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and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PHILIP A. JINKS

Appeal No. 2005-1693
Application No. 10/192,333

ON BRIEF

Before HANLON, PAK and PAWLIKOWSKI, Administrative Patent Judges.

HANLON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the final rejection of claims 1 through 11, all of the claims pending in the application. The claims on appeal are directed to a method of making a medicinal inhalation device and a component for the device using a thermal chemical vapor deposition (CVD) process. Claim 2 is illustrative and reads as follows:

2. A method of making a component for a medicinal inhalation device comprising a step of forming a fluorocarbon $(CF_2)_n$-type polymer thin film on a surface of the component, said forming step comprising the sub-steps of:

a) exposing a monomer gas to a source of heat having a temperature sufficient to pyrolyze the monomer gas, the monomer gas selected to produce upon pyrolysis a source of reactive species that includes polymerizable CF_2 species and that selectively promotes CF_2 polymerization, the reactive species source being in the vicinity of the surface on which the fluorocarbon polymer film is to be formed; and

b) maintaining the surface substantially at a temperature lower than that of the heat source to induce deposition and polymerization of the CF_2 species on the surface.

The sole issue in this appeal is whether the examiner properly rejected claims 1 through 11 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Warby (WO '154)[1] and Gleason (WO '356).[2]

I.

According to the appellant, medicinal inhalation devices are well-known pharmaceutical drug delivery devices. They typically comprise a plurality of hardware components as well as a number of internal surfaces that may come into contact with medicinal formulations during storage and delivery. Often, the material comprising a particular component is found to be unsuitable due to surface interactions between the material and the medicinal formulation. See Brief at 3; Specification at 1, lines 14-29. In an effort to avoid these interactions, the interior surfaces and components of medicinal inhalation devices have been coated with fluorocarbon polymers, such as polytetrafluoroethylene, using various processes, including plasma coating. See Specification at 2, lines 6-15.

However, these coatings are said to suffer several drawbacks. Specifically, continuous plasma polymerization is said to produce fluorocarbon polymer films with a high degree of cross-linking which results in film brittleness, an undesirable property for long term stability during storage and/or use in conjunction with movable components. Furthermore, films

[1] International Publication No. WO 99/42154 published on August 26, 1999, and naming Warby as the inventor.

[2] International Publication No. WO 97/42356 published on November 13, 1997, and naming Gleason, et al. as the inventors.

produced by this process are said to show chemical instability as well as potentially reactive surface sites due to residual unpaired electrons from the polymerization process. Specification at 5, lines 1-9.

According to the appellant (Specification at 5, lines 23-27):

> [A] fluorocarbon $(CF_2)_n$-type (i.e. PTFE-type) polymer thin film having enhanced chemical and mechanical stability can be realized by forming the fluorocarbon polymer film through a thermal CVD method in which a monomer gas is pyrolyzed to generate a source of polymerizable CF_2 species.

The steps of the appellant's thermal CVD process are:

a) exposing a monomer gas to a source of heat having a temperature sufficient to pyrolyze the monomer gas, the monomer gas selected to produce upon pyrolysis a source of reactive species that includes polymerizable CF_2 species and that selectively promotes CF_2 polymerization, the reactive species source being in the vicinity of the surface on which the fluorocarbon polymer film is to be formed; and

b) maintaining the surface substantially at a temperature lower than that of the heat source to induce deposition and polymerization of the CF_2 species on the surface. See claim 2. Preferably, the monomer gas includes hexafluoropropylene oxide. Specification at 7, lines 1-2.

The fluorocarbon $(CF_2)_n$-type polymer thin films produced by this process are said to have a high compositional CF_2 fraction and a low degree of cross-linking density. Specification at 7, lines 23-27. Thus, the films are flexible, i.e., non-brittle, and exhibit superior mechanical stability. According to the appellant, "This is especially desirable for the operation of movable or flexible components or assemblies, in particular valves and their individual components." See

Specification at 8, lines 16-21.

The films are also said to exhibit superior chemical stability and inertness, which in conjunction with enhanced mechanical stability, is advantageous for long-term performance of the medicinal inhalation device as well as the reduction of undesirable interactions between a component or a surface of the device and a medicinal formulation. Specification at 8, lines 21-25.

II.

In the specification, the appellant discloses that (Specification at 7, lines 18-21):

> A method [of] forming a $(CF_2)_n$-type (i.e. PTFE-type) polymer thin film on a surface of a structure comprising the steps of a) and b) [of the claimed method] is known from WO 97/42356 [Gleason]. However, said document is silent with respect to medicinal inhalation devices and components for such devices.

According to Gleason, the disclosed thermal CVD process is useful in a wide range of thin film applications, including biomedical applications. Gleason at 6, lines 23-26. The appellant recognizes as much. Brief at 5. Nevertheless, the appellant argues that (Brief at 5):

> The reference to "biomedical applications" in Gleason apparently is in regards to what would be exterior coatings on implants, probes, tubing, wires and the like, and does not appear to suggest application to the inner, formulation-contacting surfaces of a medicinal aerosol device.

Significantly, the claim does not require the film to be formed on the "inner, formulation-contacting surfaces" of a medicinal inhalation device. The claim merely requires a fluorocarbon $(CF_2)_n$-type polymer thin film to be formed on "a surface of the component." See E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433, 7 USPQ2d 1129, 1131 (Fed.

Cir.), cert. denied, 488 U.S. 986 (1988) (limitations appearing in the specification will not be read into the claims).

Furthermore, the method of claim 2 is not even limited to making components for a medicinal inhalation device. The phrase "a component for a medicinal inhalation device" in the preamble of claim 2 is merely a statement of intended use and fails to patentably distinguish the claimed method from the method disclosed in Gleason. See In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) (the preamble of a claim does not limit the scope of the claim when it merely states a purpose or intended use of the invention). There is no reason to believe that wires, tubing, etc. coated with a $(CF_2)_n$-type polymer thin film according to the thermal CVD process disclosed in Gleason could not be used in a medicinal inhalation device. Thus, Gleason alone appears to satisfy the limitations of claim 2.

III.

The examiner has rejected claim 2 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Warby[3] and Gleason.[4] Answer at 3-4.

Warby discloses a process for depositing a layer of a polymerized fluorinated hydrocarbon, such as polytetrafluoroethylene, on the surface of the components of a medical inhalation device using a cold plasma polymerization treatment. See, e.g., Warby at 7, lines

[3] The appellant refers to International Publication No. WO 99/42154 as "Bespak." However, in this decision, we refer to the publication as "Warby." See footnote 1, supra.

[4] Claims 1 through 11 are subject to the same ground of rejection. The appellant has argued the claims as a group. We have selected claim 2 to decide the appeal. See 37 CFR § 41.67(c)(1)(vii) (2004).

2-26. The examiner recognizes that Warby does not deposit the coating using a thermal CVD process. Nevertheless, the examiner relies on Gleason for its teaching of using a thermal CVD process to form a $(CF_2)_n$-type polymer thin film on articles having biomedical applications. Answer at 3-4.

The examiner explains that (Answer at 3-4):

> [B]ecause WO '356 [Gleason] discloses that use of the claimed thermal [method] to deposit PTFE coatings with monomers such as hexafluoropropylene oxide on surfaces such as biomedical devices is advantageous over the continuous plasma method such as that shown in WO '154 [Warby] in that the deposited coatings' properties more closely resemble those of bulk PTFE which are advantageous for biomedical devices and such methods allow for coating on temperature sensitive substrates (page 1, lines 14-25, page 2, lines 14-26, page 3, line 14 to page 6, line 28, examples), it would have been obvious to have applied the PTFE coatings on the MID [medical inhalation device] surfaces using the processes described in WO '356 [Gleason] so as to achieve the superior coatings having properties similar to bulk PTFE and to allow for coating on the temperature sensitive substrates.

The appellant argues that there is no motivation or suggestion in the cited art to coat the components of the medicinal inhalation device of Warby with a fluorocarbon polymer film using the claimed thermal CVD process. Specifically, the appellant argues that Warby does not recognize the disadvantages associated with the disclosed plasma deposition process. Therefore, Warby would not have suggested alternative deposition processes, such as the thermal CVD process disclosed in Gleason. Brief at 4-5.

The appellant's argument is not persuasive. Significantly, one cannot show nonobviousness by attacking a reference individually, as the appellant has done, where the rejection is based on a combination of references. In re Keller, 642 F.2d 413, 425, 208 USPQ

871, 881 (CCPA 1981). Thus, it is not fatal to the rejection based on 35 U.S.C. § 103(a) that Warby does not disclose the claimed thermal CVD process. As discussed above, the examiner relies on the teachings of Gleason to establish that it would have been obvious to one of ordinary skill in the art to coat the components of the medicinal inhalation device disclosed in Warby with a fluorocarbon polymer film using a thermal CVD process.

The appellant further argues that one of ordinary skill in the art would not have expected the benefits of the thermal CVD process disclosed in Gleason to be applicable in the context of medicinal inhalation devices. Brief at 5.

We disagree. The examiner points out that the coatings formed by the thermal CVD process disclosed in Gleason are stable, chemically resistant, and have a low coefficient of friction in comparison to coatings formed by prior continuous plasma methods. See Answer at 4, 5-6. Furthermore, Gleason discloses that the thermal CVD process produces a film having a relatively high CF_2 fractionality and a low degree of crosslinking in contrast to a film formed by a continuous plasma CVD process. See, e.g., Gleason at 27, lines 23-26; see also Gleason at 29, lines 18-20 (a low cross-linking density enables a high degree of flexibility in the deposited films).

We find that one of ordinary skill in the art would have considered these properties desirable in a film used to coat the components of a medicinal inhalation device, such as the medicinal inhalation device disclosed in Warby. Compare appellant's specification at 7, lines 23-27 (fluorocarbon $(CF_2)_n$-type polymer thin films formed by claimed process have a high

compositional CF_2 fraction and a low degree of cross-linking density); see also Specification at 8, lines 16-21.

For the reasons set forth above, the combined teachings of Warby and Gleason would have suggested the method of claim 2 to one of ordinary skill in the art. Their combined teachings also provide a reasonable expectation of success. Therefore, the rejection of claim 2 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Warby and Gleason is affirmed.

Claims 1 and 3 through 11 stand or fall with the patentability of claim 2. Therefore, the rejection of claims 1 and 3 through 11 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Warby and Gleason is also affirmed.

IV.

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

AFFIRMED

ADRIENE LEPIANE HANLON Administrative Patent Judge	)	
	)	BOARD OF PATENT APPEALS AND INTERFERENCES
CHUNG K. PAK Administrative Patent Judge	)	
BEVERLY A. PAWLIKOWSKI Administrative Patent Judge	)	

ALH/alh

3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427