

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte WINSTON A. ANDREWS, GLORIA R. DUMLAO  
and TERRY R. KNAPP

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Appeal No. 1997-4259  
Application No. 08/259,474

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ON BRIEF

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Before METZ, FRANKFORT, and ROBINSON, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 17 and 27 through 31, which are all of the claims remaining in the application. Claims 18 through 26 and 32 through 36 have been canceled.

As noted on page 1 of the specification, appellants' invention relates to surgical implants or prostheses (e.g., breast implants), and more particularly to a filler material

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for implants comprising a flexible shell enclosing a filler material and implants containing the filler material.

Independent claims 1, 7, 9, 12, 27 and 30 are representative of the subject matter before us on appeal and a copy of those claims, as reproduced from the Appendix to appellants' brief, is attached to this decision.

The sole prior art reference of record relied upon by the examiner in rejecting the appealed claims is:

Destouet et al. (Destouet)      4,995,882      Feb. 26,  
1991

Claims 9 and 30 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification which fails to provide an adequate written description of the invention. According to the examiner (answer, page 4), appellants have failed to define standard mammographic procedures, intensities and exposure times.

Claims 9 and 30 additionally stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing

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to particularly point out and distinctly claim that which appellants regard as their invention. As indicated on page 4 of the answer, it is the examiner's view that,

[w]ith respect to claims 9 and 30, there is no basis for "standard mammographic procedures, intensities and exposure times."

In addition to the foregoing rejections, claims 1 and 12 stand rejected under 35 U.S.C. § 102(b) as anticipated by or in the alternative, under 35 U.S.C. § 103 as obvious over Destouet.

Claims 2 through 11, 13 through 17 and 27 through 31 stand rejected under 35 U.S.C. § 103 as being unpatentable over Destouet in view of appellants' own specification (page 6, lines 4-20).

Rather than reiterate the examiner's full statement of the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellants regarding those rejections, we make reference to the examiner's answer (Paper No. 17, mailed January 7, 1997) for the examiner's complete

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reasoning in support of the rejections, and to appellants' brief (Paper No. 15, filed September 30, 1996) and reply brief (Paper No. 18, filed March 7, 1997) for the arguments thereagainst.

#### OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art reference, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determinations which follow.

We turn first to the examiner's rejection of appealed claims 9 and 30 under 35 U.S.C. § 112, first paragraph, which rejection is based upon the written description requirement of the first paragraph of § 112. In general, the test for determining compliance with the written description requirement of § 112 is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the

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later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language under consideration. See Wang Laboratories Inc. v. Toshiba Corp., 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1556, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991); see also In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (fed. Cir. 1983).

In this particular instance, after considering appellants' disclosure as a whole and recognizing that the claimed subject matter does not need to be described in haec verba in the specification in order for the specification to satisfy the written description requirement, it is our opinion that the originally filed specification provides adequate support for the invention claimed. In particular, we note that while the exact "standard mammographic procedures, intensities and exposure times" are not set forth in the specification, we share appellants' view that one skilled in this particular art at the time of appellants' invention would have understood what the standard mammographic procedures,

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intensities and exposure times were intended to be for a standard mammography examination of a normal (i.e., natural) human breast. The applied Destouet patent itself (in col. 2) discloses that mammography is best performed at low X-ray energies and with a phototimer placed beneath the film screen cassette that automatically terminates each exposure when sufficient X-rays have been transmitted to yield an appropriately darkened film after development. Moreover, we also note the patent of record to Scott P. Bartlett et al. (U.S. Patent No. 5,391,203, filed Apr. 13, 1992), which patent (in col. 9) refers to radiographic methods known to those of ordinary skill in the art and described in Plastic and Recon. Surgery 84:722 (1989). As noted in In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991), the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled in the art and already available to the public. Thus, like appellants, we consider that the subject matter of claims 9 and 30 on appeal is reasonably supported by the original disclosure of the application and that these claims and the disclosure meet the requirements of 35 U.S.C. §

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112, first paragraph. Accordingly, we will not sustain the examiner's rejection of claims 9 and 30 under 35 U.S.C. § 112, first paragraph.

Turning next to the examiner's rejection of claims 9 and 30 under 35 U.S.C. § 112, second paragraph, it follows from our determination above that we do not share the examiner's view that there is no basis for "standard mammographic procedures, intensities and exposure times." Given that standard mammographic procedures, intensities and exposure times were known to those skilled in the art at the time of appellants' invention, we are of the view that appellants do particularly point out and distinctly claim that which they regard as their invention in claims 9 and 30 on appeal and it is our opinion that the scope and content of the subject matter embraced by appellants' claims 9 and 30 on appeal (as it regards standard mammographic procedures, intensities and exposure times) is reasonably clear and definite. For that reason, we will not sustain the examiner's rejection of appellants' claims 9 and 30 on appeal under 35 U.S.C. § 112, second paragraph.

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We next look to the examiner's prior art rejections of the appealed claims, turning first to the rejection of claims 1 and 12 under 35 U.S.C. § 102(b) as being anticipated by Destouet. In

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this regard, we will sustain the examiner's rejection of independent claim 12 based on Destouet, but not the rejection of independent claim 1.

While it is true that Destouet broadly discloses that any biocompatible triglyceride having an effective atomic number of 5.9 can be used as a filler material in a silicon envelope for breast implants, this patent only specifically describes naturally occurring peanut oil and sunflower seed oil as examples of suitable filler materials. There is nothing in the Destouet patent that specifically recognizes the existence of biocompatible synthetic triglycerides like those claimed by appellants in claim 1 on appeal or which teaches or suggests the use of biocompatible synthetic triglycerides as a filler material in a surgically implantable prosthesis. Since Destouet does not sufficiently describe or adequately teach a filler material for a surgically implantable prosthesis wherein said filler material comprises a biocompatible synthetic triglyceride, this patent does not place the public in possession of any such claimed subject matter and we must

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therefore refuse to sustain the examiner's rejection of claim  
1 under 35 U.S.C. § 102(b).

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With regard to claim 12 on appeal, we reach a different result. Claim 12 is directed to a surgically implantable prosthesis containing any filler material that is "capable of being provided in a range of viscosities thereby permitting the filler material to have a selectable viscosity." It is the examiner's position (answer, page 7) that the triglycerides of Destouet are "clearly capable of being provided in a range of viscosities." We agree with the examiner. Peanut oil and sunflower seed oil that may be subjected to different processing parameters or provided with some form of thickening agent are inherently "capable of being provided in a range of viscosities" (emphasis added), thus permitting them to be produced with a selectable viscosity.

In a case such as this, where there is a reasonable basis to conclude that a given property or characteristic for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art product, it is incumbent upon appellants to prove that the prior art products do not in fact possess the characteristics relied upon. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655,

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1658 (Fed. Cir. 1990); In re Fitzgerald, 619 F.2d 67, 70 205  
USPQ 594, 596 (CCPA 1980); In re Best, 562 F.2d 1252, 1254-55,  
195 USPQ 430, 433 (CCPA 1977); In

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re Glass, 474 F.2d 1015, 1019, 176 USPQ 529, 532 (CCPA 1973);  
In re Ludtke, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971)  
and In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229  
(CCPA 1971). Appellants have provided no evidence or  
convincing line of reasoning which establishes that the  
triglycerides of Destouet lack the capability attributed to  
them by this panel of the Board and by the examiner in the  
earlier Office actions. Thus, appellants have not satisfied  
their burden of proof in attempting to overcome the rejection  
of claim 12 under 35 U.S.C. 102(b) based on Destouet and the  
examiner's rejection of claim 12 will therefore be sustained.

As for the examiner's rejection of claim 12 under 35  
U.S.C. § 103 based on Destouet, we will also sustain this  
rejection, given that anticipation or lack of novelty is the  
ultimate or epitome of obviousness. See In re Fracalossi, 681  
F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982) and In re  
Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

Regarding the examiner's rejection of claim 1 under

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35 U.S.C. § 103 based on Destouet alone, we will not sustain this rejection. Stated simply, the examiner has not set forth a prima facie case of obviousness. As was urged by appellants on pages 10-12 of the brief, the mere fact that a claimed species or subgenus may be encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. See In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) and In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). In this regard, we direct the examiner's attention to § 2144.08 of the Manual of Patent Examining Procedure (MPEP).

With respect to the examiner's rejection of claims 2 through 11, 13 through 17 and 27 through 31 under 35 U.S.C. § 103 as being unpatentable over Destouet in view of appellants' own specification (page 6, lines 4-20), in addition to pointing out that Destouet (col. 3, lines 8-26) discloses an implant filled with any biocompatible triglyceride, it is the examiner's position that

[a]pplicant [sic] admits that changing the viscosity by reacting pure, fully saturated fatty acids of the desire carbon length with

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purified glycerol in an esterification reaction is well known. (See page 6, lines 4-20.) Therefore, it would have been obvious to one of ordinary skill in the art to have used the synthetic triglycerides produced by these old and well known methods in the implant of Destouet et al. since Destouet et al. specifically discloses using any biocompatible triglyceride.

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Like appellants (brief, pages 12-15), we are of the opinion that the examiner has entirely misconstrued the scope of the appellants' admission on page 6 of the specification. While appellants do concede that triglyceride compositions like those of the invention "can be prepared using standard methods known to those skilled in the art such as by reacting pure, fully saturated fatty acids of the desired carbon length with purified glycerol in an esterification reaction" and that the resulting triglycerides are purified from the reaction mixture by known techniques to provide a pure, non-contaminated triglyceride, they have in no way admitted that changing the viscosity to be that which is disclosed and claimed in the present application is known in the art to be achievable by any such method, as has been suggested by the examiner. Nor has the examiner put forth any factual basis to support a conclusion that any of the other characteristics set forth in the claims subject to this rejection are known in the art or would have been the natural result flowing from producing a synthetic triglyceride by using the admittedly old process mentioned by appellants. For these reasons, we will not sustain the examiner's rejection of claims 2

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through 11, 13 through 17 and 27 through 31 under 35 U.S.C. § 103 as being unpatentable over Destouet in view of appellants' own specification (page 6, lines 4-20).

To summarize our decision, we note that the examiner's rejections of claims 9 and 30 under 35 U.S.C. § 112, first paragraph, and of claims 9 and 30 under 35 U.S.C. § 112, second paragraph, have not been sustained. The examiner's rejection of claims 1 and 12 under 35 U.S.C. § 102(b)/§ 103 has been sustained with regard to claim 12, but not as to claim 1. The examiner's rejection of appealed claims 2 through 11, 13 through 17 and 27 through 31 under 35 U.S.C. § 103 as being unpatentable over Destouet in view of appellants' own specification (page 6, lines 4-20) has also not been sustained.

In addition to our determinations above, we find it necessary to REMAND this application to the examiner for a consideration of whether or not a rejection of the claims on appeal would be appropriate under either or both 35 U.S.C. § 112, first paragraph, as being nonenabling, and/or 35 U.S.C. §

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112, second paragraph, as being indefinite. Our concern here is that we find no clear basis upon which to select a given viscosity for the filler material or the implant as a whole based on providing a tactile response that is "substantially the equivalent of the tactile response of a normal human breast." Appellants apparently intend to encompass a viscosity range of "greater than about 30 cps" (claim 2), and more specifically preferably of between about 10,000 cps and about 50,000 cps, in a temperature range of between about 32EC and about 40EC (specification, page 8). However, with regard to the filler material itself we find no criteria for determining a conversion between tactile response and viscosity, while for the breast implant and/or prosthesis claimed we find no consideration of other factors which affect the tactile response, like the material from which the envelope is made, the thickness of such envelope material or the degree of filling of the envelope. Nor do we have any standards given to determine exactly what is a tactile response that is substantially the equivalent of the tactile response of a normal human breast, as set forth in a number of the claims on appeal and in appellants'

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specification. In this regard we note that the tactile response of a normal human breast is itself a variable quantity depending on factors such as the age of a patient, breast size, fitness level of the patient, etc., and this is before we further qualify the tactile response by indicating that it need only be "substantially the equivalent" of the tactile response of a normal human breast. See, for example, Ex parte Brummer, 12 USPQ2d 1653, 1655 (Bd. Pat. App. & Inter. 1989).

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With regard to claims 7, 9, 10 and 12 through 14 we additionally invite the examiner's attention to U.S. Patent No. 5,407,445 (cited by appellants in the IDS filed June 19, 1995) wherein a biocompatible filler material for breast implants is disclosed which has variable viscosity, improved radiolucency close to that of normal breast tissue, and is said to be similar in consistency and feel to the natural human breast.

It follows from the foregoing that the decision of the examiner is affirmed-in-part.

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

AFFIRMED-IN-PART and REMAND

ANDREW H. METZ	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
	)	BOARD OF PATENT
CHARLES E. FRANKFORT	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
	)	
	)	
	)	
DOUGLAS W. ROBINSON	)	
Administrative Patent Judge	)	

CEF/sld

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Claims

1. A filler material for a surgically implantable prosthesis comprising a biocompatible synthetic triglyceride.

7. A breast implant containing a biocompatible filler material having a viscosity providing a tactile response substantially the equivalent of the tactile response of normal human breast.

9. The breast implant of claim 7 wherein the filler material is radiolucent under standard mammographic procedure.

12. A surgically implantable prosthesis containing a filler material capable of being provided in a range of viscosities thereby permitting the filler material to have a selectable viscosity.

27. A breast implant comprised of a filler material within a flexible envelope, the filler material being a synthetic triglyceride having a viscosity providing the tactile response substantially the equivalent of the tactile response of a normal human breast.

30. The breast implant of claim 27 wherein the filler material is radiolucent under standard mammographic procedures, intensities, and exposure times.

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AFFIRMED-IN-PART and REMAND

Prepared: July 18, 2001