United States District Court,
D. Massachusetts.

HARVEST TECHNOLOGIES CORPORATION,
Plaintiff.
v.
CYTOMEDIX,
INC. Defendant.

No. Civ.A. 02-12077-PBS

Sept. 9, 2004.

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MEMORANDUM AND ORDER

SARIS**, J.**

I. INTRODUCTION

Plaintiff Harvest Technologies Corporation ("Harvest") seeks a declaratory judgment that its SmartPReP and SmartPReP2 systems (collectively, "SmartPReP"), which process blood to heal wounds and tissue, do not violate Cytomedix's U.S. Patent No. 5,165,938 (issued Nov. 24, 1992) (the " "8 patent"). Harvest also is seeking damages for false advertising, unfair competition, intentional interference with contractual relationships, and unfair and deceptive acts and practices. Cytomedix has counterclaimed for infringement of the "8 patent. Harvest filed a motion for summary judgment of non-infringement, and later moved for summary judgment of invalidity because of anticipation. Cytomedix has filed a cross-motion for partial summary judgment of infringement.

After hearing and review of the briefs, the Court *DENIES* Harvest's motion for summary judgment of non-infringement, *ALLOWS* Cytomedix's motion for summary judgment of infringement, and *DENIES* Harvest's motion for summary judgment of invalidity.

II. BACKGROUND

A. Science

Because this patent involves wound healing and tissue repair, some background on the role of blood in wound healing is helpful. FN1 Whole blood is made up of red and white cells, platelets, and plasma. Red blood cells carry oxygen, and white blood cells, including macrophages, assist wound-healing by fighting off infections. Platelets participate in the clotting process. Plasma is the water-like substance in blood where the platelets and blood cells are located. There are other substances within the blood plasma, such as the plasma protein fibronogen, which plays an important role in the clotting process and wound repair.

FN1. This primer is drawn from the largely undisputed scientific background recited in the Declaration of David J. Kuter, D. Phil., M.D., Director of Clinical Hematology at Massachusetts General Hospital and Associate Professor of Medicine at Harvard Medical School and Massachusetts Institute of Technology. Cytomedic's expert, Dr. John H. Hartwig, Ph.D., an Associate Professor of Anatomy and Cellular Biology in the Department of Medicine at Brigham & Women's Hospital, generally agreed with the description of the science. (Hartwig Decl. at para. 6.)

When a wound occurs, a blood clot is formed on top of the wound to prevent further bleeding. The clot begins to form when platelets become activated by exposed collagen, a protein found within the body's tissue, and bind to damaged tissue. An enzyme within the body converts fibrinogen, which is found in blood plasma, to fibrin strands. The fibrin strands form a three-dimensional scaffold at the site of the wound that captures additional platelets, white blood cells, and red blood cells to form a clot. The clot creates a hemostatic barrier that prevents further bleeding and allows the regeneration of tissue. Cells bind to the platelet/fibrin scaffold.

Platelets contain "alpha granules," which themselves possess over twenty known growth factors, proteins that facilitate tissue growth and repair. During the clot-forming process, the combined effect of thrombin, collagen and thromboxame A2 (another substance made by platelets) causes the platelets to become activated, at which point they release alpha granules. Granules move to the surface of the platelet and release their growth factors. Some growth factors attract certain kinds of cells (like smooth muscle cells) to the wound. Others stimulate mitosis of cells. The activated platelet surface also serves as a site upon which coagulation factors become activated upon the generation of thrombin and as a binding site for clotting factors and white blood cells, which fight infection.

This process wherein blood platelets are activated by the presence of biological release agents such as thrombin or collagen is known as the "platelet release reaction." ('982 patent at 2:14-20.)

B. *The* "8 patent

The "8 patent, entitled "Wound Healing Agents Derived from Platelets," contains twelve claims, all describing a process of applying over either a wound or damaged tissue an effective amount of treating composition containing the materials released by the platelets during the "platelet release reaction."

Claims 1 and 12 are independent claims, and the rest are dependent. The claims most debated here state:

1. A process for treating damaged, live, animal tissue which comprises applying over the damaged tissue an effective amount of a treating composition containing the materials released by platelets during the platelet release reaction and facilitating healing of the damaged tissue.

...

3. The method of claim 1 wherein said platelets are isolated from blood prior to release of the materials.

...

12. A process for treating a wound of a live animal which comprises applying over the wound an effective amount of a treating composition containing the materials released by platelets during the platelet release reaction and facilitating healing of the wound

The "Detailed Description of the Invention" in the "8 specification describes stabilizing and centrifuging blood to obtain a platelet-rich plasma ("PRP") (3:20-22.) The PRP is then usually centrifuged again, the platelet-free plasma is again removed, and the remaining platelet pellets are suspended in a buffer solution. (3:36-38.) The more purified PRP is then activated with a biological release agent, such as thrombin, and it is allowed to sit for five to ten minutes. The thrombin coagulates the fibrinogen and activates platelets, causing them to release alpha granules containing the platelet-derived growth factor ("PDGF") and platelet-derived angiogenesis factor ("PDAF"). (3:52-56.) The PRP is then again centrifuged, leading to the separation of the "supernatant," which contains the growth and angiogenic factors, from the platelets and fibrin. (3:60-63.) The platelet-free and fibrin-free supernatant is then mixed with a carrier substance (like collagen) to create the composition applied to the wounds. (4:1-4.) The composition, which typically is a paste, is then applied to the wound in a layer approximately one millimeter thick, once per day. (4:16-20.) The specification states that the process may be used to treat internal wounds as well.

B. *The SmartPReP System*

The SmartPReP System is also designed to take advantage of the platelet release reaction to heal wounds. With SmartPReP, blood is taken from a patient, mixed with an anticoagulant to stabilize it, and placed in a dual-chamber, disposable container. The container is centrifuged to separate the red blood cells, in one chamber, from the platelet-poor plasma and a platelet concentrate, in the other chamber. About two-thirds of the platelet-poor plasma is removed, and the remaining platelet-poor plasma and the platelet concentrate are mixed to create a platelet-rich plasma, or "autologous platelet concentrate" ("APC"), as Harvest names it. This concentrate includes some red blood cells, plasma, platelets, white blood cells, and various plasma proteins such as fibrinogen. The APC is drawn into a syringe, and thrombin is drawn into a second syringe. The syringes are clasped into a dual dispensing liquid or spray applicator, which, when used, simultaneously dispenses the APC and the thrombin in their correct proportionate amounts to the wound. Harvest states that it is an unknown issue of fact how soon upon application of the liquids to the wound the platelet release reaction begins, but it suggests that it takes at least five to thirty seconds after mixture, and possibly five to ten minutes.

III. SUMMARY JUDGMENT STANDARD

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." ' Barbour v. Dynamics Research Corp., 63 F.3d 32, 36 (1st Cir.1995) (quoting Fed.R.Civ.P. 56(c)). "To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position." Rogers v. Fair, 902 F.2d 140, 143 (1st Cir.1990); *see also* Celotex Corp. v. Catrett, 477 U.S. 317, 325, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

"Once the moving party has properly supported its motion for summary judgment, the burden shifts to the non-moving party, who 'may not rest on mere allegations or denials of his pleading, but must set forth specific facts showing there is a genuine issue for trial." ' Barbour, 63 F.3d at 37 (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986)). "There must be 'sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." ' Rogers, 902 F.2d at 143 (quoting Anderson, 477 U.S. at 249-50) (citations and footnote in *Anderson* omitted). The Court must "view the facts in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor." Barbour, 63 F.3d at 36.

IV. DISCUSSION

A. *Infringement*

"Determining whether a patent has been infringed involves two steps: (1) claim construction to determine the scope of the claims, followed by (2) determination whether the properly construed claim encompasses the accused structure." Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed.Cir.1998). An accused device may infringe a given patent claim, and thus the patent, in one of two ways: literally, or under the doctrine of equivalents. Jurgens v. McKasy, 927 F.2d 1552, 1560 (Fed.Cir.1991). "Literal infringement requires that the accused device contain each limitation of the claim [at issue] exactly; any deviation from the claim precludes a finding of literal infringement." Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1454 (Fed.Cir.1998).

B. *Claim Construction*

To construe a patent claim, courts principally consult evidence intrinsic to the patent, including the claims themselves, the specification, and the prosecution history. Deering Precision Instruments v. Vector Distribution Sys., Inc., 347 F.3d 1314, 1322 (Fed.Cir.2003). The Court indulges a strong presumption that claim terms carry their ordinary and customary meaning. *Id*. The ordinary meaning of a claim must be determined "from the standpoint of a person of ordinary skill in the relevant art." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed.Cir.2002). "The use of extrinsic evidence to construe the scope of a claim is improper where the ordinary and accustomed meaning of a claim term does not render the claim unclear and where the patentee has not chosen to be his own lexicographer." *N*. Telecom Ltd. v. Samsung Elecs., 215 F.3d 1281, 1288 (Fed.Cir.2000). "While the Court may rely on expert testimony to understand the technology and the ordinary meaning of terms to practitioners in the art, expert testimony may not be used to contradict claim language or the specification." VLT Corp. v. Lambda Elecs., 238 F.Supp.2d 347, 350 (D.Mass.2003).

The Federal Circuit clarified the relationship between claim language and the specification in Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed.Cir.2002), stating that "[c]onsulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims." The Federal Circuit emphasized that "dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms," id. at 1202, for such sources "are objective resources that serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art," id. at 1203. However, "the intrinsic

record also must be examined in every case to determine whether the presumption of ordinary and customary meaning is rebutted." Id. at 1204. "Further, the presumption also will be rebutted if the inventor has disavowed or disclaimed the scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Id. at 1203.

C. *Treating Composition*

Harvest argues that the phrase "the materials released by platelets during the platelet release reaction" in the '982 patent should be interpreted to be the supernatant free of platelets, cells, and fibrin. (Kuter Decl. at para. 25.) Under this interpretation, SmartPReP does not infringe since those elements remain in the APC after centrifuging. Harvest does not argue that the dictionary meanings of the terms require this interpretation, but rather argues that the inventor disclaimed coverage of products including those factors in prosecuting his patent to overcome prior art. Cytomedix responds that those statements were either taken out of context or directed to another, later-canceled claim.

"[A]rguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary." CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1155 (Fed.Cir.1997) (quoting Southwall Techs. Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.1995)). *See also* Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed.Cir.1990) (holding that statements about a term made in separate but related patent served to define and limit term in patent at issue, despite otherwise different claim language); Watts v. XL Sys., 232 F.3d 877, 883 (Fed.Cir.2001) ("It is irrelevant in this case whether Watts' prosecution history remarks were directed to claim 18 specifically because there is no clear indication that they were not."). "Arguments made during the prosecution of a patent application are given the same weight as claim amendments." Elkay Mfr. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed.Cir.1999) (noting that "[i]t is ... irrelevant whether Elkay emphasized this argument at the time, or indeed whether Elkay had to relinquish an interpretation"). *But see* Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 832 (Fed.Cir.2003) ("While on its face this statement appears to limit claim scope, it cannot do so absent some claim language.... The applicants' inaccurate statement cannot override the claim language itself, which controls the bounds of the claim."); Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053-54 (Fed.Cir.1989) (noting that erroneous remark by attorney would not change scope of patent, for "[t]he claims themselves control").

"[T]he scope of the disclaimer must be determined by what 'a competitor would reasonably believe that the applicant had surrendered." ' Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1361 (Fed.Cir.2001) (holding that statements made to distinguish certain claims of parent application from prior art limited scope of patent issuing from separate claims where statements spoke generally of "the present invention"). However, "the alleged disavowing statements [must] be both so clear as to show reasonable clarity and deliberateness, ... and so unmistakable as to be unambiguous evidence of disclaimer." Omega Eng'g v. Raytek Corp., 334 F.3d 1314, 1325 (Fed.Cir.2003) (citations omitted).

The Court starts, as it must, with the language of the claims themselves. Claim 1 reads: "a treating composition containing the materials released by platelets during the platelet release reaction." Nothing in the plain language of this claim suggests that the composition must contain only these materials. *See* Cytomedix, Inc. v. Little Rock Foot Clinic, P.A., No. 02-4783, 2004 WL 609330 (N.D.Ill. March 24, 2004) (interpreting the same claim language).

Harvest's principal argument is that Knighton, the inventor of the '982, specified that his invention was of

the supernatant free of platelets, cells and fibrin in prosecuting the patent. Harvest points to several passages from the prosecution history, the strongest three of which are quoted below.

After the Patent Office stated that the prior art showed that platelets contain wound healing substances and it would be obvious to combine platelets and a carrier, namely collagen, to produce a wound-healing composition, Knighton argued:

Claim 64 is allowable over Antoniades because the composition, containing material released from the granules, is substantially free of other material found in platelets outside of the granules. In contrast, in Antoniades, the platelets are lysed ... with the result that extra-granular platelet material is mixed with the contents of the granules. This might not matter for Antoniades because PDGF is later separated by precipitation, gel electrophoresis, or other means from the lysed cellular material. In the case of applicant's invention, only the contents of the granules are used in the composition.

(Mesiti Decl. Ex. I, Amendment and Response of Jan. 19, 1988 at 28.) Although Harvest argues that the term "applicant's invention" refers to the entire patent, *see* Ballard, 268 F.3d at 1361, the passage expressly states that this argument is intended to apply only to claim 64, which read:

A topical therapeutic composition for application to tissue for the purpose of forming granulation tissue and/or capillaries and/or epithelial tissue, said composition being in the form of an ointment, salve, cream or solution and comprising

(i) the material released from the alpha granules of human platelets; and

(ii) a pharmaceutically acceptable carrier or diluent therefore

wherein said composition is substantially free of (i) blood or plasma contaminants or (ii) other material found in human platelets outside of said alpha granules.

(*Id*. at 7-8 (emphasis added).) Claim 64 excludes extra-granular platelet material, unlike Antoniades' composition. Therefore, there was a clear indication that this argument was specific to one claim. CVI/Beta, 112 F.3d at 1155.

In response to another prior art rejection, Knighton again amended his claims and argued:

- MOST IMPORTANT

[The specification] sets forth the procedure for preparing the materials released by platelets. After the release reaction the platelet ghosts FN2 and fibrin are removed by centrifugation.... *The resultant "supernatant" is what is applied to a wound in toto. Applicant does not isolate individual factors from this supernatant and does not otherwise process this supernatant in ways that would affect the bioactivity of the multitude of factors contained therein. Applicant* "names" *this supernatant "the materials released by platelets in the* platelet *release reaction*." This expression is well known in the art as evidenced by the excerpts from the text on hematology and applicant should not have its claims limited to a centrifugation process for manufacturing the supernatant. Finally, even though the Examiner has asserted that the previous claims could be read broadly, applicant has consistently used "material released" in the claims to mean "the materials" released.... *This phrase [materials released from platelets] refers to the actual physical stuff or*

soup in its entirety which is released by platelets- without further processing or isolation of factors contained therein.

FN2. Platelet ghosts are the bodies of the activated platelets.

(Mesiti Decl. Ex. R, May 18, 1990 Preliminary Amendment at 5-6 (second emphasis added).) The context of this passage was the rejection by the Examiner on the grounds that prior art disclosed that isolated platelet-derived growth factor ("PDGF") may be beneficial in wound healing. The patentee therefore explained that the invention referred to all of the components released, not just PDGF.

Harvest underscores the express definition of "the materials released by the platelet reaction" as the supernatant from which the platelet ghosts and fibrin have been removed by centrifuge, and argues that this sentence is a clear disavowal of a composition containing other blood components. If this definition stood alone, Harvest may well have a prevailing argument. However, later in the passage, the inventor states that "materials released from platelets" refers to the "actual physical stuff or soup in its entirety which is released by platelets-without further processing or isolation of factors contained therein." In this latter definition, there is no reference to the fibrin-free or platelet-free limitation on the contents of the stew. The two definitions in the same passage must be read in sync; accordingly, in light of Knighton's motive in writing the passage-he was attempting to include components, namely all of the materials released instead of one isolated material, PDGF, not to exclude components-and the word "soup" in the definition, the Court does not read the passage as a clear "disavowal" of the plain meaning of Claim 1.

Finally, in arguing for claims 76-86 and 89 of a parent application, Knighton stated:

Regarding the 102 rejection, claims 76-86 and 89 do not "read on" the *Annals of Surgery* article because as discussed more completely below the "injection" into the cornea was not "topical application." Furthermore ... the ... article suggests platelets play a role *along with other cell types* in natural wound healing. Applicant's present discovery is that platelet released material *alone* is sufficient to heal wounds without the concurrent activity of macrophages and other cell types present in natural wound healing.

...

The examiner has yet to address the first reason for nonobviousness. Why is it obvious that platelet released material "alone" could heal wounds when the point of the *Annals of Surgery* article was to show that platelets at least participate in natural wound healing along with macrophages and other cell types.

(Mesiti Decl. Ex. P, Response of Nov. 20, 1989 at 8, 9.)

This passage is not a clear disavowal of coverage such as to limit the claims, for it does not define specific terms in the claims and does not require the invention to be free of other components. Knighton did not state that his "composition" could not include other components, but rather that it did not have to. In the context of the prosecution history, Knighton made the same argument with respect to claims 87 and 88, which required a composition "substantially free of (i) blood or plasma contaminants and (ii) platelet ghosts or other material found in human platelets but not released by said platelets." (*Id.* at 13.) Knighton noted that these claims, which were ultimately canceled, showed his "preferred" embodiment (*id.*), but he did not state that they represented the only embodiment.FN3

FN3. Cytomedix's expert recently mentioned in his own patent application that the '982 patent requires isolating the platelets from red blood cells, plasma, and white blood cells. The Court declines to rely on this extrinsic evidence.

Accordingly, the Court adopts Cytomedix's claim construction that the term "treating composition containing the materials released by platelets during the platelet release reaction" means "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components."

D. ***Infringement by the Dual-Chamber-Applicator***

Harvest concedes that its products other than those using a dual-chamber applicator infringe under Cytomedix's construction. Harvest argues though that even if the claims are construed not to include the platelet-free, cell-free and fibrin-free requirement, summary judgment of infringement is inappropriate for its products that use a dual-chamber applicator because the APC and the thrombin do not come into contact until the moment of application and there is a disputed issue of fact about how long it takes for the platelet-release reaction to occur. Cytomedix's own statements suggest that it takes five to thirty seconds to begin, and possibly five to ten minutes to be effective. Therefore, Harvest asserts, the treating composition does not contain materials " *released* by platelets during the platelet release reaction" (claims 1, 12) at the time of application, for the material has not yet been released at the time of application. Even if the product did contain these materials, Harvest argues, there is an issue about whether it is an "effective amount."

Claim One provides: "a process ... which comprises applying over the damaged tissue an effective amount of a treating composition containing the materials released by platelets during the platelet release reaction." The word "apply" is variously described as "to put in use," "to bring into action," "to lay or spread on," or "to put into operation or effect." Webster's Ninth New Collegiate Dictionary at 97 (1983).

In the context of the claims, the proper definition of "apply" is "to lay or spread on." The claims state "applying *over* the damaged tissue." The natural meaning of applying "over" something is that something is laid or spread over it. Consistent with that definition, the Abstract notes: "The compound is applied directly to wounds and initiates healing." ('982 patent at Abstract.) The summary of the invention states: "The activated PRP within the carrier may then be applied to a wound." '982 patent at 2:58-59.

Harvest argues that the claims require the platelet release reaction to have occurred *before* the application of the composition to the wound. It contends that the past tense of "release" indicates that the materials already have been released at the time of applying the composition.

However, the claim language does not state that the materials must be released before application to the wound. While the claim could have expressly specified the sequence, the fact that it did not means that it is entitled to its full scope, encompassing both pre-application mixtures and post-application mixtures. The argument with respect to a lack of effective amount was not adequately developed. Therefore, Cytomedix's motion for summary judgment of infringement with regards to the dual applicator products is *ALLOWED*.

E. ***Validity***

Harvest has moved for summary judgment of invalidity on the grounds that the '982 patent was anticipated

by U.S. Patent No. 4,485,096 (issued Nov. 27, 1984) ("Bell").FN4 While Harvest argues that the '982 is expressly anticipated, Cytomedix argues primarily that the '982 is not inherently anticipated by Bell.

FN4. Harvest mentions several times that the '982 patent is invalid over the prior art that is cited in the patent based on Cytomedix's interpretation, but does not develop the argument. (*See* Kuter Reply Decl. at para. 12.) Accordingly, the issue of obviousness will await trial.

A patent, and each one of its individual claims, is statutorily presumed to be valid. 35 U.S.C. s. 282. However, the "presumption [of validity] is weakened where the most pertinent prior art was not considered by the Patent Office." Nossen v. United States, 189 Ct.Cl. 1, 416 F.2d 1362, 1371 (Ct.Cl.1969). In addition to the statutory presumption, "a claim must be construed to uphold its validity if possible." Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed.Cir.1987) (holding that inclusion of the word "only" in the clause of a patent's claim limitation saved a later patent from invalidation by anticipation, as the word "only" could not be read out of the prior patent's claim).

"A person shall be entitled to a patent unless ... the invention was described in a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." 35 U.S.C. s. 102(e). "Anticipation under 35 U.S.C. s. 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention." Lewmar Marine, 827 F.2d at 747. Anticipation must be proven "by clear and convincing evidence." Mentor H/S, Inc. v. Med. Device Alliance, Inc., 244 F.3d 1365, 1377 (Fed.Cir.2001).

Even if a limitation is not expressly present, "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." Shering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377 (Fed.Cir.2003) (finding metabolite DCL anticipated because a person ingesting a drug, loratadine, would necessarily metabolize DCL, even though at the time of first ingestion the prior art did not explicitly disclose DCL). "[I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure." *Id*. "In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." *Id*. at 1379. *See also* Toro Co. v. Deere & Co., 355 F.3d 1313, 1317-22 (Fed.Cir.2004) (holding that fertilizer farm machine employing concentrated water jets could anticipate farm machine designed to lift and fracture the soil despite indications that fertilizer machine taught away from that use). However, "[i]nherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed.Cir.2002). In addressing anticipation, "the district court must first construe limitation[s], to set with clarity the scope of subject matter that the [prior art] must expressly or inherently anticipate." Toro, 355 F.3d at 1321.

According to Harvest, the Bell Patent discloses a wound treatment having all of the claim elements of independent Claims 1 and 12 of the "8 patent. While the Bell patent is primarily directed towards the creation of a skin patch to be applied to wounds, it contains similarities to the healing pastes at issue here. The Bell specification describes a treatment for burns or other skin wounds (Bell Patent 1 :18-22, Abstract) that "is suitable for the treatment of a wound to the skin of a human being or other animal" (17:27-40). Through a method of covering the wound with a treating composition (18:60 to 19:1), Bell discloses the healing of human tissue, rabbit tissue, guinea pigs, rats and other mammalian animal tissue (5:59-60; 7:20-30; 11:41-42; 17:36-40).

More specifically, Bell discloses the formation of a collagen lattice (1:39) to which a "contractile agent" is added and becomes incorporated (1:39-41). One example of a contractile agent is blood platelets. (1:41-42; 4:31-35; 13:31-34; 17:36-40; 18:12-13; 18:60-61.) Thrombin may be added to the platelet concentrate to form a treating composition for wound healing (4:66-68; 5:6-11; 14:32-38; 17:47-50), and will cause a platelet release reaction to occur (5:8-10, 51-53). Bell further discloses combining collagen with blood platelets to form a gel mixture having blood platelets disbursed within the gel mixture. (18:1-4, 12-13.) Moreover, the Bell Patent discloses that its wound treatment results in vascularization in the area where the treating composition is applied. (11:43-47; 16:28-29).

Cytomedix makes multiple arguments why Bell does not disclose an "effective amount" of a treating composition. First, it argues generally that Bell discloses a skin bandage, not a healing paste, and that Bell teaches away from the '982 patent because it mentions that "outdated" platelets, meaning five-to-seven-day old platelets, were used. These outdated platelets might no longer possess active platelets.

Second, Cytomedix argues that after the contraction by the platelets and fibroblasts, much of the liquid is removed from Bell's invention, removing along with it platelet-released material. If the tissue were then seeded with epidermal cells, the lattice would contract in a dramatically greater degree, so that only 3% to 5% of the original platelet-released material would remain. Additionally, according to Cytomedix, in those experiments in which keratinocyte or epidermal cells were grown on the collagen solution, those cells likely consumed the platelet-released factors, for platelet-released factors typically have a lifespan as free molecules on the order of less than one hour in the presence of living tissue. Therefore, Cytomedix argues that there is no clear and convincing evidence that the Bell patent discloses an effective amount to facilitate the healing of damaged tissue. Cytomedix also notes that Bell describes the contraction process as taking from six hours to several days, well beyond the one-hour span. It argues that Harvest has not provided any scientific tests that demonstrate that any platelet released factors remain. Finally, it argues that claims 5 and 7-8 in the '982 patent are specific to human beings, and while Bell mentions that his invention would work on humans, he never provides an experiment showing that it did work.FN5

FN5. There is also a battle of the experts over the role of Cyto chalasin B in the Bell patent.

Harvest argues that the "outdated" platelets must still be active or else they would not contract.FN6 Harvest adds that many of Cytomedix's arguments are specific to disclosures in Bell that use epidermal or keratinocyte cells, but Bell specifies that his invention does not require these cells. Harvest argues that Cytomedix's expert lacks support for the 3-5% platelet release factors remaining after epidermal cells are added in Example 15 because Bell itself states that the contraction is completed before the epidermal cells are added. Harvest argues that it does not have to prove the process was used in humans so long as it was disclosed. Finally, Harvest attacks the "one-hour lifespan" for platelet-released factors statement because Cytomedix's expert never described what he meant or why it matters if the molecules are "free."

FN6. The Court notes that the '982 patent also mentions the use of outdated platelets, 4:59-61.

The record is inadequately developed to resolve the issue of inherent anticipation. Specifically, neither expert has demonstrated with test results whether or not an effective amount of the platelet-released materials exist in the treating composition made by Bell, but rather both opine based on background

knowledge. While Dr. Kuter makes a strong argument for inherent anticipation, both experts are highly qualified and disagree on the factual issues involved in this determination. Therefore, the motion for summary judgment of invalidity is *DENIED*.

ORDER

Plaintiff's motion for summary judgment of non-infringement (Docket No. 60) is *DENIED*. Defendant's motion for summary judgment of infringement (Docket No. 69) is *ALLOWED*. Plaintiff's motion for partial summary judgment of invalidity (Docket No. 76) is *DENIED*. A trial is set for November 29 at 9:00 a.m.

D.Mass.,2004.
Harvest Technologies Corp. v. Cytomedix, Inc.