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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KWAN WOO SHIN, KEEL YONG LEE,
TAE KYU AHN, and GI YOONG TAE

Appeal 2019-003333
Application 15/131,485[1]
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a liposome, which have been rejected as containing new matter, being anticipated and/or being obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

The extracellular matrix, which is "composed of proteoglycans, such as heparan sulfate, chondroitin sulfate, and keratin sulfate, nonproteoglycan

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[1] We use the word "Appellant" to refer to "Applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Sogang University Research Foundation. (Appeal Br. 3.)

polysaccharides such as hyaluronic acid, fibers such as collagen and elastin, fibronectin, and laminin," "is mainly in charge of the structural support of animals." (Spec. ¶¶ 3, 4.)

A liposome is a spherical vesicle having at least one lipid bilayer, is biocompatible, and is widely used as a drug delivery system. (*Id.* ¶ 5.) Appellant's invention is directed to "a liposome that is capable of promoting cell attachment and growth by delivering the extracellular matrix to cells." (*Id.* ¶ 7.)

Claims 1–4 and 6–13 are on appeal. Claim 1 is representative and reads as follows:

> 1. A liposome for delivering an extracellular matrix, the liposome comprising:
>
> (a) a phospholipid membrane having an anionic lipid and a neutral lipid, which are self-assembled; and
>
> (b) an extracellular matrix bound to the anionic lipid solely by ionic bonding to be disposed on a surface of the anionic lipid;
>
> wherein the extracellular matrix is at least one selected from the group consisting of fibronectin, collagen, laminin, and elastin.

(Appeal Br. 26.)

The prior art relied upon by the Examiner is:

Name	Reference	Date
John D. Rossi et al., *Binding of Fibronectin to Phospholipid Vesicles*, 258 (5) J. Biological Chem, 3327-3331 (1983)		
Weiner	US 5,366,958	Nov. 22, 1994
Rogers	US 2014/0234217 A1	Aug. 21, 2014
Siepis	US 2015/0216803 A1	Aug. 6, 2015
Xiao Zheng Shu et al., *Disulfide-crosslinked hyaluronan-gelatin hydrogel films: a covalent mimic of the extracellular matrix for in vitro cell growth*, 24 Biomaterials, 3825-3834 (2003).		

The following grounds of rejection by the Examiner are before us on review:

Claims 1–4 and 6–12 under 35 U.S.C. § 112(a) as reciting new matter not supported by the original written description.

Claims 1–4, 7, 9, 11, and 13 under 35 U.S.C. § 102(a)(1) as anticipated by Rossi.

Claims 1, 3, 4, 7, 9, and 11–13 under 35 U.S.C. § 103 as unpatentable over Weiner.

Claims 1–4, 6–11, and 13 under 35 U.S.C. § 103 as unpatentable over Weiner, Rogers, and Siepis.

Claims 1–4, 6–11, and 13[2] under 35 U.S.C. § 103 as unpatentable over Rossi, Rogers, and Siepis.

[2] The Examiner's rejection also refers to claim 12. However, the Examiner does not address the limitations of claim 12 in this rejection and does separately reject this method claim as being obvious over Rossi and Shu. Thus, we understand the Examiner's inclusion of claim 12 under this ground to have been an inadvertent error.

Claim 12 under 35 U.S.C. § 103 as unpatentable over Rossi or Weiner and Shu.[3]

DISCUSSION

New Matter

The Examiner explains that claim 1 recites that the ECM is "selected from the group consisting of fibronectin, collagen, laminin, and elastin" and that the ECM is bound to the anionic lipid of the phospholipid membrane "***'solely'*** by ionic bonding to be disposed on a surface of the anionic lipid." (Ans. 3; Final 2.) According to the Examiner, the Specification as originally filed does not include the term "solely" and while the Specification at page 13, paragraph 76 does state that "'synthetic liposome contains DOPS (an anionic lipid) and thus has anionic charge, and induces ionic bonding with collagen or fibronectin using the anionic charge'", the "[S]pecification nowhere indicates that laminin and elastin also bind [] to DOPS by ionic bonding." (Ans. 7.)

Appellant explains that "the [S]pecification discusses only a single type of binding—ionic bonding—between the protein and the anionic lipid (Specification pg. 6, para. [0029]; pg. 13, para. [0076])." (Reply Br. 3.)

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[3] The Examiner's rejection refers also to a published US application to Marriott. However, claim 12 depends from claim 1, and the rejection of claim 1 as being anticipated by Marriott was withdrawn by the Examiner in the Answer in light of an amendment to the claim. (Ans. 2.) The Examiner did not rely on Shu to address any limitations of claim 1, but rather to address the cell growth limitation of claim 12. In light of the foregoing, we understand the Examiner's reference to Marriott in this rejection to have been an inadvertent error.

Furthermore, regarding whether laminin or elastin can bind to an anionic lipid via ionic bonding, Appellant explains that "it was known that each of the four recited proteins can be given a positive charge, or expose a positively charged region, by lowering the pH." (*Id.*) In light of the foregoing, argues Appellant, "it is reasonable to conclude that Applicant was in possession of the invention comprising the feature 'solely by ionic bonding'" despite the lack of *ipsis verbis* support. (*Id.*)

We agree with Appellant that the Specification reasonably conveys that the inventor possessed the subject matter of claim 1.

> A description adequate to satisfy 35 U.S.C. § 112, first paragraph, must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.' In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citation omitted, alteration in original). Paragraph 29 of the Specification clearly identifies the ECM being bound to the liposome "by ionic bonding with the anionic lipid" of the phospholipid membrane and Paragraph 30 of the Specification clearly identifies each of "fibronectin, collagen, laminin, and elastin" as components from which the ECM is selected. We find this sufficient description of the claim requirement that the bonding to the anionic lipid of the liposome is solely by ionic bonding.[4]

[4] The Examiner's "questioning" whether "laminin and elastin also bind [] to DOPS [known in the art as a negatively charged phospholipid] by ionic bonding [like collagen and fibronectin] or by hydrogen bonds, dipole-dipole interactions or by other bonding" (Ans. 7) seems to us to be a concern of

Thus, we reverse the Examiner's rejection of claims 1–4 and 6–12 under 35 U.S.C. § 112(a) as reciting new matter.

II

Anticipation

The Examiner finds that Rossi discloses "small unilamellar sonicated vesicles containing DPPC and DPPA and fibronectin bound to the liposomes." (Final 9; Ans. 8.) The Examiner notes that "irrespective of Rossi's interpretation of the nature of bonding" as possibly having "some hydrophobic character" in light of the observation that "the fibronectin-liposome binding is not affected by high salt concentrations and does not depend on head charge," that the liposomes of Rossi are the same anionic liposomes claimed and fibronectin is bound to it. (*Id.*) In light of the foregoing, the Examiner indicates that the Appellant must show experimentally that the interaction of Rossi is different than what is claimed, i.e. solely through ionic interactions. (*Id.*)

We agree with the Examiner's prima facie finding of anticipation. Appellant's claim 1 is a composition that has 3 required elements: an anionic lipid and a neutral lipid, which together form the phospholipid membrane of the liposome, and an extracellular matrix that is disposed on a surface of the anionic lipid, where the extracellular matrix is at least one of fibronectin, collagen, laminin, or elastin. Rossi teaches combining together DPPC and dipalmitoyl phosphatidic acid (DPPA) in a 4:1 (mol/mol) mixture to make a phospholipid vesicle to which fibronectin is then added. (Rossi 3327–28

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whether this aspect of the invention is enabled. However, that is not a rejection on review before us.

(Experimental Procedures).) DPPC is indicated in Appellant's Specification to be a neutral lipid (Spec. ¶ 21) and DPPA is indicated in Appellant's Specification to be an anionic lipid (Spec. ¶ 15). Thus, Rossi teaches all the components required by Appellant's claim. Moreover, Rossi teaches that the fibronectin is bound to the liposome. (Rossi at 3228 ("It was found that fibronectin bound to all of these vesicle types," i.e., vesicles containing lipids with either negative, neutral, or positive surface head groups.) In light of the fact that Rossi's composition includes all of the requisite ingredients required by Appellant's claim, we conclude that the Examiner has established a prima facie case of anticipation and it was appropriate for the Examiner to require Appellant to prove that the composition does not necessarily or inherently possess the binding characteristic between the fibronectin and anionic lipid that is claimed. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively[.]") Thus, we disagree with Appellant that the Examiner "improperly attempt[ed] to shift the burden onto Appellant" (Appeal Br. 17; *see also* Reply Br. 4.)

Rather than present experimental evidence to prove the fibronectin of Rossi was not bound solely by ionic bonding to the anionic lipid, Appellant argued that Rossi itself concluded "that the interaction is 'not . . . merely electrostatic in nature.'" (Appeal Br. 16; *see also* Reply Br. 4.) We disagree that Rossi arrived at such a categorical conclusion or that the Examiner

ignored a "clear[] report[]" by Rossi "that the fibronectin does not bind to the liposomes 'solely by ionic binding'" (Appeal Br. 16; *see also* Reply Br. 4). Rossi states only "that the interaction [of fibronectin to the lipid vesicle] ***may not*** be merely electrostatic in nature ***but might*** also have some hydrophobic character." (Rossi 3329 (emphasis added).) According to Rossi, this possibility is because "[e]xtrinsic proteins which bind only by electrostatic interactions are ***generally dissociated*** under either very high or low ionic strength conditions" but "identical results were obtained for vesicles in the presence and absence of high salt" and there was a lack of selectivity for head group charge. (*Id*. at 3328–29 (emphasis added).)

Rossi's hypothesis regarding the nature of the binding of fibronectin to the liposome is not proof that binding thereto is not solely electrostatic, nor is it proof that binding with the anionic lipid of the liposome is "solely by ionic bonding." Indeed, Rossi's hypothesis regarding binding to the liposome generally is itself premised on a generalization, i.e., Rossi accepts that it is not the case that all extrinsic proteins which bind by electrostatic interactions will necessarily dissociate under either very high or low ionic strength conditions. In light of the foregoing, we do not find that the Appellant has overcome the Examiner's prima facie case of anticipation of claim 1.

Claim 13 is "[a] method for preparing a liposome for delivering an extracellular matrix of claim 1." Appellant argues that the Examiner's rejection of claim 13 fails for the same reason it argued the Examiner's rejection failed as to claim 1. (Appeal Br. 16.) As just discussed, we disagree with Appellant's contention that the Examiner did not establish anticipation of claim 1.

Claims 2–4, 7, 9, and 11 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

Thus, we affirm the Examiner's rejection of claims 1–4, 7, 9, 11, and 13 under 35 U.S.C. § 102(a)(1) as anticipated by Rossi.

Non-Obviousness over Weiner alone or in combination

The Examiner finds that Weiner teaches liposomal compositions containing fibronectin where the fibronectin is covalently or non-covalently linked to the surface of the liposome. (Final 11.) The Examiner further finds that Weiner teaches a number of lipids that can be combined to make the liposomes including "DSPC, DPPC, cholesterol, phosphatidylserine, phosphatidylethanolamine and phosphatidic acid." (*Id.*) According to the Examiner:

> Although Weiner specifically teach through examples fibronectin connected to negatively charged liposomes, since liposomes are known to be formed using any phospholipid or mixture of phospholipids, it would have been obvious to one of ordinary skill in the art to use liposomes containing a mixture of phospholipids including phosphatidic acid or phosphatidylserine and attach fibronectin non-covalently to the surface from the teachings of Weiner. One of ordinary skill in the art would expect fibronectin to bind to a negatively charged liposome containing either phosphatidic acid since on col. 2, lines 36-38 Weiner states that fibronectin binds to negatively charged hyaluronic acid.

(*Id.*)

We disagree with the Examiner's conclusion of obviousness. As Appellant notes (Appeal Br. 20), Weiner is concerned with covalent conjugation of a liposome to fibronectin. The only mention of fibronectin non-covalently bound to phospholipid is in a statement referencing a

suggestion in prior art studies "as a possible means of targeting liposomes to particular body sites rich in collagen." (Weiner 2:56–59.) Nowhere does Weiner suggest making noncovalently bound fibronectin liposome compositions. Rather, Weiner explains that its invention is to "new and substantially improved compositions . . . for enhancing localized retention of administered bioactive agents . . . . When fibronectin is *covalently linked* to a bioactive agent or to its carrier, the affinity of the resulting conjugate for appropriate sites in vivo is greatly increased." (Weiner 3:49–59 (emphasis added).) Weiner states:

> The present invention involves methods and formulations of conjugates of fibronectin (i.e., fibronectin *covalently bound* to amine-containing compounds such as lipids, . . . acidic phospholipids, derivatized phospholipids or liposomes) which have numerous advantages for use as drug delivery or carrier systems. Fibronectin *covalently bound* to bioactive agents may be administered directly or incorporated into a liposome preparation which is then administered in vivo. Alternatively, if fibronectin is bound to a lipid, this conjugate may be incorporated into the lipid bilayer of liposomes containing an entrapped bioactive agent.

(*Id.* at 4:27–40 (emphasis added).) While we agree with the Examiner that Weiner describes acidic phospholipids including phosphatidic acid or phosphatidylserine may be used "[a]ccording to another embodiment of the present invention" (*see, e.g.*, *id.* 6:47–51), it does so in the context of "the present invention," which is a covalently conjugated fibronectin phospholipid composition. Thus, Weiner is not "suggestive of the non-covalent binding of fibronectin to the liposomes," just because it mentions in passing other "studies [that] have suggested utilization of fibronectin non-covalently bound to lipid vesicles as a possible means of targeting liposomes to particular body sites rich in collagen" (*id.* at 2:56–59). Consequently, we

do not agree with the Examiner that one of ordinary skill in the art would have found it obvious in light of Weiner's teachings to "use liposomes containing a mixture of phospholipids including phosphatidic acid or phosphatidylserine and attach fibronectin non-covalently to the surface" of a liposome (Final 11).

The Examiner's further rejections of claims for obviousness involving Weiner, Rogers, and Siepis, and Weiner in combination with Shu rely on Weiner as teaching "the [claimed] attachment of fibronectin" to liposomes (*see, e.g.*, Ans. 10). That is, the Examiner only relies on Rogers and Siepis for teaching specific phospholipids that are known to be used in making liposomes. (*See, e.g.*, *id.*; Final 12.) The Examiner only relies on Shu for the known use of fibronectin and collagen, when coated onto hyaluronan, as enhancing cell attachment and that disulfide-crosslinked hyaluronan-gelatin (matrix protein) mimics the extracellular matrix for in vitro cell growth. (*See e.g.*, Ans. 6.) For the reasons just discussed, we do not agree with the Examiner that Weiner teaches or suggests the non-covalent attachment of fibronectin to a liposome, much less to the anionic lipid of a phospholipid membrane of a liposome.

Thus, we reverse the Examiner's rejection of claims 1, 3, 4, 7, 9, and 11–13 under 35 U.S.C. § 103 as unpatentable over Weiner and claims 1–4, 6–11, and 13 under 35 U.S.C. § 103 as unpatentable over Weiner, Rogers, and Siepis, and claim 12 under 35 U.S.C. § 103 as unpatentable over Weiner and Shu.

Non-Obviousness over Rossi, Rogers, and Siepis

The Examiner finds that Rossi, in addition to teaching the combination of DPPC and DPPA, also teaches "in the experimental section . . . the use of dipalmitoylethanoloamine." (Final 12; Ans. 5.) According to the Examiner:

> one of ordinary skill in the would be motivated to use specific phospholipids such as DOPC, POPE, DOPS and mixtures with a reasonable expectation of success since specific phospholipids or mixture of specific phospholipids could be used for the formation of liposomes as also evident from the reference of Rogers (Abstract and 0043) and Siepis (Abstract and 0091-0092).

(Final 12–13.) Only claims 6, 8, and 10 concern liposomes that are required to include DOPC, POPE, and DOPS.

We conclude that the Examiner has not presented a prima face case of obviousness with respect to claims 6, 8, and 10, the claims that were not also rejected as being anticipated by Rossi.

Appellant argues only that Rogers and Siepis do not compensate for the alleged deficiency of Rossi not teaching the ECM bound to the anionic lipid "solely by ionic bonding" regarding claim 1. (Appeal Br. 23–24.) As noted above in the anticipation discussion, we agree that the Examiner has set out a prima facie case of anticipation with respect to claim 1 and Rossi, and thus we do not find Appellant's argument with respect to whether or not claim 1 is obvious from Rossi, Rogers, and Siepis to be persuasive. *See generally In re Bush*, 296 F.2d 491, 496 (CCPA 1961) (the Board may rely on less than all of the references relied upon by the Examiner). "It is well settled that 'anticipation is the epitome of obviousness.'" *In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002) (quoting *Connell v. Sears, Roebuck &*

Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983)). Thus, as to claims 1–4, 7, 9, 11, and 13, we affirm the Examiner's rejection of these claims as not being patentable over Rossi.

Nevertheless, as to claims 6, 8, and 10, "[a]n examiner bears the initial burden of presenting a prima facie case of obviousness. Once the examiner establishes a prima facie case of obviousness, the burden shifts to the applicant to rebut that case." *In re Huai-Hung Kao*, 639 F.3d 1057, 1066 (Fed. Cir. 2011). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (*quoting In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

The Examiner's obviousness position as to claims 6, 8, and 10, appears to be that because Rogers and Siepis teach DOPC, POPE (a phosphoethanolamine derivative), and DOPS are phospholipids that can be used in the preparation of a lipid assembly (Rogers ¶ 43 (identifying DOPC, POPE, and DOPS as non-cationic lipids), Siepis ¶¶ 91–92 (identifying POPE and DOPC as neutral lipids and DOPS as an anionic lipid) and Rossi identifies the use of DPPC, DPPA, and an ethanolamine derivative (dipalmitoylphosphatidylethanolamine) as phospholipids for making a phospholipid vesicle, picking DOPC, POPE, and DOPS as compared to the combinations Rossi used would have been obvious. We do not find the Examiner's conclusory position to satisfy the necessary articulated reasoning to support obviousness.

Rossi teaches the use of an ethanolamine derivative having a positive head group charge (Rossi 3328) in combination with DPPC, which

Appellant's Specification teaches is a neural lipid (Spec. ¶ 21) or DPPA having a negative head group charge (Rossi 3328) in combination with the neutral lipid DPPC. Moreover, Rossi teaches the inclusion of the ethanoloamine derivative in its two component lipid membrane because it had positively charged head groups and in order to examine whether the change in surface charge changed the interaction of fibronectin with the lipid vesicle. (*Id.*) Rossi does not teach a combination of three lipids to make a single lipid vesicle.

While Rogers and Siepis teach a number of different lipids for use in a lipid assembly, the Examiner has not provided any rationale supporting a reason that one of ordinary skill in the art would have substituted the anionic lipid DOPS for DPPA in Rossi, substituted the neutral lipid DOPC for DPPC in Rossi, and then also included an ethanolamine derivative that does not have a positive head group together with those other two phospholipids. That one could have combined them is not a sufficient reason to support doing so in light of Rossi's clear teaching of two component vesicles.

Thus, for the foregoing reason, we reverse the Examiner's rejection of claims 6, 8, and 10 as being obvious over Rossi, Rogers, and Siepis.

Non-Obviousness of Claim 12 over Rossi and Shu

Claim 12 is a method for promoting cell growth, which method only requires bringing the liposome of claim 1 into contact with animal cells. We explained above, the Examiner's findings regarding the teachings of Shu, when discussing the obviousness rejections by the Examiner of the claims over Weiner. According to the Examiner, it would have been obvious to one having ordinary skill in the art to have used the DPPC-DPPA liposome

vesicle of Rossi with fibronectin bound thereto "for attachment of cells and subsequent growth of cells since it is known in the art that extracellular matrix material is involved in the growth of cells and Shu teaches extracellular matrix protein and hyaluronan combination enables it to attach to cells for their growth." (Final at 13–14.)

We conclude that the Examiner has not presented a prima face case of obviousness with respect to claim 12.

Appellant argues only that Shu does not compensate for the alleged deficiency of Rossi not teaching the ECM bound to the anionic lipid "solely by ionic bonding" regarding claim 1. (Appeal Br. 24–25.) As noted above in the anticipation discussion, we agree that the Examiner has set out a prima facie case of anticipation with respect to claim 1 and Rossi, and thus we do not find Appellant's argument to be persuasive.

Nevertheless, similar to the obviousness rejection of claims 6, 8, and 10, just discussed, the Examiner has not articulated a reason *why* one of ordinary skill in the art would have used the lipid vesicle with fibronectin bound thereto in place of the fibronectin that Shu teaches when coated onto hyaluronan results in enhanced cell attachment and mimics the extracellular matrix for in vitro cell growth (Ans. 10–11). That one could make the substitution because it was a known fibronectin composition is not a sufficient reason to support doing so particularly where Rossi does not provide any teaching regarding properties that would support using its fibronectin lipid vesicle construction in place of a simple fibronectin or the oligopeptides containing fibronectin-derived RGD peptide to attach to hyaluronan (Shu 3826) and the Examiner does not point to any teaching in Shu regarding sought after properties.

Thus, for the foregoing reason, we reverse the Examiner's rejection of claim 12 as being obvious over Rossi and Shu.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–4, 6–12	112(a)			1–4, 6–12
1–4, 7, 9, 11, 13	102(a)(1)	Rossi	1–4, 7, 9, 11, 13	
1, 3, 4, 7, 9, 11–13	103	Weiner		1, 3, 4, 7, 9, 11–13
1–4, 6–11, 13	103	Weiner, Rogers, Siepis		1–4, 6–11, 13
1–4, 6–11, 13	103	Rossi, Rogers, Siepis	1–4, 7, 9, 11, 13	6, 8, 10
12	103	Weiner, Shu		12
12	103	Rossi, Shu		12
Overall Outcome			1–4, 7, 9, 11, 13	6, 8, 10, 12

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART