United States District Court,
D. Massachusetts.

MBO LABORATORIES, INC,
Plaintiff.
v.
BECTON, DICKINSON AND COMPANY,
Defendant.

No. CIV.A.03-10038 RCL

Sept. 6, 2005.

Background: Owner of patent for safety system for disposing of used hypodermic needles sued competitor for infringement.

Holdings: Construing claims, the District Court, Lindsay, J., held that:
(1) requirement that needle be shielded "immediately" meant that needle had to be shielded simultaneously with its withdrawal from donor;
(2) requirement that guard "slidably receive" needle meant that guard had to be stationary body into which movable needle retracted; and
(3) requirement that blocking flange be "mounted" on guard meant that flange had to be attached to exterior surface of guard.

Claims construed.

Court-Filed Expert Resumes

36,885. Construed.

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MEMORANDUM ON CONSTRUCTION OF CLAIMS

LINDSAY**, District Judge.**

This is a patent infringement action in which the plaintiff, a closely held Massachusetts corporation called MBO Laboratories, Inc. ("MBO"), alleges that the defendant, Becton, Dickinson and Company ("Becton"), a company that manufactures and sells medical devices, infringed MBO's United States Patent No. RE. 36,885 ("the '885 patent"). The '885 patent relates to a safety needle and blood collection and sampling system that is designed to reduce the risk of injury caused to healthcare workers by needlesticks from contaminated needles. MBO claims that Becton's SafetyGlide ^{TM} shielding hypodermic needle infringes claims 13, 19, 20, 27, 28, 32, and 33 of the '885 patent. Both parties briefed their respective views as to the construction of the claims at issue and presented argument at a *Markman* hearing on July 20, 2005.

Discussion

1. The applicable legal standards

A. Patent infringement analysis-general points

[1] There are two steps to a patent infringement analysis. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc). First, the meaning and scope of the patent claims alleged to have been infringed must be determined. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). This step is commonly referred to as "claim construction." Second, the accused device must be compared to the properly construed claims to determine whether the device infringes the patent. Cybor Corp., 138 F.3d at 1454. While the second step presents a question of fact for the fact-finder, the first step is a question of law for the court. Markman, 517 U.S. at 372, 116 S.Ct. 1384 (holding that "the construction of a patent, including terms of art within its claims, is exclusively within the province of the court"). It is this first step, claim construction, that is the subject of this memorandum.

The Supreme Court has emphasized that the purpose of patent claims is to apprise the public of what is protected by a particular patent. Markman, 517 U.S. at 373, 116 S.Ct. 1384 (noting that "[i]t has long been understood that a patent must describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them' " (quoting McClain v. Ortmayer, 141 U.S. 419, 424, 12 S.Ct. 76, 35 L.Ed. 800 (1891))); Phillips v. AWH Corp., 415 F.3d 1303, 2005 WL 1620331, at (Fed.Cir. July 12, 2005) (emphasizing that "it is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled' " [citation omitted]); *see also* Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989) (stating that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention"). While the construction of the claims of a patent is closely akin to construing other written documents, like contracts or statutes, special considerations apply to patent claim construction, based upon the need for the public, and other inventors, to understand as clearly as possible the scope of a patentee's claimed invention. Therefore, in construing the claims of a patent, a court must first look to matters in the public record. Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1340 (Fed.Cir.1999) (emphasizing that "the language of the claims, the specification and the prosecution history are principally involved in construing patent claims because these constitute the public record") (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996)).

[2] The primary sources for guidance in claim construction are the intrinsic sources: the language of the claim; the written description portion of the specification, including any relevant drawings; and the prosecution history. Phillips, 415 F.3d 1303, 2005 WL 1620331, at *6; Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc., 206 F.3d 1408, 1414 (Fed.Cir.2000); *see* Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324-25 (Fed.Cir.2002) (interpreting the claim terms in light of the intrinsic evidence and explaining that "[t]he intrinsic evidence may provide context and clarification about the meaning of claim terms"); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed.Cir.1996) (noting that "intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language"; emphasizing that allowing the public record to be altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make the right of the public to be on notice of the patent's limitations meaningless); *see also* Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed.Cir.1999) (stating that "[d]etermining the limits of a patent claim requires understanding its terms in the context in which they were used by the inventor, considered by the examiner, and understood in the field of the invention").

(1) The words of the claim

[3] [4] In construing the claims of a patent, the court's initial resort is to the words of the claim itself. Teleflex, 299 F.3d at 1324 (beginning claim construction analysis "as always, with the words of the claim"); Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir.1995) (noting that "resort must be had in the first instance to the words of the claim" (quoting Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir.1984))). The court "must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999). The "ordinary and customary" meaning of a claim term is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d 1303, 1312; Teleflex, 299 F.3d at 1325 (explaining that the court must presume that claim terms carry their ordinary meaning, as understood by someone of ordinary skill in the art of which the invention is a part).

[5] It is important to note that "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d 1303, 1313; *see* Medrad, Inc. v. MRI Devices, Corp., 401 F.3d 1313, 1319 (Fed.Cir.2005) (explaining that the court "cannot look at the ordinary meaning of the [disputed claim] term ... in a vacuum," but must, instead, "look at the ordinary meaning [of the term] in the context of the written description and the prosecution history"); Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1351 (Fed.Cir.2004) (noting that the proper definition of a disputed claim term is the "definition that one of ordinary skill in the art could ascertain from the intrinsic evidence in the record"). Thus, the construing court should look at "the context in which a [claim] term is used in the asserted claim." Phillips, 415 F.3d at 1314 (explaining that the context "can be highly instructive"). "Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id*. (citing Vitronics, 90 F.3d at 1582). Because patentees normally use claim terms "consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Phillips, 415 F.3d at 1314 (citing Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed.Cir.2001)). Likewise, differences among claims can guide the court in "understanding the meaning of particular claim terms." Phillips, 415 F.3d at 1314.

[6] [7] Furthermore, plain English words are entitled to their plain English meaning, In re Wright, 866 F.2d 422, 425 (Fed.Cir.1989), unless it is apparent from the patent specification and the prosecution history that the inventor used a term with a different meaning, Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996). In short, while terms used in a patent generally should be construed to have the ordinary meaning they had at the time of the patent application, a patentee is still entitled to "choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." Vitronics, 90 F.3d at 1582 (citing Hoechst Celanese Corp., 78 F.3d at 1578); *see* Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1368 (Fed.Cir.2003) (explaining that "[a] patent applicant may consistently and clearly use a term in a manner either more or less expansive than its general usage in the relevant art, thereby expanding or limiting the scope of the term in the context of the patent claims").

(2) The written description and drawings of the specification

[8] The specification operates "as a sort of dictionary, which explains the invention and may define terms used in the claims." Markman, 52 F.3d at 979-80. By statute, the specification must contain "a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use [the invention]." 35 U.S.C. s. 112, para. 1. FN1 For that reason, the specification is "highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1314 (quoting Vitronics, 90 F.3d at 1582, and citing numerous cases emphasizing the importance of the specification in construing the disputed claims); *see* Network, LLC v. Centraal Corp., 242 F.3d 1347, 1352 (Fed.Cir.2001) (emphasizing that "[t]he claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose").

FN1. In addition, the rules of the Patent and Trademark Office ("PTO") require that the patent application claims "conform to the invention as set forth in the remainder of the specification" and that "the terms and phrases used in the claims ... find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." Phillips, 415 F.3d at 1317

(quoting 37 C.F.R. s. 1.75(d)(1)). Accordingly, it is "entirely appropriate for the court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Phillips, 415 F.3d at 1317.

A court may use the specification, first, to identify the ordinary meaning of disputed claim terms. Vitronics, 90 F.3d at 1582 (stating that "the specification ... is the single best guide to the meaning of a disputed term"). "The specification, of which the claims are part, teaches about the problems solved by the claimed invention, the way the claimed invention solves those problems, and the prior art that relates to the invention. These teachings provide valuable context for the meaning of the claim language." Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1554 (Fed.Cir.1997), *overruled on other grounds by* Cybor Corp., 138 F.3d 1448.

[9] In addition, the specification may sometimes narrow or otherwise alter the ordinary meaning of claim terms. The categories of cases in which this may occur, as set forth in various Federal Circuit opinions, are not entirely consistent. Indeed, some of the categories seem to overlap. Nevertheless, one may glean from the relevant precedents four principal ways in which the patent specification may modify the ordinary meaning of claim terms.

The best-established method is that by which "the patentee [has] acted as his own lexicographer and clearly [has] set forth a definition of the disputed claim term in either the specification or prosecution history." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). Accordingly, the construing court should consider carefully the written description portion of the patent specification to discern any special meaning that the patentee may have given to any terms found in the patent's claims. Phillips, 415 F.3d at 1315-16 (explaining that, where the patentee has defined a claim term in a way that "differs from the meaning it would otherwise possess," the patentee's lexicography controls). While the definition of a term in the specification must be expressed "clearly," it need not be done explicitly. "Indeed, [the Federal Circuit] ha[s] specifically held that the written description of the preferred embodiments 'can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format.' " Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed.Cir.2001) (quoting SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1344); *see* Vitronics, 90 F.3d at 1582 (explaining that "[t]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). *But cf.* Teleflex, 299 F.3d at 1325 (stating that "an inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision' ") (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994)). For example, "when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term 'by implication.' " Bell Atlantic, 262 F.3d at 1271 (quoting Vitronics, 90 F.3d at 1582).

A second category in which the specification may modify the ordinary meaning of a claim term is when the claim term, if given its ordinary meaning, " 'so deprive[s] the claim of clarity' as to require resort to the other intrinsic evidence for a definite meaning.' " CCS Fitness, 288 F.3d at 1367 (quoting Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed.Cir.1999)). In this situation, it is not the claim term itself that is ambiguous, but the claim as a whole.

Third, "[t]he patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a

claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, 299 F.3d at 1325, 1327 (noting that the specification must include "clear statements of scope" that limit the claim term).

Finally, several Federal Circuit cases suggest that characteristics of the invention that the specification describes as, or otherwise indicates are, "important" may modify the meaning of claim terms. For example, in *Toro,* the court construed the claims of a patent for a convertible vacuum/blower that provided for a "cover" "including" a "restriction ring." 199 F.3d at 1301. The *Toro* court stated that "[i]t is a matter of interpretation of the words 'including' and 'cover' to determine whether, as a matter of law, the claim require[d] that the cover and the ring [be] attached to each other[.] The specification described the restriction ring as 'buil[t] ... as part of the air inlet cover,' and d[id] not suggest that the cover and the ring [could] be two distinct components to be inserted and removed separately. To the contrary, the specification describe[d] the advantages of the unitary structure as important to the invention." *Id*.

[10] [11] While "the claims must be read in view of the specification, ... limitations from the specification are not to be read into the claims." Teleflex, 299 F.3d at 1326 (citations omitted). Generally then, claims are not delimited by the preferred embodiment disclosed in the specification. *See, e.g.,* Phillips, 415 F.3d at 1323 (emphasizing that, "although the specification often describes very specific embodiments for the invention, [the court] ha[s] repeatedly warned against confining the claims to these embodiments"; "expressly reject[ing] the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment"); Interactive Gift Express v. Compuserve, 231 F.3d 859, 874 (Fed.Cir.2000); Dow Chem. Co. v. United States, 226 F.3d 1334, 1342 (Fed.Cir.2000); Tate Access Floors v. Maxcess Techs., 222 F.3d 958, 966 (Fed.Cir.2000); *see also* CCS Fitness, 288 F.3d at 1366 (stating that "[a]n accused infringer ... [cannot] narrow a claim term's ordinary meaning ... simply by pointing to the preferred embodiment"). That is true even if the specification reveals only one preferred embodiment. Teleflex, 299 F.3d. at 1327 (explaining that "the number of embodiments disclosed in the specification is not determinative of the meaning of disputed claim terms"); *see* CCS Fitness, 288 F.3d at 1366 (noting that "a patentee need not 'describe in the specification every conceivable and possible future embodiment of his invention' " (quoting Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed.Cir.2001))). To avoid importing the limitations contained in the specification into the patent claims, the court must keep in mind that the purpose of the specification is to "teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." Phillips, 415 F.3d at 1323 (citing Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed.Cir.1987), and explaining that one of the best ways to teach a person how to make and use the invention is to "provide an example of how to practice the invention in a particular case"). Most of the time, on "reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to" teach one skilled in the art how to practice the invention, "or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive." Phillips, 415 F.3d at 1323.

(3) The prosecution history

[12] The third intrinsic source of evidence for claim construction, along with the claims and the specification, is the prosecution history. Phillips, 415 F.3d at 1317. This history consists of a "complete record of all the proceedings before the Patent and Trademark Office ['PTO'], including any express representations made by the applicant regarding the scope of the claims." Vitronics, 90 F.3d at 1582; *see* Phillips, 415 F.3d at 1316. The prosecution history is often of critical significance in determining the meaning of the claims, *see* Vitronics, 90 F.3d at 1582, because it "limits the interpretation of claim terms so

as to exclude any interpretation that was disclaimed during prosecution," Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.1995).

[13] Like the specification, the prosecution history also can modify the meaning of claim terms either because the patentee has acted as his or her own lexicographer, Teleflex, 299 F.3d. at 1325, or because the prosecution history includes "expressions of manifest exclusion or restriction," id. at 1326; *see* Phillips, 415 F.3d at 1317 (explaining that "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be"). The prosecution history, however, "often lacks the clarity of the specification and thus is less useful for claim construction purposes" because it "represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation." Phillips, 415 F.3d at 1317. In addition, although the prosecution history can, and should, be used to understand the language of the claims, it cannot "enlarge, diminish, or vary" the limitations in the claims. Markman, 52 F.3d at 980.

(4) Extrinsic evidence

[14] If a claim term, read in light of the intrinsic evidence, remains ambiguous, the court may turn to extrinsic sources of evidence to resolve the ambiguity. Phillips, 415 F.3d at 1317-18 (explaining that extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises" [citation omitted]); *see* Vitronics, 90 F.3d at 1583 (cautioning that, "where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper"); *see also* Bell Atlantic, 262 F.3d at 1269 (adding that "extrinsic evidence may be used only to assist in the proper understanding of the disputed limitation; it may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history" [citations omitted]). When the implications of two pieces of extrinsic evidence, such as the testimony of two witnesses of ordinary skill in the art, are contradictory, they are inconclusive. CCS Fitness, 288 F.3d at 1368.

[15] [16] In construing a patent claim, extrinsic evidence is generally "less reliable than the patent and its prosecution history." Phillips, 415 F.3d at 1318. Technical dictionaries, however, can help the court " 'to better understand the underlying technology' and the way in which one of skill in the art might use the claim terms." *Id*. (quoting Vitronics, 90 F.3d at 1583 n. 6); Bell Atlantic, 262 F.3d at 1267 (explaining that "[d]ictionaries and technical treatises, which are extrinsic evidence, hold a 'special place' and may sometimes be considered along with the intrinsic evidence when determining the ordinary meaning of claim terms"). FN2 In sum, "[j]udges ... may ... rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." Vitronics, 90 F.3d at 1584 n. 6; *see* Phillips, 415 F.3d at 1318-19 (concluding that, while "extrinsic evidence may be useful to the court, ... it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence"). FN3·FN4

FN2. For technical terms, the Federal Circuit "caution[s] against the use of non-scientific dictionaries 'lest dictionary definitions ... be converted into technical terms of art having legal, not linguistic significance.' " Bell Atlantic Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267 (Fed.Cir.2001) (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed.Cir.1998)). For common, non-technical terms, "the dictionary definitions of common words are often less useful than the patent documents themselves in establishing the usage of ordinary words in connection with the claimed

subject matter." Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299 (Fed.Cir.1999).

FN3. Some extrinsic material may never be considered. For example, claims must be construed without reference to the accused device. *See* SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1118 (Fed.Cir.1985).

FN4. The court in *Phillips* noted that several cases, most notably Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed.Cir.2002), suggest "a somewhat different approach to claim construction, in which the court [should give] greater emphasis to dictionary definitions of claim terms and [assign] a less prominent rule to the specification and the prosecution history." 415 F.3d at 1318. The *Phillips* court criticized the *Texas Digital* approach because, among other things, the *Texas Digital* methodology "placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and the prosecution history." 415 F.3d at 1321.

B. The doctrine of claim differentiation

[17] An additional consideration in claim construction is the doctrine of claim differentiation. Under this doctrine, "each claim in a patent is presumptively different in scope." Wenger Mfg., Inc. v. Coating Mach. Sys., Inc., 239 F.3d 1225, 1233 (Fed.Cir.2001). Claim differentiation, however, does not require "that every limitation [ ] be distinguished from its counterpart in another claim, but only that at least one limitation [ ] differ." Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed.Cir.2000); *see* Wenger, 239 F.3d at 1233 (noting that the doctrine of "[c]laim differentiation ... is clearly applicable when there is a dispute over whether a limitation found in a dependent claim should be read into an independent claim, and that limitation is the only meaningful difference between the two claims").

[18] "However, claim differentiation is not a 'hard and fast rule of construction,' and cannot be relied upon to 'broaden claims beyond their correct scope.' " Wenger, 239 F.3d at 1233 (quoting Kraft Foods, 203 F.3d at 1368); *see also* Toro Co., 199 F.3d at 1302 (explaining that "the doctrine of claim differentiation does not serve to broaden claims beyond their meaning in light of the specification and does not override clear statements of scope in the specification and the prosecution history"); Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed.Cir.1998) (emphasizing that claims written in "different words may ultimately cover substantially the same subject matter"; stating that the doctrine of claim differentiation cannot enlarge the scope of disputed claims). Thus, "although different claims should be presumed to cover different inventions, 'if a claim will bear only one interpretation, similarity [with another claim] will have to be tolerated.' " Laitram Corp. v. Morehouse Indus., Inc., 143 F.3d 1456, 1463 (Fed.Cir.1998) (quoting Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed.Cir.1991) [alterations in original]).

C. The recapture rule FN5

FN5. As discussed *intra,* the '885 patent is a reissue patent. Betcon argues that, in seeking a reissue of a previous patent (United States Patent No. 5,755,699), MBO sought to "recapture" claims scope surrendered in the prosecution of the earlier patent. Relying on Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911-12 (Fed.Cir.2004) (explaining that where "the proper construction of the claims is clear, the questions of priority and validity are separate issues that must be separately addressed"), and Beery v. Thomson Consumer Elecs., Inc., 2004 WL 1945316, at (S.D.Ohio Aug.18, 2004) (remarking that "reissue arguments

prematurely throw complex validity issues into the claim-construction fray"; emphasizing that the validity of the reissue patent "should not drive claim construction analysis"), MBO insists that the "recapture rule" concerns solely the validity of a patent and is irrelevant to the issue of claim construction. The *Liebel-Flarsheim* case is inapposite because the proper construction of the patent claims is not clear in this case. *Beery,* likewise, does not alter the analysis below.

[19] Under the recapture rule, "claims that are 'broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution' are impermissible." Hester Indus., Inc. v. Stein, Inc., 142 F.3d 1472, 1480 (Fed.Cir.1998) (quoting In re Clement, 131 F.3d 1464, 1468 (Fed.Cir.1997)). This rule effectively "prevents a patentee from regaining through reissue the subject matter that he had surrendered in an effort to obtain allowance of the original claims." In re Clement, 131 F.3d at 1468. In applying the recapture rule, the court must first "determine whether and in what 'aspect' the reissue claims are broader than the patent claims." *Id.; see* Hester Indus., Inc., 142 F.3d at 1480 (explaining that "[a] reissue claim that does not include a limitation present in the original patent claims is broader in that respect"). Next, the court must "determine whether the broader aspects of the reissue claims relate to surrendered subject matter." In re Clement, 131 F.3d at 1468-69; Hester Indus., Inc., 142 F.3d at 1480. In determining whether the patent applicant surrendered a particular subject matter, the court must "look to the prosecution history for arguments and changes to the claims made in an effort to overcome a prior art rejection." In re Clement, 131 F.3d at 1469, and cases cited; Hester Indus., Inc., 142 F.3d at 1480-81 (explaining that surrender of a particular subject matter "can occur by way of arguments *or* claim changes made during the prosecution of the original patent application" [emphasis in original]).

[20] Whether a reissue patent violates 35 U.S.C. s. 251 (dealing with the reissue of defective patents) "is a question of law, which [the court must] review *de novo* " (emphasis in original). *N. Am. Container v. Plastipak Packaging, Inc.,* 415 F.3d at 1349-50 (Fed.Cir. 2005). Accordingly, in evaluating the reissue patent, this court owes no deference to the patent examiner.

With the foregoing legal principles in mind, I turn to the patent-in-suit.

2. The '885 Patent

The '885 patent is a broadening, reissue patent based on the United States Patent No. 5,755,699 ("the '699 patent").FN6 The '885 patent discloses a safety needle and blood collection and sampling system that precludes accidental needlestick injury by a contaminated needle by capturing the needle within a protective guard (also referred to as the "body") immediately after the needle is withdrawn from the donor. The invention "(1) shields the blood-contaminated needle simultaneously with its withdrawal from the donor, and (2) uses a separate shielded needle in a blood sample tube holder for the safe drawing of blood samples," greatly reducing the probability of "an exposed contaminated point being in any injury-causing proximity to a medical worker. " '885 patent, col. 2, ll. 57-62. On withdrawal of the blood-contaminated needle from the donor, the needle is immediately retracted within a snap-on guard, and a shield blocks reemergence of the contaminated needle. '885 patent, col. 3, ll. 3-6.

FN6. The reissue process allows an applicant to remedy certain problems with the original patent, even if the correction broadens the patent claims, provided that the "broadening reissue" application is filed within two years after the issue date of the original patent. *See* 35 U.S.C. s. 251 (setting forth the procedure for reissue of defective patents); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1354 (Fed.Cir.1998) (noting

that "[a]n inventor's failure to appreciate the scope of an invention at the time of the original patent grant, and thus an initial intent not to claim the omitted subject matter, is a remediable error"); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1575 (Fed.Cir.1991) (discussing the reissue statute and stating that, where "the inventors established that they had claimed less than they had a right to claim, that they had done so in error, and that there was not deceptive intention[, t]he application for reissue fully complied with the statutory and regulatory requirements").

A. The prosecution history

On November 8, 1990, MBO filed its first United States patent application (Serial No. 610583) for a safety needle system offering healthcare workers protection from injury- specifically infection- by used hypodermic needles. MBO's original application contained 29 claims and focused on a shielding assembly for needles, in which the needle was immediately blocked by an adjacent imperforate flange when the needle was retracted into a guard upon withdrawal from the patient. Becton Exh. 2. The patent examiner rejected all 29 claims as being anticipated and/or obvious over several prior art references, including Kothe (United States Patent No. 4,943,281) and Macalalad (United States Patent No. 3,709,223). Becton Exh. 3. In response, MBO amended the pending claims, adding a tubular guard into which the needle was retracted upon being withdrawn from the donor. Becton Exh. 4, pp. 1, 3, 4. MBO sought to distinguish its invention from Kothe by pointing out that the "chief feature" of its invention was not only "the safe retraction of the needle ... into the tubular member" (i.e., the body), but also "precluding the inadvertent reemergence thereof to [prevent] physical and contamination hazard." Becton Exh. 4, p. 5. MBO also explained that Kothe taught a movable needle and a reversible needle cover, and noted that with Kothe, in the absence of blood or tissue on the needle, there was "no way of telling whether the needle" had already been used. MBO maintained that, in contrast, its invention enabled the user immediately to tell "whether the needle ha[d] been used, [because the needle could not] be extended or projected once retracted" into the body after use. Becton Exh. 4, pp. 5-6. MBO further contended that, while the Kothe device was confined to syringes, its proposed invention provided "a needle safety assembly for diverse medical use, as the winged IV infusion needle ..., a double-ended blood collection needle, a catheter placement needle, a dental needle, a transfusion needle for blood bank and like purposes, and also a syringe needle." Becton Exh. 4, p. 6.

The examiner rejected the amended claims as anticipated by additional prior art references. Becton Exh. 5. In response, MBO explained, *inter alia,* that the invention in one of the prior art references, DuPont (United States Patent No. 4,915,697), provided a needle fixed to its guide by threads, and did not contain any "comparable or cooperatively associated flexible straps or separation-preventing abutments whatever." MBO added that, until "physically capped by a totally separate cap element, the DuPont needle [wa]s never prevented from hazardous reemergence, in contrast to the automatic and immediate safety means of" its invention. Becton Exh. 7, p. 7. The examiner then allowed the claims as limited and refined by the foregoing interactions with MBO. The United States Patent No. 5,176,655 (the '655 patent) thus issued on January 5, 1993.

After the '655 patent issued, MBO prosecuted a continuation-in-part application, which claimed the benefit of priority to MBO's original November 3, 1990, application. The continuation-in-part application included 17 claims. All of the claims relating to safety needle devices were limited to devices requiring retraction of the needle into the body. Becton Exh. 8. The patent examiner rejected all the claims as obvious over several prior art references, including Smith (United States Patent No. 5,026,356). Becton Exh. 9. Smith disclosed a safety needle system comprising a fixed needle and a guard that the operator manually could extend to cover

the needle tip. Becton Exh. 17. In response, MBO sought to distinguish its claimed invention from Smith by remarking that, in Smith, the needle (1) was not slidably received in the barrel; and (2) could be "fully withdrawn from the patient's flesh ... with the needle point and needle end portion fully exposed and hazardous for needlestick and contamination!" With regard to the second point, MBO particularly emphasized that the invention in Smith protected only the tip of the needle, leaving the adjoining needle end portion exposed. Becton Exh. 10, p. 8. In sum, MBO maintained that, in contrast to Smith, its invention required, among other things, a safety means "which immediately block[ed the] reemergence of [the] needle [ ] as soon as the needle [wa]s flush with [the] front surface [of the body] by unidirentional [sic] and irreversible movement." Becton Exh. 10, pp. 8-9.

The patent examiner allowed some claims and rejected others, citing Vadher (United States Patent No. 4,998,924) in view of Ranford (United States Patent No. 4,946,446). Vadher disclosed a safety needle retractable into the body, but did not disclose a movable safety means, precluding reversing movement. Ranford disclosed a safety means that fit over the body and could be locked in an extended position to block the needle. Becton Exh. 11, p. 2. In response, MBO sought to distinguish its invention from the prior art by limiting its claims to a device having "an imperforate blocking flange disposed in adjacent relation to said body front surface ...." Becton Exh. 12, p. 2. Thereafter, on March 7, 1995, the examiner allowed the patent to issue as United States Patent No. 5,395,347 ("the '347 patent"). The patent issued on March 7, 1995.

MBO also prosecuted a separate continuation application, which claimed priority to the original November 3, 1990, application. The specification of this application was substantially identical to that of the '347 patent. Claim 18, the only independent claim in this application, included the retraction limitation, the blocking flange limitation, and the immediate and positive blocking of reemergence limitation. Becton Exh. 14, pp. 2-4. The patent examiner rejected the claims as anticipated by Bayless (United States Patent No. 4,850,977) in view of Smith. Bayless disclosed a safety needle system comprising a stationary needle and a movable safety means, including a blocking flange and a spring means. Becton Exh. 15, p. 3.FN7 As noted earlier, Smith disclosed a device comprising a stationary needle and a guard that could be extended to cover the needle tip.FN8

FN7. The abstract of the invention in Bayless provided as follows:
A needle sheath for completely encasing the needle of a disposable syringe is provided as a slidable attachment to the end of the syringe. The sheath is spring loaded. A push-button locking mechanism keeps the sheath in its unactivated position, leaving the hypodermic needle exposed, as needed for use. After use of the syringe, activating the button-locking mechanism causes the sheath to be driven by the spring mechanism to cover the length of the needle. The end flaps of the sheath that were held apart by the hypodermic needle close inward and overlap, completely encasing the needle.

Becton Exh. 16.
FN8. The abstract of the invention in Smith provided as follows:
Hypodermic syringes with accompanying hypodermic syringe needles may readily utilize the disclosed safety device to achieve less operator risk of needle stick injury and less risk of body fluid contamination. In the preferred embodiment the safety device, which can be releasably affixed to the barrel of a hypodermic syringe needle, has a channel-like member that houses a forwardly movable, generally L-shaped member and a rocker spring. After injecting substances into or withdrawing body fluids from a human being or an animal, the L-shaped member is pushed forwardly somewhat beyond the tip of the hypodermic syringe needle. The downwardly action of the rocker spring cooperating with the design features of the L-shaped

member causes the L-shaped member to move downwardly past the tip of the hypodermic syringe needle and the rearwardly so that the tip of the hypodermic syringe needle becomes embedded into the L-shaped member.

Becton Exh. 17.
In response, MBO sought to distinguish its invention from Bayless by emphasizing that Bayless required, among other things, (1) a needle that is fixed to the body and never moves; (2) a separate hollow needle sheath which propels forwardly only on "manual release of a separate hooked latch"; and (3) flaps at the end of the sheath intended to be flexed and pulled apart. Becton Exh. 13, p. 3. MBO pointed out that, in contrast to Bayless, its inventioncontemplated (1) a slidable needle; (2) a body with a front surface through which the needle is extended for use and into which it is slidably retracted after use; (3) an imperforate blocking flange positioned adjacent to the front surface of the body; (4) a spring that automatically moves the blocking flange when the needle is slidably retracted into the body. MBO further noted that, in its invention, after the blocking flange is positioned "overlying and against" the front surface of the body, there is "no practical way that the flange could be 'pulled apart' like Bayless." MBO also distinguished its invention from Smith, by explaining that, like Bayless, Smith contemplated a needle that is fixed to a syringe and is immovable, and required that the operator manually extend the safety system over the needle tip. Becton Exh. 13, p. 4.

The examiner rejected each of the pending claims as being unpatentable over Bayless in view of Cohen (United States Patent No. 5,125,908). Cohen disclosed a retractable needle "in the same field of endeavor for the purpose of safely disposing of a needle." Becton Exh. 18, pp. 2-4. To overcome the examiner's rejection, MBO identified three elements "required" by its claimed invention and absent from the prior art: "(1) a body having means, as a bore, for slidably receiving a needle; (2) a safety flange transversely movable under spring force into overlying and adjacent relation to the front surface of the needle-carrying body when the needle is slidably retracted therein[; and] (3) a mount for the spring precluding any axial movement thereof along the needle-carrying body." MBO emphasized that, "with the needle retracted into the body and blocked at the body front face from emergence or any human contact," its invention would enable medical workers "positively [to] avoid [ ]" any contamination hazard. MBO explained that Bayless lacked all three features set forth above, because Bayless (1) disclosed a needle that was fixed and immovable, (2) did not contain a flange movable into overlying and adjacent relation to the needle retracted in the body at the body front face, and (3) any spring in Bayless was not axially fixed on the body. MBO also asserted that Smith lacked all three features, and that Cohen lacked "at least" features (2) and (3), because it did not disclose a flange and a spring mount. Becton Exh. 19, pp. 5-6. The patent examiner allowed MBO's claims. On May 26, 1998, the '699 patent issued.

On July 1, 1999, MBO filed a request for reissue of the '699 patent. The request was accompanied by the required reissue declaration, which stated, in relevant part, that the '699 patent was "wholly or partly inoperative or invalid" because its claims were narrower than the claims MBO was entitled to receive. Becton Exh. 21, p. 2. Specifically, MBO explained that the claims of the '699 patent called for the needle "retracting" into the body, and did not encompass advancing the body to cover the tip of the needle. MBO Exh. 2. FN9 When referring to the needle and the body, instead of using the "retraction" language of the '699 patent, the new claims used terms such as "relative movement," and "relatively moved." The PTO allowed the reissue application. The '885 patent, containing 36 claims, issued on September 26, 2000.

FN9. MBO explained that, "[p]atent claims 14, 15, 17, 18, and 19 claim[ed] less than what [they] had a right

to claim in that [these claims] fail[ed] to claim clearly that any relative movement between the needle and the body [i.e., the needle guard] connected to the safety device as disclosed w[ould] achieve the desired result of preventing needle stick hazard, whether or not the needle move[d] toward the body and connected safety device, or whether the body and connected safety device advance[d] over the needle."

As I noted earlier, MBO alleges that Becton infringes claims 13, 19, 20, 27, 28, 32, and 33 of the '885 patent. Claims 13, 19, and 20 are identical to claims 13, 19, and 20 of the '699 patent. Claims 20, 27, 28, 32, and 33 of the '885 patent are reissue claims not found in the '699 patent. The parties substantially agree on the majority of the terms in these claims. At the *Markman* hearing, the parties narrowed the disputed claim terms to the following: (1) "relative movement" versus "retraction" as these terms relate to the "movement of the guard with respect to the needle tip after the device has been used"; (2) "immediately" as that term relates to "how the spring snaps shut"; (3) "adjacent" as that term relates to the location of the blocking flange with respect to the front of the guard; and (4) "mounted on" as that term relates to the positioning of the blocking flange vis-a-vis the body. Tr. 1:7:7-1:7:12, 1:7:25-1:8:11; 1:46:3-1:46:9. Only the disputed terms are discussed below. *See* Vivid Techs. v. Am. Science & Eng'g, 200 F.3d 795, 803 (Fed.Cir.1999) (explaining that the court need only construe the claim language that is in dispute).

B. Whether the '885 patent **is limited to a blood collection system**

[21] At the Markman hearing, Becton raised, for the first time, the argument that the invention disclosed in the '885 patent should be limited to a blood collection system. That argument had not been made in the claim construction papers filed by Becton prior to the hearing. MBO objected to the late inclusion of an argument as to the nature of the invention, asserting unfair surprise. MBO's objection is well-founded. The failure of Becton to raise the argument in its pre-hearing briefs constitutes a surrender of any right it otherwise might have had to challenge the nature of the invention in this proceeding. Accordingly, I hold that Becton has waived this argument. More to the point, however, as MBO correctly points out, Becton has previously conceded that MBO "incorporated by reference the teachings of the '655 patent" (disclosing an invention that was not limited to blood collection) into the '885 patent. Becton's Response *Markman* Brief, p. 16, n. 9. In light of the foregoing considerations, I hold that no issue as to the nature of the invention is properly before me.

C. The application of the recapture rule

[22] The reissue claims in dispute are broader than the original patent claims in that, *inter alia,* they no longer contain the "retraction" limitation, and no longer require the immediate capture of the needle by the guard, and the positioning of the flange flush against the guard. Moreover, as in *N. Am. Container,* 415 F.3d at 1350, "the broader aspect[s] of the reissue claims relate[ ] to subject matter that was surrendered during the prosecution of the original-filed claims." Hester Indus., Inc., 142 F.3d at 1480-81 (focusing on the "arguments and changes to the claims made [by the patentee throughout the prosecution history] in an effort to overcome a prior art rejection"; emphasizing that "[a]rguments made to overcome prior art can [ ] evidence admission sufficient to give rise to a finding of surrender"). Indeed, during prosecution, as discussed in detail above, MBO sought to distinguish its invention from Bayless and Smith by pointing out that both Bayless and Smith disclosed a stationary needle and a movable safety device. MBO also contrasted its adjacent blocking flange with the separate safety device in Bayless, and emphasized the importance of immediate protection of the needle tip and the adjacent needle shank. *See, e.g.,* Becton Exh. 10, p. 8; Exh. 13, p. 4; Exh. 19, pp. 5-6. Consequently, MBO, "by way of [its] repeated prosecution arguments, surrendered claim scope that does not include these limitations." Hester Indus., Inc., 142 F.3d at

1482; *see* SciMed, 242 F.3d at 1343 (emphasizing that "the claims should not be read so broadly as to encompass the distinguished prior art structure").

D. Claim 13

Claim 13 of the '885 patent recites:

A method of *immediately* and positively precluding needlestick injury from a contaminated needle comprising the steps of:

providing an elongated needle having a pointed end, providing a body [i.e., guard] *slidably receiving* the needle and having a front surface through which the needle extends for use and is retracted into the body after use, providing a spring having an imperforate blocking flange portion, and affixing said spring to the body so as to preclude axial movement of said spring and to dispose the flange portion in *adjacent* relation to the body front surface and in spring-urged relation against the needle extending from the body when the needle is in use, whereby when the needle is retracted after use to bring its pointed end flush with the body front surface, the imperforate blocking flange is spring urged over the body front surface past the needle point thereby to block any reemergence of the needle from the body.

'885 patent, col.10, ll. 24-43 (emphasis added). The claim terms in dispute have been emphasized in the quoted passage above.

a. "immediately"

[23] MBO contends that the word "immediately" should mean right away or without delay. Tr. 1:31:21-1:31:23. MBO points out that the word "immediately" appears in the preamble to claim 13, describing the purpose of the invention. Citing Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002), MBO insists that the body of the claim language in claim 13 (and in claims 19 and 27) defines a structurally complete invention. MBO explains that "the preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1310 (Fed.Cir.2002) (emphasizing that, "[i]f the body of the claim sets out the complete invention, and the preamble is not necessary to give 'life, meaning and vitality' to the claim, 'then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation' "[citation omitted]).

MBO also insists that the specification uses the term "immediately" to refer solely to the action of the spring when the needle passes it and does not describe the amount of time between the withdrawal of the needle from the patient and the blocking flange's sealing of the needle tip. '885 patent, col. 6, ll. 56-58. Tr. 1:30:10-1:30:15. MBO contends that the claims of the '885 patent make clear that the body and the spring are "closely adjacent" to the patient's flesh at the injection site, but are not touching it. MBO reasons that, because there is space between the patient and the body, there necessarily would be some delay between the withdrawal of the needle tip from the patient and its recapture by the body.

Becton's position is that, in the context of the asserted claims, the term "immediately" should be interpreted to mean "simultaneously with" the needle's withdrawal from the donor. Becton explains that the use in the specification of the following phrases establishes that the needle tip is never exposed after it is inserted into the patient: (1) "upon withdrawal of the needle from the blood donor, the needle is immediately retracted within the guard and a shield positively blocks the contaminated needle point and access thereto"; (2) the

needle "is shielded simultaneously with its withdrawal from the donor whereby no inadvertent puncture can occur"; and (3) "the healthcare worker at no time has to manipulate an unshielded blood-contaminated needle." '885 patent, col. 3, ll. 3-5; col. 5, ll. 3-4; col. 8, ll. 16-17. Becton points out that, in the "Summary of the Invention" section of the specification of the '885 patent, MBO characterizes its invention as a "new and improved system which [ ] shields the blood-contaminated needle simultaneously with its withdrawal from the donor." '885 patent, col. 2, ll. 57-58. Tr. 1:55:6-1:55:8. Citing 37 C.F.R. s. 1.73 (requiring that the summary of the invention be "commensurate with the invention as claimed"), Becton argues that MBO's attempt to make its invention more comprehensive than the summary of the invention is improper as a matter of law. Becton also insists that MBO's assertions throughout the prosecution history limit all the claims, including the reissue apparatus claims 32 and 33 (in which the word "immediately" does not appear) to a method whereby the body traps the needle tip *simultaneously* with the needle's removal from the donor.FN10

FN10. The term "simultaneous" is defined as "existing or occurring at the same time." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 1094 (10 ed.1993).

In this instance, the preamble aids in the construction of the disputed claim term. As noted above, the preamble to claim 13 describes "[a] method of *immediately* and positively precluding needlestick injury from a contaminated needle ...." '885 patent, col. 10, ll. 24-26 (emphasis added). This language appears unambiguously to indicate that the term "immediately" should be interpreted to mean that the needle is shielded as it is withdrawn from the donor. It limits MBO's claims because, in this case, it is "necessary to give life, meaning, and vitality" to these claims. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed.Cir.1999).

I further note that the '885 patent is replete with MBO's assertions that its system substantially reduces or eliminates the risk presented by the "open manipulation of the contaminated needle between withdrawal and sample securement" by "shield[ing] the blood-contaminated needle simultaneously with its withdrawal from the donor." FN11 *See* Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1301 (Fed.Cir.1999) (looking to the specification in interpreting the claims of the invention). In addition, under the established principles of claim construction, the words of the '885 patent must be interpreted in light of MBO's assertions throughout the prosecution history of the original '699 patent and related patents. Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1368 (Fed.Cir.2003) (taking into account the patentee's assertions throughout the prosecution of several related patents). During the prosecution of the '699 patent, MBO sought to distinguish its invention from the prior art by emphasizing that its needle safety system provided immediate protection to healthcare workers by retracting the needle into the body at the same time as the needle is withdrawn from the donor. For example, to distinguish its invention (set forth in the '699 patent) from DuPont, MBO contended that, in contrast to DuPont, its invention provided "automatic and immediate safety means." Becton Exh. 7, p. 7.

FN11. MBO contends that in at least one embodiment, the needle is described as withdrawn from the patient and then retracted into the body. The text MBO relies on reads as follows: "Thereby, upon withdrawal of the needle from the blood donor, the needle is immediately retracted within the guard and a shield positively blocks the contaminated needle point and access thereto."'885 patent, col. 3, ll. 3-6. This language does not change my conclusion with respect to the proper construction of the term "immediately."

I conclude that, in light of the above, MBO has acted as its own lexicographer, defining the term "immediately" FN12 to mean "simultaneously" with the needle's withdrawal from the donor. Phillips, 415 F.3d at 1315-16 (explaining that, where the patentee has defined a claim term in a way that differs from the term's usual meaning, the patentee's lexicography controls); *see* Bell Atlantic Network Servs., Inc., 262 F.3d at 1268 (noting that the patentee need not have explicitly defined the term). FN13 I further conclude that the term "immediately," as I have construed it, limits reissue claims 32 and 33. My construction of this term applies with equal force to the time between the retraction of the needle within the guard and the action of the blocking flange.

FN12. The term "immediately" is defined as "without interval of time" or "as soon as." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 579 (10 ed.1993). THE OXFORD ENGLISH DICTIONARY defines the term "immediately" as follows: "[w]ithout any delay or lapse of time; instantly, directly, straightway; at once."

FN13. Although I have construed the term "immediately" to mean "simultaneously," it is worth noting that I do not perceive a significant difference between the dictionary definition of "immediately" as meaning "without interval of time" and the dictionary definition of "simultaneous" as meaning "existing or occurring at the same time."

b. "slidably receiving"

[24] MBO contends that the term "slidably receiving," which is part of the claim limitation "providing a body slidably receiving the needle," should be interpreted according to its plain meaning, i.e., a body which fits around and slides along the needle. MBO calls my attention to the following language of the specification: "The safety and guard assembly 80 in FIGS. 3 and 4 carrying needle 40 ... includes a needle shielding or guide body 82 having an opening shown as a bore extending from port means in its front surface or distal end 84 to proximal end 86 within which needle 40 is slidably received." '885 patent, col. 5, ll. 31-37. MBO recites several dictionary definitions of the terms "slide" and "receive," and concludes that nothing in these definitions mandates withdrawal or retraction of the needle into the body. According to MBO, the "slidably receiving" claim limitation encompasses any movement of the body sliding over the needle in any direction.

MBO further insists that nowhere in the specification of the '885 patent is the needle retraction emphasized or referred to as the critical feature of the invention. MBO maintains that the specification never disclaims or disavows forward motion of the body to cover the tip of the needle. MBO emphasizes that its use of the terms "retraction" and "rearwardly," in describing the preferred embodiment for the invention, is not enough to read the "retraction" limitation into all the claims, especially into the reissue claims 27, 28, 32, and 33. MBO contends that its statements during prosecution of the '699 patent did not limit the scope of its claims to retraction.

Becton explains that, the claim language, the specification, and MBO's statements to the patent examiner during the prosecution of the '699 patent support the proposition that the term "slidably receiving" should be interpreted to mean the retraction of the needle into the body. Tr. 1:72:17-1:76:18. Specifically, Becton argues that MBO's original patent application, relied on for the benefit of priority, as well as the specification of the '885 patent, clearly indicated that the following three elements are crucial to the

invention: (1) immediate blocking of the needle tip (2) by an imperforate flange adjacent to the front surface of the body (3) on retraction of the needle into the body. Accordingly, Becton insists that claims 13, 17, 19, and 20, issued in the '699 patent and then reissued in the '885 patent without change, should be interpreted to incorporate these limitations.

The disputed term is part of the following clause: "providing a body *slidably receiving* the needle and having a front surface through which the needle extends for use and is *retracted* into the body after use." It is clear from the context, that the term "slidably receiving," connotes a stationary body through which a movable needle extended for use and retracted after use.

That interpretation is confirmed by the specification. The preferred embodiment set forth in the specification contemplates the retraction of the needle into the body. The specification explains, in relevant part:

As similarly taught in [the '655 patent,] safe needle withdrawal from the donor's ... blood vessel is effected by holding the needly shielding body 82 stationary adjacent the needle skin entry point and with wings 88 relaxed to remove lugs 102 outwardly from behind lug 104. Thereupon, as shown in FIG. 6A, the base section 44 (or the tubing 48 thereat) is pulled in a proximal direction while needle guide body 82 is stationary thereby causing needle 40 to slide rearwardly in the proximal direction through the guideway thereof in body 82.

'885 patent, col. 6, ll. 46-55. While generally the preferred embodiment does not limit a claim, in this case, it is clear that MBO "intend[ed] for the claims and the embodiments in the specification to be strictly coextensive." Phillips, 415 F.3d at 1323.

This case is similar to Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361 (Fed.Cir.2003). In *Alloc,* after the patentee's claims were allowed, it added new claims that were substantially identical to the allowed claims, except without a particular limitation (the term "play"), to the final application. 342 F.3d at 1372 (explaining that the applicant never "retract [ed] or modifi[ed] the representations that secured allowance of the original claims"). In construing the claims narrowly to include the "play limitation," the court considered the specification and the prosecution history of the entire line of patent applications. Alloc, 342 F.3d at 1368 (noting that the court must "immerse[ ] itself in the specification, the prior art, and other evidence, such as the understanding of skilled artisans at the time of invention, to discern the context and normal usage of the words in the patent claim").

The *Alloc* court read into all the claims the limitations contained in the descriptions of the invention found in the section titled "Technical Problems and Objects of the Invention," which is substantially equivalent to the "Summary of the Invention" section of the '885 patent. Id. at 1369 (concluding that the specification taught that the invention as a whole, not merely a preferred embodiment, provided for "play" in the positioning of floor panels); *see also* 37 C.F.R. s. 1.73 (mandating that the summary of the invention, "be commensurate with the invention as claimed"). The *Alloc* court further emphasized that "all the figures and embodiments disclosed in the asserted patents impl[ied the existence of the play limitation] or expressly disclosed [the limitation]." 342 F.3d at 1370. The court also noted that the applicants criticized prior art that did not contain the limitation, represented to the PTO that the limitation is important to the invention, and sought to distinguish the invention from the prior art based on the existence of the limitation. Alloc, 342 F.3d at 1371. In light of all the factors set forth above, the court incorporated the "play" limitation into all the claims of the patent. Id. at 1371-72 (explaining that "[b]ecause the applicant invoked play to overcome the prior art, [it] cannot now contend that the [patent-in-suit] claims [the invention] without play").

In this case, the language of the specification and MBO's assertions throughout the prosecution history make clear that MBO intended that the preferred embodiment be coextensive with the claims. Phillips, 415 F.3d at 1323-24. The abstract of the invention, the drawings of the '885 patent, and the written description portion of the specification are all directed to retraction. '885 patent, abstract; col. 3, ll. 4-5; col. 6, ll. 46-67; col. 8, ll. 13-16. In addition, as explained more fully above, during the prosecution of the '699 patent, MBO repeatedly represented that its device encompassed a needle that retracted into the guard. MBO contended that its invention would significantly decrease or eliminate the possibility of accidental needlestick injury by retracting the needle into the guard simultaneously with the needle's withdrawal from the patient. MBO also sought to distinguish its invention from Bayless and Smith by pointing out, *inter alia,* that both Bayless and Smith disclosed stationary needles and movable safety means, whereas its invention disclosed a movable needle. Becton Exh. 13 p. 4; Exh. 19, p. 5. *See* Tr. 1:72:17-1:76:18. MBO, thus, effectively disclaimed any device that has a stationary needle with a guard extending forward over the needle. Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed.Cir.1997) (explaining that statements made by the applicant "to induce a patent grant" limit the interpretation of the disputed claims "so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance" [internal citations omitted]; emphasizing that, by "distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, [and, accordingly] he is by implication surrendering such protection"). It would be improper therefore to construe the disputed claim language to encompass what MBO had "expressly disclaimed" during the prosecution of the '699 patent. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341-43 (Fed.Cir.2001) (emphasizing that, where the applicants "discuss[ed] the disadvantages of certain prior art structures," the court should not read the claims "so broadly as to encompass the distinguished prior art").

I conclude that, in light of the language of the claim, the specification, and MBO's assertions during the prosecution of the '669 patent, the term "slidably receiving" (as well as the terms "relative movement" and "relatively moved" found in other claims) should be construed to refer to a stationary body into which the movable needle retracts. *See, e.g.,* Alloc, 342 F.3d at 1368-72.

c. to dispose the flange in "adjacent" relation to the body front surface

[25] MBO's proposed construction of the term "adjacent" is "next to." According to MBO, the only "positional limitation" on the flange is that "when the needle tip is inside the body," the flange is disposed forward of the needle tip. MBO also insists that the term "adjacent" should not be imported into reissue claims 32 and 33. Tr. 1:32:10-1:33:8.

Becton's proposed construction of the term "adjacent" is "flush with," meaning that the protective blocking flange of the spring that seals the needle in the body must be flush with the forward surface of the body. Becton maintains that, with respectto the "adjacent" limitation, MBO acted as its own lexicographer, defining the blocking flange as being "flush" with the forward surface of the body. Becton notes that, unless the flange is "right next to the front surface, it could not immediately block the [needle] tip." Thus, Becton emphasizes that, unless the blocking flange is flush with the front surface of the body, a needle would have to be "withdrawn at least a minimum predetermined distance beyond the exit" from the guard body to permit the flange to cover the needle tip. Becton insists that MBO specifically disclaimed flanges that are not "on," "directly adjacent to," or "flush with" the front surface of the body. Finally, Becton points out that the figures and other embodiments of the '885 patent show the blocking flange immediately next to the front surface of the guard.

The language of the claim is ambiguous. I, therefore, turn to the specification for illumination. The specification of the '885 patent states, in part, that "with the blocking flange face 98 immediately adjacent the forward surface of the body at 84, as soon as the needle passes behind the flange 98, the spring snaps the flange forward surface over the 84 of the body into needle-blocking position and positively precludes reemergence of the contaminated needle point from the body 82 and thus needlestick injury is absolutely avoided." '885 patent, col. 7, ll. 2-8. The specification praises this feature as "an outstanding safety feature of the invention. " '885 patent, col. 7, ll. 1-2. The specification also contrasts and criticizes safety devices in the prior art, "wherein the needle must be withdrawn at least a minimum predetermined distance beyond the exit from the tubular body," explaining that, in the prior art, "if the needle is not retracted sufficiently inwardly from the exit aperture, it is still able to be accidentally projected to cause hazard." '885 patent, col. 7, ll. 15-25.

Furthermore, during the prosecution of the '699 patent, MBO sought to distinguish its invention from Smith by arguing that the invention disclosed in Smith protected only the tip of the needle, leaving the adjoining needle end portion exposed, whereas MBO's invention covered both the needle tip and the needle shank. Becton Exh. 10, pp. 8-9. MBO also sought to distinguish its invention from Bayless by explaining, *inter alia,* that Bayless disclosed a "separate hollow needle sheath," whereas its invention had a blocking flange "adjacent" to the front surface of the body. Becton Exh. 13, pp. 3-4. *See* Ekchian, 104 F.3d at 1304 (explaining that, by "distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover"); *see also* SciMed Life Sys., Inc., 242 F.3d at 1341-42, 1342-43 (noting that it is improper for the court to construe disputed claims "to cover what was expressly disclaimed" during prosecution history).FN14 In light of the foregoing, I construe the term "adjacent" to mean contiguous or connected with the front surface of the body.FN15

FN14. MBO further sought to distinguish its invention from the prior art by limiting its claims to a device having "an imperforate blocking flange disposed in adjacent relation to said body front surface ...." Becton Exh. 12, p. 2.

FN15. Becton's proposed construction of the term "adjacent" to mean "flush" is not entirely accurate, because "flush" means "[e]ven or level with the adjacent surface." *See* OXFORD ENGLISH DICTIONARY.

E. Claims 19 and 20

Claim 19 of the '885 patent provides:

A method of *immediately* and positively precluding needlestick injury from a contaminated needle comprising the steps of:

providing an elongated needle having a pointed end, providing a body *slidably receiving* the needle and having a forward surface through which the needle extends from the body for use and is retracted toward and into the body after use, providing a spring having an imperforate blocking flange, and, affixing said spring to the body so as to preclude axial movement of said spring with respect to the body and to dispose the flange in *adjacent* relation to the body forward surface and in spring-urged relation to bear against the

needle extending from the body when the needle is in use, whereby when the needle is retracted after use to bring its pointed end into *immediate proximity* to the body forward surface, the imperforate blocking flange is spring urged over the body forward surface past the needle pointed end thereby to block any reemergence of the needle from the body and past the flange to present a needlestick hazard.

'885 patent, col.12, ll. 34-57 (emphasis added). The claim terms in dispute have been emphasized in the passage quoted above.

[26] "Unless the patent otherwise provides, a claim term cannot be given a different meaning in the various claims of the same patent." Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1331 (Fed.Cir.1999); *see CAE Screenplates,* 224 F.3d at 1317 (citing Phonometrics, Inc. v. Northern Telecom, Inc., 133 F.3d 1459, 1465 (Fed.Cir.1998), where the court explained that "[a] word or phrase used consistently throughout a patent claim should be interpreted consistently"). Therefore, having interpreted the disputed terms "immediately," "slidably receiving," and "adjacent" as they are found in claim 13, I need not discuss these same terms again when they appear in other claims. The meaning of the term is the same in all of the claims in issue.

(A) the pointed end of the needle being in the "immediate proximity" to the body forward surface

[27] Citing several dictionaries, MBO contends that the term "immediate proximity" (and the term "proximity" found in claim 27) should be construed to mean "near." MBO points out that the phrase "flush with," used in the original claim 13, has not been made part of claims 19 and 27. To support its position, MBO relies on Tandon Corp. v. U.S. Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed.Cir.1987) (explaining that "[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims").

Becton proposes that the disputed terms be construed to mean that the pointed end of the needle is "flush with" the forward surface of the body. According to Becton, during the prosecution of the '347 patent, MBO sought to distinguish its invention from the prior art by amending its claims (1) to require immediate blocking of the needle tip by movement of the "flange over the front surface of the body," and (2) to emphasize that the safety flange slipped over the needle tip when the needle tip was "flush with [the] front surface" of the body. Becton Exh. 10 p. 9; Exh. 12, p. 4. Citing SciMed Life Sys., Inc., 242 F.3d at 1342, and Ekchian, 104 F.3d at 1304, Becton maintains that the court's construction of the disputed terms cannot include the subject matter that MBO had previously disclaimed.

The language of the claim strongly supports Becton's proposed interpretation of the disputed claim term. It provides that, as soon as the pointed end of the needle comes "into immediate proximity to the body forward surface," the flange is "spring urged over the body forward surface past the needle pointed end." The flange simply cannot go "over the body forward surface" and "past the needle pointed end" unless the needle tip is at least flush with the forward surface of the body.

The specification also supports Becton's proposed construction. In particular, the specification explains that, "with the blocking flange face 98 *immediately adjacent the forward surface of the body* at 84, as soon as the needle passes behind the flange 98, the spring snaps the flange forward surface over the 84 of the body into needle-blocking position and positively precludes reemergence of the contaminated needle point from the body 82 and thus needlestick injury is absolutely avoided. While the needle may be withdrawn further into the body 82, such extra movement is unnecessary as the safety spring acts on and over the end face 84 of the

body *at the immediate point of potential emergence* of the contaminated needle" (emphases added). '885 patent, col. 7, ll. 2-12. Several points supporting Becton's construction arise from the quoted language. First, if the blocking flange face is immediately adjacent to the forward surface of the body, the needle tip must be at least flush (or level) with the forward surface of the body before the flange can snap over the body and block the needle from reemerging. Second, the phrase explaining that the flange covers the needle tip "at the immediate point of potential reemergence," also supports Becton's proposed construction of the disputed term. Third, the specification contrasts the invention with the prior art that required that "the needle ... be withdrawn at least a minimum predetermined distance beyond the exit from the tubular body." '885 patent, col. 7, ll. 16-18. Fourth, the abstract of the invention explains that "a used needle is captured immediately within its carrier upon retraction of the needle *flush with* the carrier" (emphasis added).

Finally, I note that during the prosecution of the related '347 patent, MBO sought to distinguish its invention from Smith by arguing, *inter alia,* that the safety means in its invention "immediately blocks reemergence of needle 40 as soon as the needle is flush with front surface 84." Becton Exh. 10, p. 9. *See* Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1333 (Fed.Cir.2003) (explaining that "[a]s long as the same claim limitation is at issue, prosecution disclaimer made on the same limitation in an ancestor application will attach"; emphasizing that this rule applies to continuation applications, and continuation-in-part applications); Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 265 F.3d 1294, 1305 (Fed.Cir.2001) (noting that "[t]he prosecution history of a related patent can be relevant if ... it addresses a limitation in common with the patent in suit"); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999) (clarifying that "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation"); *see also* Loral Fairchild Corp. v. Sony Corp., 181 F.3d 1313, 1327 (Fed.Cir.1999).

In light of the foregoing considerations, I conclude that the term "immediate proximity" requires that the needle tip be flush with the forward surface of the body. The same limitation applies with regard to the term "proximity" found in reissue claims 27 and 28.

F. Claims 27 and 28

Claim 27 of the '885 patent provides:

A method of *immediately* and positively precluding needlestick injury from a contaminated needle comprising the steps of:

providing an elongated needle having a pointed end, providing a body *slidably receiving* the needle and having a forwardly-facing surface through which the needle extends from the body for use and is *relatively moved* toward and into the body after use, providing a spring having an imperforate blocking flange, and affixing said spring to the body so as to preclude axial movement of said spring with respect to the body and to dispose the flange in *adjacent* relation to the body forwardly-facing surface and in spring urged relation to bear against the needle extending from the body when the needle is in use, whereby when the needle is *relatively moved* after use to bring its pointed end into *proximity* to the body forward surface, the imperforate flange is spring urged over the body forwardly-facing surface past the needle pointed end thereby to block any reemergence of the needle from the body and past the flange to present a needle-stick hazard.

'885 patent, col.15, ll. 5-27 (emphasis added). The claim terms in dispute have been emphasized in the passage quoted above.

(A) "relatively moved"

[28] MBO urges that I construe the term "relatively moved" to mean that the body, or the needle, or both, move in relation to each other so as to result in the pointed end of the needle being covered by the body. MBO calls my attention to the reissue declaration it submitted to the PTO on July 1, 1999, where it informed the PTO that "relative movement" encompassed both the retraction of the needle into the body and the movement of the body over the tip of the needle. MBO Exh. 2, p. 2. MBO thus claims that its proposed definition of the term "relative" is consistent with the prosecution history *of the reissue application*. MBO contends that it never sought to distinguish its invention from the prior art based on retraction, because much of prior art disclosed a retraction feature.

Becton proposes that the phrase "relatively moved" be construed to encompass only the retraction of the needle into the body. Citing Bayer AG v. Elan Pharm Research Corp., 212 F.3d 1241, 1254 (Fed.Cir.2000), and Pharmacia & Upjohn Co. v. Mylan Pharm., Inc., 170 F.3d 1373 (Fed.Cir.1999), Becton explains that the court must use an objective test in determining whether certain claims were surrendered during patent prosecution. Becton further emphasizes that under Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349-50 (Fed.Cir.2004), claim terms must be interpreted in a way consistent with the terms' definition and usage in related patent applications. Becton argues that, in light of these principles, the "relatively moved" language of the reissue claims should be limited to mean solely the retraction of the needle into the body after use. Becton insists that to construe MBO's patent claims otherwise would effectively allow MBO to recapture the subject matter it disclaimed during patent prosecution.

The language of the claim is broad and ambiguous. I, therefore, turn to the specification and the prosecution history for clarification. The specification of the '885 patent is focused exclusively on the embodiment wherein the needle retracts into the body. '885 patent, abstract; col. 3, ll. 3-6; col. 6 ll. 45-59, 62-64; col. 7 ll. 3-6, 8-12; col. 8 ll. 13-15. As explained more fully above, I conclude that, under the circumstances of this case regarding the retraction limitation, the preferred embodiment is coextensive with the claims of the '885 patent. In addition, during the prosecution of the '699 patent, MBO sought to distinguish its movable needle from stationaryneedles disclosed in Bayless and Smith- both of which disclosed a stationary needle and a movable guard- by pointing out that MBO's invention had a movable needle. I determine, then, that the term "relatively moved," as well as the term "relative movement," found in claim 32, refers to the retraction of the needle into the body.

G. Claim 32

Claim 32 of the '885 patent provides:

A safety system comprising:

a needle having an axis, a proximal portion, and a distal portion terminating in a pointed end, a needle pointed end shielding body configured to receive the needle and to enable relative axial slidable movement of said body and said needle, said needle and said body being movable relative to one another between a first position and a second position, said needle and said body in said first position thereof having said distal portion of said needle and said pointed end thereof extending forwardly of said body for use outwardly of said body and in said second position thereof having said needle pointed end in said body, a movable safety

device cooperatively associated with said needle and *mounted on said body* for blocking emergence of said needle pointed end forwardly of said body subsequent to *relative movement* of said needle and said body into said *second position,* said safety device including (1) an imperforate blocking flange disposed forwardly of said needle pointed end when said needle and said body lie in said *second position,* and (2) a spring for moving said flange in a needle blocking direction transversely of said body into a position blocking emergence of said needle pointed end forwardly of said body.

'885 patent, col.16, ll. 23-49 (emphasis added). The claim terms in dispute have been emphasized in the passage quoted above.

(A) "mounted on said body"

[29] MBO insists that the term "mounted on" should be construed to mean "attached to" something or "fixed securely to a support." Becton claims that the words "mounted on" should be construed to mean "attached to the exterior surface of the body."

The claim language unambiguously indicates that the disputed term should be interpreted to mean "attached to the exterior surface of the body." In addition, the drawings of the '885 patent uniformly display a blocking flange that is attached to the exterior surface of the body. Furthermore, in describing the spring and the flange, the preferred embodiment explains that the gripping legs of the spring "snap past the body projections 94, and positively hold the spring on the body with no chance or [sic] accidental removal." '885 patent, col. 6, ll. 10-12. I, therefore, construe the term "mounted on" to mean "attached to the exterior surface" of the body.

H. Claim 33

Claim 33 of the '885 patent provides:

A needle system according to claim 32 wherein flange is positioned relative to said needle to prevent *relative movement* of said needle and said body from said second position into said first position.

'885 patent, col.16, ll. 50-53 (emphasis added). The claim term in dispute has been emphasized in the passage quoted above. The disputed claim term has been construed above in connection with claim 27. I attribute to it in this claim the same meaning as it has in claim 27. *See* Georgia-Pacific Corp., 195 F.3d at 1331 (explaining that the same word in a patent has the same meaning).

Summary

In summary, and as described in greater detail above, I construe the disputed terms as follows:

(1) **immediately**-simultaneously with the needle's withdrawal from the donor;

(2) **slidably receiving**-a movable needle retracts into a stationary body;

(3) **adjacent**-the protective blocking flange is contiguous or connected with the forward face of the body;

(4) **immediate proximity, proximity**-the protective blocking flange is flush with the body;

(5) **relatively moved, relative movement**-the needle is retracted into the body;

(6) **mounted on said body**-the protective blocking flange is attached to the exterior surface of the body.

SO ORDERED.