Judge McMahon

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11 CIV 0573

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

APOLLO INTELLECTUAL PROPERTIES LLC,

Plaintiff,

-against-

BECTON, DICKINSON AND COMPANY,

Defendant.

CIVIL ACTION NO.: ___-CV-___

COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Apollo Intellectual Properties, LLC ("Apollo IP"), by and through its attorneys, Niehaus LLP, files this action complaining of defendant Becton Dickinson and Company ("BD"), and alleges as follows:

NATURE OF THIS ACTION

(1) Plaintiff Apollo IP brings this action against defendant BD for infringement of Apollo IP's rights to U.S. Patent No. 7,465,294 (the '294 Patent) for safety needles. The patented safety syringe technology virtually eliminates the risk of needlestick injuries to consumers, healthcare practitioners and caregivers. Potentially deadly infectious agents such as the Human Immunodeficiency Virus ("HIV"), hepatitis, and the like can be spread through accidental needlesticks.

(2) BD is a manufacturer of various medical devices, including syringes and other needle products. BD is now manufacturing and marketing a series of needles that infringe upon the claims of the '294 Patent, thereby harming Apollo IP, which seeks damages for BD's unlawful conduct and for all relief permitted under the law.

PARTIES

(3) Plaintiff Apollo IP is a New York company with its principal place of business in New York, New York.

(4) Defendant BD is a New Jersey corporation with its principal place of business in Franklin Lakes, New Jersey. BD may be served with process in this action by serving its registered agent for the service of process in the State of New York, CT Corporation System, 111 Eighth Avenue, New York, New York 10011.

JURISDICTION AND VENUE

(5) This Court has subject matter jurisdiction under the patent laws set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 271, 281-285 and in Title 28 of the United States Code, particularly 28 U.S.C. §§ 1331 and 1338(a).

(6) This Court has personal jurisdiction over BD. BD is registered as an active foreign business corporation with authority to transact business in New York and regularly transacts business within New York and the Southern District of New York.

(7) BD has marketed and continues to market its infringing 5mm and 8mm "AutoShield™ Pen Needle" within New York and the Southern District of New York.

(8) BD's commercial activities carried on in New York and elsewhere throughout the United States have had a substantial, direct and reasonably foreseeable effect on business and commerce in the Southern District of New York and on interstate commerce.

(9) Venue is proper in this District under 28 U.S.C. § 1391(b) and (c), 28 U.S.C. § 1400(b).

BACKGROUND FACTS

Apollo IP's Patented Safety Needle

(10) The inventions set forth in United States Patent No. 7,465,294, the patent-in-suit, protect against needlestick injuries.

(11) The patented devices retract their needle into a protective sheath after an injection is given and upon withdrawal of the needle from the patient. The mechanism can be passive so that no extra action by a healthcare worker is required to take advantage of the safety feature upon withdrawal of the needle from a patient.

(12) The environment for needle products went through a period of rapid change in the latter part of 1990s.

(13) Numerous state and federal laws governing needle products were enacted in the late 1990s and early 2000s. For example, in November of 1999, the Directive for Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens was created and on November 6, 2001, the federal Needlestick Safety and Prevention Act, P.L. 106-430 ("Needlestick Prevention Act") became law.

(14) The federal law requires employers of healthcare providers to monitor needlestick injuries and to seek input from healthcare workers when choosing safety needle products.

(15) Since 2001, OSHA regulations have required hospitals and other medical facilities to track needlestick incidents and to include healthcare employees in periodic reviews of safety programs for needle devices.

(16) Since the passage of these statutes and with the growing awareness of the risks associated with needlesticks, "safety" needle products have continued to evolve.

(17) BD's initial attempts at "safety" products incorporated inferior technologies that were nothing more than additions to conventional disposable syringe products.

(18) In the beginning phase of its safety syringe program, BD launched an early generation "safety" syringe referred to as the "Safety-Lok."

(19) The Safety-Lok requires a user to slide an outer sleeve over the needle after the needle is withdrawn from the patient.

(20) To engage the safety mechanism on the Safety-Lok, the user is required to actively slide the sleeve from its position around the barrel to its extended position over the needle.

(21) Without active user involvement, the Safety-Lok needle remains exposed, and the addition of the outer sleeve mechanism made the syringe more difficult to handle. Safety-Lok thus failed to appreciably improve needle safety over that of a conventional syringe.

(22) BD launched a second generation "safety" syringe referred to as the "Safety Glide."

(23) The Safety Glide included a small hinged lever around the base of the needle that could be manually pressed forward to cover the needle tip.

(24) Like the Safety-Lok, the safety mechanism of the Safety Glide could only be engaged after the needle was removed from the patient. Furthermore, the Safety Glide required active involvement on the part of the user, thereby increasing the risk of a needlestick injury.

(25) As the healthcare industry demanded better safety needle technology, BD – a dominant player in the syringe industry – accelerated the conversion of its product line from conventional to safety needles and sought solutions to its safety needle technology gap.

BD'S UNLAWFUL ACTS

Patent Infringement

(26) BD commercializes a safety needle, called the AutoShield™, that infringes the '294 Patent.

(27) Upon information and belief, BD knowingly infringed and continues to infringe the retractable needle technology set forth in the '294 Patent, and was aware of the '294 Patent during the course of development and commercialization of BD's "safety" needle, the AutoShield™.

(28) During a 2001 interview, the CEO of BD admitted that BD was not the first to invent many of its products and that "we're just good adapters." (Philip Siekman, Becton Dickinson Takes a Plunge With Safer Needles; By Gearing Up to Make Devices Like These the Company is Giving its Profits a Shot in the Arm, FORTUNE (October 2001) at 2 (Lexis print).)

(29) Once BD engineered a needle incorporating much of the technology disclosed in Apollo IP's patent, BD unveiled the "AutoShield™" needle in 2007.

(30) Unlike BD's earlier alleged "safety" needles, the AutoShield™ is a retractable needle.

(31) BD's AutoShield™ needles infringe Apollo IP's patent rights.

(32) Like the '294 inventions, BD's AutoShield™ needle is a retractable hypodermic needle with a tubular sheath around the needle that shields the caregiver or user of the needle from an unintended needlestick.

(33) BD's AutoShield™ needles also have an attachment structure that allows the needle to be attached to a device that handles biologically active materials.

(34) The AutoShield™ needles have a needle sheath that can slide from a position where the needle does not extend beyond the sheath to another position where the needle does extend from the sheath.

(35) Like the inventions set forth in the '294 Patent, the AutoShield™ needles have a spring or spring-like structure that slides the needle sheath between the various positions.

(36) BD's AutoShield™ needles also have a seal that operates at the point where the needle interfaces with the device that handles the biologically active materials.

(37) These features are disclosed and claimed in the '294 Patent.

(38) BD's infringement of Apollo IP's Patent is greatly damaging Apollo IP.

(39) Through BD's infringing manufacture and sale of its AutoShield™ products, BD has caused and will continue to cause harm to Apollo IP.

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 7,465,294

(40) All preceding paragraphs of this Complaint are incorporated herein by reference as if fully set forth at length.

(41) Plaintiff Apollo IP is the exclusive licensee of, and has the right to sue in its own name on United States Patent No. 7,465,294, issued Dec 16, 2008, a copy of which is attached as Exhibit A.

(42) The maintenance fees for the '294 Patent have been timely paid, and the '294 Patent has not been invalidated or found to be unenforceable in any prior litigation.

(43) At all times relevant to this action, Apollo IP, and every predecessor in interest, has complied with the notice provisions of 35 U.S.C. § 287 as it concerns the '294 Patent.

(44) BD has directly, indirectly, and/or contributorily infringed, either literally or under the doctrine of equivalents, the claims of the '294 Patent by manufacturing, using, selling, offering for sale and/or importing into the United States safety needles covered by the '294

Patent, and has induced and/or contributed to the infringement of the '294 Patent by others in the United States and within this District, and will continue to do so unless relief is granted by this Court.

(45) No right or license to practice the invention claimed in the '294 Patent has been granted to BD.

(46) BD's infringing AutoShield™ needle products infringe the basic patented features of Apollo IP's technology that deliver safety and reliability to the healthcare worker.

(47) Apollo IP has been damaged by BD's infringement and will be irreparably injured unless the infringement is enjoined by this Court as provided by 35 U.S.C. § 283.

WILLFUL INFRINGEMENT

(48) BD's acts of infringement have been willful and in deliberate disregard of the '294 Patent, and this is an exceptional case under 35 U.S.C. § 285.

(49) On information and belief, BD has previously marketed and sold inferior safety needle technology.

(50) BD sought a superior safety needle technology in order to respond to the demands of healthcare practitioners and consumers.

(51) BD was made aware of the invention set forth in the '294 Patent at least as early as August 2006 through correspondence with the named inventor of the '294 Patent, Roman Vladimirsky.

(52) BD was aware that the invention set forth in the '294 Patent was necessary in order to achieve a safe needle that would satisfy market demands.

(53) BD's infringing AutoShield™ needle products infringe the basic patented features of Apollo IP's technology that delivers safety and reliability to the healthcare worker.

(54) BD had full knowledge of and knowingly decided to copy Apollo IP's technology and use it to ward off growing demands for safer products in the marketplace.

(55) BD developed and commercialized its AutoShield™ needle products despite an objectively high likelihood that its AutoShield™ needles infringe a valid patent, in particular the '294 Patent.

(56) BD intended to develop and commercialize its AutoShield™ needle products knowing of the existence of a the '294 Patent.

PRAYER FOR RELIEF

(57) WHEREFORE, Plaintiff Apollo Intellectual Properties LLC prays that Defendant Becton Dickinson and Company will be cited to appear and answer herein and for Judgment of this Honorable Court as follows:

(a) BD be adjudged and decreed to have directly, indirectly, and/or contributorily infringed the '294 Patent;

(b) BD be adjudged and decreed to have willfully and deliberately infringed the '294 Patent;

(c) BD be ordered to pay actual damages to Apollo IP, but not less than a reasonable royalty, by reason of BD's infringement of the '294 Patent together with prejudgment interest, costs and increased damages pursuant to 35 U.S.C. § 284;

(d) This case be declared an "exceptional case" within the meaning of 35 U.S.C. §285 and reasonable attorneys' fees, costs and treble damages be awarded to Apollo IP; and

(e) Granting all other relief, at law and in equity, to which Apollo IP is entitled.

JURY DEMAND

Apollo IP demands a trial by jury as is its right under the Seventh Amendment to the Constitution of the United States or as given by statute. FED. R. CIV. P. 38.

Respectfully submitted,

Dated: January 27, 2011

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EXHIBIT A

US007465294B1

(12) **United States Patent**
Vladimirsky

(10) **Patent No.: US 7,465,294 B1**
(45) **Date of Patent: Dec. 16, 2008**

(54) **RETRACTABLE HYPODERMIC NEEDLE**

(76) Inventor: **Roman Vladimirsky**, 2700 N. Cahuenga Blvd., #3109, Los Angeles, CA (US) 90068

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 690 days.

(21) Appl. No.: **11/014,023**

(22) Filed: **Dec. 15, 2004**

Related U.S. Application Data

(60) Provisional application No. 60/572,445, filed on May 19, 2004.

(51) **Int. Cl.**
A61M 5/32 (2006.01)

(52) **U.S. Cl.** **604/192**; 604/198

(58) **Field of Classification Search** 604/110, 604/272, 192, 195, 198
See application file for complete search history.

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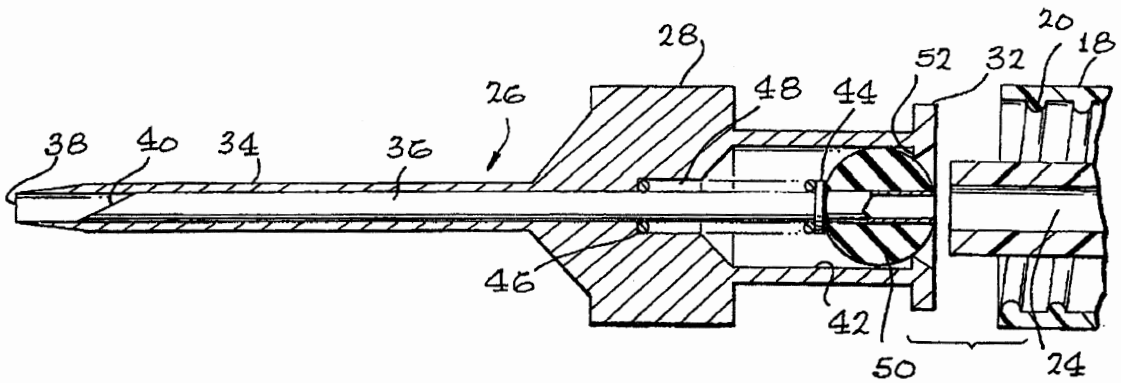
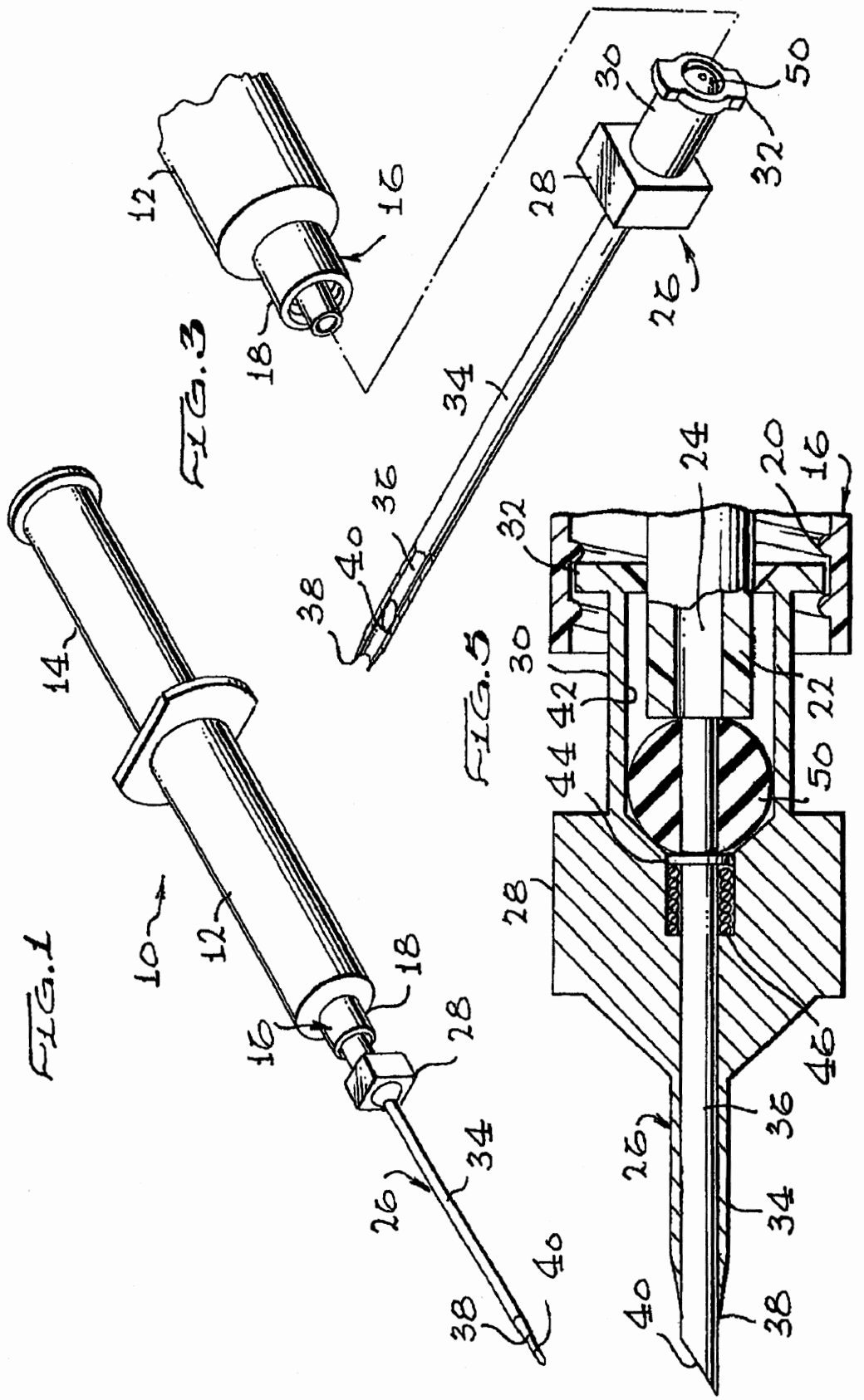
Assistant Examiner—Aarti Bhatia
(74) *Attorney, Agent, or Firm*—Allan M. Shapiro

(57) **ABSTRACT**

A needle assembly includes a sheath into which a hypodermic needle is withdrawn in a protected position. Installation of the needle assembly onto a Luer lock causes the needle to be thrust forward out of the sheath. A spring urges the needle to the withdrawn position. An elastomeric ball in the needle assembly provides sealing.

20 Claims, 3 Drawing Sheets

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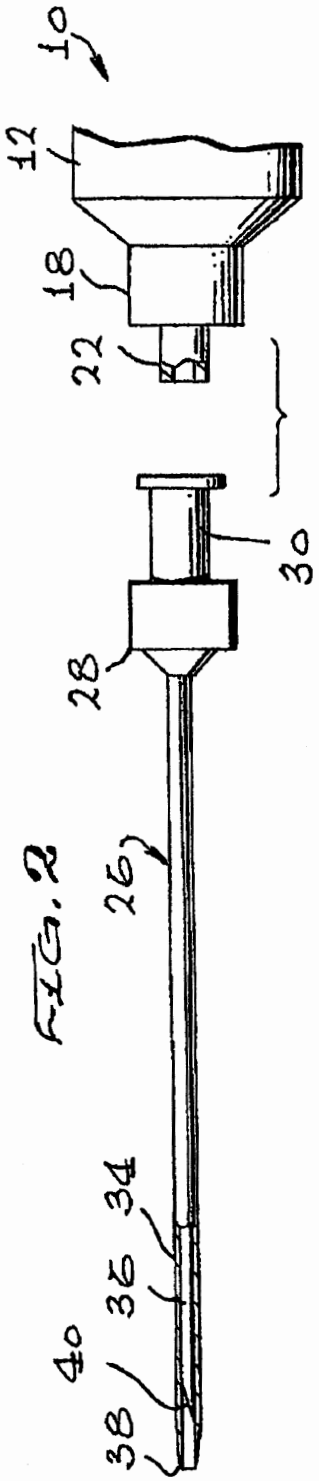
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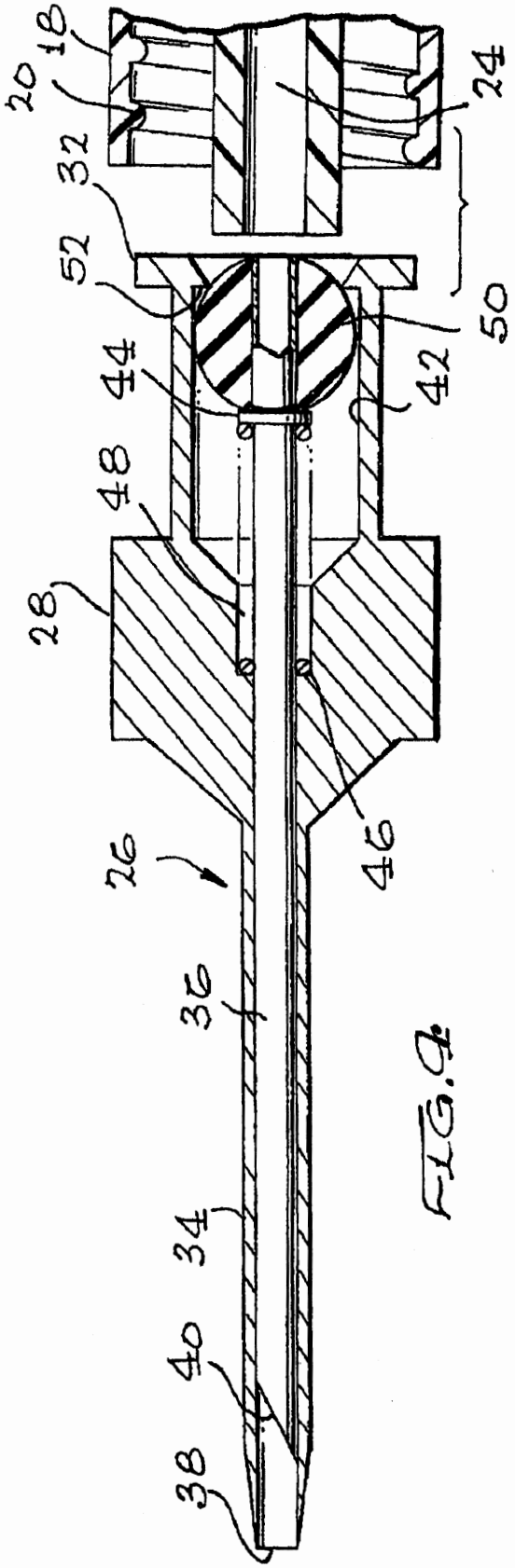
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FIG. 4

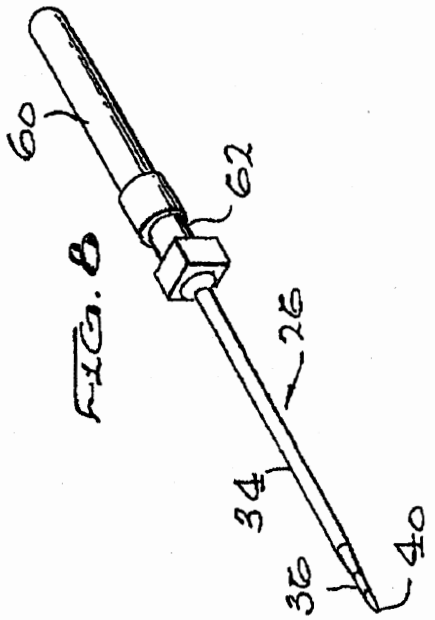

FIG. 8

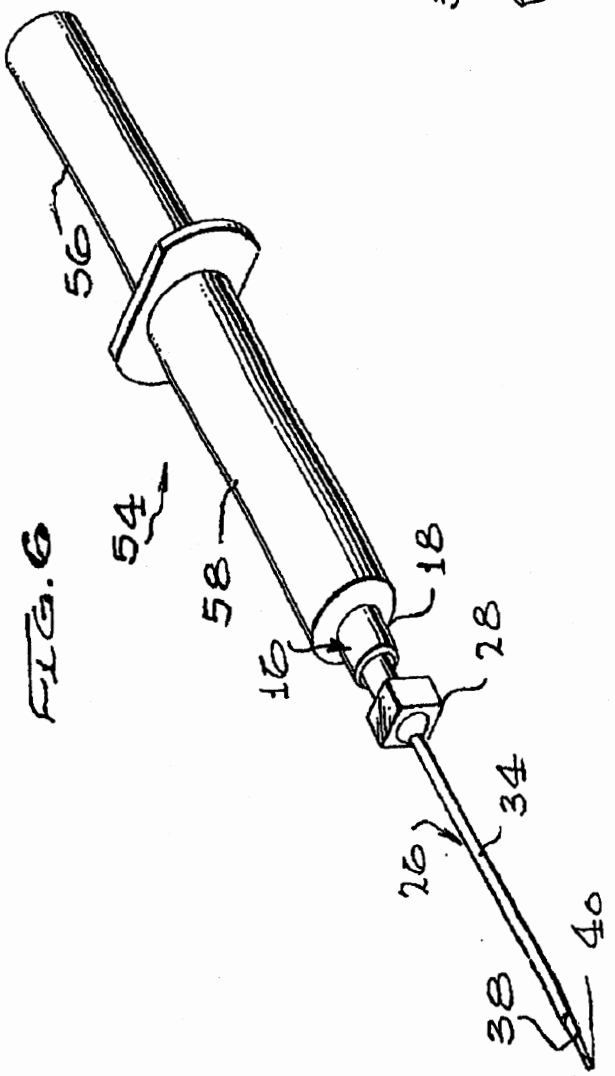

FIG. 6

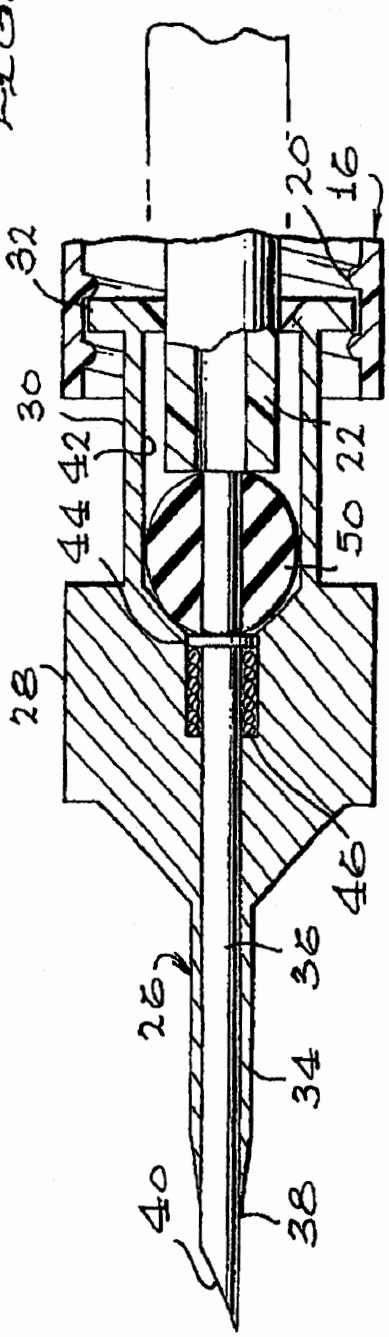

FIG. 7

RETRACTABLE HYPODERMIC NEEDLE

CROSS-REFERENCE

This application relies for priority on my application Ser. No. 60/572,445, filed May 19, 2004.

FIELD OF THE INVENTION

This invention is directed to hypodermic needle system wherein the needle is retracted into its sheath when the needle assembly is removed from a syringe, to protect personnel against inadvertent needle sticks.

BACKGROUND OF THE INVENTION

Hypodermic needles are used in medicine both to inject liquid materials into the body and to withdraw samples from the body. The usual withdrawal is the withdrawal of venous blood. Many infectious diseases are carried in the blood. It has become important in the medical arts to protect the practitioners from contact with possibly-infectious blood. Skin surface contact with blood and other body fluids is not particularly harmful, especially when the skin is healthy. The larger danger for medical practitioners is the possibility of being inadvertently stuck by a needle which carries on it elements of another person's blood. Quite a number of different apparatuses and protocols have been created to minimize risk of inadvertent sticking by a used hypodermic needle. These dangers require the need for advances in the protection from hypodermic needles, and particularly an operative system whereby the hypodermic needle is automatically withdrawn into the retracted position when the needle assembly is unmounted.

SUMMARY OF THE INVENTION

In order to aid in the understanding of this invention,

it can be stated in essentially summary form that it is directed to a retractable hypodermic needle which is mounted in an assembly including a needle sheath. The assembly body, which carries the needle sheath, is mountable on a Luer lock syringe. When mounted, the nozzle of the Luer lock extends the needle from its sheath, and when demounted, the needle is retracted into its sheath.

It is thus a purpose and advantage of this invention to provide a hypodermic needle which is in the retracted position within a sheath when it is not mounted on a syringe or similar structure.

It is another purpose and advantage of this invention to

provide a needle assembly which mounts on a Luer lock. The needle assembly includes a needle which is retracted into a needle sheath when not mounted. The needle is extended from the needle assembly when the needle assembly is mounted on a Luer lock structure.

It is another purpose and advantage of this invention to

provide a retractable hypodermic needle which is useful both for the injection of medication and for the withdrawal of body fluids, with the needle retracting into its sheath when the needle assembly is removed from its mounting.

It is another purpose and advantage of this invention to

provide a retractable hypodermic needle assembly which is inexpensive to build, reliable to use and maintains the needle when withdrawn into its needle sheath whenever the needle assembly is not mounted.

The features of this invention which are believed to be

novel are set forth with particularity in the appended claims. The present invention, both as to its organization and manner of operation, together with further objects and advantages thereof, may be best understood by reference to the following description,

taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an isometric view of a syringe with the retractable hypodermic needle assembly of this invention mounted thereon.

FIG. **2** is an enlarged side elevational view thereof, in disassembled form with parts broken away and parts taken in section.

FIG. **3** is an isometric disassembled view, with parts broken away.

FIG. **4** is an enlarged side elevational view, similar to FIG. **2**, taken generally along a center line section, with parts broken away.

FIG. **5** is a view similar to FIG. **4**, showing the needle assembly attached to the Luer lock nozzle of a hypodermic syringe or the like.

FIG. **6** is a view similar to FIG. **1**, showing the needle assembly attached to a needle holder and a blood collection tube in a phlebotomy set.

FIG. **7** is an enlarged view of the phlebotomy set taken substantially along a center line section, with parts broken away.

FIG. **8** is an isometric view of the needle assembly of this invention attached to a Luer lock on the end of an intravenous catheter tube, usually used for introducing intravenous fluid.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Syringe **10** is shown in FIG. **1**. The syringe **10** is of conventional configuration. It has a barrel **12** in which is slidably-disposed plunger **14**. The plunger can slide within the barrel to receive or dispense fluid therefrom. The barrel carries Luer lock **16** thereon. The Luer lock comprises a collar **18** which has interrupted interior threads **20** and nozzle **22** which extends past the collar **18**. Nozzle **22** is tapered and has an interior passage **24** which extends into the interior of the barrel. Thus, depression and retraction of plunger **14** moves fluid through passage **24** into or out of the syringe barrel. This is conventional construction.

The retractable hypodermic needle assembly of this invention is generally indicated at **26** in FIGS. **1**, **2**, **3**, **4**, **5**, **6**, **7** and **8**. It comprises a body **28**. In the right hand of the body is formed tube **30** which carries fingers **32**. The fingers are configured to enter into the collar **18** and engage on the interrupted threads **20** therein. It is these fingers which retain the needle assembly **26** on the syringe **10**. This is common Luer lock construction. The other end of the body **28** carries needle sheath **34**. The needle sheath is a tube which slidably carries the needle **36** therein. The needle sheath terminates in a blunt end **38**. The needle has a diagonally-cut sharp end **40**. The sharp end is retracted into the needle sheath **34** in FIG. **4** and is extended in FIG. **5**.

The needle **36** extends backward through the body **28**. Within the seal cavity **42**, within tube **30**, spring stop collar **44** is part of the needle. Compression spring **46** surrounds the needle, engages against the spring stop **44** and lies within the spring pocket **48** in body **28**. The spring urges the needle to the

right, retracted position shown in FIG. **4**. To the right of spring stop collar **44**, elastic ball **50** engages around the needle tube. In the retracted, right-most position of the needle seen in FIG. **4**, ball **50** is engaged against circular lip **52** which surrounds the right end of seal cavity **42**. The ball engages against the interior of the seal cavity, engages against the outside of the needle tube and engages against the spring stop collar **44**, as shown in FIG. **4**. The ball serves as a retracted position stop for the needle, when it is withdrawn into the sheath by compression spring **46** as shown in FIG. **4**. This is a safe position where the sharp end **40** of the needle is withdrawn into the sheath **34**. The needle will stay in the retracted

position until it is forced out into active position.

When it is desired to use the syringe to inject liquid,

the needle assembly **26** is assembled onto the Luer lock of syringe **10**. As seen in FIG. **5**, the nozzle **22** of the syringe engages against the ball **50** and presses the ball leftward in the seal cavity **42** until it engages against the left end of the cavity. At this point, the stop collar **44** is at the entrance of the spring pocket **48**. In this position the sharp end **40** of the needle **36** extends past the blunt end **38** of the needle sheath **34**. The hypodermic syringe and the needle assembly are now ready for insertion and injection. Immediately after injection, the needle is withdrawn from the patient. Thereupon, the needle assembly is removed from the syringe. Upon removal, the nozzle **22** no longer holds the needle to the exposed, left position, but the compression spring **46** moves the needle **36** and ball **50** to the right to the retracted position shown in FIG. **4**. Now the needle is thrown away. As soon as the needle is retracted into the sheath, the needle is safe. The various dimensions can be established in accordance with the amount of needle exposure which is required. Only the needle touches the patient, and as soon as the tip of the needle is retracted into its sheath, the needle is safe.

FIGS. **6** and **7** illustrate a structure where the retractable hypodermic needle **26** of this invention is used in connection with a phlebotomy set **54**. The phlebotomy set is configured for the direct withdrawal of blood from the patient to a blood collection tube **56**. The needle holder **58** of the phlebotomy set is of similar configuration to the syringe barrel **12**. It carries a nozzle **22** with a Luer lock thereon which is the same as the Luer lock **16** on syringe barrel **12**. The difference is internal of the phlebotomy set and does not affect the operation of the needle assembly **26**. The blood collection tube **56** has an elastomeric cap thereon and the blood collection tube has a vacuum therein. The blood collection tube may contain chemicals for preserving the blood or for other purposes with respect to the blood. Thus, the blood collection tube **56** is an independent structure. Interiorly of the needle holder **58** is a tubular needle directed toward the blood collection tube **56**. The interior tubular needle is in line with and is connected to the nozzle **22** and its passage **24**. The phlebotomy set is used by placing the needle assembly **26** on the needle holder **58**. This extends the needle tip from the needle sheath **34** as shown in FIG. **7**. The medical person then inserts the needle into the vein. When in position, the blood collection tube **56** is thrust down into the needle holder **58**. Thereupon the puncture needle in the needle holder punctures the rubber cap on the blood collection tube **56**. The vacuum in the blood collection tube withdraws blood from the patient, through the needle, through the sealed Luer connection, through the puncture tube into the blood collection tube. The hypodermic needle must be first inserted into the patient, before the advance of the blood collection tube so that the vacuum in the blood collection tube is not lost due to premature puncturing of its cap. After the collection is completed, the blood collection tube **56** is removed from the needle holder and the needle assembly **26** is removed from the needle holder. The removal of the needle assembly withdraws the needle **36** into its sheath **34**. Thereupon, the needle assembly can be disposed. The blood collection tube goes to the laboratory and the needle holder can be sterilized for re-use, or disposed.

The needle assembly **26** can also be used with an intravenous drip tube, as shown in FIG. **8**. The intravenous tube **60** comes from an IV fluid bag and through a dispensing pump. The end of the IV tube is provided with a Luer lock **62**, the same as the Luer lock **16**. When IV fluid is to be administered, the needle assembly **26** is attached to the Luer lock **62**. This extends the needle **36** out of its sheath **34** so that the needle can be inserted into the patient's vein. The system remains in place until completion of the fluid transfer. Thereupon, the needle is withdrawn from the patient and the needle assembly is released from the Luer lock. The release from the Luer lock permits the spring to withdraw the needle into its sheath, therefore protecting personnel against inadvertent needle sticks. An effective protection of needles has been created.

This invention has been described in its presently contemplated best modes and it is clear that it is susceptible to numerous modifications, modes and embodiments within the ability of those skilled in the art and without the exercise of the inventive faculty. Accordingly, the scope of this invention is defined by the scope of the following claims.

What is claimed is:

1. A retractable hypodermic needle assembly comprising:

a body, said body having a needle end and an attachment end, an attachment structure on the attachment end of said body for attachment to a device which handles biologically-active materials, said attachment structure comprising a Luer lock structure for engaging a Luer lock on a device for handling biological fluids and a cavity in said body for receiving the nozzle of said Luer lock;

a tubular needle sheath on the needle end of said body, a tubular hypodermic needle having a fluid passage therethrough, said hypodermic needle being slidably mounted in said needle sheath from a first position where said needle does not extend from said needle sheath to a second position wherein said needle extends from said needle sheath said body having no biologically active material space except in said needle passage;

a compression spring interengaged between said needle and said body to urge said needle towards said first position; and

a seal structure within said cavity in said body for sealing said needle with respect to a device for handling biologically active fluids.

2. The retractable hypodermic needle assembly of claim **1** wherein said cavity is a seal cavity in said body and there is a resilient seal member within said cavity, said resilient seal member being positioned to engage both said needle and said body.

3. The retractable hypodermic needle assembly of claim **1** wherein said assembly consists of a body carrying a needle sheath, a needle carrying a spring stop, a spring, and a seal.

4. The retractable hypodermic needle assembly of claim **2** wherein the nozzle of the Luer lock extends into said cavity and engages against said seal and forces said needle from said first position to said second position wherein said needle is exposed from said sheath.

5. The retractable hypodermic needle assembly of claim **4** wherein said resilient seal member is a ball engaging in said

cavity, and said ball has a hole therethrough, said needle extending through said hole in said ball so that said ball seals said needle in said cavity.

6. The retractable hypodermic needle assembly of claim 4 wherein there is a stop on said hypodermic needle and said seal member engages against said stop so that said seal member and said stop forces said needle from its first position to its second position when said seal member is engaged by the nozzle on the Luer lock on the biologically-active material handling device.

7. The retractable hypodermic needle assembly of claim 6 wherein said stop is a collar on said needle and there is a spring engaged between said collar and said body to urge said needle toward its first position.

8. The retractable hypodermic needle assembly of claim 7 wherein said resilient seal member is a ball engaging in said cavity, and said ball has a hole therethrough, said needle extending through said hole in said ball so that said ball seals said needle in said cavity.

9. A retractable hypodermic needle assembly comprising:

a body, said body having an attachment end and a needle end, said attachment end of said body being configured to receive and attach to a Luer lock on a biologically-active fluid-handling device wherein the Luer lock has a nozzle thereon which extends into said body when said body is attached to a Luer lock;

a tubular needle sheath on said needle end of said body, a cavity in said body, a needle opening in said tubular needle sheath, said needle opening extending into said cavity in said body;

a hypodermic needle slidably mounted within said needle sheath, said hypodermic needle extending into said cavity, a spring structure interengaged between said needle and said body to urge said needle to a first position with respect to said body wherein said needle is retracted into said needle sheath, said needle and said sheath being configured so that when said needle is in a second position with respect to said body, said hypodermic needle extends out of said tubular needle sheath to a sufficient extent to be able to be used for hypodermic needle purposes; and

a seal within said body interengaged between said needle and said body to seal said needle to the nozzle of a Luer lock when said body is attached to a biologically-active fluid-handling device.

10. The retractable hypodermic needle assembly of claim 9 wherein there is a stop on said needle, said seal engaging said stop and sealing said needle within said cavity.

11. The retractable hypodermic needle assembly of claim 10 wherein said attachment end of said assembly is configured so that the nozzle of a Luer lock can extend into said cavity and is configured so that when a Luer lock is engaged therein, the nozzle of the Luer lock thrusts said needle from its first position to its second position so that whenever said assembly is attached to a Luer lock, said needle is in its second position and whenever said needle assembly is unattached to a Luer lock, said needle is in its first position.

12. The retractable hypodermic needle assembly of claim 9 wherein said seal is sized and positioned to be engaged by the nozzle of the Luer lock and said seal engages the needle to thrust said needle from its first to its second position.

13. The retractable hypodermic needle assembly of claim 9 wherein there is a stop collar on said needle and there is a spring in said body engaging said stop collar to thrust said needle toward its first position and said seal engages against said collar so that when the nozzle of the Luer lock engages against said seal it moves said needle to its second position.

14. The retractable hypodermic needle assembly of claim 13 wherein said seal is a substantially spherical elastomeric seal with a needle hole therethrough and said seal is positioned to surround said needle and engage against said stop.

15. The retractable hypodermic needle assembly of claim 9 wherein the biologically active fluid handling device is a syringe and the barrel of said syringe carries the Luer lock.

16. The retractable hypodermic needle assembly of claim 9 wherein the biologically active fluid handling device is a phlebotomy set and the needle holder of said phlebotomy set carries the Luer lock.

17. The retractable hypodermic needle assembly of claim 9 wherein the biologically active fluid handling device is an intravenous line which carries the Luer lock thereon.

18. The method of exchanging biologically active fluid between a biologically active fluid handling device and a patient comprising the steps of:

attaching a retractable hypodermic needle assembly onto a Luer lock of a biologically active fluid handling device wherein the hypodermic needle assembly has a cavity therein to receive the nozzle of the Luer lock and has a needle sheath which completely contains the hypodermic needle in a first position;

attaching the assembly to the Luer lock so that the nozzle of the Luer lock engages the needle and thrusts the needle to a second position where the needle extends from the sheath;

puncturing the patient with the hypodermic needle and exchanging biologically active fluid between the patient and the biologically active fluid handling device;

withdrawing the needle from the patient; and

removing the hypodermic needle assembly from the Luer lock so that an internal spring structure within the body withdraws the needle into the sheath into the first position so that the needle is fully engaged in the sheath in the protected position.

19. The retractable hypodermic needle assembly of claim 10 wherein there is a lip in said seal cavity, said lip holding said seal within said cavity to hold said hypodermic needle assembly in said first position retracted inside said sheath.

20. A retractable hypodermic needle assembly comprising:

a body, said body having a needle end and an attachment end, attachment structure on the attachment end of said body for direct attachment to a device which handles biologically-active materials;

a tubular needle sheath secured directly on the needle end of said body, a tubular hypodermic needle slidably mounted in said needle sheath from a first position where said needle does not extend from said needle sheath to a second position wherein said needle extends from said needle sheath;

a spring structure interengaged directly between said needle and said body to urge said needle towards said first position; and

a seal structure within said body directly engaging said body and said needle for sealing said needle with respect to a device for handling biologically active fluids.

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