could comprise a basic protein. The application provides only support within the meaning of Article 6 and disclosure within the meaning of Article 5 of the PCT for the compositions defined in claims 4 and 7. Consequently, the search has been established for the parts of the application which appear to be clear and supported, namely an aqueous composition comprising a denaturing agent that is SDS, a chelator that is CTDA, a buffering agent that is Tris HCl and a protease that is proteinase K, as well as other compositions comprising as the basic agent, an alkali metal hydroxide, a soluble alakline earth metal hydroxide, an alkali metal oxide or an organic base.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
OSLER, HOSKIN & HARCOURT LLP
1500 - 50 O'Connor Street
OTTAWA, Ontario
Canada, K1P 6L2

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 6 July 2006 (06-07-2006)

Applicant's or agent's file reference
18058

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA2006/000380	14 March 2006 (14-03-2006)	16 March 2005 (16-03-2005)

International Patent Classification (IPC) or both national classification and IPC
IPC: ***C12N 15/10*** (2006.01), ***C12P 19/34*** (2006.01), ***C07H 1/06*** (2006.01), ***C12N 9/50*** (2006.01), ***C07H 21/04*** (2006.01)

Applicant
DNA GENOTEK INC. ET AL

1. This opinion contains indications relating to the following items :

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[X]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA	Date of completion of this opinion	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	20 June 2006 (20-06-2006)	Robin Green (819) 997-3077

Box No. I **Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed

   [ ] a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :

   a. type of material

      [ ] a sequence listing

      [ ] table(s) related to the sequence listing

   b. format of material

      [ ] on paper

      [ ] in electronic form

   c. time of filing/furnishing

      [ ] contained in the international application as filed.

      [ ] filed together with the international application in electronic form

      [ ] furnished subsequently to this Authority for the purposes of search.

3 [ ] In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statement that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments :

Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of :

[ ] the entire international application

[X] claim Nos. 1-3, 6 and 15-21

because:

[ ] the said international application, or the said claim Nos. relate to the following subject matter which does not require an international search *(specify)* :

[X] the description, claims or drawings *(indicate particular elements below)* or said claim Nos. are so unclear that no meaningful opinion could be formed *(specify)* :

Claim Nos. 1-3, 6 and 15-21

See Continuation of Box III, Supplemental Box.

[ ] the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify):*

[ ] no international search report has been established for said claims Nos.

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13*ter*.1(a) or (b).

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	5 and 7-13	YES
	Claims	4 and 14	NO
Inventive step (IS)	Claims	5 and 7-13	YES
	Claims	4 and 14	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims	None	NO

2. Citations and explanations :

The documents referred to below are numbered in the order of appearance of the documents cited in the International Search Report.

D1: WO 03/104251 A2 (BIRNBOIM, C.) December 18, 2003.

D1 discloses aqueous compositions for preserving and extracting nucleic acid from saliva, wherein the nucleic acid extracted remains stable at room temperature under ambient conditions for prolonged periods of time (more than 365 days). Said composition comprises a chelating agent, denaturing agent, buffering agent and a protease. More specifically, said reference teaches that said chelating agent is diaminocyclohexane tetraacetate (CDTA), denaturing agent is SDS, buffering agent is Tris HCl, and said protease is proteinase K.

The invention of the present application is directed to a composition that extracts nucleic acid from a sample of bodily fluid and preserves said nucleic acid from degradation when stored at room temperature for prolonged periods of time. Moreover, said extracted and preserved nucleic acid can be used directly in an amplification reaction without further processing.

Novelty

D1 discloses specific compositions for the prevention and extraction of nucleic acid in a sample of bodily fluid, wherein said sample can be stored at room temperature for prolonged periods of time without the degradation of the extracted nucleic acid. The composition of D1 comprises among others, SDS, CDTA, Tris-HCl and proteinase K. As such, said reference discloses a composition that comprises all the components of claim 4. Although the feature of the preferred embodiment in claim 1, that the composition does not inhibit nucleic acid amplification, was not tested in said reference, such a feature is considered to be an inherent feature of the composition. Therefore, the subject matter defined by claims 4 and 14 (as it relates to claim 4) is considered not to comply with Article 33(2) of the PCT.

No single document discloses the subject matter defined in claims 5 and 7-13 of the present application and accordingly, the subject mater defined by these claims is deemed novel and meets the requirements of Article 33(2) of the PCT.

Inventive Step

Claims 4 and 14 lack novelty under Article 33(2) of the PCT and as such, they are also considered to lack an inventive step under Article 33(3) of the PCT.

D1 discloses a composition wherein the denaturing agent is SDS, a chelator is CDTA, a buffer is TRIS-HCl and a protease is proteinase K, for use in the extraction and preservation of nucleic acid in a sample of bodily fluid. However, it would require undue experimentation for a skilled person to arrive at the specific composition defined by claim 5. Accordingly, the subject matter defined in claim 5 is considered to comprise an inventive step and is in compliance with Article 33(3) of the PCT.

Moreover, the prior art neither teaches nor suggests an aqueous composition comprising the basic agents defined in claim 7, for the preservation and extraction of nucleic acid, such that said composition does not inhibit nucleic acid amplification. As such, the subject matter defined in claims 7-13, as it relates to the aqueous composition comprising the basic agents of claim 7, is considered to comprise an inventive step and is in compliance with Article 33(3) of the PCT.

(continued in Supplemental Box: see Continuation of Box V.)

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

Claims 1 and 13 do not comply with Article 6 of the PCT. The percentage of said claims should be defined as either wt./vol. or vol./vol.

Claim 1 does not comply with Rule 6.3 (a) of the PCT. The aqueous composition of said claim is defined in terms of the desired result instead of the technical features that would allow one skilled in the art to ascertain the components of the composition.

Claim 1 does not comply with Article 6 of the PCT. Said claim is directed to a composition for extracting nucleic acid, yet it would appear from the disclosure that the composition is for both the preservation and the extraction of nucleic acid, as indicated by the fact that the nucleic acid remains stable for at least 14 days. Applicant should ensure that the preamble of the claim is in accordance with the claim as a whole.

Claim 1 does not comply with Article 6 of the PCT. Said claim is broader in scope than the teachings of the description. Applicant has only provided support for the preservation and extraction of nucleic acid from a sample of saliva. It is not clear that said composition can be used for the extraction and preservation of nucleic acid from any bodily fluid and as such, applicant should limit said claim to that of saliva.

Claims 3-4 do not comply with Article 6 of the PCT. The application provides support within the meaning of Article 6 and disclosure within the meaning of Article 5 of the PCT for an aqueous composition as defined in claim 5. The application is devoid of guidance as to how one skilled in the art can manipulate the specific components of the composition to achieve the composition defined in claim 5. As such, said skilled technician would be faced with undue scientific experimentation to derive a composition with the components defined in claim 4 that would result in a composition that preserves DNA extracted from a sample of bodily fluid for at least 14 days at room temperature and does not inhibit nucleic acid amplification when present at an amount of at least 2% of the total volume of the amplification reaction.

Claim 6 does not comply with Article 6 of the PCT. The applicant only provides support for those basic agents defined in claim 7 and as such, the term "basic agent" should be limited accordingly. Moreover, the description does not define the term "basic agent" and therefore, does not comply with Article 5 of the PCT.

Claim 21 does not comply with Article 6 of the PCT. Said claim should depend on claim 20 instead of claim 16.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: Box No. III.

Claims 1-3, 6 and 15-21 do not comply with Article 6 and Rule 6.3(a) of the PCT. The aqueous composition of claim 1 is not defined by technical features that would allow one skilled in the art to ascertain with any degree of certainty what is encompased by the claim. As such, claims dependent thereon are also not defined in terms of technical features. The claimed aqueous composition may relate to any number of possible compositions due to the fact it is defined by function or desired result. Consequently, the written opinion of the International Searching Authority on novelty and inventive step has been established on those parts of the application which appears to be clear, namely the composition defined by claims 4 and 7 and dependent claims thereon.

Claim 3 does not comply with Article 6 of the PCT. The application provides support within the meaning of Article 6 and disclosure within the meaning of Article 5 of the PCT for a single composition that comprises SDS as a denaturing agent, Cyclohexanediamine tetraacetate (CDTA) as a chelator, Tris-HCl as a buffer and proteinase K as a protease. In the present case, the claim lacks support and the application so lacks disclosure that a meaningful search over the whole of the claimed scope is impossible. Consequently, the written opinion on novelty and inventive step has been established for the parts of the application which appear to be clear and supported, namely, that composition defined in claim 4.

Claim 6 does not comply with Article 6 of the PCT. This objection is directed to the term "basic agent". This claim defines the component of the composition in such broad and insufficient technical terms that a meaningful written opinion on novelty and inventive step over the whole scope claimed cannot be performed. The claimed 'basic agent' is not defined within the application and may relate to any number of possible agents. The application provides support within the meaning of Article 6 and disclosure within the meaning of Article 5 of the PCT for a 'basic agent' that is an alkali metal hydroxide, a soluble alkaline earth metal hydroxide, an alkali metal oxide or an organic base. As such, the written opinion on novelty and inventive step has been established for these definitions of 'basic agent' which are regarded as being clear and supported.

Continuation of Box No. V.

Therefore, claims 5 and 7-13 appear to involve an inventive step in view of the documents cited in the International Search Report and comply with Article 33(3) of the PCT.

Industrial Applicability

The subject matter of claims 1-21 appears to have industrial applicability and therefore, fulfills the requirements of PCT Article 33(4).

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

RECEIVED
2004 MAR 30 A 11:53

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
SMART & BIGGAR
Attn. Robinson, J.Christopher
Box 11560, Suite 2200
650 West Georgia Street
Vancouver, BC V6B 4N8
CANADA

2200-650 WEST GEORGIA ST.
VANCOUVER, B.C

Date of mailing *(day/month/year)* 30/03/2004	
Applicant's or agent's file reference 81331-141	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/CA 03/00869	International filing date *(day/month/year)* 06/06/2003
Applicant DNA GENOTEK INC.	

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Gwenaëlle Blanca

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication. (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

RECEIVED
2004 MAR 30 A 11:58
2200-650 WEST GEORGIA ST
VANCOUVER, B.C.

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
81331-141		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CA 03/00869	06/06/2003	07/06/2002
Applicant		
DNA GENOTEK INC.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readble form.

   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 10

   ☐ as suggested by the applicant.

   ☒ because the applicant failed to suggest a figure.

   ☐ because this figure better characterizes the invention.

   ☐ None of the figures.

Form PCT/ISA/210 (first sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 03/00869

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-67 (completely), 68-73 (partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-67 (completely), 68-73 (partially)

methods of preparing a bodily fluid or tissue, in particular a mucin-containing bodily fluid or tissue (sputum), in view of further analysis comprising contacting said bodily fluid or tissue with a composition comprising a chelating agent, a denaturing agent, and possibly a reducing agent, wherein the pH of said composition is greater than 5.0, and compositions useful in said methods.

---

2. claims: 68-73 (partially), 74-90 (completely)

a device comprising a first region for collecting a biological sample and a second region containing a composition for preserving a nucleic acid, a barrier capable of disestablishment between said first and second regions, a means for closing said container and a means for disestablishing said barrier such that said composition is capable of contacting said biological sample, a method of manufacturing said device, and a method of preserving a nucleic acid from a bodily fluid making use of said device.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 03/00869

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12Q1/68 C12N15/10 B01L3/14 G01N1/38

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12Q C12N B01L G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ, WPI Data, MEDLINE, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/44158 A (EPITOPE INC; BESTWICK RICHARD K (US); GOLDSTEIN ANDREW S (US)) 8 October 1998 (1998-10-08) the whole document page 3, lines 11-13 page 9, lines 8-12 page 11, line 22 - page 12, line 28 page 19, line 9 - page 21, line 26 page 28, line 2 - line 3 ----- -/--	15-17, 21, 23-26, 28-42, 48, 50-52, 58-67

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 November 2003	30. 03. 2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Pinta, V

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 89/06704 A (MICROPROBE CORP) 27 July 1989 (1989-07-27) the whole document page 10, lines 31-36 page 24, line 34 - page 25, line 8 page 27, line 1 - line 32	1-4,6,9, 14-19, 21-26, 28-42, 48,50-52
X	WO 01/034844 A (KRUPEY JOHN; LIGOCHEM INC (US)) 17 May 2001 (2001-05-17) the whole document page 6, line 29 - page 7, line 1 page 29, line 7 - line 30	15,16, 21,25, 26, 28-42, 48,50-52
X	US 6 242 188 B1 (WU WHEI-KUO ET AL) 5 June 2001 (2001-06-05) the whole document column 3, line 66 - column 8, line 6 column 12, line 25 - column 14, line 20	15-18, 21, 23-26, 28-33, 36-40, 42,43
Y		68-73
X	LOENS K ET AL: "Detection of Mycoplasma pneumoniae in spiked clinical samples by nucleic acid sequence-based amplification." JOURNAL OF CLINICAL MICROBIOLOGY. UNITED STATES APR 2002, vol. 40, no. 4, April 2002 (2002-04), pages 1339-1345, XP002260172 ISSN: 0095-1137 the whole document	1,3,4,6, 9,14-16, 21,25, 26, 28-33, 40,42, 48,50-52
X	RYMASZEWSKI Z ET AL: "Estimation of cellular DNA content in cell lysates suitable for RNA isolation." ANALYTICAL BIOCHEMISTRY. UNITED STATES JUL 1990, vol. 188, no. 1, July 1990 (1990-07), pages 91-96, XP008002847 ISSN: 0003-2697 the whole document	15-17, 21, 23-26, 29-37, 40,42, 48,50-52

-/--

International Application No
PCT/CA 03/00869

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 91/02740 A (UNIV TEXAS) 7 March 1991 (1991-03-07) the whole document page 7, line 19 - line 21 page 8, line 22 - line 24 page 9, line 15 - line 22 page 17, line 10 - page 19, line 31	15-19, 21-26, 28-37, 40-43, 48-52
X	WO 97/05248 A (CHOMCZYNSKI PIOTR) 13 February 1997 (1997-02-13) the whole document page 7, line 21 - page 9, line 14	15-19, 21, 23-26, 28-38, 40, 42-48, 50-52
X	EP 0 586 024 A (GEN PROBE INC) 9 March 1994 (1994-03-09) the whole document column 2, line 24 - column 6, line 33 example 5	54-57
Y	EP 0 734 684 A (ORTHO PHARMA CORP) 2 October 1996 (1996-10-02) the whole document column 8, line 24 - line 27 figures 3,4,11,13	68-73
A	WO 99/29904 A (SIERRA DIAGNOSTICS INC) 17 June 1999 (1999-06-17) the whole document claims 1-13 example 6; table 2 page 13, line 15	
A	WO 01/060517 A (ANTIGEN PRODUKTIONS GMBH; HELFTENBEIN ELKE (DE)) 23 August 2001 (2001-08-23)	

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		CA 2285384 A1	08-10-1998
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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Robinson, J.Christopher
ROBINSON, Christopher, J.
Smart & Biggar
Box 11560 Vancouver Centre, Suite 2
650 West Georgia Street
Vancouver, British Columbia V6B 4N8
CANADA

PCT

WRITTEN OPINION
(PCT Rule 66)

Sent prior by fax on 15-07-2004

Date of mailing (day/month/year)	20.07.2004
Applicant's or agent's file reference: 81331-141	REPLY DUE within 1 month(s) and 15 days from the above date of mailing
International application No.: PCT/CA 03/00869	International filing date (day/month/year): 06.06.2003
Priority date (day/month/year): 07.06.2002	
International Patent Classification (IPC) or both national classification and IPC: C07H21/00	
Applicant: DNA GENOTEK INC. et al.	

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 07.10.2004

Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer: Pinta, V Formalities officer (incl. extension of time limits): Humbert, C Telephone No. +31 70 340-4129

Form PCT/IPEA/ 408 (Cover Sheet) (January 2004)

I. Basis of the opinion

1. With regard to the elements of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-29	as originally filed

Claims, Numbers

52-90	as originally filed
1-51	received on 09.06.2004 with letter of 03.06.2004

Drawings, Sheets

1/11-11/11	as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 68-73 (partially), 74-90 (completely)

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 68-73 (partially), 74-90 (completely)

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-4, 6, 9, 15-24, 26, 28-52, 58-67
Inventive step (IS)	Claims	1-73
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

1 RELEVANT DOCUMENTS

The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO 01/60517 A (ANTIGEN PRODUKTIONS GMBH; HELFTENBEIN ELKE (DE)) 23 August 2001 (2001-08-23).
D2: EP-A-0 734 684 (ORTHO PHARMA CORP) 2 October 1996 (1996-10-02).
D3: WO 98/44158 A (EPITOPE INC; BESTWICK RICHARD K (US); GOLDSTEIN ANDREW S (US)) 8 October 1998 (1998-10-08).
D4: WO 89/06704 A (MICROPROBE CORP) 27 July 1989 (1989-07-27).
D5: WO 01/34844 A (KRUPEY JOHN; LIGOCHEM INC (US)) 17 May 2001 (2001-05-17).
D6: US-B-6 242 1881 (WU WHEI-KUO ET AL) 5 June 2001 (2001-06-05)
D7: LOENS K ET AL: "Detection of Mycoplasma pneumoniae in spiked clinical samples by nucleic acid sequence-based amplification." JOURNAL OF CLINICAL MICROBIOLOGY. UNITED STATES APR 2002, vol. 40, no. 4, April 2002 (2002-04), pages 1339-1345.
D8: RYMASZEWSKI Z ET AL: "Estimation of cellular DNA content in cell lysates suitable for RNA isolation." ANALYTICAL BIOCHEMISTRY. UNITED STATES JUL 1990, vol. 188, no. 1, July 1990 (1990-07), pages 91-96.
D9: WO 91/02740 A (UNIV TEXAS) 7 March 1991 (1991-03-07).
D10: WO 97/05248 A (CHOMCZYNSKI PIOTR) 13 February 1997 (1997-02-13).
D11:EP-A-0 586 024 (GEN PROBE INC) 9 March 1994 (1994-03-09).
L1: applicant's letter dated 03-06-2004.

2 UNITY OF INVENTION (Rule 13 PCT)

2.1 The IPEA agrees with the objection put forward by the ISA as to lack of unity, the reasons for the objection being as follows:

2.1.1 The single general concept underlying the invention may be regarded as preparing a biological sample, in particular a mucin-containing bodily fluid (sputum), by contacting said sample with a composition to form a mixture in view of further analysis. However, this concept is known from the prior art, as illustrated in D1 (p. 3, l. 22 to p. 6, l. 30 and figure 1) and D2 (col. 8, l. 24-27, col. 9, l. 23-35 and figures 3, 4 and 13), and cannot therefore be considered as novel.

2.1.2 In view of the above, the problems to be solved in the present application can be formulated as follows:

2.1.2.1 a first problem can be formulated as the provision of further compositions and methods using the same for preparing a (mucin-containing) bodily fluid or tissue in view of further analysis. The solution provided is a composition comprising a chelating agent, a denaturing agent, and possibly a reducing agent, wherein the pH of said composition is greater than 5.0.

2.1.2.2 a second problem can be formulated as the provision of further devices useful for collecting a biological sample and allowing it to be brought into contact with a composition to form a mixture, and methods of manufacturing or using the same. The solution proposed is a device comprising a container comprising a first region for collecting the sample, a second region containing a composition, wherein said first and second regions are separated by a barrier capable of disestablishment, means for closing said container and means for disestablishing said barrier such that said composition is capable of contacting said sample.

2.1.3 The absence of a single general concept linking the two (groups of) inventions set out in item 2.1.2 results in the definition of the following inventions:

2.1.3.1 Invention I: claims 1-67 (completely), 68-73 (partially); methods of preparing a bodily fluid or tissue, in particular a mucin-containing bodily fluid or tissue (sputum), in view of further analysis comprising contacting said bodily fluid or tissue with a composition comprising a chelating agent, a denaturing agent, and possibly a reducing agent, wherein the pH of said composition is greater than 5.0, and compositions useful in said methods.

2.1.3.2 Invention II: claims 68-73 (partially), 74-90 (completely); a device comprising a first region for collecting a biological sample and a second region containing a composition for preserving a nucleic acid, a barrier capable of disestablishment between said first and second regions, a means for closing said container and a means for disestablishing said barrier such that said composition is capable of contacting said biological sample, a method of manufacturing said device, and a method of preserving a nucleic acid from a bodily fluid making use of said device.

2.2 In conclusion, the groups of claims are not linked by common or corresponding special technical features and define two different inventions not linked by a single general inventive concept. The application, hence does not meet the requirements of unity of

invention as defined in Rules 13.1 and 13.2 PCT.

2.3 As the applicant has not had a search report drawn up on the other invention (Rule 40 PCT), the application will be prosecuted on the basis of the invention in respect of which a search has already been carried out, in other words the invention first mentioned in the claims (invention I). The applicant should therefore limit the application to the invention searched and excise those parts of the application relating to the other invention.

3 **AMENDMENTS** (Art. 34(2) PCT)

3.1 The amendments filed with the letter dated 03-06-2004 (L1) do not introduce subject-matter which extends beyond the content of the application as filed, according to Article 34(2)(b) PCT.

3.2 The attention of the applicant is drawn to the fact that, contrary to the statement made in L1 (p. 2), the wording of claim 42 has not been amended compared to claim 42 as filed. In addition, the IPEA is not of the opinion that such a modification would be a correction of a clear error, since the application mentions dodecyl sulfate or soluble salts thereof as suitable denaturing agents (e.g. p. 7, l. 4 and 6; p. 16, l. 2).

4 **NOVELTY** (Art. 33(2) PCT)

4.1 D3 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent, a denaturing agent, and a reducing agent, wherein said reducing agent is an antioxidant free-radical scavenger (phenol), and wherein the pH of said composition is greater than 5.0 (buffering capacity of about pH 6 to pH 9) (p. 3, l. 11-13; p. 19, l. 23 to p. 20, l. 9). Preferred chelating agents are EDTA, EGTA, sodium tripolyphosphate and EDTPO (p. 19, l. 27-29). Said chelating agents may be considered as analogs of the chelating agents of claim 26. Denaturing agents comprise guanidinium thiocyanate or phenol (p. 19, l. 30 to p. 20, l. 1). Chaotropic agents such as guanidinium thiocyanate are strong inhibitors of nucleases. Said composition may comprise SDS (p. 9, l. 15-17; p. 19, l. 31; p. 20, l. 5-9). Some of the compounds comprised in said composition are also antimicrobial agents, for instance SDS (p. 19, l. 30-31; p. 20, l. 5-9). In addition, Example 1 discloses a particular embodiment wherein the aqueous composition comprises a chelating agent (EDTA) and a denaturing agent (SDS), wherein the pH of said composition is 8.0 (p. 28, l. 2-3).

4.1.1 Moreover, D3 discloses a method of recovering nucleic acids (DNA or RNA, p. 9, l. 11-12) from oral samples, preferably mucosal transudate (p. 12, l. 15-23), comprising the steps of obtaining a sample from a subject (p. 12, l. 24-28), contacting said sample with a composition as in item 3.1 above (p. 19, l. 22-23) to form a mixture, contacting said mixture with a protease (p. 20, l. 3), and recovering said nucleic acid from said mixture (p. 20, l. 19-p. 21, l. 26).

4.1.2 Therefore, the subject-matter of claims 15-17, 21, 23, 24, 26, 28-43, 45, 48, 50-52 and 58-67 is not new.

4.2 D4 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA), a denaturing agent (guanidium thiocyanate), SDS, and a reducing agent (mercaptoethanol (2-hydroxyethanthiol)), wherein the pH of said composition is greater than 5.0 (the composition is buffered with Tris-HCl pH 7.6) (p. 10, l. 31-36). D4 discloses also an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA), SDS and a denaturing agent (guanidium thiocyanate), wherein the pH of said composition is about 6 to 8.5 (p. 17, l. 27-32). Finally, D4 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA, EGTA), SDS and a denaturing agent (lysozyme), wherein the pH of said composition is greater than 5.0 (8.0) (p. 24, l. 35 to p. 25, l. 4; p. 27, l. 10-14).

4.2.1 Moreover, D4 discloses a method of preserving a nucleic acid contained in sputum comprising the steps of obtaining sputum from a subject (p. 10, l. 12-15; p. 36, l. 1) and contacting said sputum with a composition comprising a chelating agent (EDTA) and a denaturing agent, wherein the pH of said composition is greater than 5.0 (p. 10, l. 31-36), wherein said sputum is saliva (fluid from periodontal pockets) from a mammal (human), and wherein said nucleic acid is RNA from a bacterium.

4.2.2 Therefore, the subject-matter of claims 1-4, 6, 9, 15-20, 22-24, 28-43, 45, 48 and 50-52 is not new.

4.3 D5 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA) and a denaturing agent (guanidium thiocyanate), wherein the pH of said composition is greater than 5.0 (7.0) (p. 29, l. 8-10). D5 discloses also an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA) and a denaturing agent (SDS), wherein the pH of said composition is greater than 5.0 (8.0) (p. 29, l. 27-28).

4.3.1 Therefore, the subject-matter of claims 15, 16, 20, 28-43, 45, 48 and 50-52 is not new.

4.4 D6 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA, EGTA; col. 6, l. 40; col. 7, l. 1-4), a denaturing agent (membrane-fluidizing compounds (aromatic alcohols) at a concentration between 0.001% and 10%; col. 6, l. 39-40; col. 7, l. 29-51), and a reducing agent (antioxidant vitamin (tocopherol: vitamin E); col. 6, l. 22-23), wherein the pH of said composition is between 3 and 12, between 4 and 10, or more preferably between 5 and 10 (col. 4, l. 5; col. 12, l. 35-36). D6 discloses also an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA), and a denaturing agent (lipid), wherein the pH of said composition is 8 (Example 6, reagent C).

4.4.1 Therefore, the subject-matter of claims 15-18, 21, 23, 24, 28-33, 36-40, 42 and 43 is not new.

4.5 D7 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA), a denaturing agent (guanidinium thiocyanate), wherein the pH of said composition is 6.2 (abstract; p. 1341, col. 1, "Nucleic acid extraction")).

4.5.1 Moreover, D7 discloses a method of preserving a nucleic acid contained in sputum comprising the steps of obtaining sputum from a subject (p. 1340, "Respiratory specimens"), wherein said sputum is from a mammal, and contacting said sputum with a composition comprising a chelating agent (EDTA) and a denaturing agent (guanidinium thiocyanate), wherein the pH of said composition is greater than 5.0 (6.2), and wherein said nucleic acid is RNA from a bacterium (M. pneumoniae).

4.5.2 Therefore, the subject-matter of claims 1, 3, 4, 6, 9, 15, 16, 28-33, 40, 42, 48 and 50-52 is not new.

4.6 D8 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA), a denaturing agent (guanidinium thiocyanate), and a free-radical scavenger reducing agent (phenol), wherein the pH of said composition is greater than 5.0 (12.3, neutralized to 7.0) (p. 92, l. 28-34 ("DNA standard [...] KH2PO4").

4.6.1 Therefore, the subject-matter of claims 15-17, 23, 24, 29-37, 40-42, 48 and 50-52 is not new.

4.7 D9 discloses "solution I" and "solution II" that upon mixing result in an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA), a denaturing agent (guanidinium thiocyanate) and a reducing agent (mercaptoethanol), wherein the pH of said composition is greater than 5.0, and said composition does not contain ascorbic acid (p. 17, l. 12 to p. 18, l. 5; p. 19, l. 19-31). Said denaturing agent can also be urea (p. 7, l. 25). SDS may also be added (p. 8, l. 8-16). Said composition comprises further an inhibitor of ribonuclease, wherein said inhibitor is heparin.

4.7.1 Therefore, the subject-matter of claims 15-20, 22-24, 28-37, 40-43 and 48-52 is not new.

4.8 D10 discloses an aqueous composition suitable for preserving a nucleic acid comprising a chelating agent (EDTA), a denaturing agent (guanidinium thiocyanate, or alternatively urea) and a reducing agent (aminoethanethiol, or mercaptoethanol), wherein the pH of said composition is greater than 5.0, and said composition does not contain ascorbic acid (p. 7, l. 21 to p. 9, l. 14). Said composition may also comprise alcohols in the range of 15-30% by volume, for instance methanol or ethanol.

4.8.1 Therefore, the subject-matter of claims 15-19, 23, 24, 28-38, 40, 42-48 and 50-52 is not new.

4.9 In view of the above, the present application does not meet the requirements of Article 33(2) PCT because the subject-matter of claims 1-4, 6, 9, 15-24, 26, 28-52 and 58-67 is not new.

5 **INVENTIVE STEP** (Art. 33(3) PCT)

5.1 In view of the above, the subject-matter of claims 1-4, 6, 9, 15-24, 26, 28-52 and 58-67 does not involve an inventive step in the sense of Article 33(3) PCT.

5.2 Dependent claims 5, 7, 8, 10-14, 25, 27 and 53 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, involve an inventive step.

5.3 As to claims 54-57:

5.3.1 Document D11, considered to represent the most relevant state of the art, discloses a method of reducing the viscosity of a mucin-containing bodily fluid or tissue (sputum),

wherein said bodily fluid or tissue is contacted with a composition comprising a disulfide bond reducing agent (e.g. N-acetyl-cysteine, cysteine, 2-mercapto-ethane sulfonate, dithiothreitol), wherein the pH of said composition is greater than 5.0 (8.0), thereby reducing disulfides contained in said mucin (col. 6, l. 4-33; Example 5). Said method comprises further therecovery of a nucleic acid (Example 5).

5.3.2 The subject-matter of claim 54 differs from D11 in that the composition comprises in addition to the reducing agent a chelating agent and a denaturing agent.

5.3.3 The problem to be solved by claim 54 may be regarded in the light of the prior art as providing methods of reducing the viscosity of a mucin-containing bodily fluid or tissue using alternative compositions. The proposed solution is a method involving a composition comprising a reducing agent, a chelating agent and a denaturing agent.

5.3.4 However, the description of the present application indicates that the effect of reducing the viscosity of a mucin-containing bodily fluid is provided by the reducing agent (p. 5, l. 9-11; p. 14, l. 14-15; p. 16, l. 21-24). No indication could be found that the chelating agent or the denaturing agent would have any effect related to the reduction of the viscosity of the sputum. Accordingly, their addition to the composition do not contribute to solve the problem posed.

5.3.5 The solution proposed cannot therefore be considered as involving an inventive step, since it is merely one of many straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

5.4 As to claims 68-73:

5.4.1 Document D2, considered to represent the most relevant state of the art, discloses a method of preserving a nucleic acid from a bodily fluid comprising placing a preservative composition into a second region of a container that is separated from a first region by a barrier (Fig. 3, Fig. 4), placing said bodily fluid into a first region of said container, closing said container and disestablishing said barrier such that said composition contacts said bodily fluid to form a mixture (col. 8, l. 24-27), thereby preserving said nucleic acid.

5.4.2 The subject-matter of claim 68 differs from D8 in that the composition placed in said second region of said second container is a composition of any of claims 15-53.

5.4.3 The problem to be solved by the present invention may therefore be regarded as providing a method of preserving a nucleic acid for a bodily fluid making use of alternative preservative compositions.

5.4.4 The proposed solution is a composition of any of claims 15-53.

5.4.5 This solution cannot however be considered as involving an inventive step for the following reasons:

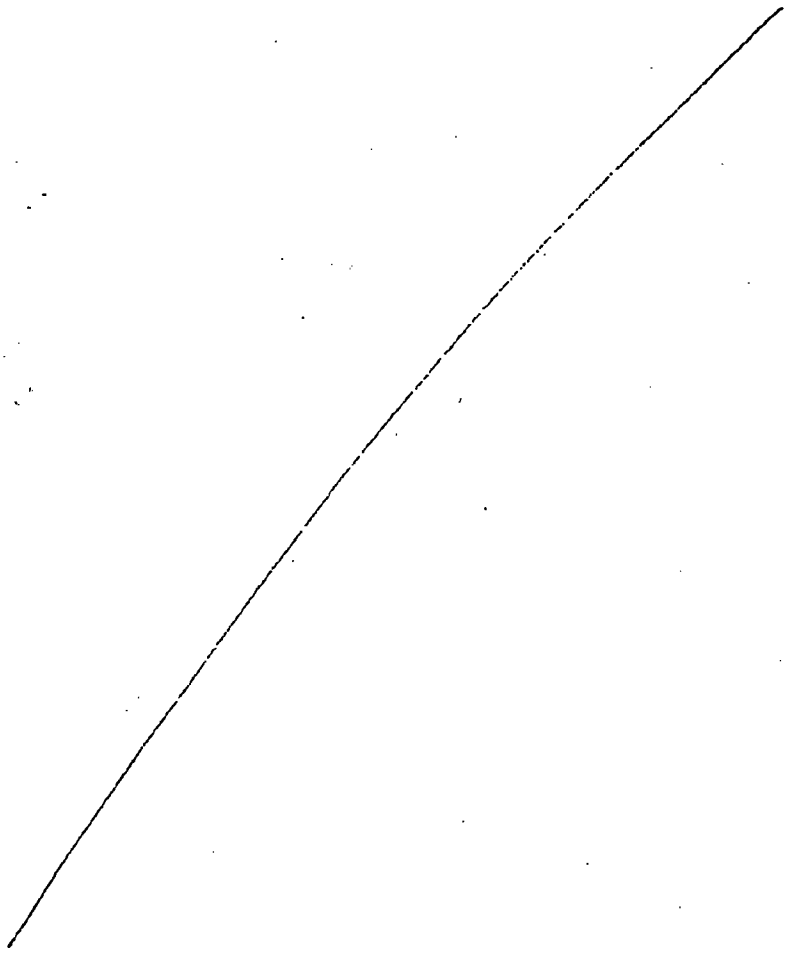
5.4.6 Compositions according to claims 15-53 are known from the prior art (cf. item 3 above). Document D6 discloses some of said compositions (cf. item 3.4 of the present communication), and discloses further a kit comprising a vial containing such compositions (claim 32). In view of D8 taken in combination with D6, it would be obvious for the skilled person to replace the preservative composition of D8 by a composition of D6, thereby arriving at a method according to claim 68 without the exercise of inventive skill.

5.5 In view of the above, the present application does not meet the requirements of Article 33(3) PCT, because the subject-matter of claims 1-73 does not involve an inventive step.

6 FURTHER OBSERVATIONS

6.1 Claims 10-13 and 53 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not defined. The claims attempt to define the subject-matter in terms of the result to be achieved, i.e. that the nucleic acid to be preserved should remain stable for more than 14 to 360 days, or that the reducing agent should retain activity for at least 46 days in the presence of oxygen, ambient air, ambient light, and alkaline pH. Such definitions amount only to claiming the underlying technical problem. The subject-matter of said claims should be defined in more concrete terms, viz. in terms of how the effect is to be achieved.

6.2 According to the PCT Guidelines Chapter 5, item 5.21, the subject-matter of claim 15 has to be interpreted as a composition **suitable for** preserving a nucleic acid. Similarly, the subject-matter of claims 29-32 and 50-52 has to be interpreted as methods **suitable for** preserving DNA, RNA, mRNA or viral RNA. A composition suitable for preserving at least one of said types of nucleic acids and having all the features of the compositions of claims 15 and/or 48 would therefore take away the novelty of all of said claims 15, 29-32 and/or 48, 50-52, respectively (cf. item 3 of the present communication).



SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	Filing Date	November 24, 2008
	Group	3761
	IDS Filed	April 4, 2011

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Rule 71(3) EPC Communication for European Patent Application No. 06846923.8 dated March 8, 2011.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

Electronic Acknowledgement Receipt

EFS ID:	9803686
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Terese Miffitt
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245/005001
Receipt Date:	04-APR-2011
Filing Date:	24-NOV-2008
Time Stamp:	16:12:33
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	50245_005001_IDS.PDF	44807 2306127a16117a8cec7e429f023523e2c0505527	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Filed (SB/08)	50245_005001_1449.PDF	34733 27770c1b819aff66daab4652870a0e9b52f8c4eb	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	NPL Documents	50245_005001_Rule_71_3_EPC_Comm.PDF	289610 2a393ac82b14f542365ed211253a7bb6c34b7b07	no	6
Warnings:					
Information:					
		Total Files Size (in bytes):	369150		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
Filed:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicant submits the reference listed on the enclosed Form PTO-1449, a copy of which is provided. The reference is a communication from a foreign patent office in a counterpart application.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed before the receipt of a first Office Action on the merits.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: April 4, 2011

Kristina Bicker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	§ 371(c) Date	November 24, 2008
	Group	3761
	IDS Filed	May 4, 2011

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Office Action for Mexican Patent Application No. MX/a/2008/007253 dated March 30, 2011 (English translation provided).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

Electronic Acknowledgement Receipt

EFS ID:	10016366
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Greg Harnett
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245/005001
Receipt Date:	04-MAY-2011
Filing Date:	24-NOV-2008
Time Stamp:	14:50:19
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	50245_005001_Ids.PDF	45811 b616c9c6ab1186279d683e5d9c689b6d32d38786	no	1

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Filed (SB/08)	50245_005001_1449.PDF	36053 17028ce7d4c172dbafa35c3b95c1ba691db34e9e	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	NPL Documents	50245_005001_Office_Action_for_MX_a_2008_007253.PDF	260962 f4b462de842b5962f32cfc6a23665021e1165525	no	3
Warnings:					
Information:					
		Total Files Size (in bytes):	342826		

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PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
§ 371(c) Date:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

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If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: May 4, 2011

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
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Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	11/24/2008	Rod Muir	50245/005001	4566

21559 7590 05/10/2011

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
05/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	12/096,767	MUIR ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/13/10,4/4/11,5/4/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species: (1) the species of Figs. 1-11 and 22-24 and (2) the species of Figs. 12-21. The species are independent or distinct because they have characteristics that are physically mutually exclusive with respect to one another. Specifically the species of Figs. 12-21 includes a funnel having a piercing member, whereas the species of Fig. 1-11 and 22-24 has either a lid or vial with a piercing member but no funnel. Thus there can be no piercing member if there is no funnel, rendering the species physically mutually exclusive with respect to one another. Additionally the lid of species (1) functions to close the vial to prevent leakage of fluid contained therein and the addition of a funnel is not necessary and thus species (1) is a non-obvious variant of species (2).

It is noted that once a species is elected, the claims directed to the device, method of use and kit will be examined because all of the independent method and kit claims are linking claims. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

The devices and associated methods of use, based upon their different structures and modes of piercing the existing sealing membrane and accessing the contents of the vial, would be differently classified, requiring separate searches for each invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

2. A telephone call was made to Kristina Biecker-Brady on April 27, 2011 to request an oral election to the above restriction requirement, but did not result in an election being made. This written requirement is in response to a request from the applicants via their representative for clarification regarding the basis of the election of species requirement.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.H./

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	371(c) Date	November 24, 2008
	Group	3761
(37 C.F.R. § 1.98(b))	IDS Filed	January 13, 2010

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant
	4,583,971	April 22, 1986	Bocquet et al.
	4,741,346	May 3, 1988	Wong et al.
	5,140,043	August 18, 1992	Darr et al.
	5,364,763	November 15, 1994	Kacian
	5,496,562	March 5, 1996	Burgoyne
	5,567,309	October 22, 1996	Classon et al.
	5,807,527	September 15, 1998	Burgoyne
	5,817,630	October 6, 1998	Hofmann et al.
	5,980,834	November 9, 1999	Bruno
	6,176,836	January 23, 2001	Trudil et al.
	6,242,188	June 5, 2001	Dattagupta et al.
	6,291,178	September 18, 2001	Schneider
	6,309,827	October 30, 2001	Goldstein et al.
	6,503,716	January 7, 2003	Lai et al.
	6,551,777	April 22, 2003	Shuber et al.
	6,582,415	June 24, 2003	Fowles et al.
	6,617,170	September 9, 2003	Augello et al.
	6,716,392	April 6, 2004	Putcha et al.
	6,869,769	March 22, 2005	Burgoyne
	7,482,116	January 27, 2009	Birnboim
	2001/0008614	July 19, 2001	Aronowitz

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.H./

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	Serial No.	12/096,767
	Applicant	Muir et al.
	371(c) Date	November 24, 2008
	Group	3761
	IDS Filed	January 13, 2010

U.S. PATENT DOCUMENTS			
	2002/0026046	February 28, 2002	Pasloske et al.
	2002/0081575	June 27, 2002	Small et al.
	2004/0038269	February 26, 2004	Birnboim

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
	CA 2072331	December 26, 1992	Canada	
	CA 2236240	October 29, 1999	Canada	
	EP 0273015	June 29, 1988	Europe	English Abstract
	EP 0586024	March 9, 1994	Europe	
	EP 0734684	October 2, 1996	Europe	
	EP 1207208	May 22, 2002	Europe	
	WO 89/06704	July 27, 1989	W.I.P.O.	
	WO 91/02740	March 7, 1991	W.I.P.O.	
	WO 97/05248	February 13, 1997	W.I.P.O.	
	WO 98/44158	October 8, 1998	W.I.P.O.	
	WO 99/29904	June 17, 1999	W.I.P.O.	
	WO 01/34844	May 17, 2001	W.I.P.O.	
	WO 01/60517	August 23, 2001	W.I.P.O.	English Abstract
	WO 02/44691	June 6, 2002	W.I.P.O.	
	WO 03/104251	December 18, 2003	W.I.P.O.	

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.H./

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	371(c) Date	November 24, 2008
	Group	3761
(37 C.F.R. § 1.98(b))	IDS Filed	January 13, 2010

	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
	Birnboim, "Effect of Lipophilic Chelators on Oxyradical-Induced DNA Strand Breaks in Human Granulocytes: Paradoxical Effect of 1,10-Phenanthroline," *Archives of Biochemistry and Biophysics* 294(1):17-21 (1992).
	Birnboim, "Extraction of High Molecular Weight RNA and DNA from Cultured Mammalian Cells," *Methods in Enzymology* 216:154-160 (1993).
	Birnboim and Doly, "A Rapid Alkaline Extraction Procedure for Screening Recombinant Plasmid DNA," *Nucleic Acids Research* 7(6):1513-1524 (1979).
	Birnboim and Jevcak, "Fluorometric Method for Rapid Detection of DNA Strand Breaks in Human White Blood Cells Produced by Low Doses of Radiation," *Cancer Research* 41:1889-1892 (1981).
	Clarke and Martell, "Stabilities of the Alkaline Earth and Divalent Transition Metal Complexes of the Tetraazamacrocyclic Tetraacetic Acid Ligands," *Inorganica Chimica Acta* 190:27-36 (1991).
	French et al., "Ultra-Rapid DNA Analysis Using HyBeacon™ Probes and Direct PR Amplification from Saliva," *Molecular and Cellular Probes* 16:319-326 (2002).
	Garcia-Closas et al., "Collection of Genomic DNA From Adults in Epidemiological Studies by Buccal Cytobrush and Mouthwash," *Cancer Epidemiology, Biomarkers & Prevention* 10:687-696 (2001).
	Heath et al. "Use of Buccal Cells Collected in Mouthwash as a Source of DNA for Clinical Testing," *Archives of Pathology and Laboratory Medicine* 125:127-133 (2001).
	Hiraide et al., "Speciation of Iron in River Water," *Analytical Sciences* 4:605-609 (1988).
	Loens et al., "Detection of *Mycoplasma Pneumoniae* in Spiked Clinical Samples by Nucleic Acid Sequence-Based Amplification," *Journal of Clinical Microbiology* 40(4):1339-1345 (2002).
	Lum and Marchand, "A Simple Mouthwash Method for Obtaining Genomic DNA in Molecular Epidemiological Studies," *Cancer Epidemiology, Biomarkers & Prevention* 7:719-724 (1998).
	Nilsson et al., "Real-Time Monitoring of DNA Manipulations Using Biosensor Technology," *Analytical Biochemistry* 224:400-408 (1995).
	Pershadsingh and McDonald, "A High Affinity Calcium-Stimulated Magnesium-Dependent Adenosine Triphosphatase in Rat Adipocyte Plasma Membranes," *Journal of Biological Chemistry* 255(9):4087-4093 (1980).
	Roberts et al., "UV Laser Machined Polymer Substrates for the Development of Microdiagnostic Systems," *Analytical Chemistry* 69:2035-2042 (1997).
	Rymaszewski et al., "Estimation of Cellular DNA Content in Cell Lysates Suitable for RNA Isolation," *Analytical Biochemistry* 188:91-96 (1990).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.H./

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	371(c) Date	November 24, 2008
	Group	3761
(37 C.F.R. § 1.98(b))	IDS Filed	January 13, 2010

	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
	Seutin et al., "Preservation of Avian Blood and Tissue Samples for DNA Analyses," *Canadian Journal of Zoology* 69:82-90 (1991).
	Terasaki et al., "Saliva as DNA Source for HLA Typing," *Human Immunology* 59:597-598 (1998).
	van Schie and Wilson, "Saliva: A Convenient Source of DNA for Analysis of Bi-Allelic Polymorphisms of Fcγ Receptor IIA (CD32) and Fcγ Receptor IIIB (CD16)," *Journal Immunological Methods* 208:91-101 (1997).
	Videira and Werner, "Assembly Kinetics and Identification of Precursor Proteins of Complex I from *Neurospora Crassa*," *European Journal of Biochemistry* 181:493-502 (1989).
	International Preliminary Report on Patentability for PCT/CA2006/002009 dated April 23, 2008.
	Transmittal of the International Search Report and Written Opinion of the International Searching Authority for PCT/CA2006/002009 dated March 30, 2007.
	Transmittal of The International Search Report and The Written Opinion of the International Searching Authority for PCT/CA06/000380 dated July 6, 2006.
	Communication from European Patent Office regarding EP 03729743 dated October 1, 2007.
	Transmittal of the International Search Report for PCT/CA03/00869 dated March 30, 2004.
	Written Opinion for PCT/CA03/00869 dated July 20, 2004.
	Applicant's Letter in Response to the Written Opinion for PCT/CA03/00869 dated June 3, 2004.

EXAMINER /Melanie Hand/	DATE CONSIDERED 05/05/2011
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	**Art Unit**
	MELANIE J HAND	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/05/2011								
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	**Art Unit**
	MELANIE J HAND	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/05/2011								
	37	÷								
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	48	÷								
	49	÷								

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.H./

Sheet 1 of 1

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	Filing Date	November 24, 2008
	Group	3761
	IDS Filed	April 4, 2011

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Rule 71(3) EPC Communication for European Patent Application No. 06846923.8 dated March 8, 2011.

EXAMINER /Melanie Hand/	DATE CONSIDERED 05/05/2011
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	§ 371(c) Date	November 24, 2008
	Group	3761
	IDS Filed	May 4, 2011

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
/M.H/	Office Action for Mexican Patent Application No. MX/a/2008/007253 dated March 30, 2011 (English translation provided).

EXAMINER	/Melanie Hand/	DATE CONSIDERED	05/05/2011

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rod Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
Filing/371(c) Date:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

REPLY TO RESTRICTION REQUIREMENT

In reply to the Restriction Requirement dated May 10, 2011, Applicant elects the species of Group I, Figs. 1-11 and 22-24, without traverse. Claims 1-49 read on the elected species.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: October 11, 2011

Kristina Bleker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rod Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
§ 371(c) Date:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136, Applicant hereby petitions that the period for replying to the Restriction Requirement dated May 10, 2011 in connection with the above-captioned application be extended for four months, to and including October 11, 2011 (as October 10, 2011 was a federal holiday).

Authorization is hereby provided to charge $990.00 to Deposit Account No. 03-2095 for the fee required by 37 C.F.R. § 1.17(a). If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: October 11, 2011

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

Electronic Patent Application Fee Transmittal

Application Number:	12096767
Filing Date:	24-Nov-2008
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Filer:	Kristina Bieker-Brady/Adrianne Zappi
Attorney Docket Number:	50245/005001

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 4 months with $0 paid	2254	1	990	990

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**990**

Electronic Acknowledgement Receipt

EFS ID:	11161273
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Cindy Vaccaro
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245/005001
Receipt Date:	11-OCT-2011
Filing Date:	24-NOV-2008
Time Stamp:	16:07:05
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$990
RAM confirmation Number	2831
Deposit Account	032095
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	50245_005001_Rep_RR.PDF	36053 023420ed2a45f27e5910121ba2b34bf1afb88da9	no	1
Warnings:					
Information:					
2	Extension of Time	50245_005001_EOT.PDF	42976 9fdc7055749828a98a2c9d142fcdc1a5e95ed627	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30410 2539e5c5381e5a10474df2ae0ecc66c4cfef4d18	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	109439		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))		
	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Rod Muir et al.
	Filing Date	November 24, 2008
	Group	3761
	IDS Filed	December 15, 2011

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant
	6,138,821	Oct. 31, 2000	Hsu

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
	WO 97/48492	Dec. 24, 1997	WIPO	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Australian Office Action (AU 2006324337) dated August 18, 2011.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rod Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
Filed:	November 24, 2008	Examiner:	Hand, Melanie Jo
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the enclosed Form PTO-1449, copies of which are enclosed, with the exception of U.S. patents and U.S. patent application publications. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed before the receipt of a first Office action on the merits.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: December 15, 2011

Kristina Bieker-Brady, Ph.D.
Reg. No. 59,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

Electronic Acknowledgement Receipt

EFS ID:	11627926
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Cindy Vaccaro
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245/005001
Receipt Date:	15-DEC-2011
Filing Date:	24-NOV-2008
Time Stamp:	15:36:54
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	WO_9748492.PDF	860016 4f68bca100828bf037a08429e8184f2018701cdc	no	22

Warnings:	
Information:	

2	Non Patent Literature	AU2006324337_OA_08_18_11.PDF	136284 a179b7e867d417a93be3b484eeff6126712f705d	no	2
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	50245_005001_1449.pdf	12477 da6aaced3da62fe607ff32537a00500bfadc9227	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Transmittal Letter	50245_005001_IDS.PDF	48161 0f478f8db941914230819b4f367f4233f659424f	no	1
Warnings:					
Information:					
		Total Files Size (in bytes):	1056938		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	11/24/2008	Rod Muir	50245/005001	4566

21559 7590 12/27/2011

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
12/27/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	12/096,767	MUIR ET AL.	
	Examiner	Art Unit	
	MELANIE HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-49* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-16,18-32 and 34-49* is/are rejected.

8)☒ Claim(s) *17 and 33* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *09 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. The election of species requirement is withdrawn upon further review of papers submitted under 35 U.S.C. 371 and the policy of the USPTO regarding restriction in national stage applications where no lack of unity of invention is found in the PCT application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "approximately" in claim 7 is a relative term which renders the claim indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore the scope of the phrase "approximately equal to" is indeterminate.

4. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear which industry standard is referred to in the claim and it is the examiner's position that which industry standard is referred to would not be apparent to one of ordinary skill in the art. Thus the scope of the claim is unclear. For examination purposes, the T501 tube recited in claim 40 is interpreted as an example, but not a clear definition, of an industry standard for blood collection tubes.

5. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The T501 tube recite dint he claim has several different variations of varying volumes and thus it is not clear which variation of the T501 tube is encompassed in the scope of the claim. Thus the scope of the claim is unclear and indefinite. A copy of a table available from Simport Plastics, the maker of the T501 tubes recited in the claim (according to the applicant's specification), is attached hereto as evidence of the examiner's position and basis for the rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 5-8, 11-14, 19, 26-30, 35-38, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Loretti et al (EP 273,015 A2) (translation of specification (hereafter referred to as "translation") is cited and attached hereto).

With respect to **claim 1:** Loretti discloses a container system for releasably storing a substance, comprising: a) a vial, cartridge 7, comprising a first open end for receiving a sample, a second end comprising cylindrical inner part 17, fully functional as a sample storage chamber, and a piercing member, trocar 13 (Abstract); and b) a lid 8 configured to removably engage said vial via fastening means 19, 20, said lid 8 comprising a reservoir for holding the substance by

accommodating vial 3 holding the substance therein, and a pierceable membrane, stopper 14, sealing the substance within said reservoir, specifically within vial 3 which is held in the reservoir of lid 8 (Abstract), wherein, when said system is closed by removable engagement of said vial 7 with said lid 8, said vial 7 and said lid 8 are movable to a piercing position in which the piercing member 13 disrupts the pierceable membrane 14 to allow fluid communication between said reservoir and said chamber 17, wherein the chamber 17 is sealed against leakage to the outside of the container system in the piercing position via the sealing engagement of vial 7 with vial 3 and lid 8 via the fastening means 19, 20 and locking means 21,22 that effects the engagement. (English abstract; Translation, Page 1, ¶¶15, 17, 18, 19)

With respect to **claims 2,19:** The examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 19. The lid 8 disclosed by Loretti comprises a wall defining all or a portion of the perimeter of said reservoir, said wall having a sealing means in the form of a sealing surface, namely the surface having fastening means 19, for sealingly attaching said pierceable membrane following movement of said container system to said piercing position by placing the vial 3 having said pierceable membrane 14 therein, and engaging the fastening means components 19, 20.

With respect to **claims 5,26:** It is the examiner's position that Loretti discloses that the device, wherein the stopper is or maintains intact and pierceable, is used at least at room temperature, i.e. approximately 20-25 deg. C, which overlaps the claimed range of "temperatures from about -80°C to about 70°C." The examiner is interpreting this limitation as meaning the membrane is and maintains intact and pierceable at any temperature from about -80°C to about 70°C, rather than a pierceable membrane that must be intact and piercable at every temperature from about

-80℃ to about 70℃.

With respect to **claims 6,27:** The pierceable membrane 14 of vial 3 is sealingly attached to said sealing surface by a fastener, namely components 21 and 22 of fastener component 20 of the sealing surface and a joint seal 10. (Translation, Page 1, ¶¶15,20)

With respect to **claim 7:** The width of said first end of vial/cartridge 7 is approximately equivalent to the width of said second end 17 inasmuch as the second end has a conical shape that tapers inward from the portion of vial 7 contiguous with the first end, thus portions of the second end are equal in width to the first end and remaining portions have widths less than, or approximately equal to, the width of the first end. It is noted that the applicant has not explicitly recited the qualitative or quantitative limits of the phrase “approximately equal to” thus the claim is given its broadest reasonable interpretation.

With respect to **claim 8:** The second end of vial 7 disclosed by Loretti tapers inward from the middle portion and first end, thus said first end is generally wider than said second end. (Fig. 3)

With respect to **claims 11-13,28,29:** The piercing member 13 disclosed by Loretti extends approximately perpendicularly from a base surface of said chamber/funnel inasmuch as the base of the trocar 13 extends perpendicularly, however the tip is angled inwardly toward the first open end of the vial 7 and thus extends approximately perpendicularly. (Abstract, Fig. 3)

With respect to **claims 14,30:** The piercing member 13 disclosed by Loretti comprises a side wall in that it is cylindrical and a first cutting edge extending from a first pointed corner to a

second corner that defines the intersection between said cutting edge and said side wall. (Abstract, Fig. 3)

With respect to **claims 20,36:** The examiner is **not** invoking 35 U.S.C. 112, sixth paragraph, in the interpretation of claim 20 in view of the recitation of sufficient structure for the sealing means to render 35 U.S.C. 112, sixth paragraph inapplicable. The sealing means disclosed by Loretti comprises a sealing wall about the interior circumference of said lid 8 that sealingly engages a surface of said vial 7 when the system is said piercing position. (Translation, Page 1, ¶19)

With respect to **claim 21:** The vial 7 and said lid 8 disclosed by Loretti are considered herein to be sized for shipping in both an unattached state and an attached state inasmuch as any article of any size is capable of being shipped and the claim does not place any restrictions on what constitutes an entity that can or cannot be shipped.

With respect to **claim 22:** Loretti discloses a container system for releasably storing a substance, comprising: a) a vial 3 comprising a chamber fully functional for retaining a sample (Abstract); b) a lid 8 comprising a reservoir fully functional for holding the substance when the lid and cartridge 7 are engaged, enclosing the vial 3 (Abstract, Fig. 3); and a pierceable membrane, stopper 14, sealing the substance within said reservoir (Abstract); and c) a funnel, cartridge 7, comprising a first open end for receiving said sample by receiving the vial 3, a piercing member 13 and a channel, opening 12 and the lumen of funnel 7 contiguous therewith, extending from said first open end to a second open end and being in fluid communication with said chamber when the trocar pierces stopper 14, said funnel 7 being removably attachable via fastening means 19, 20 to said lid 8 at said first open end and releasably attached via piercing

of the stopper 14 by the trocar 13 to said vial at said second end, wherein, when said system is closed by removable attachment of said lid 8 to said funnel 7, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, via said channel 12, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position via the stopper 14 and the trocar blocking the opening created when the trocar pierced the stopper 14. (Abstract, (Translation, Page 1, ¶19))

With respect to **claims 23:** The examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 19. The lid 8 disclosed by Loretti comprises a wall defining all or a portion of the perimeter of said reservoir, said wall having a sealing means in the form of a sealing surface, namely the surface having fastening means 19, for sealingly attaching said pierceable membrane following movement of said container system to said piercing position by placing the vial 3 having said pierceable membrane 14 therein, and engaging the fastening means components 19, 20.

With respect to **claim 35:** The system disclosed by Loretti comprises sealing means, the engagement of stopper 14 and the trocar 13 blocking the opening created when the trocar pierced the stopper 14 for sealing said chamber against leakage to the outside of said container system. (Abstract, Translation, Page 1, ¶19)

With respect to **claim 37:** The vial is releasably attached to funnel 7 via piercing of the stopper 14 by the trocar 13 at said second end of funnel 7 and sized for attachment to a cap, lid 8, when released from said funnel.

With respect to **claim 38:** The vial disclosed by Loretti allows storage of a sample and sealing via stopper 14 and is thus considered herein to be configured for use in standard laboratory equipment.

With respect to **claims 42,43:** The limitation of claim 42 is directed to an intended use of the vial and system disclosed by Loretti and thus the limitation bears little patentable weight. As the system of Loretti meets al of the structural and functional limitations of claim 42 and the claim(s) from which it depends, the vial is fully functional to store a sample of a substance wherein said substance is a composition for the stabilization and recovery of a nucleic acid, wherein the nucleic acid is DNA or RNA, from a biological sample.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3, 9, 10, 24, 41 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti et al ('015) in view of Goldstein et al (U.S. Patent No. 6,309,827).

With respect to **claims 3,10,24:** The reservoir disclosed by Loretti defines an inner volume at least as great as that of the vial inasmuch as the entire vial is housed within the reservoir prior to engagement of the piercing member and vial 7 with the lid as shown in Fig. 5. Loretti does not disclose a volume for the reservoir or the vial. wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance. Goldstein discloses a tube for the incubation and analysis of nucleic acids from a sample of oral fluid impregnated with wherein the sample tube for holding the nucleic acid has a volume of 0.5 – 2.0 mL of diagnostic marker solution DMRS. Goldstein discloses that the dilution is at a ratio of 1:1-1:20 v/v assay diluent: oral fluid-DMRS sample. Thus the total sample volume in the collection and incubation tube is at least 1.0-4.0 mL, which overlaps the range disclosed by the applicant. As the tube disclosed by Goldstein is intended to allow the mixing of therapeutic substances and fluids as in the Loretti device for a process that is well-known (i.e. DNA analysis via collection of bodily fluid) one of ordinary skill in the art would be motivated to modify the device disclosed by Loretti so as to be able to enclose

and accommodate sample sizes as disclosed by Goldstein to facilitate secured and sealed mixing of fluids for diagnostic or treatment purposes. ('827, Abstract, Col. 11, ll. 19-26, Col. 12, ll. 56-64)

With respect to **claims 9,41:** Loretti does not disclose a volume for the vial 3 and thus does not disclose that the chamber is configured to receive about 1 ml to about 16 ml of said sample. Goldstein discloses that the dilution is at a ratio of 1:1-1:20 v/v assay diluent: oral fluid-DMRS sample. Thus the total sample volume in the collection and incubation tube is at least 1.0-4.0 mL, which overlaps the range disclosed by the applicant. The motivation to modify the device disclosed by Loretti such that the lid reservoir is sized to accommodate a tube with a sample size as disclosed by Goldstein is stated above with respect to claims 3, 10 and 24.

With respect to **claim 45:** Loretti discloses a method of combining a substance, a drug, with a liquid, comprising: (a) providing a container system meeting all of the structural and functional limitations of claim 22; (b) providing the sample to the chamber in the vial 3 through said funnel via breakable seal 16 and opening 12 (Abstract, Fig. 3); and (c) closing said container system by removably attaching said lid 8 to said first open end of said funnel via fasteners 19 and 20 (Translation, Page 1, ¶19); and (d) piercing said membrane 14 to release said substance into said chamber by moving said system to said piercing position. (Translation, Page 1, ¶19)

Loretti discloses combining a liquid and a drug, but does not explicitly disclose that the liquid or the substance is a biological sample. Goldstein discloses combining a substance, a diagnostic marker solution (DMRS) for analysis of DNA with an oral fluid sample, i.e. a biological sample, and a liquid, an assay diluent. As the tube disclosed by Goldstein is intended to allow the mixing of therapeutic substances and fluids as in the Loretti device for a process that is well-

known (i.e. DNA analysis via collection of bodily fluid) one of ordinary skill in the art would be motivated to use the device of Loretti to provide diagnostic analysis of biological fluids as disclosed by Goldstein with a reasonable expectation of success. ('827, Abstract, Col. 11, ll. 19-26, Col. 12, ll. 56-64)

With respect to **claims 46,47:** Loretti discloses combining a liquid and a drug, but does not explicitly disclose that the liquid or the substance is a nucleic acid preserving substance. The substance disclosed by Goldstein, the diagnostic marker solution, is a nucleic acid preserving substance inasmuch as it detects/binds and does not degrade, dissolve or destroy the nucleic acid. ('827, Abstract, Col. 11, ll. 19-26) The diagnostic solution is added to an oral fluid, i.e. a biological sample. The motivation to use the device of Loretti for analysis of a biological sample is stated above with respect to claim 45.

With respect to **claim 48:** Loretti discloses that the sample is stored in a vial thus the sample is fully capable of being archived once the drug is administered as a result of removing the vial from the system. Loretti discloses the combination of a liquid and a drug, but does not disclose a method according to claim 45 as stated above in the rejection of claim 45 because Loretti does not disclose a biological sample. Goldstein discloses combining a substance, a diagnostic marker solution (DMRS) for analysis of DNA with an oral fluid sample, i.e. a biological sample, and a liquid, an assay diluent. ('827, Abstract, Col. 11, ll. 19-26, Col. 12, ll. 56-64) The motivation to use the device of Loretti for analysis of a biological sample is stated above with respect to claim 45.

12. Claims 4, 15, 25 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti et al (‘015) in view of Fowles et al (U.S. Patent No. 6,582,415).

With respect to **claims 4,25:** Loretti does not disclose any materials for the stopper/pierceable membrane 14 and thus does not disclose that it is inert. However, rubber vial stoppers, which are inert, are well-known in the art as supported by Fowles (‘415, Col. 1, ll. 33-47) and provide a sufficient seal for sterile mixing conditions while allowing piercing of the stopper to access the contents of the vial without opening the vial and causing spilling or contamination. Thus one of ordinary skill in the art would be motivated to modify the device disclosed by Loretti such that the piercable member is rubber and inert as disclosed by Fowles to prevent the risk of spilling and contamination.

With respect to **claims 15,31:** Loretti does not disclose that the side wall further includes a second cutting edge. Fowles discloses a piercing member 152 with a tip that comprises a bevel, i.e. it has a first cutting edge on oen side of the flat tip and a second cutting edge on the side or the opposing flat face of the tip. ('415, Fig. 12, Col. 15, ll. 22-36) Fowles discloses that piercing member 152 is part of piercing assembly 128 for piercing a vial stopper, just as in the Loretti device. Thus one of ordinary skill in the art would be motivated to modify the device disclosed by Loretti such that the piercing member has a second cutting edge at the side wall in the form of a bevel as disclosed by Fowles with a reasonable expectation of success to provide an effective piercing member that can penetrate the stopper and access a vial's contents.

13. Claims 16,18, 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti et al (‘015) in view of Niedospial et al (U.S. Patent No. 6,832,994).

With respect to **claims 16,18,32,34:** Loretti does not disclose that said vial 7 comprises a plurality of piercing members. Niedospial discloses a dual-spike configuration for piercing the stopper of a vial, comprising two piercing members 34 and 36. Niedospial discloses that one member 34 is for dispensing medicament into or out of the vial and member 36 for venting air during the dispensing process so that air doe snot accumulate in the vial, resulting in less available volume for adding medicament. Thus one of ordinary skill in the art would be motivated to modify the device disclosed by Loretti such that the pierceable member is replaced with the dual-spike piercing means disclosed by Niedospial to provide a means for venting air that would otherwise accumulate in vial 3, reducing the available storage volume in vial 3.

14. Claims 39, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti et al (‘015) in view of Suavold et al (U.S. Patent Application Publication No. 2002/0197275).

With respect to **claims 39,40:** Loretti does not disclose any dimensions for the vial 3 and thus does not disclose that the vial has dimensions that conform with industry-standard dimensions for a blood collection tube. As stated in item 4 of this Office action, the T501 tube recited in claim 40 is interpreted as an example of an industry standard blood collection tube. Suavold discloses collection of a section of small intestine for diagnostic and research purposes for improving glucose metabolism. Suavold discloses a polypropylene tube from Simport as the collection device for the sample. Given the attached information regarding Simport T501 tubes as being manufactured from polypropylene, it is the examiner's position that one of ordinary skill in the art would readily recognize that Suavold is referring to a T501 tube when disclosing the Simport polypropylene tube. As the device of Loretti is fully functional for use in collecting a

biological sample in the existing vial, one of ordinary skill in the art would be motivated to modify the method of using the device disclosed by Loretti by replacing the vial with a Simport blood collection tube as disclosed by Suavold with a reasonable expectation of success, rendering the limitation of claim 39 regarding dimensions conforming to an industry standard for blood collection tubes unpatentable. (‘275, [0044])

15. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti et al (‘015).

With respect to **claims 42,43:** The limitation of claim 42 is directed to an intended use of the vial and system disclosed by Loretti and thus the limitation bears little patentable weight. As the system of Loretti meets all of the structural and functional limitations of claim 42 and the claim(s) from which it depends, though Loretti does not disclose that the substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample wherein the nucleic acid is DNA or RNA, one of ordinary skill in the art would be motivated to use the system of Loretti to store such a substance in the vial with a reasonable expectation of success.

16. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loretti et al (‘015).

With respect to **claim 49:** Loretti discloses a container system for sample collection and storage, comprising a container system meeting all of the structural and functional limitations of claim 22. Loretti does not disclose instructions for the use thereof and thus does not disclose a kit as claimed, however it is the examiner's position, because of the multiple components and

lack of functionally associated or integral indicia or other clear guides for assembly or use, one of ordinary skill in the art would be motivated to provide instructions for the assembly and use of the device of Loretti, rendering the claimed kit unpatentable.

Allowable Subject Matter

17. Claims 17 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

18. The following is a statement of reasons for the indication of allowable subject matter: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests a funnel comprising three piercing

members. The closest prior art of record is the combination of Loretti et al and Niedospial. The addition of a third piercing member to the Niedospial dual-spike piercing member is neither possible nor obvious, as such a modification may result in destruction of the device and each spike has a specific and different function with respect to the other spike, wherein the function of a third spike would be unclear as no third spike is disclosed or suggested either by Loretti or Niedospial.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/

Primary Examiner, Art Unit 3761

Notice of References Cited	Application/Control No. 12/096,767	Applicant(s)/Patent Under Reexamination MUIR ET AL.	
	Examiner MELANIE HAND	Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,309,827 B1	10-2001	Goldstein et al.	435/6.11
*	B	US-2002/0197275 A1	12-2002	Sunvold et al.	424/195.18
*	C	US-6,582,415 B1	06-2003	Fowles et al.	604/413
*	D	US-6,832,994 B2	12-2004	Niedospial et al.	604/411
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	EP 273015 A2	06-1988	European Patent	LORETTI et al.	A61J 01/00
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	http://www.simport.com/products/tubes-caps-and-vials/tubes/t501.html, Copyright 2009-2011.
	V	English translation of specification for EP 273015 A2, http://worldwide.espacenet.com.
	W	English translation of claims for EP 273015 A2, http://worldwide.espacenet.com.
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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CONFIRMATION NO. 4566

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/096,767	11/24/2008 RULE	604	3761	50245/005001

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**** CONTINUING DATA ************************

This application is a 371 of PCT/CA2006/002009 12/11/2006
which claims benefit of 60/748,977 12/09/2005

**** FOREIGN APPLICATIONS ************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/15/2009

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /MELANIE J HAND/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ON	15	49	2

ADDRESS

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110
UNITED STATES

TITLE

CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

FILING FEE RECEIVED		
1590	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	**Art Unit**
	MELANIE J HAND	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/05/2011	12/15/2011							
	1	÷	✓							
	2	÷	✓							
	3	÷	✓							
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	33	÷	O							
	34	÷	✓							
	35	÷	✓							
	36	÷	✓							

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	**Art Unit**
	MELANIE J HAND	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/05/2011	12/15/2011							
	37	÷	✓							
	38	÷	✓							
	39	÷	✓							
	40	÷	✓							
	41	÷	✓							
	42	÷	✓							
	43	÷	✓							
	44	÷	✓							
	45	÷	✓							
	46	÷	✓							
	47	÷	✓							
	48	÷	✓							
	49	÷	✓							
	50	÷	-							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	29	vial same (standard typical) same volume near3 (centi$5 milli$5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:03
L2	0	(vial adj pharmaceutical same volume near3 (centi$5 milli$5 cm mm))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:10
L3	0	(vial adj pharmaceutical) same volume near3 (centi$5 milli$5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:10
L4	601	vial same (standard typical) and volume near3 (centi$5 milli$5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:10
L5	2	vial adj $5pharmaceutical and volume near3 (centi$5 milli$5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:11
L6	0	vial adj $5pharmaceutical same volume near3 (centi$5 milli$5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:13
L7	2	vial same $5pharmaceutical same volume near3 (centi$5 milli$5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:13

L8	48	("20010008614" | "20020026046" | "20020081575" | "20040038269" | "4583971" | "4741346" | "5140043" | "5364763" | "5496562" | "5567309" | "5807527" | "5817630" | "5980834" | "6176836" | "6242188" | "6291178" | "6309827" | "6503716" | "6551777" | "6582415" | "6617170" | "6716392" | "6869769" | "7482116").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:14
L9	1	L8 and volume near3 (centi$5 milli $5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:14
L10	10	604/403.ccls. and volume near3 (centi$5 milli$5 cm mm)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:18
L11	1	l10 and vial	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:19
L12	0	l8 and t501	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:23
L13	1	t501 adj tube	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:23
L14	2	l8 and stopper same (rubber elastomer inert)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 12:50
L16	730	(604/411).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:29

L17	435	(604/414).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:29
L18	151	(604/412).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:29
L19	435	(604/414).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:29
L20	749	(604/415).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:29
L21	614	(604/416).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:44
L22	0	l2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:45
L23	471	l21 and @pd<="20051209"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:45
L24	169098	(spike pierc$3 needle trocar) same (multiple plurality "at least two" three)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:55
L25	28300	(spike pierc$3 needle trocar) near3 (multiple plurality "at least two" three)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:56

L26	28277	(spike pierc$3 needle trocar) near3 (multiple plurality three)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:56
L27	21573	(spike needle trocar) near3 (multiple plurality three)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:56
L28	5666	(spike needle trocar) near3 (three)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:56
L29	219	needle near3 three and stopper	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:57
L30	37	needle adj three and stopper	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:58
L31	37	needle adj three and stopper	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 13:58
L32	15	blood and tube and simport	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 14:39
L33	0	l32 and "501"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 14:40
L34	26	muir-rod$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/17 15:03

S1	47	("20010008614" | "20020026046" | "20020081575" | "20040038269" | "4583971" | "4741346" | "5140043" | "5364763" | "5496562" | "5567309" | "5807527" | "5817630" | "5980834" | "6176836" | "6242188" | "6291178" | "6309827" | "6503716" | "6551777" | "6582415" | "6617170" | "6716392" | "6869769" | "7482116").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 08:36
S2	405	(604/414).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 09:00
S3	727	(604/415).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 09:00
S4	705	(604/411).CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 09:00
S5	1755	radiopharmaceutical and vial	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 09:50
S6	19	radiopharmaceutical and vial and polymethylmethacrylate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 09:50
S7	363	(radiopharmaceutical and (gamma beta)).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 09:53
S8	17	("3673411" | "4851702" | "5397902" | "5810768" | "5944190" | "6113555" | "6344031" | "6366633").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 10:01

S9	4	(("6997917") or ("6832994")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 10:19
S10	2	("20020115980").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/03/08 10:20
S11	2	("20090216213").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/04/27 09:00
S12	2	("20090221948").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/05/05 12:05
S13	2	("20090299307").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/05/06 10:28
S14	2	("20090299341").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/05/06 11:27
S15	2	("20090299308").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/05/06 12:56
S16	2	("20090306630").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/05/06 14:43
S17	19	("2001060517" "734684" "9844158" "8906704" "2001034844").pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/11/28 07:43

S18	5	(US-20030220601-$ or US-20020115980-$).did. or (US-7799009-$ or US-6113555-$ or US-6832994-$).did.	US-PGPUB; USPAT	OR	OFF	2011/11/28 07:51
S19	2	"0270315"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 11:07
S20	78	"270315"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 11:08
S21	61	"273015"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 11:08
S22	3	("4606734").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 11:11
S23	26	muir-rod$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 15:53
S24	11	kirkland-derek$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 15:53
S25	15	curry-ian$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 15:53
S26	10	sunstrum-roy$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 15:53

S27	22	lem-paul$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 15:54
S28	22	birnboim-h$.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 15:54
S29	1	(vial and lid and funnel and pierc $4).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/12/16 15:56

EAST Search History (Interference)

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12/17/2011 3:04:35 PM
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	Art Unit
	MELANIE HAND	3761

SEARCHED			
Class	Subclass	Date	Examiner
604	411, 412, 414-416	12/17/11	MJH

SEARCH NOTES		
Search Notes	Date	Examiner
class searches	12/17/11	MJH
text-limited search of 604/403	12/17/11	MJH
inventor search	12/17/11	MJH

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

	/MELANIE HAND/ Primary Examiner.Art Unit 3761

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rod Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
Filing/371(c) Date:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

REPLY TO OFFICE ACTION

In reply to the non-final Office Action dated December 27, 2011, Applicant submits the following amendment and remarks.

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently Amended) A container system for releasably storing a substance, comprising:

a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall; and

b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir,

wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

2. (Previously Presented) The container system of claim 1 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir, said wall having a sealing surface for sealingly attaching said pierceable membrane.

3. (Previously Presented) The container system of claim 1, wherein said reservoir is

configured to retain about 1 ml to about 4 ml of said substance.

4. (Previously Presented) The container system of claim 1, wherein said pierceable membrane is inert.

5. (Previously Presented) The container system of claim 1, wherein said pierceable membrane remains intact and pierceable at temperatures of from about -80°C to about 70°C.

6. (Previously Presented) The container system of claim 1, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

7. (Currently Amended) The container system of claim 1, wherein the width of said first end is ~~approximately~~ equivalent to the width of said second end.

8. (Previously Presented) The container system of claim 1, wherein said first end is generally wider than said second end.

9. (Previously Presented) The container system of claim 1, wherein said chamber is configured to receive about 1 ml to about 16 ml of said sample.

10. (Previously Presented) The container system of claim 9, wherein said chamber is configured to receive about 1 ml to about 4 ml of said sample.

11. (Previously Presented) The container system of claim l, wherein the said piercing member extends from a base surface of said chamber.

12. (Previously Presented) The container system of claim 11, wherein said piercing

member extends approximately perpendicularly from said base.

13. (Previously Presented) The container system of claim 11, wherein said piercing member is angled inwardly or outwardly toward said first open end of said vial.

14. (Cancelled)

15. (Currently Amended) The container system of ~~claim 14~~ claim 1, wherein said side wall further includes a second cutting edge.

16. (Previously Presented) The container system of claim 1, wherein said vial comprises a plurality of piercing members.

17. (Previously Presented) The container system of claim 16, wherein said vial comprises three piercing members.

18. (Previously Presented) The container system of claim 16, wherein said vial comprises two piercing members.

19. (Previously Presented) The container system of claim 1, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system following movement of said container system to said piercing position.

20. (Previously Presented) The container system of claim 19, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said vial when the system is said piercing position.

21. (Previously Presented) The container system of claim 1, wherein said vial and said

lid are sized for shipping in both an unattached state and an attached state.

22. (Currently Amended) A container system for releasably storing a substance, comprising:

a) a vial comprising a chamber for retaining a sample

b) a lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir; and

c) a funnel comprising a first open end for receiving said sample, a piercing member and a channel extending from said first open end to a second open end and being in fluid communication with said chamber, said funnel being removably attachable to said lid at said first open end and releasably or permanently attached to said vial at said second end, wherein said piercing member comprises a side wall, and a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall;

wherein, when said system is closed by removable attachment of said lid to said funnel, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, via said channel, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

23. (Previously Presented) The container system of claim 22 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir and including a sealing surface for sealingly attaching said pierceable membrane,

24. (Previously Presented) The container system of claim 22, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

25. (Previously Presented) The container system of claim 22 wherein said pierceable

membrane is inert.

26. (Previously Presented) The container system claim 22, wherein said pierceable membrane maintains intact and pierceable at temperatures of from about -80°C to about 70°C.

27. (Previously Presented) The container system of claim 22, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

28. (Previously Presented) The container system of claim 22, wherein said piercing member extends from an interior surface of said funnel.

29. (Previously Presented) The container system of claim 28, wherein said piercing member is angled inwardly or outwardly toward said first open end of said funnel.

30. (Cancelled)

31. (Currently Amended) The container system of ~~claim 30~~ claim 22, wherein said side wall includes a second cutting edge.

32. (Previously Presented) The container system of claim 22, wherein said funnel comprises a plurality of piercing members.

33. (Previously Presented) The container system of claim 32, wherein said funnel comprises three piercing members.

34. (Previously Presented) The container system of claim 33, wherein said funnel comprises two piercing members.

35. (Previously Presented) The container system of claim 22, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system.

36. (Previously Presented) The container system of claim 35, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said funnel when the system is in the piercing position.

37. (Previously Presented) The container system of claim 22, wherein said vial is releasably attached to said funnel and sized for attachment to a cap when released from said funnel.

38. (Previously Presented) The container system of claim 22, wherein said vial is configured for use in standard laboratory equipment.

39. (Cancelled)

40. (Previously Presented) The container system of claim 38, wherein said vial is a T501 tube.

41. (Previously Presented) The container system of claim 22, wherein said chamber is sized to hold about 1 ml to about 16 ml.

42. (Previously Presented) The container system of claims 1 or 22, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample.

43. (Previously Presented) The container system of claim 42, wherein said nucleic acid is DNA or RNA.

44. (Previously Presented) A method of combining a substance with a biological sample, comprising:

(a) providing the container system of claim 1;

(b) providing the sample to the chamber in the vial; and

(c) closing said container system by removably attaching said lid to said vial; and

(d) piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

45. (Previously Presented) A method of combining a substance with a biological sample, comprising:

(a) providing the container system of claim 22;

(b) providing the sample to the chamber in the vial through said funnel; and

(c) closing said container system by removably attaching said lid to said first open end of said funnel; and

(d) piercing said membrane to release said substance into said chamber by moving said system to said piercing position.

46. (Previously Presented) The method of claim 44 or 45, wherein the substance is a nucleic acid preserving substance.

47. (Previously Presented) The method of claim 44 or 45, wherein the sample is a biological sample.

48. (Previously Presented) The method of claim 44 or 45, for archiving the sample.

49. (Previously Presented) A kit for sample collection and storage, comprising:

a) a container system of claim 1 or 22; and

b) instructions for the use thereof.

50. (Cancelled)

51. (New) The container system of claim 1, wherein the substance is a liquid.

52. (New) The container system of claim 22, wherein the substance is a liquid.

53. (New) The container system of claim 1, additionally comprising a solid or semi-solid material within said vial and maintained separate from the substance in the reservoir of said lid until said pierceable membrane is disrupted.

54. (New) The container system of claim 22, additionally comprising a solid or semi-solid material within said vial and maintained separate from the substance in the reservoir of said lid until said pierceable membrane is disrupted.

REMARKS

Claims 1-49 are pending. Claims 17 and 33 are deemed allowable. Claims 7, 39, and 40 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 1, 2, 5-8, 11-14, 19, 26-30, 42, and 43 are rejected under 35 U.S.C. § 102(b) for anticipation by Loretti et al. (EP 0 273 015; hereinafter "Loretti"). Claims 3, 9, 10, 24, 41, and 45-48 are rejected under 35 U.S.C. § 103(a) for obviousness over Loretti in view of Goldstein et al. (U.S. Patent No. 6,309,827; hereinafter "Goldstein"). Claims 4, 15, 25, and 31 are rejected under 35 U.S.C. § 103(a) for obviousness over Loretti in view of Fowles et al. (U.S. Patent No. 6,582,415; hereinafter "Fowles"). Claims 16, 18, 32, and 34 are rejected under 35 U.S.C. § 103(a) for obviousness over Loretti in view of Niedospial et al. (U.S. Patent No. 6,832,994; hereinafter "Niedospial"). Claims 39 and 40 are rejected under 35 U.S.C. § 103(a) for obviousness over Loretti in view of Sunvold et al. (U.S. Patent Application Publication No. 2002/0197275; hereinafter "Sunvold"). Finally, claims 42, 43, and 49 are rejected under 35 U.S.C. § 103(a) for obviousness over Loretti.

By this reply, Applicant cancels claims 14, 30, and 39, amends claims 1, 7, 15, 22, and 31, adds new claims 51-54, and addresses each of the rejections.

Telephonic Interview

Applicant and Applicant's representatives wish to thank Examiner Hand for the courtesy of a telephonic interview (the "Interview") on January 25, 2012, during which the indefiniteness, anticipation, and obviousness rejections were discussed. Applicant believes that agreement with the Examiner was reached during the Interview and that each of the present rejections may now be withdrawn. The remarks below reflect the content of the Interview.

Support for the Amendment

Support for the amendment to claims 1 and 22 is found in prior claims 14 and 30, respectively. Claim 7 is amended for clarity. Claims 15 and 31 are amended to correct claim dependencies. Support for new claims 51 and 52 is found throughout the specification, for

example, at page 7, lines 6-8, and in the Examples, where only a liquid substance is used in the reservoir. Support for new claims 53 and 54 is found throughout the specification, for example, at page 1, lines 15–17, and page 9, line 10. No new matter is added by the amendment.

Rejections under 35 U.S.C. § 112, second paragraph

The Office rejects claim 7 for use of the term "approximately." Claim 7 has been amended to remove this term. This rejection may now be withdrawn.

Claim 39 stands rejected for indefiniteness. Claim 39 has been cancelled. This rejection may now be withdrawn.

Finally, the Office rejects claim 40 for indefiniteness, stating that the "T501 tube recited in the claim has several different variations of varying volumes and thus it is not clear which variation of the T501 tube is encompassed in the scope of the claim" (Office Action, p. 3). As was discussed during the Interview, T501 tubes are familiar to one of skilled in the art (see, e.g,. the T501 product sheet included with the present Office Action) and encompass a genus of tubes designed with different volumes (between 1.2 and 5.0 mL), sizes (12.5 mm in diameter and 43-93 mm in length), and styles (round bottom and self-standing). Thus, the metes and bounds of claim 40 would be clear to one of skill in the art. In addition, the sizing of the T501 tube of claim 40 is consistent with sizes recited in the other pending claims, such as claim 41, which recites that a chamber of the vial is "sized to hold about 1 ml to about 16 ml." This rejection may now be withdrawn.

Rejections under 35 U.S.C. § 102(b)

The Office rejects claims 1, 2, 5-8, 11-14, 19, 26-30, 42, and 43 for anticipation by Loretti, stating:

> Loretti discloses a container system for releasably storing a substance, comprising: a) a vial, cartridge 7, comprising a first open end for receiving a sample, a second end comprising cylindrical inner part 17, fully functional as a sample storage chamber, and a piercing member, trocar 13 (Abstract); and b) a lid 8 configured to removably engage said vial via fastening means 19, 20, said lid 8 comprising a reservoir for holding the substance by accommodating vial 3 holding the

> substance therein, and a pierceable membrane, stopper 14, sealing the substance within said reservoir, specifically within vial 3 which is held in the reservoir of lid 8 (Abstract), wherein, when said system is closed by removable engagement of said vial 7 with said lid 8, said vial 7 and said lid 8 are movable to a piercing position in which the piercing member 13 disrupts the pierceable membrane 14 to allow fluid communication between said reservoir and said chamber 17, wherein the chamber 17 is sealed against leakage to the outside of the container system in the piercing position via the sealing engagement of vial 7 with vial 3 and lid 8 via the fastening means 19, 20 and locking means 21,22 that effects the engagement. (Office Action, pp. 3-4.)

As was discussed during the Interview, Loretti fails to teach each and every limitation of the container system of present claims 1-13, 15-29, 31-38, 40-49, and 51-54. In particular, Loretti fails to teach a container system whereby the vial and the lid can be engaged and moved to a piercing position in which the piercing member of the vial disrupts the pierceable membrane of the lid "*to allow fluid communication between said reservoir [of the lid] and said chamber [of the vial]*." In Loretti, puncture of stopper 14 of vial 3 with trocar 13 only allows fluid communication between vial 3 and the interior of trocar 13. Fluid communication is never achieved between vial 3 (identified by the Office as the component holding a substance within the reservoir of the lid) and cartridge 7 (identified by the Office as housing the chamber of the vial). Thus, Loretti fails to teach a container system that allows fluid communication between a reservoir of the lid and a chamber of the vial following disruption of a pierceable membrane of the lid by a piercing member of the vial, as is recited in present independent claims 1 and 22 and their dependent claims.

Furthermore, the piercing of stopper 14 of vial 3 by trocar 13 in the Loretti device allows fluid in vial 3 to flow out of the device via conduit 12. Thus, Loretti fails to teach a device in which "the chamber [of the vial] is sealed against leakage to the outside of the container system in the piercing position."

Finally, to further distinguish Loretti, Applicant has amended independent claims 1 and 22 to recite a piercing member that "comprises a side wall, and a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall." Loretti teaches only trocar 13 as a piercing member. Trocar 13 of

Loretti has a tubular body and lacks a "side wall" and "a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall." Thus, Loretti fails to teach these limitations of the container system of present independent claims 1 and 22 and their dependent claims.

During the Interview, Examiner Hand acknowledged that Loretti fails to teach each of the limitations of present independent claims 1 and 22 discussed above. Accordingly, Applicant respectfully requests that the rejection of independent claims 1 and 22 and their dependent claims for anticipation by Loretti be withdrawn.

Rejections under 35 U.S.C. § 103(a)

The Office rejects claims one or more of 3, 4, 9, 10, 15, 16, 18, 24, 25, 31, 32, 34, 39-43, and 45-49 under 35 U.S.C. § 103(a) for obviousness over Loretti alone or Loretti in view of one of Goldstein, Fowles, Niedospial, and Sunvold. As was acknowledged by Examiner Hand during the Interview, none of Goldstein, Fowles, Niedospial, and Sunvold, whether considered alone or in combination with Loretti, remedies the deficiencies of Loretti discussed above. Accordingly, the present obviousness rejections may now be withdrawn.

CONCLUSION

Applicant submits that present claims 1-13, 15-29, 31-38, 40-49, and 51-54 are in condition for allowance, and such action is respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: February 2, 2012

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

Electronic Acknowledgement Receipt

EFS ID:	11987334
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Lindsay Curtin
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245/005001
Receipt Date:	02-FEB-2012
Filing Date:	24-NOV-2008
Time Stamp:	17:14:19
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		50245_005001_Reply_OA.PDF	761194 089e54816c9dc79df723f7683b79583d494bed50	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	9
	Applicant Arguments/Remarks Made in an Amendment	10	14
Warnings:			
Information:			
	Total Files Size (in bytes):	761194	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 12/096,767	Filing Date 11/24/2008	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	82		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☒ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	110		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	192		TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	02/02/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 54	Minus	** 55	= 0	X $30 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $125 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/ANGELA JONES/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No. Serial No. Applicant 371 (c) Date Group IDS Filed	50245/005001 12/096,767 Muir et al. November 24, 2008 3761 March 9, 2012

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
	JP H6-78282	Nov. 4, 1994	Japan	Yes

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
	Notice of Reasons for Rejection for Japanese Patent Application No. 2008-543626, dated January 17, 2012. (English Language Translation Provided)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

Electronic Acknowledgement Receipt

EFS ID:	12270364
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Megan Kiley
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245/005001
Receipt Date:	09-MAR-2012
Filing Date:	24-NOV-2008
Time Stamp:	16:29:29
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	50245_005001_JP_678282_with_Translation.PDF	1033810 dc1a3fe75e3f40818649ab7e650a21eecf57ebf3	no	17

Warnings:	
Information:	

2	Non Patent Literature	50245_005001_JP_OA_INCLUDING_TRANSLATION.PDF	761231 84a72cd2458f265886fcae67d4fe45d7e5b379bf	no	12
Warnings:					
Information:					
3	Transmittal Letter	50245_005001_IDS.PDF	56354 6584320de5b8c2f0eaae3e53aa27a5d77bb7d86e	no	1
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	50245_005001_1449.PDF	36004 ed7464a2f32c6142d149c155c9eb28a38f365471	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
		Total Files Size (in bytes):	1887399		

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT
ATTORNEY DOCKET NO. 50245/005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rod Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
371 (c) Date:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449, copies of which are enclosed. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed after the mailing of a first Office action on the merits, but before the mailing of a final Office action or a Notice of Allowance. I, the undersigned, hereby certify that each item of information contained in this statement was first cited in a communication from a foreign patent office in a counterpart foreign application, dated January 17, 2012, which is not more than three months prior to the filing of this statement.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: March 9, 2012

Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

21559 7590 04/05/2012

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER
HAND, MELANIE JO

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 04/05/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	11/24/2008	Rod Muir	50245/005001	4566

TITLE OF INVENTION: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	07/05/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

21559 7590 04/05/2012

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	11/24/2008	Rod Muir	50245/005001	4566

TITLE OF INVENTION: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	07/05/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
HAND, MELANIE JO	3761	604-415000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

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❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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UNITED STATES DEPARTMENT OF COMMERCE
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Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	11/24/2008	Rod Muir	50245/005001	4566

21559 7590 04/05/2012

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 04/05/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 308 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 308 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	12/096,767	MUIR ET AL.	
	Examiner	Art Unit	
	MELANIE HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the reply filed 2/2/12*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *1-13,15-29,31-38,40-49 and 51-54*.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/15/11,3/19/12
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Melanie J Hand/
Primary Examiner, Art Unit 3761

EXAMINER'S COMMENT

Response to Arguments

1. Applicant's arguments, see Remarks, filed February 2, 2012, with respect to the rejection of claim 40 under 35 U.S.C. 112 and independent claims 1, 22, 44, 45 as amended have been fully considered and are persuasive. The rejection of claim 40 under 35 U.S.C. 112, independent claims 1 and 22 and claim 45 under 35 U.S.C. 103 have been withdrawn.

2. The rejections of claims 7 and 39 under 35 U.S.C. 112 are moot in view of the amendment to the claims.

Allowable Subject Matter

3. Claims 1-13, 15-29, 31-38, 40-9 and 51-54 are allowed.

REASONS FOR ALLOWANCE

4. The following is an examiner's statement of reasons for allowance:

a. With respect to claims 1 and 22, the applicant amended the claim to recite a vial comprising a piercing member comprising a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall, which is not disclosed or suggested by the closest prior art of record, the Loretti reference. Claims 2-13, 15-29, 31-38, 40-43 and 51-54 depend directly or ultimately from claim 1 or claim 22 and are thus also allowed.

b. With respect to claims 44, 45 and 49, these claims recite a container system according to claim 1 or claim 22 and are thus also allowed. Claims 46-48 depend from claim 44 or 45 and are thus also allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
12096767	MUIR ET AL.
Examiner	**Art Unit**
MELANIE HAND	3761

ORIGINAL		INTERNATIONAL CLASSIFICATION																	
CLASS	SUBCLASS	CLAIMED										NON-CLAIMED							
604	415	A	6	1	B	19 / 00 (2006.01.01)													
CROSS REFERENCE(S)		A	6	1	F	5 / 32 (2006.01.01)													
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																		

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE

(Assistant Examiner) (Date)

Total Claims Allowed: 50

/MELANIE HAND/
Primary Examiner.Art Unit 3761 4/1/12

(Primary Examiner) (Date)

O.G. Print Claim(s)	O.G. Print Figure
1	3

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	**Art Unit**
	MELANIE HAND	3761

SEARCHED			
Class	**Subclass**	**Date**	**Examiner**
604	411, 412, 414-416	12/17/11	MJH

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
class searches	12/17/11	MJH
text-limited search of 604/403	12/17/11	MJH
inventor search	12/17/11	MJH

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**
604	411, 412, 414-416	4/1/12	MJH

	/MELANIE HAND/ Primary Examiner.Art Unit 3761

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Rod Muir et al.
	Filing Date	November 24, 2008
	Group	3761
	IDS Filed	December 15, 2011

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant
/M.H./	6,138,821	Oct. 31, 2000	Hsu

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
/M.H./	WO 97/48492	Dec. 24, 1997	WIPO	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
/M.H./	Australian Office Action (AU 2006324337) dated August 18, 2011.

EXAMINER /Melanie Hand/	DATE CONSIDERED 04/01/2012
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b))	Attorney Docket No.	50245/005001
	Serial No.	12/096,767
	Applicant	Muir et al.
	371 (c) Date	November 24, 2008
	Group	3761
	IDS Filed	March 9, 2012

U.S. PATENT DOCUMENTS			
Examiner's Initials	Document Number	Publication Date	Patentee or Applicant

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Translation (Yes/No)
/M.H./	JP H6-78282	Nov. 4, 1994	Japan	Yes

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)	
/M.H./	Notice of Reasons for Rejection for Japanese Patent Application No. 2008-543626, dated January 17, 2012. (English Language Translation Provided)

EXAMINER /Melanie Hand/	DATE CONSIDERED 04/01/2012
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 4566

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/096,767	11/24/2008 RULE	604	3761	50245/005001

APPLICANTS

Rod Muir, South Mountain, ON, CANADA;
Derek Kirkland, Chelsea, QC, CANADA;
Ian Curry, Kanata, ON, CANADA;
Roy Sunstrum, Richmond, ON, CANADA;
Paul Lem, Ottawa, ON, CANADA;
H. Chaim Birnboim, Ottawa, ON, CANADA;

**** CONTINUING DATA ************************

This application is a 371 of PCT/CA2006/002009 12/11/2006
which claims benefit of 60/748,977 12/09/2005

**** FOREIGN APPLICATIONS ************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/15/2009

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /MELANIE J HAND/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		ON	15	49	2

ADDRESS

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110
UNITED STATES

TITLE

CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

FILING FEE RECEIVED		
1590	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

EAST Search History (Prior Art)

<This search history is empty>

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	417	(604/414).CCLS.	US-PGPUB; USPAT; UPAD	OR	OFF	2012/04/01 11:20
L2	684	(604/411).CCLS.	US-PGPUB; USPAT; UPAD	OR	OFF	2012/04/01 11:20
L3	606	(604/415).CCLS.	US-PGPUB; USPAT; UPAD	OR	OFF	2012/04/01 11:20
L4	121	(604/412).CCLS.	US-PGPUB; USPAT; UPAD	OR	OFF	2012/04/01 11:20
L5	1	("0000006").PN.	US-PGPUB; USPAT; UPAD	OR	OFF	2012/04/01 11:20
L6	536	(604/416).CCLS.	US-PGPUB; USPAT; UPAD	OR	OFF	2012/04/01 11:20
L7	989	(604/403).CCLS.	US-PGPUB; USPAT; UPAD	OR	OFF	2012/04/01 11:20

4/ 1/ 2012 11:22:11 AM
C:\ Users\ mhand\ Documents\ EAST\ Workspaces\ 12096767.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	**Art Unit**
	MELANIE J HAND	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/05/2011	12/15/2011	04/01/2012						
1	1	÷	✓	=						
2	2	÷	✓	=						
3	3	÷	✓	=						
4	4	÷	✓	=						
5	5	÷	✓	=						
6	6	÷	✓	=						
7	7	÷	✓	=						
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10	10	÷	✓	=						
11	11	÷	✓	=						
12	12	÷	✓	=						
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14	15	÷	✓	=						
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29	31	÷	✓	=						
30	32	÷	✓	=						
31	33	÷	O	=						
32	34	÷	✓	=						
33	35	÷	✓	=						
34	36	÷	✓	=						

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	12096767	MUIR ET AL.
	Examiner	**Art Unit**
	MELANIE J HAND	3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	05/05/2011	12/15/2011	04/01/2012						
35	37	÷	✓	=						
36	38	÷	✓	=						
	39	÷	✓	-						
37	40	÷	✓	=						
38	41	÷	✓	=						
39	42	÷	✓	=						
40	43	÷	✓	=						
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43	46	÷	✓	=						
44	47	÷	✓	=						
45	48	÷	✓	=						
46	49	÷	✓	=						
	50	÷	-	-						
47	51			=						
48	52			=						
49	53			=						
50	54			=						

Docket No.: 50245-005001
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Rod MUIR et al.

Application No.: 12/096,767	Confirmation No.: 4566
§ 371(c) Date: November 24, 2008	Art Unit: 3761
For: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE	Examiner: Melanie Jo Hand

REPLY TO NOTICE OF ALLOWANCE AND NOTICE OF ALLOWABILITY

In reply to the Notice of Allowance and Notice of Allowability dated April 5, 2012, in connection with the above-captioned application, and having confirmation number 4566, Applicant submits the following:

A completed fee transmittal form PTOL-85;

Authorization to deduct the issue fee of $1,740.00 required by 37 C.F.R. § 1.18(a) and the publication fee of $300.00 from Deposit Account No. 03-2095; and

An Amendment After Allowance under 37 C.F.R. § 1.312.

Applicant submits that all of the requirements for allowance of this application have been met.

If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Dated: June 5, 2012

Respectfully submitted,

By _____

Kristina Bieker-Brady, Ph.D.
Registration No.: 39,109
CLARK & ELBING LLP
101 Federal Street
15th Floor
Boston, Massachusetts 02110
(617) 428-0200

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

21559 7590 04/05/2012
CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	11/24/2008	Rod Muir	50245/005001	4566

TITLE OF INVENTION: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	07/05/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
HAND, MELANIE JO	3761	604-415000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Clark & Elbing LLP
2 Kristina Bieker-Brady, Ph.D.
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: DNA Genotek Inc.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Ontario, Canada

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies .....

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 03-2095 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☒ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date June 5, 2012

Typed or printed name Kristina Bieker-Brady, Ph.D. Registration No. 39,109

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Docket No.: 50245-005001
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Rod MUIR

Application No.: 12/096,767 | Confirmation No.: 4566

§ 371(c) Date: November 24, 2008 | Art Unit: 3761

For: CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE | Examiner: Melanie Jo Hand

AMENDMENT AFTER ALLOWANCE UNDER 37 C.F.R. § 1.312

Prior to issuance of the patent, Applicant respectfully requests entry on this amendment under 37 C.F.R. § 1.312 for the above-captioned patent application.

AMENDMENTS TO THE CLAIMS

1. (Previously Presented) A container system for releasably storing a substance, comprising:

a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall; and

b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir,

wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

2. (Previously Presented) The container system of claim 1 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir, said wall having a sealing surface for sealingly attaching said pierceable membrane.

3. (Previously Presented) The container system of claim 1, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

4. (Previously Presented) The container system of claim 1, wherein said pierceable membrane is inert.

5. (Previously Presented) The container system of claim 1, wherein said pierceable membrane remains intact and pierceable at temperatures of from about -80°C to about 70°C.

6. (Previously Presented) The container system of claim 1, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

7. (Previously Presented) The container system of claim 1, wherein the width of said first end is equivalent to the width of said second end.

8. (Previously Presented) The container system of claim 1, wherein said first end is generally wider than said second end.

9. (Previously Presented) The container system of claim 1, wherein said chamber is configured to receive about 1 ml to about 16 ml of said sample.

10. (Previously Presented) The container system of claim 9, wherein said chamber is configured to receive about 1 ml to about 4 ml of said sample.

11. (Previously Presented) The container system of claim l, wherein the said piercing member extends from a base surface of said chamber.

12. (Previously Presented) The container system of claim 11, wherein said piercing member extends approximately perpendicularly from said base.

13. (Previously Presented) The container system of claim 11, wherein said piercing

member is angled inwardly or outwardly toward said first open end of said vial.

14. (Cancelled)

15. (Previously Presented) The container system of claim 1, wherein said side wall further includes a second cutting edge.

16. (Previously Presented) The container system of claim 1, wherein said vial comprises a plurality of piercing members.

17. (Previously Presented) The container system of claim 16, wherein said vial comprises three piercing members.

18. (Previously Presented) The container system of claim 16, wherein said vial comprises two piercing members.

19. (Previously Presented) The container system of claim 1, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system following movement of said container system to said piercing position.

20. (Currently Amended) The container system of claim 19, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said vial when the system is in said piercing position.

21. (Previously Presented) The container system of claim 1, wherein said vial and said lid are sized for shipping in both an unattached state and an attached state.

22. (Previously Presented) A container system for releasably storing a substance, comprising:

a) a vial comprising a chamber for retaining a sample

b) a lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir; and

c) a funnel comprising a first open end for receiving said sample, a piercing member and a channel extending from said first open end to a second open end and being in fluid communication with said chamber, said funnel being removably attachable to said lid at said first open end and releasably or permanently attached to said vial at said second end, wherein said piercing member comprises a side wall, and a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall;

wherein, when said system is closed by removable attachment of said lid to said funnel, said system is movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, via said channel, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

23. (Previously Presented) The container system of claim 22 wherein said lid comprises a wall defining all or a portion of the perimeter of said reservoir and including a sealing surface for sealingly attaching said pierceable membrane,

24. (Previously Presented) The container system of claim 22, wherein said reservoir is configured to retain about 1 ml to about 4 ml of said substance.

25. (Previously Presented) The container system of claim 22 wherein said pierceable membrane is inert.

26. (Previously Presented) The container system claim 22, wherein said pierceable membrane maintains intact and pierceable at temperatures of from about -80°C to about 70°C.

27. (Previously Presented) The container system of claim 22, wherein said pierceable membrane is sealingly attached to said sealing surface by an adhesive, a heat-sealing treatment, a fastener, or any combinations thereof.

28. (Previously Presented) The container system of claim 22, wherein said piercing member extends from an interior surface of said funnel.

29. (Previously Presented) The container system of claim 28, wherein said piercing member is angled inwardly or outwardly toward said first open end of said funnel.

30. (Cancelled)

31. (Previously Presented) The container system of claim 22, wherein said side wall includes a second cutting edge.

32. (Previously Presented) The container system of claim 22, wherein said funnel comprises a plurality of piercing members.

33. (Previously Presented) The container system of claim 32, wherein said funnel comprises three piercing members.

34. (Previously Presented) The container system of claim 33, wherein said funnel comprises two piercing members.

35. (Previously Presented) The container system of claim 22, wherein said system comprises sealing means for sealing said chamber against leakage to the outside of said container system.

36. (Previously Presented) The container system of claim 35, wherein said sealing means comprises a sealing wall about the interior circumference of said lid that sealingly engages a surface of said funnel when the system is in the piercing position.

37. (Previously Presented) The container system of claim 22, wherein said vial is releasably attached to said funnel and sized for attachment to a cap when released from said funnel.

38. (Previously Presented) The container system of claim 22, wherein said vial is configured for use in standard laboratory equipment.

39. (Cancelled)

40. (Previously Presented) The container system of claim 38, wherein said vial is a T501 tube.

41. (Previously Presented) The container system of claim 22, wherein said chamber is sized to hold about 1 ml to about 16 ml.

42. (Previously Presented) The container system of claims 1 or 22, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample.

43. (Previously Presented) The container system of claim 42, wherein said nucleic acid

is DNA or RNA.

44. (Previously Presented) A method of combining a substance with a biological sample, comprising:

(a) providing the container system of claim 1;

(b) providing the sample to the chamber in the vial; and

(c) closing said container system by removably attaching said lid to said vial; and

(d) piercing said membrane to release said substance into said chamber by moving said lid and said vial to said piercing position.

45. (Previously Presented) A method of combining a substance with a biological sample, comprising:

(a) providing the container system of claim 22;

(b) providing the sample to the chamber in the vial through said funnel; and

(c) closing said container system by removably attaching said lid to said first open end of said funnel; and

(d) piercing said membrane to release said substance into said chamber by moving said system to said piercing position.

46. (Previously Presented) The method of claim 44 or 45, wherein the substance is a nucleic acid preserving substance.

47. (Previously Presented) The method of claim 44 or 45, wherein the sample is a biological sample.

48. (Previously Presented) The method of claim 44 or 45, for archiving the sample.

49. (Previously Presented) A kit for sample collection and storage, comprising:

a) a container system of claim 1 or 22; and

b) instructions for the use thereof.

50. (Cancelled)

51. (Previously Presented) The container system of claim 1, wherein the substance is a liquid.

52. (Previously Presented) The container system of claim 22, wherein the substance is a liquid.

53. (Previously Presented) The container system of claim 1, additionally comprising a solid or semi-solid material within said vial and maintained separate from the substance in the reservoir of said lid until said pierceable membrane is disrupted.

54. (Previously Presented) The container system of claim 22, additionally comprising a solid or semi-solid material within said vial and maintained separate from the substance in the reservoir of said lid until said pierceable membrane is disrupted.

REMARKS

Claim 20 is amended to correct a typographical error. No new matter has been added by the amendment

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 03-2095, under Order No. 50245-005001 from which the undersigned is authorized to draw.

Dated: June 5, 2012

Respectfully submitted,

By _____

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Electronic Patent Application Fee Transmittal

Application Number:	12096767
Filing Date:	24-Nov-2008
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Filer:	Kristina Bieker-Brady/Cindy Vaccaro
Attorney Docket Number:	50245/005001

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	1501	1	1740	1740
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**2040**

Electronic Acknowledgement Receipt

EFS ID:	12936012
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Cindy Vaccaro
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245/005001
Receipt Date:	05-JUN-2012
Filing Date:	24-NOV-2008
Time Stamp:	13:38:34
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2040
RAM confirmation Number	11397
Deposit Account	032095
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	50245_005001_Reply_NOA.PDF	176777 5fa17807288c32afbeece8269bdef26bd2c1ce83	no	3
Warnings:					
Information:					
2		50245_005001_Amend.PDF	402990 e1bcc98b814590dd8b23f9468a9fd258928d1907	yes	10

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment after Notice of Allowance (Rule 312)	1	1
Claims	2	9
Applicant Arguments/Remarks Made in an Amendment	10	10

Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32148 ecef891aa41ad7fdb5af4494b4d52dcd19e26303	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	611915		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Supplemental Application Data Sheet

Application Information

Application number::	12/096,767
Filing Date::	06/09/08
Application Type::	Regular
Subject Matter::	Utility
Suggested Classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R?::	None
Number of CD disks::	
Number of copies of CDs::	
Sequence submission?::	
Computer Readable Form (CRF)?::	
Number of copies of CRF::	
Title::	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
Attorney Docket Number::	50245/005001
Request of Early Publication?::	No
Request of Non-Publication?::	No
Suggested Drawing Figure::	
Total Drawing Sheets::	15
Small Entity?::	~~Yes~~ No
Petition Included?::	No
Petition Type::	
Licensed US Govt. Agency::	

Contract or Grant Numbers::

Secrecy Order in Parent Appl.?:: No

Applicant Information

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Country of Residence::	Canada
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State or Province of mailing address::	Ontario
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State or Province of mailing address::	Ontario
Country of mailing address::	Canada
Postal or Zip Code of mailing address::	K1H 6P2

Correspondence Information

Correspondence Customer Number:: 21559

Representative Information

Representative Customer Number:: 21559

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This Application	National stage of	PCT/CA2006/002009	12/11/06
PCT/CA2006/002009	An application claiming the benefit under 35 USC 119(e)	60/748,977	12/09/05

Assignee Information

Assignee name::	DNA GENOTEK INC.
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Country of mailing address::	Canada
Postal or Zip Code of mailing address::	~~K2G 5W6~~ K2K 1L1

Electronic Acknowledgement Receipt

EFS ID:	12940601
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Cindy Vaccaro
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245-005001
Receipt Date:	05-JUN-2012
Filing Date:	24-NOV-2008
Time Stamp:	17:13:45
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	50245_005001_Supp_ADS.PDF	115845 552e9302c4e4a6a9757938919120acccc5357f27	no	6

Warnings:	
Information:	

This is not an USPTO supplied ADS fillable form	
Total Files Size (in bytes):	115845

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	11/24/2008	Rod Muir	50245-005001	4566

21559 7590 06/18/2012

CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
06/18/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Response to Rule 312 Communication	Application No.	Applicant(s)
	12/096,767	MUIR ET AL.
	Examiner	Art Unit
	MELANIE HAND	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

1. ☒ The amendment filed on *05 June 2012* under 37 CFR 1.312 has been considered, and has been:

   a) ☒ entered.

   b) ☐ entered as directed to matters of form not affecting the scope of the invention.

   c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
   Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

   d) ☐ disapproved. See explanation below.

   e) ☐ entered in part. See explanation below.

/Melanie J Hand/
Primary Examiner, Art Unit 3761

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/096,767	07/17/2012	8221381	50245-005001	4566

21559 7590 06/27/2012

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 669 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Rod Muir, South Mountain, ON, CANADA;
Derek Kirkland, Chelsea, QC, CANADA;
Ian Curry, Kanata, ON, CANADA;
Roy Sunstrum, Richmond, ON, CANADA;
Paul Lem, Ottawa, ON, CANADA;
H. Chaim Birnboim, Ottawa, ON, CANADA;

PATENT
ATTORNEY DOCKET NO. 50245-005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rod Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
§ 371 (c) Date:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

DEFICIENCY PAYMENT UNDER 37 C.F.R. § 1.28 (c)

Applicant, as a large entity, submits herewith a deficiency payment based on large entity status for the above-referenced application. Small entity status was earlier established in good faith, and fees as a small entity were paid in good faith.

The deficiency payment is itemized as follows:

Fee	**Date paid**	**Small entity fee paid**	**Current large entity fee**	**Deficiency**
Extension of Time	October 11, 2011	$990.00	$1,980.00	$990.00

The total deficiency payment owed therefore is $990.00, and Applicant authorizes the Office to charge this amount to Deposit Account No. 03-2095. If there are any other charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: June 28, 2012

Kristina Bieker-Brady, Ph.D.
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Electronic Acknowledgement Receipt

EFS ID:	13133265
Application Number:	12096767
International Application Number:	
Confirmation Number:	4566
Title of Invention:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE
First Named Inventor/Applicant Name:	Rod Muir
Customer Number:	21559
Filer:	Kristina Bieker-Brady/Claire Yotts
Filer Authorized By:	Kristina Bieker-Brady
Attorney Docket Number:	50245-005001
Receipt Date:	28-JUN-2012
Filing Date:	24-NOV-2008
Time Stamp:	17:21:20
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	50245_005001_Def_Payment.PDF	101413 aa7c87e30205e3d1d8d42246f27c95da95d346b8	no	1

Warnings:	
Information:	

Total Files Size (in bytes):	101413

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

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PATENT
ATTORNEY DOCKET NO. 50245-005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rod Muir et al.	Confirmation No.:	4566
Serial No.:	12/096,767	Art Unit:	3761
§ 371 (c) Date:	November 24, 2008	Examiner:	Melanie Jo Hand
Customer No.:	21559		
Title:	CONTAINER SYSTEM FOR RELEASABLY STORING A SUBSTANCE		

DEFICIENCY PAYMENT UNDER 37 C.F.R. § 1.28 (c)

Applicant, as a large entity, submits herewith a deficiency payment based on large entity status for the above-referenced application. Small entity status was earlier established in good faith, and fees as a small entity were paid in good faith.

The deficiency payment is itemized as follows:

Fee	Date paid	Small entity fee paid	Current large entity fee	Deficiency
Extension of Time	October 11, 2011	$990.00	$1,980.00	$990.00

The total deficiency payment owed therefore is $990.00, and Applicant authorizes the Office to charge this amount to Deposit Account No. 03-2095. If there are any other charges, or any credits, please apply them to Deposit Account No. 03-2095.

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Respectfully submitted,

Date: June 28, 2012

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UNITED STATES PATENT AND TRADEMARK OFFICE

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MAILED
SEP 19 2012
OFFICE OF PETITIONS

In re Patent No. 8,221,381 :
Issue Date: July 17, 2012 :
Application No. 12/096,767 : NOTICE
Filed: June 9, 2008 :
Attorney Docket No. 50245-005001 :

This is a notice regarding your request for acceptance of a fee deficiency submission under 37 CFR 1.28 on June 28, 2012.

The Office no longer investigates or rejects original or reissue patent under 37 CFR 1.56. **1098 Off. Gaz. Pat. Office 502 (January 3, 1989)**. Therefore, nothing in this Notice is intended to imply that an investigation was done.

Your fee deficiency submission under 37 CFR 1.28 is hereby **ACCEPTED**.

This patent is no longer entitled to small entity status. Accordingly, all future fees paid in this patent must be paid at the large entity rate.

Inquiries related to this communication should be directed to the undersigned at (571) 272-3208.

/KOC/
Karen Creasy
Petitions Examiner
Office of Petitions

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Delaware on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
	5/4/2015	for the District of Delaware

PLAINTIFF	DEFENDANT
DNA GENOTEK INC.	ANCESTRY.COM DNA, LLC

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	US 8,221,381 B2	7/17/2012	DNA Genotek Inc.
2			
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy