United States District Court,
S.D. Florida, Miami Division.

NOVARTIS CONSUMER HEALTH INC,
Plaintiff.
v.
ELAN TRANSDERMAL TECHNOLOGIES, INC,
Defendant.
Elan Transdermal Technologies, Inc., Elan Transdermal Limited,
Counterclaimants.
v.
Novartis Consumer Health, Inc,
Counterclaim Defendant.

No. 01-1120-CIV

May 10, 2002.

Harvey W. Gurland, Jr., Duane Morris, MIAMI, FL, James Galbraith, Jeffrey Ginsberg, Thomas J. Meloro, Kenyon & Kenyon, New York, NY, for Plaintiff/Counterclaim Defendant.

Flavio Rose, Gary N. Frischling, Jon D. Gingrich, Marc A. Fenster, Morgan Chu, Richard Birnholz, Irell & Manella, Los Angeles, CA, Eugenia Chu, Terri Ellen Tuchman Meyers, Kluger Peretz Kaplan & Berlin, Miami, FL, for Elan Transdermal Technologies, Inc., Elan Transdermal Limited.

ORDER

K. MICHAEL MOORE**, District Judge.**

THIS CAUSE is before the Court for a claim construction ruling pursuant to Markman v. Westview Instruments, 517 U.S. 370, 116 S .Ct. 1384 (1996). The Court held a *Markman* hearing on April 24, 2002. At the hearing, the parties presented the disputed language in both Novartis's U.S. Patent No. 5,834,011 ("the '011 patent") and Elan's U.S. Patent No. 4,946,853 (the "'853 patent").

BACKGROUND

Novartis, a Delaware corporation which develops and produces, *inter alia,* nicotine patches to aid in smoking cessation, brought this action against Elan Transdermal Technologies, Inc. ("Elan"), a Florida corporation which also develops and produces nicotine patches. Novartis brought this suit on the grounds of patent infringement, based on Elan's alleged infringement of U.S. Patent No. 5,834,011 ("the '011 patent"). *See* Pl's. Compl. para. 4. According to the Plaintiff's complaint, the '011 patent describes and claims a method of assisting a person to quit smoking by transdermally administering nicotine via a nicotine patch. Id. at para. 5. Elan, along with Elan Transdermal Ltd., counterclaimed alleging that Novartis's Habitrol

Nicotine Patch product infringes Elan's U.S. Patent No. 4,946,853 (the "'853 patent").

Novartis's '011 patent makes one claim for "a method of assisting a person to quit smoking, comprising transdermally administering nicotine via a dermally applicable patch adhered to the skin at a dosage rate approximately the same as provided when absorbing nicotine by smoking." *See* '011 patent, col. 18, lines 10-15. The parties dispute the meaning of (1) "dosage rate," (2) "transdermally administering nicotine," and (3) "dermally applicable patch."

Elan's '853 patent makes a number of claims but the claims at issue are numbers 33 and 39. *See* '853 patent, col. 14, lines 13-23 & 43-52. FN1 The language in dispute states that "nicotine is distributed in a sold, semi-solid, or mucilaginous medium." The parties disagree about the meaning of (1) "distributed," and (2) "mucilaginous medium."

FN1. Claim 33 reads in its entirety: "A method of treating withdrawal symptoms associated with smoking cessation, which method comprises administering once-daily, percutaneously to a person in need of said treatment an amount of nicotine sufficient to maintain in said person plasma levels of nicotine substantially equivalent to trough plasma levels resulting from intermittent smoking, wherein said nicotine is distributed in a solid, semi-solid or muciloginous medium which is effective to permit controlled release of said nicotine to the skin." Claim 39 reads "A method for combating the psychological dependence that occurs through frequent smoking, which method comprises administering once-daily, percutaneously to a person in need of said treatment an amount of nicotine sufficient to maintain in said person plasma levels of nicotine substantially equivalent to trough plasma levels resulting from intermittent smoking, wherein said nicotine is distributed in a solid, semi-solid or mucilaginous medium which is effective to permit controlled release of said nicotine to the skin."

CLAIM CONSTRUCTION

Claim construction is a matter of law for the Court to decide. *See* Markman, 517 U.S. 370, 116 S.Ct. 1384. In construing the language of a patent claim, the Court must first "look to the words of the claims themselves ..." Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The Court should also "review the specification to determine whether [within the claim] the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Id*. The Court "may also consider the prosecution history of the patent" because it may contain "express representations made by the applicant regarding the scope of the claims." *Id*. Lastly, the Court may consider extrinsic evidence, such as the dictionary definitions of the relevant terms if the intrinsic evidence does not "unambiguously describe the scope of the patented invention." *Id*. at 1583. The Court begins its discussion with Novartis's '011 patent.

I. Novartis's '011 Patent

Novartis's '011 patent makes one claim for "a method of assisting a person to quit smoking, comprising transdermally administering nicotine via a dermally applicable patch adhered to the skin at a dosage rate approximately the same as provided when absorbing nicotine by smoking." *See* '011 patent, col. 18, lines 10-15. The major dispute in this claim construction centers around what dosage rate Novartis claims in this patent.

1. "dosage rate"

Elan argues that the dosage rate should be construed to require individualization. In other words, Elan interprets the patent to mean that dosage rates should be custom tailored to each patient based on his or her unique smoking pattern. Elan bases its interpretation on language from the claim and the specification. FN2 The cited language, however, simply does not suggest that Novartis's claim requires individualization. All the language cited by Elan could just as fairly be interpreted to require that different patches be designed for different typical groups of smokers (e.g. light, medium and heavy smokers). In fact, Elan presents only one paragraph of the specification which in any was suggests individualization. FN3 *See* ' 011 patent, col. 6, lines 26-44.

FN2. Elan cites the following language: "A method of assisting *a person* to quit smoking, comprising transdermally administering nicotine via a dermally applicable patch adhered *to the skin* ....;" 011 patent, col. lines 18, 10-15 "It is another object of the present invention to provide a method for allowing transdermal administration of the nicotine from a patch to the bloodstream at various time intervals which approximate *the normal smoking pattern of an individual* " id. at col. 3, lines 1-5 "By applying nicotine in a level approximating that obtained by the smoker's normal smoking patterns, there is a reduced need for the smoker to obtain nicotine as a result of tobacco smoking ...;" id. at col. 4, lines 9-14 "the nicotine in the patch is allowed "to transdermally migrate into the person's bloodstream at a rate sufficient to correspond to the nicotine level in the blood normally achieved by *that user's* smoking patterns." Rose Decl. at 29-30 (Emphasis added by Elan).

FN3. This paragraph reads "Various modifications to the patch can be made in order to vary the dose and rate of nicotine absorption into the users bloodstream. It is important to provide a patch such that nicotine administration can approximate the level of nicotine in the bloodstream of the user which is normally achieved through tobacco smoking. One of the techniques which can be used in order to determine nicotine levels in the bloodstream as a result of smoking is to measure the actual nicotine levels in the bloodstream immediately after the smoking of a cigarette. These measurements can be made several times over a typical day of the smoking, including prime points immediately before and after the smoking of the cigarettes ... The transdermal patch and the method of use therefore can be conveniently and easily tailored to the particular user." '011 patent, col. 6, lines 26-44.

The language of this paragraph, however, suggests that the patch will not generally be customized but "modifications ... can be made" for customization if so desired. Simply because the patch "can be" custom tailored to a particular user does not suggest that it must be. The language of the cited paragraph supports the interpretation that customization is only one option. The fact that this is the only paragraph in the entire specification which directly mentions customization supports this interpretation. Additionally, this interpretation is supported by the use of the word "approximately" in the text of the claim itself, which suggests that the patch will not be able to exactly replicate the natural levels of nicotine in any given user's bloodstream. In sum, nothing in the language of the claim, specification or prosecution history suggests that Novartis's claim be limited to individualization, and the Court declines such an interpretation.

Elan suggests then that the Court should construe the dosage rate in Novartis's claim to be limited to between 25 and 42 nanograms of nicotine per milliliter (ng/ml) of blood. Elan bases this interpretation on one of the nine examples in the '011 specification, which states that such levels are "comparable to those produced by smoking." *See* '011 patent, col 10, 54-63. FN4 However, the example cited by Elan does not state or even imply that other levels would not also be comparable to those produced by smoking. Thus,

while the language in this example does suggest that Novartis's claim should be interpreted to *include* nicotine levels between 25 and 42 ng/ml, it does not suggest that the claim should be limited to such levels.

FN4. The example actually describes the nicotine level in terms of "salivary nicotine content," however, Elan has translated the numbers into the equivalent blood nicotine level and Novartis does not dispute the accuracy of such translation.

Moreover, the conclusion that the dosage rate should be limited to 25 to 42 ng/ml, conflicts with other language of the specification which states "at the start of a smoking reduction program it is desired to have about *ten* nanograms of nicotine per milliliter in the persons blood stream." '011 patent, col. 7, lines 51-59 (emphasis added). It makes little sense to suggest that Novartis would state ten nanograms per milliliter was the most desirable dosage, and then within the same document, limit its claim to dosage levels three to four times higher than that desirable dosage. Thus, this Court can not interpret Novartis's claim to be limited to doses between 25 and 42 ng/ml.

Elan argues that if neither of these interpretations is adopted, the language describing the dosage rate must be considered fatally indefinite. Once a patent has been issued, however, it is presumed valid, and the accused infringer bears the burden of demonstrating invalidity by clear and convincing evidence. *See* North Am. Vaccine, Inc. v. Am. Cyanamid Co., 7 F.3d 1571, 1579 (Fed.Cir.1993). If possible, claims should be construed to sustain their validity. *See* ACS Hosp. Systems, Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed.Cir.1984).

The Federal Circuit has made it clear that claims may be drafted in functional terms when the terms are "reasonably precise in light of the subject matter" asserted. *See Exxon Research & Eng'g Co. v. United States,* 265 F.3d 1379 (Fed.Cir.2011) (finding that a claim stating a catalyst must be treated "for a period sufficient" to attain a 30% increase in catalyst productivity was not indefinite); Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576 (Fed.Cir.1986) (finding that claim language stating that a product must be "so dimensioned" as to fit within a certain part of a car was not indefinite); *see also* W.L. Gore & Assoc, Inc. v. Garlock, Inc., 721 F.2d 1540, 1557 (Fed.Cir.1983); Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1557 (Fed.Cir.1996), *cert. denied,* 18 U.S. 1005, 116 S.Ct. 2523, overruled on other grounds, Festo Corp. v. Shoketsu Kinzoku KogyoKabushiki Co., Ltd., 234 F.3d 558, 574 (Fed.Cir.2000). In the present case, Novartis's claim is drafted in functional terms, stating that the dosage rate at which nicotine will be administered transdermally should be "approximately the same as provided when absorbing nicotine by smoking." '011 patent, col. 18, lines 10-15.

The test to determine whether a patent term defined in functional terms fails for indefiniteness is "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1217 (Fed.Cir.1991); *Exxon Research,* 265 F.3d at 1377; Modine Mfg. Co., 75 F.3d 1545, 1557. It is clear to the Court that experts can provide answers as to how much nicotine is absorbed by smoking. In fact, both parties provided evidence regarding how much nicotine is absorbed into the bloodstream through smoking. *See e.g.,* Benowitz, et. al, Clin. Pharmacol. Ter. (1982). Thus, the Court finds that one skilled in the art of this patent would likely understand the meaning of this phrase in light of the specification and thus the claim is not indefinite.

Moreover, the use of the word "approximately" does not render a claim indefinite. *See* Andrew Corp. v. Garbriel Elecs., Inc., 847 F.2d 819 (Fed.Cir.), cert. denied, 488 U.S. 927 (1988) (holding that phrases "close

to," "substantially equal," and "closely approximate" do not necessarily render a claim indefinite); Rosemount Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1546-47 (Fed.Cir.1984) (finding that phrase "close proximity" did not render a claim indefinite); Seattle Box Co. v. Indus. Crafting & Packing, 731 F.2d 818, 826 (Fed.Cir.1984) (holding that phrase "substantially equal" did not render claim indefinite); W.L. Gore & Assoc, Inc. v. Garlock, Inc., 842 F.2d 1275, 1280 (Fed.Cir.1988) (finding that term "about" did not render a claim indefinite); Modine Mfg. Co., 75 F.3d at 1557 (holding that the phrase "relatively small" diameter was not indefinite). These cases teach that the degree of precision with which claims must be stated in order to meet the definiteness requirement is a "function of the nature of the subject matter." *See* Miles Labs. Inc. v. Shandon Inc., 997 F.2d 870, 875 (Fed.Cir.1993). Again, what really matters is whether those skilled in the art would understand what is claimed. Amgen Inc., 927 F.2d at 1217.

In this case, both parties acknowledge that there is some variation amongst smokers in the amount of nicotine they absorb through smoking and the studies presented by the parties reflect this conclusion. Elan, itself, has described its patch in general functional terms as well, stating that it allows the maintenance of "plasma nicotine concentrations *comparable* to those produced by cigarette smoking." Mulligan et al., *Clinical and Pharmacokinetic Properties of a Transdermal Nicotine Patch,* 47 Clin, Pharmacol. Ther. 33, 336 (1990) (emphasis added).FN5 Thus, the Court finds that based on the nature of this subject matter, the use of the word "approximately" is reasonable.

FN5. Moreover, in defending a South African counterpart to the ' 853 patent, a board member of the Elan Corp. and "instructing attorney in respect of all Nicotine patch litigation," stated "[I]t would have been impossible for me to define this invention accurately by simply saying 5 to 15 nanograms per milliliter is the [blood nicotine] trough level, because Mr. X wearing one of my patches, might be one of these individuals who has a trough level of 25. Mr. Y might have a trough level of 2 ... so we gave ranges [in the specification] that are commonly accepted, but you had to use the functional term."

Furthermore, the Court construes the word "approximately" in the '011 claim to indicate that while Novartis's patch will provide a level of nicotine that falls somewhere within the range that would naturally be produced "when absorbing nicotine through smoking," Novartis does not claim that the patch will perfectly replicate any individual's exact normal nicotine absorption. In other words, the word "approximately" distinguishes the claim from one which achieves perfect individualization or customization. *See* Amendment mailed April 6, 1992 at 6 ("it is important to provide a patch such that nicotine administration can approximate the level of nicotine in the bloodstream of the user which is normally achieved through tobacco smoking."); Amendment mailed Oct 7, 1997 at 3 ("[The claim] is generalized, as it should be, and the generalized word "approximately" is properly utilized ... the claim is generalized with respect [to] dosage rate and, rightfully, encompasses short-term patches as well as long-term patches as long as the dosage rate is approximately the same as provided when absorbing nicotine by smoking, as set forth in the claim;") Amendment mailed October 7, 1997 at 3 ("[T]he claim is not directed to a particular brand of cigarette, or whether it is filter or non-filter or whether the smoker is a deep inhaler or a light puffer .")

While ideally the Court could determine at this stage specifically what range of nicotine levels are covered by the claim, the fact that the Court is unable to so does not render the claim indefinite. The Court's inability to construe a specific range at this stage is the result of the limited data provided thus far by the parties. First, the only data provided by the parties is in graph form, rather than numerical form, preventing the Court from determining an exact numerical range. Second, the parties have not made it clear to the Court during what times it can fairly be said the bloodstream is "absorbing" nicotine. In other words, the Court

cannot determine whether a smoker's bloodstream continues to absorb nicotine after he finishes smoking or when he goes to sleep. This information, which would no doubt be obvious to an expert, is necessary to interpret the graphs provided by the parties. Third, it is not clear to the Court whether the studies provided by the parties fairly represent nicotine absorption by a full range of smokers. If the studies were done using special high-nicotine cigarettes, or involved smoking unusually large numbers of cigarettes,FN6 they may not be representative of the levels of nicotine that would be absorbed by a full range of smokers. Most importantly, however, the parties have not yet provided the Court with any expert testimony, which is certainly required to resolve the issue. Thus, the Court must leave the determination of the range of nicotine levels in smokers to the experts.

FN6. There was a suggestion that at least one study involved participants smoking 30 cigarettes a day, which may be representative of some smokers but cannot fairly represent the full range of smokers.

Therefore, the Court adopts Novartis's proposed construction, which is essentially the same as the actual language of the claim.FN7 The meaning of "the level of nicotine in the person's bloostream achieved through tobacco smoking" will be determined at trial or on summary judgment through the use of expert testimony. Besides empirical studies and other sources, these experts should consider the language in the specification which suggests that 25-42 ng/ml is within the acceptable range, as well as the language in the claim which suggests that 10 ng/ml is within the range, in developing an opinion as to what nicotine levels are covered by this claim.FN8

FN7. Novartis's proposed construction is "the delivery of nicotine into a persons bloodstream at a level that approximates the level of nicotine in the person's bloodstream achieved through tobacco smoking."

FN8. Elan also argues that Novartis disclaimed blood levels below "roughly 15 ng/ml" during the prosecution. Elan basis this argument on the fact that Novartis said its invention substitutes not for a cigarette but for the habit of smoking and therefore "requires a rate sufficient to correspond to the level in the blood achieved by smoking, not simply by a single cigarette." Elan argues that because blood levels of nicotine "immediately after smoking a cigarette" are roughly 15 ng/ml, Novartis disclaimed all lower levels. However, it is possible that Novartis was distinguishing a cigarette from the habit of smoking, in that a cigarette produces a certain blood level nicotine which then dissipates, however the habit of smoking causes a more consistent rate of nicotine in the bloodstream throughout the day. Thus, the comment does not necessarily suggest an intent to disclaim levels below 15 ng/ml. Moreover, Elan fails to present any evidence that the blood levels of nicotine "immediately after smoking a cigarette" are the only levels with which Novartis was concerned. Novartis's patent, itself, indicates that it considered, inter alia, blood levels immediately before smoking as well. *See* '011 patent, col. 6, lines 37-39. Thus, the Court believes this argument may be flawed. Nonetheless, any experts testifying on the meaning of "dosage rate" may consider this evidence for what it is worth.

2. "transdermally administering nicotine"

Elan argues that the word "administering" should be limited to active administration rather than passive administration. It bases this construction on the second definition in Merriam Webster's Collegiate Dictionary, which defines "administration" as "meting out." However, the Court can not use extrinsic

evidence to contradict evidence from the claim or specification. *See* Vitronics Corp., 90 F.3d at 1582. The specification to the '011 patent specifically states "a selected amount of nicotine is applied to a dermally applicable patch and this patch is then placed on the skin of the person in whom smoking reduction is desired. This *allows* the nicotine in the patch to transdermally *migrate* ..." '011 patent at col. 3, lines 63-67 (emphasis added). The use of the words "allows" and "migrate" in the specification suggests that the administration may be passive. Thus, even if the specification elsewhere uses other more active verbs (e.g."releases"), the quoted language suggests that "administration" should not be limited solely to active administration.

Moreover, even if the Court were to consider extrinsic evidence, the verb "to administer" is also defined as "to apply as a remedy ." *See* Administer, American Heritage Dictionary of the English Language: Fourth Ed. (2000). "To apply" is defined as "to bring into nearness with something; put on, upon or to." Id. at Apply. This definition, which is more properly applied in context of administering a drug,FN9 suggests that the administration could be passive. Thus, for these reasons, the Court adopts Novartis's construction of this phrase: "Allowing nicotine to migrate through a person's skin into a person's bloodstream."

FN9. The American Heritage Dictionary's definition of administer also includes "meting out" but it indicates that this definition is more commonly used in reference to administering justice, i.e. meting out justice. The definition in American Heritage suggests that "to apply as a remedy" is the better definition to describe the administration of a drug.

3. "dermaliy applicable patch"

Elan argues that a "dermaliy applicable patch" must include a pad while Novartis argues that the phrase simply means "a patch capable of being adhered to the skin." Elan asserts that the term "dermaliy applicable patch" is a coined term made up for purposes of Novartis's patent and as such, does not have an ordinary meaning. However, when these ordinary words are placed together in this particular phrase, the meaning is non-ambiguous. While this may be the first time the words "dermaliy," "applicable," and "patch" have been used as a phrase, this Court finds that any person familiar with the individual words, would interpret the phrase to mean a patch which is capable of being applied to the skin. Nothing in the phrase "dermaliy applicable patch" suggests that the patch must include a pad. Where a phrase has an ordinary meaning or the meaning is clear from a plain reading of the claim, it is not necessary to consider additional intrinsic evidence. *See* J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1568 (Fed.Cir .1997)

While examination of further intrinsic evidence is unnecessary in this case, an examination of such evidence supports the Court's conclusion. Novartis specifically stated that its "claim is directed to a method which does not rely on any patch structure but can be practiced with any dermaliy applicable patch." Amendment mailed October 7, 1997 at 2. Elan argues that this statement begs the question of what a "dermaliy applicable patch" means. Elan is correct that this statement does not define "dermaliy applicable patch" but it does suggest what a "dermally applicable patch" is not. The statement teaches that a "dermally applicable patch" is not a description of a patch structure. The Court construes the statement to mean that different patch structures may be used so long as the patch can be applied to the skin. Thus, this statement suggests that a pad is not required for a "dermally applicable patch." *See also,* Amendment mailed Dec. 13, 1988 at 17 ("... it is apparent that the actual details of construction of the patch *per se* are not important.")

Moreover, the '011 patent also makes reference to other patch structures which, according to Novartis, do

not include pads. *See* '011 patent, col. 5, lines 16-20 ("Other forms of dermally applicable patches which can be used in connection with the present invention are illustrated for example, in U.S. Pat. No. 3,797,494 to Zaffaroni, U.S. Pat. No. 3,731,683 to Zaffaroni; U.S. Pat. No. 4,336,243 to Sanvordeker et al.") Elan argues that the PTO told Novartis that those patents are not legally part of the disclosures of the '011 patent.FN10 Even assuming this is true, however, they are still relevant in determining what Novartis meant when it used the term "dermally applicable patch." If the ' 011 patent discussed patch structures that did not utilize pads, Novartis could not have intended the phrase "dermally applicable patch" to exclude patches without a pad.

FN10. The evidence presented by Elan, however, does not necessitate the conclusion that the reference to the three patents was disavowed by the PTO. The letter presented by Elan only refers to one of three patents referenced in Novartis's specification and fails to explain why that one patent was not incorporated by reference. The letter does not specifically address the issue of whether a pad is necessary for a dermally applicable patch. Moreover, Elan does not explain why the reference to these patents remains in the specification if it was disclaimed by the PTO.

It is true that the embodiment in the '011 patent utilizes a pad. However, as Elan has argued so vigorously in support its own patent, "[P]articular embodiments appearing in the specification will not generally be read into the claims ... what is patented is not restricted to the examples but is defined by the words of the claims." Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed.Cir.1988); *see also* SRI Int'l Inc. v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1121 (Fed.Cir.1985); Netword, LLC v. Central Corp., 242 F.3d. 1347, 1352 (Fed.Cir.2011); Burke, Inc. v. Bruno Indep. Living Aids, Inc., 183 F.3d 1334, 1341 (Fed.Cir.1999). Those few cases which limit a claim to particular embodiment only do so (1) where the claim is not a method claim; (2) where the language of the claim, itself, supports the conclusion; and (3) where there is no intrinsic evidence suggesting an alternative interpretation. *See* Gen. Am. Trans. Corp. v. Cyro-Trans, Inc., 93 F.3d 766, 770 (Fed.Cir.1996); Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed.Cir.2000). In the present case, Novartis's claim is a method claim; nothing in the language of the claim itself, supports Elan's construction; and there is intrinsic evidence suggesting an alternative construction. Therefore, for all the reasons discussed, we cannot adopt Elan's limitation, and instead adopt Novartis's construction which is "a patch capable of being adhered to the skin."

II. Elan's '853 Patent

Elan's '853 patent makes a number of claims but the claims at issue are number 33 and 39. *See* '853 patent, col. 14, lines 13-23 & 43-52. The language in dispute states that "nicotine is distributed in a sold, semi-solid, or mucilaginous medium." The parties disagree about the meaning of (1) "distributed;" and (2) "mucilaginous medium."

1. "distributed"

The dispute regarding the construction of the word "distributed" actually involves two disagreements. First, Novartis argues that in the context of the ' 853 patent, "distributed" must be read to specifically mean "uniformly distributed in a medium formed by mixing and/or heating the nicotine with a solidifying or gel-forming agent or mixing thereof." However, this limitation which Novartis seeks to impose in Claim 33, already exists in Claim 1 of the ' 853 patent.FN11 Where some claims are broad and others narrow, the limitations of the narrow claim cannot be read into the broad claim. *See* D.M.I., Inc. v. Deere & Co., 755 F.2d 1570, 1574 (Fed.Cir.1985). "Where, as here, the limitation sought to be 'read into' a claim already

appears in another claim, the rule is far more than 'general.' It is fixed. It is long and well established. It enjoys an immutable and universally applicable status comparatively rare among rules of law. Without it, the entire statutory and regulatory structure governing the drafting, submission, examination, allowance, and enforceability would crumble." *Id*. Therefore, in an effort not to crumble the entire statutory and regulatory structure surrounding patent applications, the Court will not read the language of Claim 1 into Claim 33, and will adopt Elan's more general construction, which construes "distributed" to mean "spread out."

FN11. Claim 1 states: "A preparation for a once-daily, percutaneous administration of nicotine which comprises nicotine *uniformly* distributed in a solid, or semi-solid medium which can be placed in intimate contact with the skin, said solid or semi-solid medium comprising *a given amount of nicotine in a solution of a solidifying or gel forming agent mixture thereof in a suitable solved or mixture of solvents, said mixture thereby having been mixed or heated to form said solid or semi-solid medium,* wherein said medium is effective to permit controlled release of said nicotine to the skin." '853 Patent, claim 1 (emphasis added).

The second dispute with regard to the meaning of the word "distributed" is whether nicotine in an adhesive layer is within the scope of Elan's claim. Novartis argues that nicotine in an adhesive layer is not included within the scope of Elan's claim whereas Elan claims that it is included. The specification to the '853 patent specifically states "an initial burst or priming dose of nicotine may be required to achieve rapid effective plasma levels to curb the nicotine craving or smoking urge. Such can be supplied by applying a device or dosage form in which *an amount of nicotine is included in a layer of adhesive* " '853 patent, col. 7, lines 11-16 (emphasis added). This language seems to clearly suggest that nicotine in the adhesive layer is within the scope of the patent.

Novartis, however, argues that the specification suggests that this "priming dose" of nicotine which may be included in the adhesive layer, is not part of the nicotine which "is distributed in a solid, semi-solid or mucilaginous medium." This does not appear to be completely true, however, because the claim indicates that the nicotine would be "freely permeable" between the two layers. *See* '853 patent, col. 7, line 20. Thus, the nicotine which is "distributed in a sold, semi-solid or mucilaginous medium" would be distributed to the adhesive, as it would freely permeate into the adhesive.

Novartis also argues that Elan's construction would invalidate its own patent. However, the argument that an opposing party's construction would invalidate its own patent does not seem particularly convincing. Elan responds that it does not believe its construction will invalidate its patent. The fact that Elan is not concerned that this construction will invalidate its patent strongly suggests that it will not. Moreover, if Elan is not concerned that this construction might invalidate its patent, there is no reason for the Court to so concern itself. Therefore, for these reasons, the Court adopts Elan's proposed construction which is that nicotine included in an adhesive layer is within the scope of the claim.

2. "mucilaginous medium"

Elan argues that "mucilaginous medium" should be defined as "a sticky, viscid medium." Novartis proposes that the term be construed as "creams, gels, ointments and pastes." Elan bases its construction on the dictionary definition of the word "mucilaginous ." Novartis bases its argument on the fact that the ' 853 claim specification states that the "the term mucilaginous medium as used herein *embraces* creams, gels, ointment and pastes." 853' patent, col 6, lines 7-9 (emphasis added). The relevant meaning of "embraces," however, is "to include as part of something broader." *See embrace, The American Heritage Dictionary of*

the English Language, 4th Ed., 2000. Thus, Elan's specification does not require limiting "mucilaginous" to those four substances.

Novartis also argues that Elan's reading is overbroad because it would cover "anything sticky or viscid." This argument fails for three reasons. First, Elan used the word "mucilaginous medium" in the claim and if the definition of this term happens to be broad, the Court will not narrow it from its ordinary meaning unless the text of the patent so requires. In this case, Novartis has presented nothing in the '853 patent or prosecution history which suggests a narrower meaning. Second, Elan's construction requires that the medium be *both* sticky and viscid, not one or the other. Finally, the term "viscid" is "used of a fluid" and thus would not include all adhesives. *See The American Heritage Dictionary of the English Language,* 4th Ed., 2000. Therefore, the Court must adopt Elan's construction, which is that a "mucilaginous medium" is "a sticky, viscid medium."

Therefore, having been advised in the premises, it is hereby ORDERED AND ADJUDGED that Novartis's '011 patent and Elan's '853 patent shall be construed in a manner consistent with this Order.

DONE AND ORDERED.

S.D.Fla.,2002.
Novartis Consumer Health Inc. v. Elan Transdermal Technologies, Inc.