UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* STEVE GRANICK and SVETLANA A. SUKHISHVILI

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Appeal 2007-2829
Application 10/852,090[1]
Technology Center 1700

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Decided: 21 February 2008

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Before TEDDY S. GRON, CAROL A. SPIEGEL, and MARK NAGUMO, *Administrative Patent Judges*.

*PER CURIAM*

DECISION ON APPEAL

Introduction

This is an appeal under 35 U.S.C. § 134 from an examiner's final rejections of Claims 47 and 52-87 of Application 10/852,090, filed May 24, 2004, under: (1) 35 U.S.C. § 102(e) over Ghadiri, U.S. Patent 6,613,875 B1, issued September 2, 2003; (2) 35 U.S.C. § 102(e) over Steiner et al. (Steiner), U.S. Patent Application Publication 2004/0077528 A1, published

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[1] This application is a divisional of Application 09/715,870, filed November 15, 2000, now U.S. Patent 6,740,409 B1, issued May 25, 2004.

April 22, 2004; and (3) 35 U.S.C. § 103(a) in view of Steiner. Appellants have not questioned the prior art status of Ghadiri and Steiner. The patentability of no claim other than independent Claims 47, 60, and 69 has been argued separately. Accordingly, all dependent claims stand or fall with Claims 47, 60, and 69 upon which they respectively depend. Claims 60 and 69 are transcribed below (Brief (Br.), Claims Appendix (App'x)):

> 60. A method of removing a film from a surface, comprising:
>
> providing a film on a surface, the film comprising a first layer including a first polymer, and a second layer including a second polymer, the second polymer hydrogen bonded to the first polymer; and
>
> subjecting the film to an environmental change selected from a change in pH, a change in ionic strength, exposure to an electric field, or exposure to dissolved ions; wherein said environmental change is of a sufficient magnitude to cause the film to be removed from the surface.
>
> 69. A method of releasing an agent from a film into an environment, comprising:
>
> providing a film comprising
>
> a first layer including a first polymer having a plurality of hydrogen bond donating moieties.
>
> a second layer including a second polymer having a plurality of hydrogen bond accepting moieties, and
>
> an agent; and
>
> subjecting the film to an environmental change selected from a change in pH, a change in ionic strength, exposure to an electric field, or exposure to dissolved ions; wherein said environmental change is of a sufficient magnitude to cause the agent to be released from the film.

The appealed rejections are REVERSED.

The *per curiam* decision to reverse all the final rejections on appeal is supported by the following separate opinions of Judges Gron, Spiegel, and Nagumo.

GRON, *Administrative Patent Judge*.

Claim interpretation is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). "[I]n proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification." *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983). The Federal Circuit has emphasized that the terms which define the scope and content of the subject matter claimed must be construed in a manner consistent with the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315-16 (Fed. Cir. 2005)(*en banc*). The specification is the primary aid in deciphering claim language. *Id.* at 1315.

A patent applicant may be his own lexicographer. *Phillips v. AWH Corp.*, 415 F.3d at 1316. However, it is not otherwise permitted to import limitations from the specification into the claims in order to narrow the scope of the subject matter claimed and thus circumvent applied prior art teachings. *Id.* at 1323. The scope of the subject matter claimed should not be limited to the specific embodiments in the specification. *Id.*

Claims are interpreted as they reasonably would have been interpreted by persons having ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d at 1323. Persons having ordinary skill in the art rarely limit claim terminology to the scope of the specification's embodiments. *Id.* Still, claims must be reasonably interpreted in light of the specification.

The outcome of this appeal depends on the reasonable interpretations persons having ordinary skill in the art would have given the terms "polymer," "surface," and "film" in Claims 47, 52-68, 74-76, and 83-87 (Br., App'x) and the terms "polymer" and "film" in Claims 69-73 and 77-82 (Br., App'x) in light of the supporting specification (Examiner's Answer (Ans.), pages 4-8 (pp. 4-8)). The Examiner argues that, granting the terms "polymer," "surface," and "film" in Appellants' claims their broadest reasonable interpretations in light of a specification without any definitions, the methods defined by Appellants' Claims 47 and 52-87 are described by Ghadiri, described by Steiner, and would have been obvious to a person having ordinary skill in the art in view of Steiner's teachings (Ans. 2-4). I conclude that the Examiner erred rejecting Appellants' claims over Ghadiri, over Steiner, and in view of Steiner because persons having ordinary skill in the art reading Appellants' claims in light of their supporting specification:

(1) reasonably would not have broadly interpreted the term "surface" in Appellants' claims to include a base layer of cyclic peptide including between 6 and 16 amino acids upon which another layer of cyclic peptide including between 6 and 16 amino acids is stacked in parallel fashion for assembly of Ghadiri's molecular tubes;

(2) reasonably would not have broadly interpreted the term "surface" in Appellants' claims to mean Steiner's in vivo permeable membrane;

(3) reasonably would not have broadly interpreted the term "film" in Appellants' claims to include Ghadiri's spontaneously assembled stacks of cyclic peptides including between 6 and 16 amino acids atop one another in parallel fashion; and

(4) reasonably would not have broadly interpreted the "film" in Appellants' claims which comprises first and second layers of first and second polymers to encompass the polymeric active agent entrapped or encapsulated by a polymeric transport enhancer Steiner describes.

While a person having ordinary skill in the art might reasonably find that Ghadiri's stacks of cyclic peptides including between 6 and 16 amino acids may be held together by hydrogen bonding, may be assembled and disassembled by varying pH, and may be employed as carriers, molecular sieves, reaction vessels, and membrane channels for retaining and releasing agents by varying the pH of the environment, I conclude that persons having ordinary skill in the art would not have construed a stack of cyclic peptides including between 6 and 16 amino acids to be a "film," a "film on a surface," or a "film to be removed from . . . [a] surface" of Appellants' Claims 47 and 60. I also conclude that persons having ordinary skill in the art would not have construed any of Ghadiri's stacked cyclic peptides including between 6 and 16 amino acids to be a "film" of Appellants' method Claim 69 which comprises and releases an agent when subjected to an environmental change.

I see no error in the Examiner's finding that Appellants' specification does not explicitly define the terms "polymer," "surface," and "film" recited in Appellants' claims. Rather, the specification (a) teaches that polymers for use in the present invention "contain . . . hydrogen bond donors and/or hydrogen bond acceptors . . ." (Specification (Spec.), p. 4), (b) lists specific polymers having repetitive monomeric units and copolymers thereof which may be used to form the polymer layers which comprise the "film[s]" (Spec., pp. 4-7 and 9-11), and (c) contemplates "film" layers made from

polymers having "a molecular weight of at most 5000g/mol, more preferably at most 2000g/mol." (Spec., p. 7, ll. 20-25). The specification also teaches that polynucleotides and polyamino acids may be used to form the film layers (Spec., p. 4, ll. 4-7, and p. 7, ll. 1-3). While I conclude therefrom that the polymers referred to in Appellants' claims do not necessarily exclude cyclic peptides having between 6 to 16 amino acid residues, I cannot agree with that persons having ordinary skill in the art reading Appellants' specification reasonably would have interpreted the term "polymer" in Appellants' claims to include cyclic peptides having between 6 and 16 amino acids. Nevertheless, the more limited interpretation I would give to the term "polymer" in Appellant's claims is not essential to justify my conclusion that all the Examiner's final rejections should be reversed.

Considering the term "surface," Appellants' specification teaches (Spec., p. 2, ll. 1-4):

> In a third aspect, the present invention is a method of forming a film, including contacting a surface with a first polymer having a plurality of hydrogen bond donating moieties, and contacting the surface with a second polymer having a plurality of hydrogen bond accepting moieties.

"The films may be formed on a surface, such as the surface of a monolithic solid, or particles" (Spec., p. 7, ll. 4-5). The specification relates (Spec., p. 7, ll. 20-31):

> It is also possible to form the film by evaporating the first polymer onto a surface, followed by evaporation of the second polymer onto the surface, and repeating these steps until the desired thickness is achieved . . . .
>
> Examples of materials, either as monolithic solids, or particles, which may be coated include semiconductors such as silicon or germanium, polymers such as polyethylene and TEFLON, ceramics

> such as glass or alumina, and minerals such as mica. The films may be coated onto a surface, with an agent contained in the film, which may be released at a later time by destruction of the film.

In the Examples section of the specification, it is said that "[t]he films were formed on either glass, Teflon or germanium surfaces" (Spec., p. 10, l. 8).

Granting the term "surface" its broadest reasonable interpretation consistent with the Specification, I conclude that the term "surface" in Appellants' Claims 47, 52-68, 74-76, and 83-87 (Br., App'x), when it is interpreted in a manner consistent with the Specification's disclosure that the "surface" on which a multilayer film is provided, and from which the multilayer film is to be removed, must be solid enough for application of a multilayer "film" thereto and subsequent removal of a multilayer film therefrom. In light of Appellants' supporting Specification, I find that Ghadiri's stacked cyclic peptides including between 6 and 16 amino acids are not the kind of "surfaces" on which Appellants' method Claims 47 and 60 may provide a "film" and from which Appellants' method Claims 47 and 60 may remove that "film".

I also conclude that the Examiner clearly erred in finding that a person having ordinary skill in the art reasonably would have understood from Appellants' disclosure that Steiner's target membrane is a "surface" onto which the polymer layers which comprise Appellants' multilayer film may be provided and from which Appellants' multilayer film may be removed in accordance with Appellants' method Claims 47 and 60 and the solution deposition procedures for depositing the film-forming polymer layers described by their supporting Specification.

However, Appellants' Claim 69 is directed to a method of releasing an agent from a multilayer film without reference to a surface. Accordingly, it must be determined whether the agent-comprising multilayer "film" defined by Appellants Claims 69-73 and 77-82 (Br., App'x) may be broadly interpreted to encompass (a) Ghadiri's stacks of two or more layers of cyclic peptides having 6 to 16 amino acids containing an active agent, or (b) Steiner's active agent/transport enhancer composite which facilitates transport of the active agent through a target membrane by hydrogen bonding.

Each of Appellants' Claims 47, 60, and 69 minimally provide a "film comprising a first layer including a first polymer having a plurality of hydrogen bond donating moieties . . . [and] a second layer including a second polymer having a plurality of hydrogen bond accepting moieties" (Br., App'x). The Examiner finds that both Ghadiri and Steiner describe a multilayer film from which an agent may be released by subjecting the film to a change in pH, ionic strength, exposure to an electric field, or exposure to dissolved ions.

In support of the Examiner's preliminary finding that Ghadiri anticipates the methods Appellants claim, the Examiner states (Ans. 3):

> Ghadiri describes a "stack . . . formed by bonding a disk of polymers having hydrogen donating moieties . . . to a stack of disks of cyclic peptides (<u>claimed surface of particle</u>) and another disk (<u>claimed second layer</u>) of polymers having hydrogen accepting moieties . . . to the first layer (See Fig. 9b).

In support of the Examiner's preliminary finding that Steiner anticipates the methods Appellants claims, the Examiner states (Ans. 4):

> Steiner et al disclose a method for delivering a drug comprising <u>hydrogen bonding</u> to a membrane (claimed surface) **degradable** transport enhancer such as natural or synthetic polymer (claimed first polymer layer)(See P98) such as proteins (See P91) or fumaryl dektopiperazine (See P78) having hydrogen bonded thereto active agent (P19, 77) such as insulin or glucagon (claimed second polymer layer)(See P33, 80).

The Examiner found that Ghadiri describes a "film" comprising two layers of hydrogen bonding polymers. The Examiner found that Steiner describes a "film" comprising two layers of hydrogen bonding polymers. The Examiner disagreed with Appellants' argument that the term "film" comprising two or more layers of polymers in Appellants' claimed methods, and the significance of the term "film" to the subject matter claimed, have been misinterpreted (Ans. 4-5). As the Examiner interpreted the term "film" in Appellants' claims, neither of the requisite first and second layers of first and second polymers which comprise the "film" must be macroscopic in any dimension. Thus, the Examiner surmised that the "film[s]" of the methods Appellants claim, and all dimensions of the multilayers thereof, may be molecular in size. The sole basis for the Examiner's interpretation of the scope of the term "film" in Appellants' claims is the statement (Ans. 5):

> In the absence of definitions for terms "surface", "film" and "polymer" in the specification as filed, the Examiner has given the broadest reasonable interpretation of [the] claims consistent with the specification . . . .

Reading Ghadiri's disclosure, the Examiner finds (Ans. 7):

> A layer of a first molecular tube of cyclic peptides in Ghadiri provides **<u>claimed surface</u>** which is *covered* with a layer of a second molecular tube of cyclic peptides which is covered with a layer of a third molecular tube of cyclic peptides (claimed second polymer

> layer). Since cyclic peptides are polymers, the second molecular tube of cyclic peptides is a first polymer layer as claimed, the third molecular tube of cyclic peptides is a second polymer layer as claimed, and both first and second polymer layers form claimed film on the surface. Moreover, there is no negative limitation in the claims that claimed surface should not be in a tubular form. . . . .

Reading Steiner's disclosure, the Examiner finds (Ans. 8):

> Steiner discloses a membrane surface (claimed surface) coated with a transport enhancer such as natural or synthetic **polymer** (See P78)(claimed first polymer layer) having hydrogen bonded (See P89) coating ("entrapped")(See P80) of an active agent such as proteins (which are polymers), e.g. insulin (See P80), glucagon (See P100)(claimed second polymer layer). Steiner et al teach that the transport enhancer hydrogen bonded to a membrane is **degradable** (at or near neutral pH of the body fluid), i.e., it is **removed** from the membrane surface at near neutral pH of the body fluid.

While the Examiner states that the term "film" has been given its broadest reasonable interpretation consistent with the specification, I find no reference to, or mention of, the Specification's use of the term in the Examiner's Answer. I find that the Examiner's interpretation of the term "film" is inconsistent with the collective references to, and applications and descriptions of, the term in the Specification.

In the BACKGROUND, the Specification clearly teaches that polymer films may be produced "through self-assembly of the films, layer-by-layer" (Spec. 1, ll. 10-11). "The layers may be build (sic) up from a solution, and in the assembly process, molecules may become trapped between the layers" (Spec. 1, ll. 13-15). In the BRIEF SUMMARY, the Specification describes "a method of forming a film, including contacting a surface with a first polymer having a plurality of hydrogen bond donating

moieties, and contacting the surface with a second polymer having a plurality of hydrogen bond accepting moieties" (Spec., p. 2, ll. 1-4).

On page 4, the Specification lists film-forming polymers suitable for use in the disclosed invention (Spec. 4, ll. 1-16):

> Polymers for use in the present invention include polymers containing hydrogen bond donors and/or hydrogen bond acceptors, for example polycarboxylic acids such as polyacrylic acid and polymethacrylic acid; polynucleotides such as poly(adenylic acid), poly(uridylic acid), poly(cytidylic acid), . . . poly(inosinic acid); polymers of vinyl nucleic acids such as poly(vinyladenine); polyamino acids such as polyglutamic acid and poly(ε-N-carbobenzoxy-L-lysine); polyalcohols such as poly(vinyl alcohol); poyethers such as poly(ethylene oxide), poly(1,2-dimethoxyethylene), poly(vinylmethyl ether), and poly(vinylbenzo-18-crown-6); polyketones and polyaldehydes such as poly vinyl butral and poly(N-vinyl-2-pyrrolidone); polyacrylamides such as polyacrylamide, polymethacrylamide and poly(N-isopropylacrylamide); polyamines such as poly(4-amine)styrene; polyesters such as poly(cyclohexane-1,4-dimethylene terephthalate) and polyhydroxy methyl acrylate; polyphosphazenes such as poly(bis(methylamino)phosphazene) and poly(bis(methoxyethoxyethoxy)phosphazene; polysaccharides such as carboxymethyl cellulosel and copolymers thereof.

On pages 4-6, the Specification provides examples of preferred pairs of the above-listed film-forming polymers for use in forming each layer of the multilayer films (Spec. 4-6).

Every layer comprising the "films" described in the Specification appears to have been provided by depositing a solution of a film-forming polymer onto a surface and evaporating the solvent (Spec. 7, ll. 5-25):

> The film is formed by dissolving at least one of the polymers into a solvent, to form a solution. The solution is then contacted with the surface . . . . A solution of the second polymer is next contacted with the layer of the first polymer on the surface . . . and forming a film. The process of contacting the surface with a solution of the first

> polymer and then a solution of the second polymer may be repeated until a film of the desired thickness is formed. If more than two polymers are to be used to form the film, a solution of the additional polymers may be contacted with the growing film. . . . Aerosol deposition is also possible. . . . It is also possible to form the film by evaporating the first polymer onto a surface, followed by evaporation of the second polymer onto the surface, and repeating these steps until the desired thickness is achieved . . . .

Moreover, Appellants teach that "the films may be used to change [a wide variety of] the properties of the surface (surface roughness, reflectivity, color, hydrophobicity, chemical reactivity, etc.), and optionally, the original surface properties may be restored by destruction of the films" (Spec. 7-8, bridging sentence).

The Specification teaches that "[a]ny agent can be included in the film, as long as it can be dissolved or dispersed in the solvent in which at least one of the polymers is dissolved, or if the molecule can be evaporated with one of the polymers" (Spec. 8). "The films may be destroyed in order to release the agent trapped in the film so that the agent may carry out its own effect . . . or to simply release the polymers of the film into a solution . . . (Spec. 9).

All the Specification's examples provide "film[s]" by depositing layers of film-forming polymers onto solid surfaces from solutions thereof (Spec. 9-11). "This process was repeated 10-20 times until the desired film thickness was achieved" (Spec. 10, ll. 3-5).

Persons having ordinary skill in the art would have reasonably interpreted the term "film" in Appellants' method claims in light of the entirety of the supporting Specification's disclosure. The "film" of Appellants' claimed methods comprises (1) a first layer of polymer having

hydrogen bond donating moieties provided by deposition from a solution of film-forming polymer and solvent evaporation, and (2) a second layer of a second polymer having hydrogen bond accepting moieties formed by deposition from a solution of a film-forming polymer and solvent evaporation. No other kinds of films and film-forming techniques are described, suggested, and/or enabled by the supporting specification.

> What Phillips now counsels is that in the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public-i.e., those of ordinary skill in the art-that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source."

*Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1145 (Fed. Cir. 2007), *r'hg denied, citing Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005).

To conclude, as did the Examiner, that Appellants' claims include methods of releasing an agent from molecular tubes of stacked cyclic peptides into a live environment by providing at least one molecular layer of one cyclic peptide having 6-16 amino acids, at least one other molecular layer of another cyclic peptide having 6-16 amino acids, and an agent in an aqueous liposome suspension which spontaneously self-assemble into molecular tubes including the agent and subjecting the molecular tubes to a change in the live environment to cause the agent to be released is unreasonable. Appellants' Specification would not have enabled persons having ordinary skill in the art to make and use Ghadiri's method. Moreover, Ghadiri's method is inconsistent with the methods of making and using the agent-delivery systems described in Appellants' disclosure.

The Examiner appears to have equated Steiner's membrane to Appellants' surface, Steiner's transport enhancer to Appellants' claimed first polymer layer, and Steiner's active agent to Appellants' claimed second polymer layer (Ans. 8). I find that both Steiner's active agent and transport enhancer may be polymers (Steiner, p. 3, 0031-33; p. 5, 0078). I find that Steiner's active agent and transport enhancer may form hydrogen bonds with each other (Steiner, p. 5, 0077). I also find that an active agent may be released from entrapment by a transport enhancer by adjusting the pH of the environment, etc. (Steiner, p. 5, 0070-73). Nevertheless, the Examiner has not pointed to any disclosure or teaching in Steiner that the active agent and the transport enhancer which masks and transports the active agent to and through a target membrane constitute a "film" which the claims define as comprising <u>a first layer</u> including a first polymer, <u>a second layer</u> including a second polymer, <u>and an agent</u>.

The Examiner points to no teaching or suggestion in Steiner that its active agent can be both the second polymer layer and the agent comprising the "film" of Appellants' method Claim 69. Moreover, the Examiner points to no teaching or suggestion in Steiner that the transport enhancer and the active agent the transport enhancer is said to entrap or encapsulate (Steiner, p. 3, 0031-34) are first and second <u>layers</u> of first and second polymers as each of Appellants' Claims 47, 60, and 69 requires. Accordingly, all the Examiner's final rejections should be reversed.

SPIEGEL, Administrative Patent Judge.

Appellants' invention is directed to "a polymer film in which the layers are held together by hydrogen bond formation between the layers" (Spec., 2:6-7). Agents, such as drugs and dyes, may be included in the polymer layers (Spec., 8:3-27). According to the 090 specification (Spec., 9:5-10),

> [t]he films may be destroyed in order to release the agent trapped in the film so that the agent may carry out its own effect (such as in the case of a dye or bioactive agent), or to simply release the polymers of the film into a solution (for example, to change the viscosity of the solution). Furthermore, the films may be used to coat particles, allowing for controlled release of the one or more substances contained in the particles.

Each polymer used to form the films of the 090 specification must include at least a hydrogen bond donor or a hydrogen bond acceptor (Spec., 2:23-24). Preferably, films are formed using two polymers, one containing hydrogen bond donors, e.g., -OH and -NH moieties, and the other containing hydrogen bond acceptors, e.g., N, O, and F, and at least one of the polymers also contains charge-forming groups, e.g., acid or base moieties or crown ethers (Spec., 2:25-29; 3:10-31). The 090 specification lists specific polymers having repetitive monomeric units, such as polycarboxylic acid, poly(ethylene oxide) ("PEO") and poly(N-vinyl-2-pyrrolidine) ("PVP"), as well as polynucleotides or vinyl-type polymers containing nucleic acid bases and polyamino acids such as polyglutamic acid (Spec., 4:1 through 7:3). The specification further describes using polymers having a wide range of molecular weights (Spec., 7:24-25 ("at

most 5000 g/mol, more preferably at most 2000 g/mol" for aerosol deposition); 9:22-24 (average molecular weights of 594,000; 327,000; and 164,000 for dip deposition); 11:1 (average molecular weights of 1,300,000 and 55,000 for dip deposition)).

According to the 090 specification (Spec., 7:4-25),

> films may be formed on a surface, such as the surface of a monolithic solid, or particles. The film is formed by dissolving at least one of the polymers into a solvent, to form a solution. The solution is then contacted with the surface, and hydrogen bonding of the polymer with the surface forms a layer of the polymer on the surface. A solution of the second polymer is next contacted with the layer of first polymer on the surface, forming hydrogen bonds between the polymers, and forming a film. The process of contacting the surface with a solution of a first polymer and then a solution of the second polymer may be repeated until a film of the desired thickness is formed.

Exemplary surfaces described in the 090 specification include monolithic solids or particles, including semiconductor materials, e.g., silicon and germanium; polymers, e.g., polyethylene and TEFLON®; ceramics, e.g., glass or alumina; and minerals, e.g., mica (Spec., 7:4-5 and 20-31). "The films may be coated onto a surface, with an agent contained in the film, which may be released at a later time by destruction of the film" (Spec., 7:29-31). "Also, the films may be used to change the properties of the surface (surface roughness, reflectivity, color, hydrophobicitiy, chemical reactivity, etc.), and optionally, the original surface properties may be restored by destruction of the films" (Spec., 7:31 through 8:2).

Ghadiri discloses nanotube structures constructed from stacked disks of cyclic peptides having between 6 and 16 amino acid residues, wherein the stacked disks are held together by hydrogen bonding, which may be used as a drug delivery system (Ghadiri, 1:16-20; 2:37-57; 3:29-38; 7:19-23; 8:36-41; 15:6-9; 16:48-57). Ghadiri's nanotubes may be loaded with agents, e.g., ions, molecules or drugs, within their channel space which has an inner diameter determined by the size of the cyclic peptide, e.g., a cyclic hexapeptide has an inner diameter of ~7Å and a cyclic dodecapeptide has an inner diameter of ~15Å (Ghadiri, 2:46-57; 3:28-32 and 56-62). Ghadiri's nanotubes may be formed by (1) synthesizing the linear form of the peptide and then cyclizing it in solution to furnish the desired cyclic peptide subunit (Ghardiri, 21:20-23), then (2) adding the peptide subunit to aqueous liposomal suspensions (*id*., 12:20-21). According to Ghadiri, the cyclic peptide subunit partitions into the lipid bilayers of the liposomes and spontaneously self-assembles into transmembrane channel structures (Ghadiri, 12:20-23). Further according to Ghadiri, the design, synthesis and characterization of artificial transmembrane pore structures (nanotubes) may provide a potential vehicle for drug delivery into living cells (Ghadiri, 14:45-55).

Steiner discloses microparticles formulations comprising an active agent, which may be charged or neutral, and a transport enhancer that masks the charge of the agent and/or forms hydrogen bonds with a target biological membrane in order to facilitate transport of the agent (Steiner, ¶¶ 19 and 77). A preferred formation comprises microparticles of insulin entrapped in diketopiperazine which hydrogen bonds to the insulin molecule to mask its charge, thereby facilitating the insulin to pass through the target membrane

(Steiner, ¶¶ 19, 24 and 80). Suitable active agents include polymers such as proteins, peptides, polysaccharides, nucleic acid molecules and combinations thereof (Steiner, ¶ 32).

The Examiner has interpreted the terms "polymer," "film," and "surface" as recited in the appealed claims to be met by the cyclic peptides and/or nanotubes (molecular tube) of Ghardiri (Ans., 5). According to the Examiner,

> [a] layer of a first molecular tube of cyclic peptides in Chadiri [sic] provides **claimed surface** which is *covered* with a layer of a second molecular tube (claimed first layer) of cyclic peptides which is covered by a layer of third molecular tube of cyclic peptides (claimed second polymer layer). Since cyclic peptides are polymers, the second molecular tube of cyclic peptides is the first polymer layer as claimed, the third molecular tube of cyclic petides [sic] is a second polymer layer as claimed, and both first and second polymer layers form claimed film on the surface. Moreover, there is no negative limitation in the claims that claimed surface should not be in tubular form. Accordingly, the reference anticipates or makes obvious claims 47 and 52-87. [Ans., 5, original emphasis.]

Further according to the Examiner,

> Steiner discloses a membrane surface (claimed surface) coated with a transport enhancer such as a natural or synthetic **polymer** (See P78) (claimed first polymer layer) having hydrogen bonded (See P 89) coating ("entrapped") (See P80) of an active agent such as proteins (which are polymers), e.g., insulin (See P80), glucagon (See P100) (claimed second polymer layer). Steiner et al [sic] teach

> that the transport enhancer hydrogen bonded to a membrane is **degradable** (at near normal pH of the body fluid), i.e. [sic] it is **removed** from the membrane surface at near neutral pH of the body fluid. [Ans., 8, original emphasis.]

The dispositive issue in this appeal is whether the Examiner erred in her interpretation of the claim terms "polymer," "film," and "surface."

Claim interpretation is a matter of law. *Markham v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). "[I]n proceedings before the PTO, claims in applications are to be given their broadest reasonable interpretation consistent with the specification." *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983). Our reviewing court has made it clear that in construing claims "we search for the ordinary and customary meaning of a claim terms to a person of ordinary skill in the art. We determine this meaning by looking first at intrinsic evidence such as surrounding claim language, the prosecution history, and also at extrinsic evidence, which may include expert testimony and dictionaries." *L.B. Plastics, Inc. v. American Home Products Inc.*, 499 F.3d 1303, 1308 (Fed. Cir. 2007) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-19 (Fed. Cir. 2005) (en banc)).

Ghadiri does not disclose a "polymer," a "film" or a "surface" as recited in independent claims 47, 60 and/or 69 when these claim terms are given their broadest reasonable interpretation consistent with the 090 specification. Steiner does not disclose or suggest a "film" as recited in independent claims 47, 60 and/or 69.

"Polymer" ordinarily and customarily is a "molecule of high relative molecular mass, the structure of which essentially comprises the multiple repetition of units derived, actually or conceptually, from molecules of low

relative molecular weight" (see IUPAC, *Compendium of Chemical Terminology: IUPAC Recommendations*, 2nd edition, compiled by A.D. McNaught and A. Wilkinson, Blackwell, Oxford (1997) ("IUPAC"), Br., 30). While the 090 specification does not provide an express definition of "polymer," the illustrative polymers and examples in the 090 specification are consistent with the ordinary and customary definition of a polymer, i.e., molecules of high relative molecular weight comprising multiple repetition of units derived from molecules of low relative molecular weight. While Ghadiri's cyclic peptides having between 6 and 16 amino acid residues are derived from multiple repetitive units (amino acid residues) of low relative molecular weight, they do not appear to be molecules of high relative molecular weight. The Examiner has not pointed to any evidence of record or usage in the 090 specification which is consistent with classifying a 6 to 16 amino acid residue cyclic peptide as a "polymer" within the scope of the claimed subject matter.

A "film" is a "generic term referring to condensed matter restricted in one dimension" (IUPAC, Br., 29). In other words, a film is a material in which one spatial dimension, thickness, is much smaller than the other two, length and width. While the 090 specification does not provide an express definition of a "film," the illustrative examples of making and using films in the 090 specification are consistent with the ordinary and customary definition of a film. According to the Examiner, two stacked cyclic peptide disks of Ghadiri form the claimed film (Ans. 5). However, the Examiner has not explained why one of ordinary skill in the art would have reasonably considered two stacked cyclic peptide disks of Ghadiri to be a conventional film, e.g., why a "short stack" would have been considered condensed matter

which is much thicker than it is long or high. Similarly, the Examiner has not pointed to any disclosure of making and using films in the 090 specification which is consistent with classifying two stacked cyclic peptide disks of Ghadiri as a "film" within the scope of the claimed subject matter.

A "surface" is a two-dimensional set of points in three-dimensional space, e.g., the outside of a sphere. While the 090 specification does not provide an express definition of a surface, the "surfaces" described by the 090 specification are consistent with this definition. In particular, the 090 specification describes surfaces as monolithic surfaces or particles which are coated with layers of films. The 090 specification further describes the film(s) as affecting the chemical, physical and/or optical properties of the surface. According to the Examiner, the "first" cyclic peptide disk of Ghadiri corresponds to the claimed "surface" because it is covered by additional cyclic peptide disks (Ans. 5). In my opinion, to equate the claimed "surface" with the claimed "film" is inconsistent with the 090 specification describing surfaces and films as distinct entities of differing materials and of films being capable of affecting the properties of the substrate.

In summary, Ghadiri does not disclose a "polymer," a "film" or a "surface" as recited in claims 47, 60 and/or 69 when these claim terms are given their broadest reasonable interpretation consistent with the 090 specification. Therefore, claims 47 and 52-87 are not anticipated by Ghadiri since Ghadiri fails to disclose each and every limitation in the claims. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631(Fed. Cir. 1987).

As to Steiner, the Examiner contends that the active agent entrapped within the transport enhancer of Steiner are the second and first polymer

layers which form the claimed film (Ans., 4 and 8). First, a fair reading of Steiner is that its "active agent" corresponds to Appellants' claimed "agent" and, therefore, Steiner fails to disclose the second polymer layer of the claimed film. Alternatively, the Examiner has not shown where Steiner discloses, teaches or suggests the "agent" required by claims 69-87. Second, the Examiner argues that "the active agent is **coated onto** microparticles of the diketopiperazine" (Ans., 4, original emphasis). However, a microparticle is not a film. Since Steiner does not fairly describe or suggest a film comprising two polymer layers as claimed, Steiner fails to anticipate the claimed invention or render it obvious.

NAGUMO, Administrative Patent Judge.

Our reviewing court has made clear that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d, 1303, 1313 (Fed. Cir. 2005).[2] In my view it suffices to find that the term "film," as used both by lay-persons and by persons skilled in the technological arts, refers to an essentially continuous, essentially two-dimensional object having at least lateral dimensions that are "large" compared to single molecules. The Examiner has not directed our attention to any disclosure in Appellants' specification that indicates that the broader definition proposed by the Examiner is one contemplated by the inventors. Nor has the Examiner directed our attention to any disclosure in

[2] Although Phillips is concerned with construing claims in patents, not in applications, much of the analysis carries over to the interpretation of claims in applications.

the prior art that indicates that the person of ordinary skill in the relevant arts might have read Appellants' specification as being directed to a broader than usual meaning of the term "film." Accordingly, it is reasonable to conclude that the term "film" should be given the broadest ordinary meaning consistent with the specification.

The columnar structures taught by Ghadiri, which the Examiner identifies broadly as films, are not films within the ordinary meaning of the term, because their lateral extent is defined by a single and relatively small molecule. The Examiner, having failed to show any use in the specification or in the art of record consistent with the proposed broad "definition", has failed to present a reference describing an embodiment within the scope of the claimed invention. Similarly, the Examiner has identified as a "film" the encapsulated active agent (i.e., the active agent encapsulated by the "transport enhancer," which may be a natural or synthetic polymer (Steiner at P78) or diketopiperazines (*Id.* at P77) described by Steiner. Although polymer films are well known, the Examiner has failed to direct our attention to any description or evidence of record that tends to show that the transport-enhancer encapsulated active agents described by Steiner are films in the conventional sense of the term. Thus, Steiner also fails to describe or suggest the claimed invention.

The Examiner's interpretation of the term "surface" in the appealed claims as reading on the surface of a single small molecule (as opposed to something much larger) is in error for similar reasons. The Examiner has failed to direct our attention to any disclosure in the specification or in the prior art of record that indicates that a person having ordinary skill in the art would have understood that the inventor intended the disputed term to cover

more than the ordinary and customary meaning revealed by the context of the intrinsic record.

These reasons are sufficient to REVERSE the Examiner's rejections.

While I cannot join the opinions of my colleagues in the details of their treatments of the critical terms in this appeal, I note that we do agree that, whatever the proper construction of these terms as they are used in Appellants' claims, the references do not describe or suggest embodiments within the scope of the claims.

## ORDER

Accordingly, it is:

ORDERED that the Examiner’s final rejection of Claims 47 and 52-87 of Application 10/852,090, filed May 24, 2004, under 35 U.S.C. § 102(e) over Ghadiri, U.S. Patent 6,613,875 B1, issued September 2, 2003, is reversed;

FURTHER ORDERED that the Examiner’s final rejection of Claims 47 and 52-87 of Application 10/852,090, filed May 24, 2004, under 35 U.S.C. § 102(e) over Steiner et al. (Steiner), U.S. Patent Application Publication 2004/0077528 A1 published April 22, 2004, is reversed;

FURTHER ORDERED that the Examiner’s final rejection of Claims 47 and 52-87 of Application 10/852,090, filed May 24, 2004, under 35 U.S.C. § 103(a) in view of Steiner, is reversed; and

FURTHER ORDERED that the application is remanded to the examiner for action consistent with the views expressed herein.

REVERSED

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