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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/008,880	11/12/2007	5284481	22-01	4173

20995 7590 09/29/2008

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 09/29/2008

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action in Ex Parte Reexamination	Control No. 90/008,880	Patent Under Reexamination 5284481	
	Examiner Catherine S. Williams	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☒ Responsive to the communication(s) filed on *13 March 2008* . b☐ This action is made FINAL.
c☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-28* are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☐ Claims _____ are patentable and/or confirmed.
4. ☒ Claims *1-28* are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____ .
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate 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.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

Reexamination Procedures

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and 37 CFR 41.33 after appeal, which will be strictly enforced.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,284,481 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c).

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

Claim Rejections - 35 USC § 102

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.

Claims 1-7,10-12,15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Block Medical (90311152.4). Block Medical discloses a compact portable apparatus for dispensing a liquid under pressure at a substantially constant flow rate over a period of time (see figures 2-3 and column 1 lines 10-19 and column 2 lines 15-25) comprising: an elongated generally, cylindrical support member (28); elongated elastic sleeve means (22) mounted and sealingly secured at fixed spaced longitudinal positioned on said support member for defining a substantially zero non-pressurized volume pressure reservoir for holding a liquid in a pressurized state for dispensing therefrom (see column 5 lines 16-27); housing means (24/26/12) comprising collapsible non-stretchable housing means (24/26) for containing said support member and said pressure reservoir for enabling said pressure reservoir to expand naturally and for confining said reservoir to fill concentrically about said support member (see figure 2 and column 3 lines 35-43) which has tubular sleeves at each end (see figure 2 for accordion structure (tubular sleeve));

o-rings (76/78) extending around the tubular sleeves and cup shaped caps (30/34) covering the o-rings; and a generally spherical rigid housing (12) with openings having stepped recesses (18/20) at either end; inlet means (52) for introducing a liquid into said elastic pressure reservoir; and outlet means (62) for dispensing liquid from said pressure reservoir to a selected site. It is noted that elements 24 and 26 read on collapsible non-stretchable housing means since these sleeves are elastic but not permanently deformed. See Plaintiff's opening claim construction brief, 3:07-cv-01200-DMS-NLS, Document 67, Filed 05/19/2008, Pages 9-11 and the Order construing patent claims, 3:07-cv-01200-DMS-NLS, Document 78, Filed 07/25/2008, Pages 5-6.

Claim Rejections - 35 USC § 103

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.

Claims 8-9,13-14,20-22 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block Medical in view of Sancoff et al (USPN 5,105,983). Block Medical meets the claim limitations as described above but does not teach that the rigid housing is formed of half shells hinged together.

However, Sancoff teaches such a clam shell construction. See figures 1-3 and column 2 lines 24-56. The housing of Sancoff is designed to not only house the pressure reservoir but also a holding reservoir (see figures 4-5).

At the time of the invention, it would have been obvious to substitute the housing of Block Medical (12) with the clam-shell housing of Sancoff (see figure 1-3). Both references teach pressurized infusion systems; therefore, a combination is proper. Additionally, the motivation for the substitution can be reasonably gleaned from the Sancoff reference in that the clam-shell housing would enable the device of Block Medical to be used with a holding reservoir that would allow for multiple fillings of the pressure reservoir by only exerting pressure on the housing and not having to go through the steps of obtaining more fluid, attaching a separate device to the pressure reservoir and then actuating the device to inject more fluid into the pressure reservoir. By substituting the housing of Sancoff one could utilize a holding reservoir and enable enhanced speed and ease of refilling of the pressure reservoir.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block Medical in view of Paikoff (USPN 4,522,302). Block Medical meets the claim limitations as described above but fails to include a kit having multiple apparatus.

However, Paikoff teaches a kit pack with multiple pre-sterilized medical agent dispensers. See figure 1B and column 3 lines 45-68.

At the time of the invention, it would have been obvious to provide multiple infusion devices as taught by Block Medical as described above in a pre-sterilized kit as taught by Paikoff. Both Block Medical and Paikoff teach medical infusion devices; therefore, a combination is proper. Additionally, it was well known in the art at the time of the invention that medical devices dispensing an agent into the body need to be free of contaminants prior to use and that contaminated, damaged or non-function unit would need to be replaced before use. The

motivation for the above combination can be reasonably gleaned from Paikoff and knowledge generally known in the medical art. Providing multiple infusion devices pre-sterilized in a kit structure would have provided enhanced ease of use both in having a pre-sterilized product and multiple products for use in case of contamination, failure or damage.

NOTICE RE PATENT OWNER'S CORRESPONDENCE ADDRESS

Effective May 16, 2007, 37 CFR 1.33(c) has been revised to provide that:

The patent owner's correspondence address for all communications in an *ex parte* reexamination or an *inter partes* reexamination is designated as the correspondence address of the patent.

> *Revisions and Technical Corrections Affecting Requirements for Ex Parte and Inter Partes Reexamination*, 72 FR 18892 (April 16, 2007)(Final Rule)

The correspondence address for any pending reexamination proceeding not having the same correspondence address as that of the patent is, by way of this revision to 37 CFR 1.33(c), automatically changed to that of the patent file as of the effective date.

This change is effective for any reexamination proceeding which is pending before the Office as of May 16, 2007, including the present reexamination proceeding, and to any reexamination proceeding which is filed after that date.

Parties are to take this change into account when filing papers, and direct communications accordingly.

In the event the patent owner's correspondence address listed in the papers (record) for the present proceeding is different from the correspondence address of the patent, it is strongly encouraged that the patent owner affirmatively file a Notification of Change of Correspondence Address in the reexamination proceeding and/or the patent (depending on which address patent owner desires), to conform the address of the proceeding with that of the patent and to clarify the record as to which address should be used for correspondence.

Telephone Numbers for reexamination inquiries:

Reexamination Practice	(571) 272-7703
Central Reexam Unit (CRU)	(571) 272-7705
Reexamination Facsimile Transmission No.	(571) 273-9900

Correspondence

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By **U.S. Postal Service Mail** to:

Mail Stop *Ex Parte* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
ATTN: Central Reexamination Unit
Randolph Building
401 Dulany St.
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Catherine S. Williams/
Catherine S. Williams
CRU Examiner
GAU 3993
(571) 272-4970

Conferees: