THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

SYNTHON IP, INC.,	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 1:05cv1267**
	)	
PFIZER INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

In this patent infringement suit, plaintiff Synthon IP, Inc. (Synthon) alleges that a commercial process used by defendant Pfizer Inc. (Pfizer) to make the pharmaceutical compound amlodipine — the active ingredient in Pfizer's well-known hypertension drug Norvasc® — infringes two patents owned by Synthon, namely U.S. Patent Nos. 6,653,481 (the '481 patent), a process patent, and 6,858,738 (the '738 patent), a derivative compound patent. As typically occurs in patent infringement suits, the parties dispute the meaning of several terms and phrases used in the patent claims in issue, thereby necessitating *Markman*[1] claim construction determinations, the results of which are recorded here.

I.

The record reflects that Pfizer is the owner of U.S. Patent No. 4,572,909 (the '909 patent), a twenty-year old patent relating to the pharmaceutical compound amlodipine. Amlodipine is used in the management and treatment of hypertension and angina pectoris and is the active ingredient in Norvasc®, a popular drug manufactured and sold by Pfizer.

[1] *Markman v. Westview Instruments*, 517 U.S. 370 (1996) (holding that the question of disputed claim terms is a question of law).

Synthon, in turn, is the owner of the '481 and '738 patents, issued on November 25, 2003, and February 22, 2005, respectively. Both the '481 and '738 patents purportedly "relate[] to novel intermediates useful in the synthesis of amlodipine and related compounds as well as to processes of making and using the same," as set forth in the patents' essentially identical specifications. The '481 patent is a 24-claim process patent relating to a process for making amlodipine using, *inter alia*, the "compound of formula (3)," one of the alleged "novel intermediates" referenced in the specification. The '738 patent, a divisional of the '481 patent, is, by contrast, a product patent comprised of 8 claims, all directed at the "compound of formula (3)" itself.

In this action, Synthon alleges that Pfizer's process for making amlodipine, a process Pfizer has allegedly used to make Norvasc® in the United States since at least 1992, infringes claims 1-4, 10-14, 18 and 20-24 of the '481 process patent, as well as all 8 claims of the '738 product patent. Pfizer, in turn, denies infringement and, as is typical in patent infringement suits, challenges the validity of the '481 and '738 patents. Pfizer also contends that the patents are unenforceable as a result of Synthon's alleged inequitable conduct in the course of the administrative proceedings before the Patent and Trademark Office (PTO). As a threshold issue, however, the parties dispute the meaning of various terms and phrases used in the patent claims in issue. Specifically at issue here are certain terms used in claims 1, 3 and 13 of the '481 patent as well as claim 2 of the '738 patent.

Central to the claim construction task is, of course, an understanding of the patents in issue. Both patents in suit relate in general to a chemical compound referred to in the patents and their file histories as "the compound of formula (3)," an organic compound that is integral to the process of producing amlodipine. The patents assert that this compound is "a new starting material" or a "novel intermediate" in the amlodipine production process.

As the patents teach, the compound of formula (3) may be produced by reacting two starting materials — one an ester or ketoester, and the other an aldehyde — in a solvent, such as isopropanol, in the presence of a catalyst, such as piperidine. This reaction creates a "crude reaction mixture" and results in the formation of the compound of formula (3), which is included within the crude reaction mixture and which, the '481 patent teaches, must then be "isolated" from that mixture. The '481 patent further teaches that the isolated form of the compound of formula (3) is then reacted with another organic compound — an aminocrotonate — to form the compound of formula (2). In this regard, the compound of formula (2), or phthalimidoamlodipine, is a protected amlodipine compound. In other words, the compound of formula (2) is essentially identical to the amlodipine compound itself, except that it also contains a phthalimide protecting group. The '481 patent thus teaches that the phthalimide protecting group is ultimately removed from the compound of formula (2) by using a deprotecting agent — namely an aqueous solution of methylamine — thereby resulting in the formation of the amlodipine compound.

With respect to the specific claims involved here, the '481 patent purports to disclose and teach in claim 1, its sole independent claim, "[a] process, which comprises **isolating from a crude reaction mixture compound of formula (3)**." The compound of formula (3) is then chemically depicted in claim 1 as follows, with R_2 representing a C_1 - C_4 alkyl group:

Claim 1 then describes "reacting said **isolated compound of formula (3)** with an alkyl 3-aminocrotonate of formula B." Formula B, in turn, is pictorially and chemically illustrated as follows, wherein R_1 again represents a C_1 - C_4 alkyl group:

Finally, claim 1 teaches that this reaction of the "**isolated compound of formula (3)** with an alkyl 3-aminocrotonate of formula B" results in the formation of a compound of formula (2), chemically depicted as follows:

The remaining claims of the '481 patent are dependent claims that add certain steps to the claimed process pertaining to the "deprotection" of the compound of formula (2) to form the "compound of formula (1)," and then ultimately the desired pharmaceutical compound amlodipine. For example, claim 2, which depends from claim 1, provides that the process "further comprises deprotecting said compound of formula (2) to form a compound of formula (1)." Formula (1), in turn, is pictured in claim 2 to have the following organic makeup, wherein R_1 and R_2 again both

represent C_1 - C_4 alkyl groups:

Claim 3, also a dependent claim, goes on to provide that the process according to claim 2 "further comprises **isolating** the compound of formula (2) before said deprotecting step." Claim 13, in turn, depends from claim 12 and includes identical language to that set forth in Claim 3, providing that the process according to claim 12 "further comprises **isolating** the compound of formula (2) before said deprotecting step." None of the remaining claims of the '481 patent are at issue here.

Unlike the '481 patent, which pertains to the process for making amlodipine using, *inter alia*, the "isolated compound of formula (3)," the '738 patent is a derivative patent directed at the "compound of formula (3)" itself. The '738 patent consists of 8 claims, 7 of which are dependent on claim 1, which describes "[a] compound having the formula (3)." As in the '481 patent, the chemical makeup of the compound of formula (3) is depicted in the '738 patent as follows, with R_2 again representing a C_1 - C_4 alkyl group:

And of particular significance here, claim 2 of the '738 patent, which depends from claim 1, requires "[t]he compound according to claim 1" to be in "**isolated form**."

The parties dispute the meaning of only five terms and phrases used in the claims in issue in the two patents. These five disputed terms, bolded in the above brief description of the patent claims, are the following:

(i) "**crude reaction mixture**," used in claim 1 of the '481 patent;

(ii) **"isolating from a crude reaction mixture compound of formula (3)**," used in claim 1 of the '481 patent;

(iii) **"isolated compound of formula (3),"** also used in claim 1 of the '481 patent;

(iv) **"isolating,"** used in claims 1, 3 and 13 of the '481 patent; and

(v) **"isolated form,"** used in claim 2 of the '738 patent.

II. Claim Construction

A. Legal principles

Markman v. Westview Instruments, 517 U.S. 370 (1996) was a watershed event in patent infringement litigation, the Supreme Court holding there that the construction of patent claims is a matter of law exclusively for the court.[2] Post-*Markman* Federal Circuit authority over the last decade has elucidated the methodology for district courts to follow in construing patent claim terms. This

[2] *See also Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999) (recognizing that the construction of patent claims is a question of law and it thus falls upon district courts to discern the meaning of the claim language); *Cybor v. FAS Technologies, Inc.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998) (en banc) (recognizing that the construction of patent claims is purely an issue of law and does not involve subsidiary or underlying questions of fact). It follows from this that appellate review is *de novo*. *See id.* Judge Mayer, concurring in the *Cybor* judgment, argued, as he has consistently argued since *Markman*, often in dissent, that factual determinations underlie the claim construction effort and that these should be reviewed more deferentially. *Id.* at 1464-65 (Mayer, J., concurring).

authority teaches that the principal guide in the interpretation of claim language must be the so-called intrinsic evidence, which includes the patent claims themselves, the patent specification, including drawings, as well as the patent's prosecution history, which itself is often colloquially referred to as the "file wrapper." *See Hockerson-Halberstadt, Inc. v. Avia Int'l, Inc.,* 222 F.3d 951, 955 (Fed. Cir. 2000); *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996).

Importantly, claim construction must proceed without regard to the putative infringing product or process and without regard to the consequences of claim construction on any infringement disputes. As the Federal Circuit put it, "[a] claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, not in light of the accused device." *SRI Int'l v. Matsushita Electric Corp. of America*, 775 F.2d 1107, 1118 (Fed. Cir. 1985). Indeed, it is only after the patent claims have been construed without reference to the accused device or process that the claims, as so construed, are then applied to the accused device or process to determine whether infringement exists. *See id.*[3]

Analysis of the intrinsic evidence must focus first on the patent claims themselves. *See Hockerson-Halberstadt*, 222 F.3d at 955; *Vitronics*, 90 F.3d at 1582. Claim terms are to be accorded their ordinary and customary meaning unless it appears that the inventor clearly stated an alternative definition in the patent specification or file wrapper. *See Athletic Alternatives, Inc. v.*

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[3] While it is important that a district court construe the patent claims without reference to the accused device, it is typically the case that the parties will craft their proffered claim term definitions with an eye toward at least influencing, if not actually determining the infringement issue and district courts will often be aware of the infringement (or possibly validity) considerations that are driving the parties' positions on claim term definitional disputes. It is worth noting that while summary judgment on infringement or non-infringement is often appropriate after the disputed claim terms have been judicially defined, this need not always be so and indeed, triable issues of fact on the question of infringement may remain after the completion of the *Markman* claim construction process.

Prince Mfg. Inc., 73 F.3d 1573, 1578 (Fed. Cir. 1996). In other words, claim terms are given their plain meaning unless the inventor, "choosing to be his or her own lexicographer," uses terms in a manner other than their ordinary meaning and clearly discloses these special or alternative meanings in the patent specification or file history. *See Vitronics*, 90 F.3d at 1582; *Beachcombers v. Wildewood Creative Products., Inc.,* 31 F.3d 1154, 1158 (Fed. Cir. 1994). Absent such a lexicography, courts 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.[4] Technical terms are likewise taken to have the meaning that they would ordinarily have to people of ordinary skill in the field of the invention, "unless it is shown that the inventor used the term with a special meaning and that persons of skill in the field would so understand the usage." *See Pall Corp. v. Hemasure, Inc.*, 181 F.3d 1305, 1309

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[4] For a more recent treatment of the proper role of dictionaries in claim construction, see *Phillips v. AWH Corp*., 415 F.3d 1303, 1320-26 (Fed. Cir. 2005) (en banc). There, the Federal Circuit affirmed the vitality of *Vitronics* and the hierarchy of claim construction tools, namely the intrinsic evidence of (i) the claims, (ii) the specification and (iii) the prosecution history and then, only if necessary, the less objective and reliable extrinsic evidence. Also, *Phillips* marks a retreat from a line of cases according dictionaries primacy in claim construction. *Id.* at 1319-22; *cf. Texas Digital Systems, Inc. v. Telegenix, Inc*., 308 F.3d 1193, 1204-05 (Fed. Cir. 2002) (seeming to elevate the role of dictionaries).

Worth noting with respect to dictionaries is the distinction between ordinary usage dictionaries for words used in common discourse and technical dictionaries for terms as they may be understood by people of ordinary skill in the pertinent field of technology. The former are essentially an intrinsic tool of claim construction, as all persons, including inventors, patent examiners, lawyers, judges, etc., essentially carry around ordinary language dictionaries in their heads and resort to them chiefly for purposes of confirmation, elucidation or greater precision. Technical dictionaries (or ordinary dictionaries purporting to offer definitions of technical terms) are, by contrast, essentially extrinsic tools of claim construction akin, in effect, to expert testimony. As such, technical dictionaries should be used only if necessary after the intrinsic sources for claim construction have been exhausted, and even then, with an awareness of their less objective nature. As noted *infra*, however, extrinsic evidence in any form may be used by a district court not to resolve a claim term dispute, but to gain an understanding of the field of the invention.

(Fed. Cir. 1999).[5]

It is well-settled that "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). And the claims are to be read and understood in the context of the entire patent as would a person of ordinary skill in the art.[6] *See Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1373 (Fed. Cir. 2005) (recognizing that a "person of ordinary skill in the art is deemed to have read the claim term[s] in the context of the entire patent") (citing *Phillips*, 415 F.3d at 1313). Accordingly, in the claim construction exercise, "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." *Phillips*, 415 F.3d at 1314 (citing *Vitronics*, 90 F.3d at 1582).

An important principle in aid of claim construction is the doctrine of claim differentiation, which embodies "the common sense notion that ordinarily language of one claim should not be so interpreted as to make another claim, such as a claim dependent on the first claim, identical in scope." *See* 5A Donald S. Chisum, *Chisum on Patents*, § 18.03[6], at 18-523 (2005). Put more

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[5] Unless the inventor sets forth any special meaning in a glossary of terms or the specification, it is hard to see how such a special meaning could be discerned in most cases without resort to extrinsic evidence.

[6] Of course, it is not often that either patent examiners or district judges — persons charged with making certain judgments concerning the meaning and scope of a patent's claims — qualify as persons of ordinary skill in the art. Nor is it necessary that they be so qualified; rather, it is sufficient if patent examiners and district judges engage the science or technology involved and gain a general understanding of the essential principles underlying the patent subject matter. Typically, the intrinsic evidence, as elucidated by the parties' counsel, is sufficient for this purpose. But in those instances where the patent subject matter is especially complex and abstruse, district judges may consider extrinsic evidence (usually in the form of expert affidavits, tutorials or hearing testimony) in the quest to gain further assistance in understanding the underlying science or technology.

simply, claim differentiation is simply the presumption that separate claims are not mere duplicates of one another in scope and meaning, but are instead significantly different from one another in some way. *See Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304 (Fed. Cir. 2001); *Comark Communications, Inc. v. Harris Corp.,* 156 F.3d 1182, 1187 (Fed. Cir. 1998) (recognizing that the doctrine of claim differentiation presumes that there is "a difference in meaning and scope when different words or phrases are used in separate claims") (quoting *Tandon Corp. v. United States Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987)). The doctrine of claim differentiation therefore teaches that if the absence of such a difference in meaning or scope of two claims would render a claim superfluous, it is presumed that the difference between the claims is significant. *See Comark,* 156 F.3d at 1187. Equally important, however, is the principle that claim terms must be interpreted consistently throughout the patent claims. *See Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995). Indeed, "[b]ecause claim terms are normally used 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.

In the event the claim language alone is not dispositive of the claim construction task, analysis should focus next on the patent's specification, including the drawings, figures and examples depicting the preferred embodiments of the invention. The patent specification is "highly relevant to the claim construction analysis" and offers "the single best guide to the meaning of a disputed [claim] term." *Vitronics*, 90 F.3d at 1582. This is particularly true where the disputed claim terms are technical terms of art. *See Phillips*, 415 F.3d at 1315 (recognizing that "[t]he best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history"). Indeed, the patent specification is typically a district court's

principle source for gaining an understanding of the patent subject matter and the underlying science or technology.

Consistent with the principle that the patented invention is defined by the claims, it is axiomatic that limitations included in the specification, including functional limitations, cannot be imported into the claims where no such limitations exist in the claims. *See Burke, Inc. v. Bruno Independent Living Aids, Inc.,* 183 F.3d 1334, 1340 (Fed. Cir. 1999).[7] It is also fundamental that a patentee is entitled to claim his or her invention broadly and is not limited to a preferred embodiment disclosed in the specification. *See Dow Chemical Co. v. United States*, 226 F.3d 1334, 1341-42 (Fed. Cir. 2000); *Kemco Sales, Inc. v. Control Papers Co., Inc.*, 208 F.3d 1352, 1362 (Fed. Cir. 2000). In other words, the disclosure of a narrower embodiment of the claimed invention in the specification does not also serve to narrow the patent claims. *See Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347-48 (Fed. Cir. 1998). It is equally clear, however, that a proposed claim interpretation that would exclude the preferred embodiment would rarely, if ever, be correct. *See SanDisk Corp. v. Memorex Prods., Inc*., 415 F.3d 1278, 1285 (Fed. Cir. 2005) (quoting *Vitronics*, 90 F.3d at 1583).

Intrinsic evidence is not limited to the patent itself; it also includes the patent's prosecution history, colloquially known as the "file wrapper." Thus, district courts may also, and often do, refer to the patent's prosecution history in interpreting disputed claim terms. For example, the prior art cited in the prosecution history informs what the patent claims do not cover. *See Vitronics*, 90 F.3d

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[7] Courts have occasionally noted the tension between this principle and the principle that the specification is often the single best guide to the meaning of a disputed claim term. The Federal Circuit in *Phillips* declined an opportunity in that case to address this issue. *See Phillips*, 415 F.3d at 1328.

at 1583. Additionally, "[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. District courts therefore have broad power to look at the prosecution history to determine "the true meaning of language used in the patent claims," since this history may demonstrate the patentee's understanding and use of the relevant terms at the time of the application. *See Markman*, 52 F.3d at 980.

Importantly, however, the prosecution history may not be used to "enlarge, diminish, or vary the limitations in the claims." *Id.* Moreover, a patentee may not construe a claim term one way during prosecution in order to obtain allowance of the patent and then in a different way during litigation in order to obtain a finding of infringement. *See Rhodia Chimi v. PPG Industries Inc*., 402 F.3d 1371, 1384 (Fed. Cir. 2005); *Omega Eng'g Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323-26 (Fed. Cir. 2003); *Southwall,* 54 F.3d at 1576. Thus, an important "purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution." *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (quotations omitted).

If no ambiguity is found in the meaning of the patent claim terms after consideration of the intrinsic evidence, including the patent claims themselves, the specification and the prosecution history, then the claim construction inquiry is at an end and the term is accorded its unambiguous plain meaning. Yet, in those relatively rare instances where the intrinsic evidence is not sufficient to resolve ambiguities in the claim language, courts may resolve the dispute by reference to extrinsic evidence, namely material outside the patent and its file history, such as expert testimony and learned treatises. *See Vitronics*, 90 F.3d at 1583. In any event, trial courts may always consult extrinsic evidence in aid of understanding the general technology involved in the patent claims at issue, but

not to vary or contradict the patent claims. *See Phillips*, 415 F.3d at 1319-24*; Vitronics*, 90 F.3d at 1584 n. 6. Trial courts may therefore consult standard dictionaries and learned technical treatises, for example, "to better understand the underlying technology and may also rely on dictionary definitions when construing term claims, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1322 (quoting *Vitronics*, 90 F.3d at 1585); *see supra* n.4, n.6.

Ultimately, the interpretation to be given a particular patent claim term must be determined based on what the inventors actually intended to envelop within the claim. *See Renishaw PLC v. Marposs Societa Perazioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). And in this regard, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips*, 415 F.3d at 1316. These principles and canons of claim construction control the construction of the five claim terms at issue here.

B. Disputed terms

While the disputed terms and phrases appear in various forms in various claims throughout the patents in suit, the parties agree that their dispute boils down to the meaning of essentially only two terms. Specifically, the parties first dispute the appropriate definition to be accorded the phrase "**crude reaction mixture**," as used in claim 1 of the '481 patent. The parties also dispute the meaning of the term "**isolating**" and its various forms, as used in claims 1, 3 and 13 of the '481 patent and claim 2 of the '738 patent. Each of these disputed terms is separately addressed.

1. Crude Reaction Mixture

Although the parties initially disputed the meaning of the term "crude reaction mixture,"

found in claim 1 of the '481 patent, this dispute eventually evaporated in the course of the *Markman* hearing, with the parties ultimately reaching essential agreement as to this disputed term. Initially, Synthon proposed that the phrase "crude reaction mixture" should be defined as

> all components of a chemical reaction, including, but not limited to, product, impurities, unreacted starting materials, catalyst(s), and solvent.

Pfizer, in turn, originally proposed the following definition for "crude reaction mixture":

> a mixture of at least the compound of formula (3), any unreacted starting materials, and any side products.

Pfizer later expanded on this proposed definition in the course of the briefing schedule, acknowledging that the "crude reaction mixture...contains at least any unreacted starting materials (*i.e.*, the aldehyde and the ester), any solvent, catalyst and any potential side products that have been formed." The primary difference between the parties' proposed definitions was the level of detail to be used in describing the nature and relative quantities of the mixture's components.

In the end, the parties sensibly agreed that the phrase "**crude reaction mixture**," found in claim 1 of the '481 patent, is appropriately defined as:

> **"a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent**."

Synthon IP Inc. v. Pfizer Inc., 1:05cv1267 (E.D. Va. Mar. 17, 2006) (Transcript, pp. 20-21).[8] Significantly, this definition is consistent with the teachings of the specification, as the detailed description of the invention, as well as the various examples set forth in the specification, make clear

[8] While no mention is made of impurities in this agreed-upon definition, there seems to be little doubt that the parties also agree that the crude reaction mixture includes stray impurities imported into the mixture by its components.

that the "crude reaction mixture" contains not only the compound of formula (3), but also unreacted starting materials and side products, as well as a catalyst and a solvent.[9]

2. Isolating

The remaining dispute concerns the term "**isolating,**" which appears in various forms throughout the patents in suit, of which the following four are in dispute:

(i) "**isolating** from a crude reaction mixture compound of formula (3)," as used in claim 1 of the '481 patent,

(ii) "**isolated** compound of formula (3)," also as used in claim 1 of the '481 patent,

(iii) "**isolating**," as used in claims 1, 3 and 13 of the '481 patent, and finally

(iv) "**isolated** form," as used in claim 2 of the '738 patent.

While the parties, in the course of the claim construction proceedings, sensibly and correctly did not dispute two general points concerning the term "isolating " — namely that "isolating" (1) generally means "separating" and (2) does not equate to "purifying" — their fundamental dispute with respect to the meaning of this particular term in the context of the patents in issue never dissolved. And not surprisingly, this fundamental dispute was plainly driven by the parties' views on what definition would be most likely to lead to a victory on the hotly disputed infringement issue.

As an initial matter, the parties agree the term "**isolating**," standing alone, generally means "**separating**." Indeed, this equation of the terms "isolating" and "separating" finds firm support in

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[9] *See., e.g.,* '481 Patent, col. 6, ll. 18-20 ("Typically the reaction is carried out in a reaction *solvent*, preferably an organic solvent such as an alcohol, especially isopropanol ... in the presence of an organic base [or catalyst] such as piperidine or piperidine acetate.") (emphasis added); *id.*, col. 6, ll. 22-25 ("The *solvent* should be one in which the *compound (3)* product is only sparingly soluble, so that it may be separated from the rest of the *unreacted starting materials* and also from any potential *side products*") (emphasis added).

the specification where the terms are used interchangeably.[10] Moreover, this general definition of the disputed term is also confirmed by reference to a standard dictionary. *See Webster's Third New International Dictionary* 1199 (1993) (providing that the term "isolate" means, *inter alia*, "to separate (as a chemical compound) from all other substances"). Yet, despite their agreement as to the general meaning of the term "isolate," the parties advance sharply divergent views on what it means to isolate or separate the compound of formula (3) from the crude reaction mixture, as required by the patent claims and specification.

In its opening claim construction brief, Synthon proposed that "isolating from a crude reaction mixture compound of formula (3)" should be defined simply as "separating the compound of formula (3) from a crude reaction mixture," with the additional condition that "this does not require that compound (3) be separated from all of the components of the crude reaction mixture (i.e., **compound (3) need not be completely pure**)." Similarly, Synthon initially proposed that the phrase "isolated compound of formula (3)" should be defined as "the compound of formula (3) that has been separated from a crude reaction mixture," and that the "isolated form" of the compound of formula (3) "does not require that compound (3) be completely pure."

Pfizer's initial proposal bore some resemblance to Synthon's, but was in fact significantly different. According to Pfizer, the phrase "isolating from a crude reaction mixture compound of formula (3)" must be construed to mean "separating the compound of formula (3) from the other materials in the crude reaction mixture." In other words, Pfizer, unlike Synthon, specified in its

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[10] *See, e.g.,* '481 Patent Specification, col. 6, ll. 22-25 ("The solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be *separated* from the rest of the unreacted starting materials and also from any potential side products") (emphasis added).

original proposed definition that the compound of formula (3) was required to be "separated *from the other components* of the crude reaction mixture." Similarly, Pfizer argued that the essentially synonymous terms "isolated compound of formula (3)," found in the '481 patent, and "isolated form," found in the '738 patent, required that the compound of formula (3) not be mixed with other compounds. Thus, Pfizer's original proffered definitions suggested the result of the isolating or separating step had to be the **pure** form of the compound of formula (3).

These divergent positions raised the question whether the various forms of the claim term "isolating" require the compound of formula (3) to be in a completely pure state following isolation and, if not, whether the patent claims or specification reveal any quantifiable manner in which to limit or describe the level of impurities permitted to remain together with the compound of formula (3) following the "isolating" step. In this regard, following significant oral and written argument, the parties ultimately reached their second and final general agreement regarding the disputed term "isolating," namely that the act of "**isolating from a crude reaction mixture compound of formula (3)**" does not require that the resulting form of compound of formula (3) be completely pure. In other words, the parties are in agreement that the act of isolation is not akin to purification of the compound of formula (3). Indeed, the embodiments and examples of the claimed process and compound disclosed in the specification make unmistakably clear that the **isolated** form of compound (3) includes some level of impurities, including some amount of unreacted starting materials. In other words, the specification acknowledges that the **isolating** process need not result in a pure form of the compound of formula (3). To illustrate this point, Example 1 of the specification describes the formation of the compound of formula (3), in part, as follows:

> Two layers are formed in the reaction mixture; the upper one was separated and the lower organic layer was again washed with 200 ml

> of 2-propanol. The organic layer, containing the desired product, was evaporated to dryness in order to remove the residual solvent.
>
> Yield: 350 g (84%), as the mixture of cis and trans isomers (6:4). Content of 2-chlorobenzaldehyde less than 5%.

'481 Patent Specification, col. 15, ll. 1-7. This particular example makes clear that even after separation of "the organic layer" containing the intermediate compound of formula (3), followed by evaporation of that layer to dryness, a quantity of unreacted starting material, namely the 2-chlorobenzaldehyde, remains present with the compound of formula (3).

Nor is this the only intrinsic evidence that the patent distinguishes between **isolating** or separating on the one hand, and **purifying** on the other. The specification is explicit that purification is an optional step that can be performed *following* isolation, and not a result achieved during or as part of isolation.[11] In this regard, it is important to note that the act of purification is set forth in a separate dependent claim of the '481 patent, namely claim 19, describing "[t]he process according to claim 1, which further comprises purifying said isolated compound of formula (3) before said reacting step... ."[12] Thus, under the doctrine of claim differentiation, isolation and purification must necessarily be viewed as separate and distinct acts, as both parties now appropriately concede. *See Phillips*, 415 F.3d at 1314-15 (recognizing that "[t]he presence of a dependent claim that adds a

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[11] *See, e.g.*, '481 Patent Specification, col. 5, ll. 26-29 (stating that "[t]he compound (3) may be prepared in a sufficiently pure state and simply isolated from a crude reaction mixture by any conventional techniques. Such an isolated form of the compound (3) can be further purified if needed or used directly in the next synthetic step"); *id.*, col. 6, ll.34-38 (stating that "[p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and the remaining starting materials can be easily removed").

[12] Claim 20 of the '481 patent, also depending from claim 1, likewise adds the sole limitation that the "isolated compound of formula (3) is *not* purified before said reacting step." (Emphasis added).

particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim") (citations omitted).

Given the parties' agreement that isolating or separating the compound of formula (3) from the crude reaction mixture need not result in compound of formula (3) that is completely pure, the next step in the analysis is to resolve the parties' dispute as to whether the patent reveals some quantifiable measure for the amount of impurities permitted to remain following the step of **isolating** the compound of formula (3). Pfizer, for its part, suggests that only "minor" amounts of impurities, including unreacted starting materials, are allowable following the act of isolation. In this regard, Pfizer modified its originally proposed constructions of the disputed terms to specify that "isolating from a crude reaction mixture compound of formula (3)" means "separating the compound of formula (3) from the other materials in the crude reaction mixture, but that after separation, the compound of formula (3) may contain only minor amounts of impurities, including impurities that may have been components of the crude reaction mixture." In support thereof, Pfizer cites to a passage from one of the preferred embodiments set forth in the patents' specifications, which provides, in pertinent part, that "[p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only *minor amounts of impurities* and the remaining starting materials can be easily removed." '481 Patent Specification, col. 6, ll. 34-38 (emphasis added).

Yet, as Synthon correctly points out, other examples submitted during the course of the prosecution of the '481 patent confirm that the amount of unreacted starting materials and other impurities remaining following isolation of the compound of formula (3) from the crude reaction mixture can collectively reach levels as high as 40 percent. Moreover, the permissible levels of

impurities following isolation cannot, as Pfizer suggests, be viewed categorically as "minor," as such a limitation is not contained in the patent claims. And, in any event, to read into the patent an undefined quantitative limitation (*i.e.* "minor amounts") on the level of allowable impurities following isolation — particularly one that is not clear from the terms of the claims and specification — would serve not to clarify a claim term, but simply to add yet another ambiguity to the disputed claim term. Imposition of a quantitative limitation such as "minor" or "small" to describe the permissible amounts of impurities following isolation of the compound of formula (3) is therefore not warranted in this instance.

To resolve the parties' remaining dispute, Synthon next proposes that the term **"isolating from a crude reaction mixture compound of formula (3)**" should be defined as "separating the compound of formula (3) from the crude reaction mixture **by any conventional or known technique**," with the latter descriptive phrase deriving from the lengthy description of the invention set forth in the specification. *See* '481 Patent Specification, col. 5, ll. 26-28 (providing that "[t]he compound (3) may be prepared in a sufficiently pure state and simply isolated from a crude reaction mixture *by any conventional techniques*") (emphasis added); *id.*, col. 6, ll. 38-39 (providing that "[r]ecovery can be by *any known technique* and is typically accomplished by a liquid-liquid phase separation optionally with washing of the oil product") (emphasis added).

Although initially appealing, this proposed definition is ultimately unpersuasive. First, and most importantly, to read the requirement into claim 1 that isolation of the compound of formula (3) from the crude reaction mixture must be performed "by any conventional or known technique" would essentially import a functional limitation into the claimed process that is not expressly contained in the claims themselves. To do so would clearly be improper under well-settled *Markman*

principles. *See Burke,* 183 F.3d at 1340 (recognizing that limitations included in the specification, including functional limitations, cannot be imported into the claims where no such limitations exist in the claims). It is also significant to note that the phrase "by any conventional or known technique" is, by its nature, a term itself not free from ambiguity; a term with a meaning that changes over time. The universe of separation techniques that were considered "conventional" or "known" by persons skilled in the relevant art at the time the patents issued may not include techniques that are now, or in the future may become, conventional.

In the circumstances, given that neither parties' proposed definitions for the remaining disputed claim terms are appropriate in this instance — namely Pfizer's "minor impurities" argument nor Synthon's "conventional or known technique" argument — an independent resolution of the disputed claim terms must be reached in light of the intrinsic evidence. And in the end, a careful review of the claims, the specification and the prosecution history teaches, as Pfizer argues, that **isolating** the compound of formula (3) from the crude reaction mixture necessarily involves separating the compound of formula (3) from the other components of the crude reaction mixture, with some impurities permitted to remain following the act of isolation. Thus, the phrase **"isolating from a crude reaction mixture compound of formula (3)**," used in claim 1 of the '481 patent, is appropriately defined as:

> "**separating the compound of formula (3) from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation**."

Corresponding definitions for the related disputed claims terms and phrases naturally flow from this definition. Accordingly, the term "**isolated compound of formula (3),"** also used in claim 1 of the

'481 patent, refers to:

> **"the compound of formula (3) that has been separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation**."

This same definition can likewise be used to describe the term "**isolated form**." That is, the "**isolated form**" of the compound of formula (3), used in claim 2 of the '738 patent, means:

> **"the form of the compound of formula (3) that has been separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation**."

The above definitions derive first from the plain language of the claims themselves. In this regard, claim 1 of the '481 patent describes a process that begins with "isolating **from** a crude reaction mixture **compound of formula (3)**." This statement, standing on its own, plainly refers to separating the compound of formula (3) **from** the crude reaction mixture. Significantly, the claim language teaches that it is the compound of formula (3) that is to be separated from the crude reaction mixture; the claim language does not teach separating the solvent or any component other than the compound of formula (3) from the crude reaction mixture. Nor does the claim language refer to separating the compound of formula (3) from only a single component of the crude reaction mixture, such as the solvent. Instead, the plain language of the patent requires that the compound of formula (3) **itself** be separated **from** the crude reaction mixture, namely from the other components of the crude reaction mixture. In other words, were the compound of formula (3) left in a mixture with the other components of the crude reaction mixture — with the exception of any permissible amounts of impurities — it would not be isolated from the crude reaction mixture as

required by claim 1 of the '481 patent.[13]

This conclusion also comports with the relevant portions of the patents' specifications. In this regard, it should first be noted that despite the fact that the patents are clearly distinct from one another — one claims a process and one claims a compound forming one part of the underlying process — the specifications set forth in the '481 and '738 patents are virtually identical, including the examples set forth therein. This fact alone suggests that the applicants did not give careful, focused thought to the specification, as it might relate to each of the two distinct patents. But even more puzzling is the fact that only 3 of the 13 examples set forth in the specification even arguably pertain to isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this particular step in the claimed inventions.

Specifically, example 1 teaches that "[t]wo layers are formed in the reaction mixture; the upper one was separated and the lower organic layer was again washed with 200 ml of 2-propanol. The organic layer, containing the desired product, was evaporated to dryness in order to remove the residual solvent." *See* '481 Patent Specification, col. 15, ll. 1-5. Example 1A, in turn, provides that "[t]he solvent was decanted and the gum like solid washed with 2 x 5 ml of IPA...[and] the solvent was evaporated leaving an oil." *Id.* at col. 15, ll. 20-22. And finally, example 4 — which is essentially identical to example 1 with the exception that a methyl rather than an ethyl is used as a starting material — teaches that "[t]he isopropanolic layer was separated and the organic layer was again washed with 53 ml of 2-propanol. The organic layer, containing the desired product, was

[13] Synthon essentially conceded this point in the course of the prosecution history when it explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." *See infra* (discussion of prosecution history).

evaporated to dryness in order to remove the residual solvent." *Id.* at col. 17, ll. 31-34. Other than these three — 1, 1A and 4 — no other examples set forth in the specification describe isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this step to the claimed process and compound.

Significantly, the removal of the solvent reflected in each of these three examples serves to isolate the compound of formula (3) from only *one* component of the crude reaction mixture and leaves the compound of formula (3) remaining in a mixture with the other components. Put differently, the removal of the solvent taught in examples 1, 1A and 4 — the only examples contained in the specification arguably dealing with isolating the compound of formula (3)[14] — serves only to isolate the solvent, as opposed to the compound of formula (3), from the remaining components of the crude reaction mixture. Leaving the compound of formula (3) still mixed with the majority of the other components of the crude reaction mixture — in levels in excess of the permissible amount of impurities permitted to remain following isolation — cannot logically result in an "isolated form" of the compound of formula (3) consistent with the patent claims and specification. Indeed, to adopt this position put forth by Synthon would essentially deprive the "isolating" requirement of any significant meaning.

It is important to note that the relevant examples in the specification refer only to "the organic layer containing the desired product," rather than to the "isolated form" of the compound of formula (3), *i.e.*, the "desired product" itself. In fact, none of the examples set forth in the specification

[14] The remaining examples deal with subsequent steps in the amlodipine production process, including, *inter alia*, the formation of the compound of formula (2) and removal of the deprotecting agent.

specifically mention the isolating step or the isolation process.[15] And this is not surprising in the circumstances, given that the examples set forth in the specification are precisely those that were included in Synthon's original application to the PTO, prior to the insertion of the "isolating" requirement in the relevant claims. *See infra* (discussion of prosecution history). In fact, it appears from a review of the prosecution history that the specification was not changed, modified or updated in any respect following the "isolating" amendments, presumably to protect the applicant's priority date. For this reason, examples 1, 1A and 4 set forth in the specification are not particularly instructive or illuminating as to the meaning of the phrase "isolating from a crude reaction mixture compound of formula (3)."

In an unsuccessful attempt to mask this inherent weakness in the available examples, Synthon assiduously avoids referring directly to isolating or separating the compound of formula (3) itself, as required by the plain language of the relevant claims. Instead, Synthon, throughout is pleadings, refers repeatedly to isolating or separating the "organic layer" or "oily layer" containing the compound of formula (3).[16] But significantly, the relevant claims of the '481 and '738 patents teach neither isolating the "oily layer" containing the compound of formula (3) from the crude reaction

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[15] The absence of a clear and detailed description of the isolating step in the specification is plainly obvious in some instances, as where the specification provides, for example, that "it is an advantage of this process that...the isolation and purification of the intermediate (3) is not necessary." '481 Patent Specification, col. 6, ll. 43-46.

[16] *See, e.g.*, Synthon's Supplemental Claim Construction Brief (Docket #121), p.3 ("the patent references decanting (pouring off) of the solvent layers as one way to isolate the **oily layer** containing compound 3"); *id.* at p.4 ("[n]ot once does the specification suggest that the separated **oily layer** must contain a particular percentage of compound (3) as compared to other materials"); *id.* at p.4 ("there is only one reference in the entire patent to a particular percentage of any remaining starting materials or other impurities in the **oily layer** after isolation of compound (3)"); *id.* at p.5 ("one passage in the specification refers to the 'recovered' **oily layer**") (emphasis added).

mixture, nor isolating merely a layer of solvent from the crude reaction mixture. Instead, the claims at issue expressly require **isolating the compound of formula (3)** from the other components of the crude reaction mixture.

It is clear, then, that under claim 1 of the '481 patent, some act or step must be taken to separate the compound of formula (3) from the other components of the crude reaction mixture, which mixture the parties have agreed includes "any unreacted starting materials or side products or any catalysts or solvent." *See supra* p.14. Indeed, the specification also makes clear that the **isolating** step must involve more than removing the solvent from the crude reaction mixture, as it expressly states that "[t]he solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be **separated from the rest of the unreacted starting materials and also from any potential side products**." '481 Patent Specification, col. 6, ll. 22-25 (emphasis added). The specification further provides that

> [p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and **the remaining starting materials can be easily removed**. Recovery can be by any known technique and is typically accomplished by a liquid-liquid phase separation optionally with washing of the oil product. It should be understood that such washing is not intended to be considered a 'purification step,' but rather merely part of the recovery.

'481 Patent Specification, col. 6, ll. 34-43 (emphasis added). And significantly, the specification summarizes the invention by recognizing that "the use of the compound (3) of our invention...allows for a reduction in side products by producing a stable intermediate that is **easily separable from the rest of the reactive starting materials**, thereby reducing the chance of side effects in subsequent reaction steps." '481 Patent Specification, col. 8, ll. 53-61 (emphasis added). Given these statements in the specification acknowledging removal of the starting materials and other side products, it is

clear that merely pouring off from the crude reaction mixture a single layer of solvent, which Synthon contends is sufficient to meet the requirement of **isolating**, does not serve to separate the compound of formula (3) from the other components of the crude reaction mixture; rather, as illustrated above, this suggested step only serves to separate or isolate most of the solvent — typically isopropanol — from the crude reaction mixture, which mixture still contains the compound of formula (3).

The conclusion reached here is also consistent with the patents' prosecution histories, as well, which is plainly an important tool in claim construction. *See, e.g, Phillips*, 415 F.3d at 1317 (providing that "[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent").[17] Thus, the '481 file wrapper reflects that the original process claims of the '481 patent did not include the terms "isolating from a crude reaction mixture" or "isolated compound of formula (3)." In fact, in February 2003, the patent examiner rejected Synthon's asserted claim 18 — which ultimately matured into claim 1 of the '481 patent — as being anticipated by the prior art on the basis that the compound of formula (3) would be formed during the reaction steps of Pfizer's '909 patent. To overcome this rejection, Sython amended its application claim 18 to include the step of "**isolating** from a crude reaction mixture compound of formula (3)."[18] Significantly, this amendment served to distinguish the claimed process from the

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[17] *See also Microsoft Corp. v. Multi-Tech Sys., Inc.,* 357 F.3d 1340, 1349-50 (Fed. Cir. 2004) (recognizing that "[t]he prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application").

[18] In this regard, Synthon's original application claim 18 — prior to the addition of the "isolating" requirement — simply claimed "[a] process, which comprises reacting a compound of formula (3)...with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." Significantly, this form of application claim 18 was rejected by the patent examiner as being anticipated by the prior art, in that the compound of formula (3) referenced in application claim

prior art by making clear that the compound of formula (3) is required to be isolated or separated from the other materials of the crude reaction mixture prior to the next step of the claimed process.[19] The patent examiner thereafter allowed amended claim 18 on the ground that it "distincts from the art of record in that the starting material is novel," noting that "[a] process using a new starting material is patentable."

Likewise, in the course of the prosecution of the '738 patent, the patent examiner rejected application claim 2 for indefiniteness, noting that it was a "substantial duplicate" of claim 1 in that it did not "limit the compounds" of claim 1. In this regard, while application claim 1 covered "a compound having the formula (3)," application claim 2 covered the compound of claim 1 in "isolated form." In response to this preliminary indefiniteness rejection, the applicants stated the following:

> Claim 1 [of the '738 patent'] is directed to a compound *per se*. Accordingly it reads on the isolated, purified compound itself as well as the compound in compositions/mixtures with other ingredients. That is, claim 1 is not avoided simply because the compound of

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18 would be formed during the reaction steps of Pfizer's '909 patent. Synthon thereafter amended its application claim 18 to cover "[a] process, which comprises *isolating from a crude reaction mixture* a compound of formula (3)...*and reacting said isolated compound of formula (3)* with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." (Emphasis added). And, in its supporting amendment papers, Synthon noted, *inter alia*, that "[s]uch an isolation step is not taught or suggested in...[the] '909 [patent]."

[19] In this regard, the applicants submitted various amendment papers to the patent examiner in July 2004 providing, *inter alia*, as follows:

> [C]laim 18 as amended requires that the compound of formula (3) be isolated from a crude reaction mixture before being reacted with an amino crotonate. Such an isolation step is not taught or suggested in [the prior art] ...Why would a worker of ordinary skill in the art try to isolate an intermediate not shown or suggested to be isolated in [the prior art]? Clearly, such a modification is not suggested or rendered obvious by the teachings of [the prior art].

> formula (3) is contained in a mixture with other compounds. Certainly any composition that contained the compound of formula (3) falls within the scope of claim 1. In contrast, claim 2 requires the compound of formula (3) to be in isolated form. A composition that contains a compound of formula (3) and, e.g., phthalimidoamlodipine of formula (2) would avoid claim 2, but not claim 1. Claim 2 is not a substantial duplicate of claim 1. Indeed, there is no reason to read claim 1 as requiring the compound of formula (3) to be in isolated form. Therefore, claim 2 is a proper dependent claim of clear and definite scope.

(Emphasis added). In other words, and of particular significance here, the applicants explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients."[20] And significantly, this statement essentially amounts to an admission by Synthon that the compound of formula (3) is not "isolated" within the meaning of the relevant patent claims if it is still contained in a mixture with other ingredients or compounds. *See, e.g., Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (recognizing that "[t]he doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretations specific meanings disclaimed during prosecution").

In sum, the definitions reached here make clear that some impurities are allowed to remain together with the compound of formula (3) following the isolation process, as the parties concede. But more importantly, by including the phrase "residual amounts of the other components," the definition also accurately requires that the compound of formula (3) be separated, at least to some

[20] Following the applicant's clarification in this regard, the patent examiner withdrew the earlier indefiniteness rejection and allowed application claim 2 of the '738 patent.

extent, from the other components of the crude reaction mixture.[21] Nothing in the patent claims or specification provides any basis to quantify more specifically the amount of impurities or the residual amounts of the other components of the crude reaction mixture that are permitted to remain following isolation of the compound of formula (3).

At this point in the litigation, it is unclear whether the claim term definitions arrived at here will be dispositive of the infringement issues by way of summary judgment. While this sometimes occurs, it need not occur, as this is not the goal or purpose of the *Markman* claim term definition process. In other words, while the definitions reached here may not be immediately dispositive of the infringement issues in this case, they need not be so; such a resolution is not the purpose of a *Markman* proceeding. Rather, it is only after the patent claims have been construed under *Markman* without reference to the accused device or process that the claims, as so construed, are then applied to the accused device or process to determine whether infringement exists. *See SRI*, 775 F.2d at 1118. It is equally clear that circumstances arising in the course of the subsequent summary judgment and/or trial proceedings in this matter may warrant further refinement or clarification of the preliminary *Markman* determinations recorded here.[22]

_____/s_____
T. S. Ellis, III
United States District Judge

Alexandria, VA
June 30, 2006

[21] Indeed, a standard dictionary defines the word "residual," in pertinent part, as "remaining after a part is taken." *See Webster's Third New International Dictionary* 1931 (1993).

[22] It should also be noted that while the intrinsic evidence was determinative of the parties' disputes in this instance, these and any earlier disputes concerning the terms set forth in the '481 and '738 patents would likely have been avoided from the outset had the inventors of the patents in issue been required to submit an approved lexicography in the course of the prosecution history.