

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

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LINDA G. CIMA and MICHAEL J. CIMA

Appeal No. 1998-2813
Application No. 08/463,203

HEARD: September 12, 2000

Before CALVERT, FRANKFORT, and JENNIFER D. BAHR, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 19 through 25 and 29 through 36. Claim 37 stands allowed. Claims 26 through 28, the only other claims remaining in the application, have been indicated by the examiner as containing allowable subject matter, but stand objected to until they are rewritten in independent form including all the limitations of the base claim and any intervening claims. Claims 1 through 18 have been canceled.

Appeal No. 1998-2813
Application No. 08/463,203

Appellants' invention relates to a medical device for tissue regeneration formed using a solid free-form fabrication method. Examples of such methods are set forth on page 4 of the specification, where it is additionally noted that three dimensional printing (hereinafter 3D-printing) is the preferred method for creating appellants' medical devices. Appellants' devices are constructed to include a matrix of successive layers of biocompatible polymeric material having interconnected pores extending throughout the matrix suitable for seeding or ingrowth of cells. Claims 19 and 21 are representative of the subject matter on appeal and a copy of those claims, as they appear in Appendix I of appellants' brief, is attached to this decision.

The single prior art reference relied upon by the examiner in rejecting the appealed claims is:

Fink et al. (Fink)	5,370,692	Dec. 6, 1994 (filed Aug. 14, 1992)
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Claims 19, 31, 32/19 and 36/19 stand rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Fink.

Claims 20, 22/20, 29, 30 and 33 through 35 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Fink or, in the

Appeal No. 1998-2813
Application No. 08/463,203

alternative, under 35 U.S.C. § 103 as being unpatentable over Fink.

Claims 21, 22/21, 23 through 25, 32/21 and 36/21 stand rejected under 35 U.S.C. § 103 as being unpatentable over Fink.

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellants regarding the rejections, we make reference to the examiner's answer (Paper No. 14, mailed January 29, 1998) for the reasoning in support of the rejections, and to appellants' brief (Paper No. 11, filed January 5, 1998) and reply brief (Paper No. 15, filed March 27, 1998) 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 Fink 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.

Appeal No. 1998-2813
Application No. 08/463,203

Regarding the examiner's rejection of claims 19, 31, 32/19 and 36/19 under 35 U.S.C. § 102(e) as being anticipated by Fink, our reading of the Fink patent indicates that it is directed to the fabrication of prosthetic implants to replace bone (i.e., medical devices) that are formed using various free-form manufacturing techniques (col. 4, line 3, et. seq.) including selective laser sintering and 3D-printing. These devices are indicated (col. 5, lines 23-34) as being constructed to maximize "the rate and quality of cell-mediated hard tissue healing" and to "optimize the rate of healing by incorporating the patient's own bone-producing cells into the implant" (emphasis added). Fink notes (col. 3, line 7, et. seq.) that the most important physical properties of the implant are the volume and size of the pores within the implant, since such factors strongly influence not only the strength of the implant but also the rate of resorption and cellular colonization. In this regard, it is indicated that pores of "at least" 200-300 micrometers in diameter are necessary in osteoconductive materials to permit ingrowth of vasculature and osteogenic cells. An example of an implant material (col. 3, lines 23-25) is said to be composed of a network of interconnecting pores in the range of approximately 200 µm diameter. While Fink generally discloses the use of resorbable, biocompatible ceramic materials to construct the

Appeal No. 1998-2813
Application No. 08/463,203

devices therein, this patent notes (col. 7, lines 31-38) that "a polymeric FFM [free-form manufacturing] reproduction may also be done using photoactive polymer techniques." Note also, column 7, line 44, et. seq., wherein a composite polymeric/ceramic process is described. When Fink uses the language "fluid materials" in describing the free-form manufacturing of an implant it is made clear in column 7, lines 37-38, that such language encompasses either liquids or masses of particles being used in the fabrication process.

In contrast to appellants' arguments in the brief and reply brief, we are of the opinion that Fink teaches a medical implant as set forth in claim 19 on appeal which is made using solid free-form fabrication methods and comprises a matrix of successive layers of biocompatible polymeric material having interconnected pores extending throughout the matrix suitable for seeding or ingrowth of cells. Again, we note that Fink discloses the use of polymeric materials in column 7, lines 31-35 and in column 7, line 46, et. seq., for making the devices therein and discloses the importance of pore structure (e.g., volume and size) within the matrix so as to allow the seeding of cells (col. 5, lines 32-34) and the ingrowth of vasculature and osteogenic cells (col. 3, lines 7-15). See also column 7, lines

Appeal No. 1998-2813
Application No. 08/463,203

20-30, wherein it is noted that a defined porosity can be introduced into the implant by various methods and that such processes "offer a range of porosities available to tailor FFM devices to specific applications." While Fink does indicate that the methods therein can be used to provide an implant that replicates bone, we observe that this patent also teaches secondary manipulation of the "design file" to compensate for the anticipated healing process, prior to forming the "sliced file" that is actually used to fabricate the implant (col. 5, lines 44+). Moreover, Fine also discloses (col. 6, line 20, et. seq.) that while the implant may be matched to the precise anatomical dimensions of the original tissue, it may also be modified to compensate for the anticipated healing responses or to provide for surgical-assist structures. Thus, appellants' arguments that Fink deals strictly with replication of bone and that the porosity of bone is smaller than that necessary to allow seeding of cells mischaracterize the disclosure of Fink and are therefore of no moment. In this regard, we again note that Fink discloses that pore sizes of "at least" 200-300 micrometers in diameter are necessary in osteoconductive materials to permit ingrowth of vasculature and osteogenic cells, and that a known matrix material is composed of a network of interconnecting pores in the range of approximately 200 μm diameter.

Appeal No. 1998-2813
Application No. 08/463,203

Based on the foregoing, we will sustain the examiner's rejection of independent claim 19 on appeal under 35 U.S.C. § 102(e). We will likewise sustain the examiner's rejection of claims 31, 32/19 and 36/19 on this basis, since we find no arguments in appellants' brief or reply brief that specifically address these claims and which particularly point out any error in the examiner's position. As indicated in 37 CFR § 1.192(c)(7), merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable.

Next for our consideration is the examiner's rejection of claims 20, 22/20, 29, 30 and 33 through 35 under 35 U.S.C. § 102(e) as being anticipated by Fink or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Fink. Claim 20, which depends from claim 19, is directed to the specific 3D-printing process used by appellants and sets forth the steps of a) spreading a first dispersion of a biocompatible polymer powder onto a bed, b) printing a layer comprising a second dispersion of biocompatible polymer in a solvent which binds the first biocompatible polymer powder to the second biocompatible polymer at locations where it is desired to have walls, and c) repeating

step b until the desired matrix is formed.¹ It is the examiner's position (answer, pages 5-6) that

Fink et al is considered to anticipate the claimed product even though the particular method steps are not recited therein because it is believed that the same product would result from the method limitations as set forth in the claim; see MPEP § 2173.05(p). Alternatively, it is not explicitly clear that the same material as disclosed by Fink et al would be the result of the claimed method steps. However, the Examiner posits that the claimed product is at least obvious in view of Fink et al alone because the Fink et al method would result in a product which is at least substantially identical to the claimed product.

The problem we see with the examiner's position here is that he has made no factual findings to support the bare conclusion stated, i.e., that the Fink method would result in a product which is at least substantially identical to the claimed product. Like appellants, we fail to find in Fink any teaching or suggestion of a medical device as claimed wherein the matrix layers of the device are formed from a biocompatible polymeric powder bonded using a polymer/solvent printed at locations where

¹ It appears to us that since the matrix as defined in independent claim 19 and also in independent claim 21 is formed of "successive layers" of biocompatible polymeric/composite material, that step c) in each of these claims should read --- repeating steps a and b until the desired matrix is formed ---, thereby providing the "successive layers" that each of these claims requires.

Appeal No. 1998-2813
Application No. 08/463,203

it is desired to form walls in the matrix. The closest embodiment found in Fink seems to be that set forth in column 7, lines 48-53, wherein ceramic particles are suspended in a liquid monomer which is subjected to laser photo polymerization whereby the particles are then trapped in the polymer after polymerization. However, we have no reason to conclude that the matrix of the device formed by appellants' method in claim 20 and

Appeal No. 1998-2813
Application No. 08/463,203

that formed in the process noted above in Fink are "substantially identical" one to the other, and the examiner has provided no reasons which mandate such a conclusion. In our view, the polymer/solvent bonding of polymeric powders in appellants' method and the laser photo polymerization suggested in Fink will result in devices with matrix structures that are clearly different from one another. Thus, we will not sustain the examiner's rejection of claim 20 under 35 U.S.C. § 102(e)/§ 103 based on Fink. It follows that the examiner's rejection of claim 22/20 will also not be sustained.

Claims 29 and 30 depend from claim 19, while claims 33 through 35 are multiply dependent, through claim 32, from either claim 19 or claim 21. As the examiner's rejection applies to those claims which depend from claim 19, we note that we find no arguments in appellants' brief or reply brief that specifically address these claims and which particularly point out any error in the examiner's position. Finding no specific arguments from appellants, we will therefore sustain the examiner's rejection of claims 29 and 30, 33/32/19, 34/32/19 and 35/34/32/19. Our disposition of claims 33 through 35 as they depend from independent claim 21 will be clear from our discussions infra.

Appeal No. 1998-2813
Application No. 08/463,203

Appeal No. 1998-2813
Application No. 08/463,203

Claims 21, 22/21, 23 through 25, 32/21 and 36/21 stand rejected under 35 U.S.C. § 103 as being unpatentable over Fink. Independent claim 21 is similar to claim 20 discussed above and for the same reasons as we noted with regard to claim 20 it is our opinion that the examiner has failed to establish a prima facie case of obviousness with regard to appellants' claim 21. We have no reason to conclude that the matrix of the device formed by appellants' method in claim 21 and that formed in the process noted above in Fink are "substantially identical" one to the other, and the examiner has provided no reasons which support or mandate such a conclusion. In our view, the polymer/solvent bonding of polymeric powders in appellants' method (claim 21) and the laser photo polymerization suggested in Fink will result in devices with matrix structures that are clearly different from one another. Thus, the examiner's rejection of claim 21 and all of the claims which depend therefrom will not be sustained.

This leaves the examiner's § 103 rejection of claims 23 through 25 as they depend from claim 19 for our consideration. In this instance, appellants have argued (brief, page 13) that Fink does not teach or suggest devices as set forth in these claims including a matrix that has walls that are 100 microns thick (claim 23), or devices including a matrix formed of the

Appeal No. 1998-2813
Application No. 08/463,203

polymers listed in claim 24, or wherein the polymer includes a biodegradable latex as required in claim 25. Since we agree with appellants, we will not sustain the examiner's rejection of claims 23/19, 24/19 or 25/19.²

In view of the foregoing, the examiner's decision rejecting claims 19, 31, 32/19 and 36/19 under 35 U.S.C. § 102(e) as being clearly anticipated by Fink is affirmed. As regards the examiner's rejection of claims 20, 22/20, 29, 30 and 33 through 35 under 35 U.S.C. § 102(e) as being anticipated by Fink or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Fink, we note that the examiner's decision has been sustained with respect to claims 29 and 30, 33/32/19, 34/32/19 and 35/34/32/19, but reversed as to claims 20, 22/20, 33/32/21, 34/32/21 and 35/34/32/21. The examiner's decision rejecting claims 21, 22/21, 23 through 25, 32/21 and 36/21 under 35 U.S.C. § 103 as being unpatentable over Fink has been reversed with regard to claim 21 and all claims which depend from claim 21.

² With respect to claim 23, while we see clear support in claim 21 for "the walls" of claim 23, we find no proper antecedent basis for "the walls" in claim 19, from which claim 23 also depends. During any further prosecution of this application before the examiner, this issue should be addressed.

Appeal No. 1998-2813
Application No. 08/463,203

However, this rejection has been sustained with respect to claims 23/19, 24/19 and 25/19. Thus, the examiner's decision rejecting the claims before us on appeal is affirmed-in-part.

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

AFFIRMED-IN-PART

IAN A. CALVERT)	
Administrative Patent Judge)	
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CHARLES E. FRANKFORT)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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Appeal No. 1998-2813
Application No. 08/463,203

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Claims

19. A medical device for tissue regeneration formed using a solid free-form fabrication method comprising a matrix of successive layers of biocompatible polymeric material having interconnected pores extending throughout the matrix suitable of seeding or ingrowth of cells.

21. A medical device for bone regeneration formed using three dimensional printing comprising a matrix of successive layers of biocompatible composite material having interconnected pores extending throughout the matrix suitable for seeding or ingrowth of cells, having pore size of at least five to forty microns in diameter,

wherein the methods comprises

a) spreading a first dispersion of a resorbable powder selected from the group consisting of calcium phosphate, hydroxyapatite, and calcium carbonate onto a bed,

b) printing a layer comprising a second dispersion of biocompatible polymer or composite powder in a solvent which binds the first powder to the second biocompatible polymer or composite powder at locations where it is desired to have walls, and

c) repeating step b until the desired matrix is made.

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Appeal No. 1998-2813
Application No. 08/463,203

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AFFIRMED-IN-PART

Prepared: July 18, 2003