Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte EVA ANN-CHRISTIN TROFAST, MAGNUS OLSSON and CLAES AHLNECK

Appeal No. 1999-0400
Application No. 08/316,938

HEARD: OCTOBER 25, 2000

Before COHEN, ABRAMS, and McQUADE, Administrative Patent Judges.[1]

McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Eva Ann-Christin Trofast et al. appeal from the final rejection of claims 1 through 8, 12 through 15, 24 through 29 and 31. Claim 30 stands allowed. Claims 18 through 23, the

[1] Administrative Patent Judge Lazarus, who sat on the panel at the oral hearing, has retired. His place has been taken by Administrative Patent Judge Abrams. See In re Bose Corp., 772 F.2d 866, 227 USPQ 1 (Fed. Cir. 1985).

only other claims pending in the application, stand withdrawn from consideration pursuant to 37 CFR § 1.142(b).

THE INVENTION

The subject matter on appeal relates to a method of agglomerating and spheronizing a finely divided powder, e.g., a powdered inhalation medicament, to improve its flow and handling characteristics. Representative claims 1, 27 and 29, the three independent claims on appeal, read as follows:

1. A method of treating a finely divided powder comprising the steps of:

a) forcing the powder through the apertures of a conical sieve to form agglomerates; and

b) spheronizing the agglomerates.

27. A method of treating a finely divided powder comprising the steps of:

a) forcing the powder through the apertures of a sieve having the form of a U-shaped trough to form agglomerates; and

b) spheronizing the agglomerates.

29. A method of treating a finely divided powder comprising the sequential steps of:

a) forcing the powder through the apertures of an oscillating sieve having the form of a U-shaped trough, to form agglomerates;

b) spheronizing the agglomerates;

c) passing the agglomerates through a sizing sieve to produce a sample of agglomerates of substantially uniform size;

d) repeating step (b); and

e) repeating step (c).

THE EVIDENCE

The references relied on by the examiner as evidence of obviousness are:

Bremer	4,038,010	Jul. 26, 1977
Watson et al. (Watson)	4,039,480	Aug. 2, 1977
Gibson	4,495,308	Jan. 22, 1985
Szczesny et al. (Szczesny)	4,514,300	Apr. 30, 1985
Edmonds	4,605,173	Aug. 12, 1986
Moriya	4,655,701	Apr. 7, 1987
Good et al. (Good)	4,689,297	Aug. 25, 1987
Sipos	5,262,172	Nov. 16, 1993
Ibsen	5,288,500	Feb. 22, 1994
Baichwal et al. (Baichwal)	5,399,358	Mar. 21, 1995
Madsen	5,547,567	Aug. 20, 1996

Edwards et al. (Edwards) 0,490,649 Jun. 17, 1992
European Patent Application

THE REJECTIONS

Claims 1, 7, 8 and 31/1 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards in view of Szczesny, Edmonds and Bremer.

Claims 2, 3, 5, 6 and 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards in view of Szczesny, Edmonds, Bremer and Gibson.

Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards in view of Szczesny, Edmonds, Bremer, Gibson, Moriya and Watson.

Claims 1, 7, 8, 12, 14/1 and 31/1 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sipos in view of Szczesny, Edmonds and Bremer.

Claims 2, 3, 5, 6, 14/2 and 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Gibson.

Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer, Gibson, Moriya and Watson.

Claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Good.

Claims 1, 8 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ibsen in view of Szczesny, Edmonds, Bremer and Baichwal.

Claims 25 through 27 and 31/27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards in view of Madsen.

Claims 25 through 28 and 31/27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards in view of Edmonds.

Clams 25 through 27 and 31/27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sipos in view of Madsen.

Claims 25 through 28 and 31/27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sipos in view of Edmonds.

Claim 29 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sipos in view of Edmonds and Good.

Attention is directed to the appellants' main and reply briefs (Paper Nos. 17 and 19) and to the examiner's answer (Paper No. 18) for the respective positions of the appellants and the examiner with regard to the merits of these rejections.

DISCUSSION

I. Grouping of claims

On page 8 in the main brief, under the "Grouping of Claims" heading, the appellants state that independent claim 1 and dependent claims 2 through 8, 12, 13 and 31/1 stand or fall together, independent claim 27 and dependent claims 25, 26, 28 and 31/27 stand or fall together, and independent claim 29 and dependent claims 14, 15 and 24 stand or fall by themselves. In accordance with these groupings and consistent with the substantive arguments advanced in the briefs, claims 2 through 8, 12, 13 and 31/1 shall stand or fall with claim 1, claims 25, 26, 28 and 31/27 shall stand or fall with claim 27, and claims 14, 15, 24 and 29 shall stand or fall alone.

II. The 35 U.S.C. § 103(a) rejection of claims 1, 7, 8 and 31/1 as being unpatentable over Edwards in view of Szczesny, Edmonds and Bremer

Edwards discloses a chemical compound for the treatment of various medical conditions such as asthma, hay fever and bronchitis. The compound has a physical form (form X) which can be administered to a patient as a micronised powder by inhalation. The mean mass aerodynamic diameter of the powder particles "is conveniently less than 50 microns, preferably in the range of from 1 to 50 microns, more preferably 1 to 10 microns, especially 1 to 5 microns" (page 3, lines 45 through 47). In order to improve its flow and handling characteristics, the powder is formed into soft pellets which readily break down to particle size in an inhaler to permit good penetration into the patient's lungs. As described in the reference,

> . . . the invention provides a process for obtaining form X in the form of soft pellets, which comprises extruding micronised form X through a sieve having apertures with a diameter in the range of from 150 to 700 microns, rolling the extruded material, and then screening the rolled material.
>
> The micronised form X is preferably extruded through a sieve having apertures with a diameter in the range of from 175 to 600 microns. The extrusion

> may conveniently be performed by passing the surface of a blade across powder on the surface of the sieve.
>
> The function of the rolling step in the process is to strengthen the agglomerates of particles formed in the extrusion step, and to mould them into a spherical shape. The rolling may conveniently be effected by allowing the agglomerates to tumble in a rotating vessel, preferably a cylindrical vessel.
>
> The screening step removes over and undersized pellets. It is conveniently performed using two sieves with apertures defining the upper and lower desired pellet diameters [page 4, lines 15 through 25].

Edwards goes on to detail a specific embodiment of this process in Example 5:

> Form X was micronised to produce a powder consisting of at least 98% by weight of particles having a diameter of less than 10 microns.
>
> 30g of the powder was then placed in one heap on a brass sieve having an aperture size between 210 and 500 microns. The powder was then extruded through the apertures of the sieve using a stainless steel pallette knife. The extrudate thus formed was then placed into a screw topped glass jar.
>
> The glass jar was then placed on to a set of rollers, which were rotated at 100rpm for between 8 and 20 minutes. The soft pellets thus formed were then sieved through an 850 micron sieve and then a 150 micron sieve, the fraction retained on the 150 micron sieve being the required product.

> The soft pellets thus produce were free flowing and relatively dust free. However the pellets when sheared, for example in a twin impinger, broke back down to the powder's original particle size distribution. This indicates that the pellets are suitable for use in a multidose dry powder inhaler that utilises volumetric metering to measure out the doses [page 11, lines 38 through 49].

The appellants do not dispute the examiner's finding (see page 4 in the answer) that Edwards meets all of the limitations in claim 1 except for the one requiring the agglomerate-forming sieve to be "conical."[2] Although the Edwards reference discloses an agglomerate-forming sieve, it does not specify its shape.

Szczesny, Edmonds and Bremer disclose sieve-like elements which are "conical" (i.e., frusto-conical) in shape. Szczesny's sieve elements 2, 12 and 13 function to dehydrate mineral grains, Edmonds' sieve element (enclosure 16 having fenestrated side walls 18) functions in conjunction with an impeller 28 to reduce the particle size of materials such as pharmaceuticals, and the sieve element described by Bremer (see

[2] The underlying disclosure (see specification page 12 and drawing Figures 8 and 8A) indicates that the appellants' agglomerating sieve is "conical" in the sense that it frusto-conical.

the background discussion at column 1, lines 15 through 35) functions in combination with a pressure roller and rotating blades to granulate pulverulent materials.

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

Edwards discloses the use of a sieve to form powder agglomerates, but does not specify its shape. Edmonds and Bremer establish that sieves for processing material particles commonly have a conical shape. In this light, and notwithstanding the appellants' arguments to the contrary, the combined teachings of Edwards, Edmonds and Bremer would have suggested the implementation of Edwards' sieve-agglomeration step via a commonplace conical sieve of the sort disclosed by Edmonds and Bremer. Although Szczesny also discloses a "conical" sieve, the manner in which it functions is not

particularly relevant to the powder treatment method disclosed by Edwards. Thus, Szczesny is, at best, superfluous to the examiner's reference combination.

In view of the foregoing, we shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 1, and claims 7, 8 and 31/1 which stand or fall therewith, as being unpatentable over Edwards in view of Szczesny, Edmonds and Bremer.

III. The 35 U.S.C. § 103(a) rejection of claims 2, 3, 5, 6 and 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards in view of Szczesny, Edmonds, Bremer and Gibson

We shall sustain the standing 35 U.S.C. § 103(a) rejection of claims 2, 3, 5 and 6 as being unpatentable over Edwards in view of Szczesny, Edmonds, Bremer and Gibson since these claims stand or fall with claim 1.

Claim 15, which stands or falls alone, depends from claim 1 via claim 2 and requires the rotatable spheronizing container recited in claim 2 to rotate at a periphery speed of from about 0.5 to 1.0 m/s. While the underlying specification (see page 7) states that this range of speeds is preferred, it does not indicate that this parameter, in and of itself, produces

optimal agglomerate characteristics as urged by the appellants (see page 19 in the main brief).

In Example 5, Edwards describes a spheronizing container (glass jar) rotational speed of 100 rpm. Without additional information, this speed cannot be converted to meters per second (m/s) for comparison with the speed range set forth in claim 15. Its disclosure, however, demonstrates a recognition by Edwards that the rotational speed of the spheronizing container is a factor contributing to the quality of the spheronized agglomerates. In cases where the difference between the claimed invention and the prior art is some range or other variable within the claims, the patent applicants must establish show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art. In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990). The appellants have made no such showing.

Therefore, we shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 15 as being unpatentable over Edwards in view of Szczesny, Edmonds, Bremer and Gibson.

IV. The 35 U.S.C. § 103(a) rejection of claim 4 as being unpatentable over Edwards in view of Szczesny, Edmonds, Bremer, Gibson, Moriya and Watson

We shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 4 as being unpatentable over Edwards in view of Szczesny, Edmonds, Bremer, Gibson, Moriya and Watson since this claim stands or falls with claim 1.

V. The 35 U.S.C. § 103(a) rejection of claims 1, 7, 8, 12, 14/1 and 31/1 as being unpatentable over Sipos in view of Szczesny, Edmonds and Bremer

Sipos discloses a process for preparing a buffered bile acid (UDCA) composition for ingestion by mammals to treat a variety of medical ailments. The process includes the steps of (1) micropulverizing the UDCA in the presence of a suitable buffer salt to obtain an ultrafine particle blend of buffered-UDCA, (2) wetting the blend with a suitable liquid to cause it to stick together, (3) granulating or extruding the blend through a 10 to 18 mesh S/S screen using an oscillating/reciprocating granulator or a twin-screw extruder at a medium-to-high speed, (4) classifying the granulated particles in a uni-sizer vessel that rotates at 15 to 45 rpm

for about 5 to 10 minutes to convert the particles to a uniform diameter particle size, (5) compacting the uniform particles in a marumerizer for about 15 to 90 seconds or in a conventional rotating coating pan for about 15 to 30 minutes, (6) drying the particles, (7) separating the microspheres using U.S. Standard sieve screens, and (8) coating the microspheres having the desired size with an acid-resistant polymer (see column 4, lines 36 through 50; column 6 lines 1 through 46; and column 7, lines 1 through 54).

The appellants do not dispute the examiner's finding (see page 5 in the answer) that Sipos meets all of the limitations in claim 1 except for the one requiring the agglomerate-forming sieve to be "conical." As was the case with Edwards, Sipos does not specify the shape of the agglomerate-forming sieve (the 10 to 18 mesh S/S screen) disclosed therein.

As also was the case with Edwards, and notwithstanding the appellants' arguments to the contrary, the combined teachings of Sipos, Edmonds and Bremer would have suggested the implementation of Sipos' sieve-agglomeration or granulation step via a commonplace conical sieve of the sort disclosed by

Edmonds and Bremer. Here again, Szczesny is, at best, superfluous to the examiner's reference combination.

Accordingly, we shall sustain the standing 35 U.S.C. § 103(a) of claim 1, and claims 7, 8, 12 and 31/1 which stand or fall therewith, as being unpatentable over Sipos in view of Szczesny, Edmonds and Bremer.

We also shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 14/1, which stands alone, as being unpatentable over Sipos in view of Szczesny, Edmonds and Bremer.

Claim 14/1 requires the spheronization step recited in parent claim 1 to be performed for about 2 to 20 minutes. While the underlying specification (see page 7) states that this time range is preferred, it does not indicate that this parameter, in and of itself, produces optimal agglomerate characteristics as urged by the appellants (see page 18 in the main brief). In any event, Sipos discloses a spheronizing step time range of 5 to 10 minutes which falls squarely within the range set forth in claim 14.

VI. The standing 35 U.S.C. § 103(a) rejection of claims 2, 3, 5, 6, 14/2 and 15 as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Gibson

We shall sustain the standing 35 U.S.C. § 103(a) rejection of dependent claims 2, 3, 5 and 6 as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Gibson since these claims stand or fall with parent claim 1.

We shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 14/2, which stands or falls alone, as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Gibson for the reasons expressed above in connection with claim 14/1.

We also shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 15, which stands or falls alone, as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Gibson.

As indicated above, claim 15 depends from claim 1 via claim 2 and requires the rotatable spheronizing container set forth in claim 2 to rotate at a periphery speed of from about 0.5 to 1.0 m/s. Sipos' spheronizing container rotates at 15 to

45 rpm. Although this speed cannot be converted to meters per second (m/s) for comparison with the speed range set forth in claim 15 without additional information, its disclosure demonstrates a recognition by Sipos that the rotational speed of the spheronizing container is a factor contributing to the quality of the spheronized agglomerates. Here again, the appellants have not made any showing that the claimed range achieves unexpected results relative to the prior art (see In re Woodruff, supra).

VII. The 35 U.S.C. § 103(a) rejection of claim 4 as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer, Gibson, Moriya and Watson

We shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 4 as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer, Gibson, Moriya and Watson since this claim stands or falls with claim 1.

VIII. The 35 U.S.C. § 103(a) rejection of claim 13 as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Good

We shall sustain the standing 35 U.S.C. § 103(a) rejection of claim 13 as being unpatentable over Sipos in view of Szczesny, Edmonds, Bremer and Good since this claim stands or falls with claim 1.

IX. The 35 U.S.C. § 103(a) rejection of claims 1, 8 and 24 as being unpatentable over Ibsen in view of Szczesny, Edmonds, Bremer and Baichwal

Ibsen pertains to an oral composition adapted to be dispersed in an aqueous carrier immediately prior to ingestion by a patient. The composition comprises particles of an active substance combined with a gelling/swelling agent capable of forming a viscous medium and a masking surface layer around the particles when dispersed in the aqueous carrier.

According to the examiner, "Ibsen discloses the claimed method, including sieving a powder which may optionally include lactose (see col. 16, line 55) in order to agglomerate the powder (see col. 15, lines 10-20), but does not disclose spheronizing the powder which has been agglomerated by sieving and the use of a conical sieve" (answer, page 7). The portions of the Ibsen disclosure referred to by the examiner relate to two distinct examples which are not described with any

meaningful specificity or clarity. In this light, the examiner's findings as to what Ibsen teaches, and does not teach, relative to the appellants' claimed method is unduly speculative. This fundamental flaw in Ibsen finds no cure in the examiner's additional application of Szczesny, Edmonds, Bremer and Baichwal.

Hence, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 1, and claims 8 and 24 which depend therefrom, as being unpatentable over Ibsen in view of Szczesny, Edmonds, Bremer and Baichwal.[3]

X. The 35 U.S.C. § 103(a) rejection of claims 25 through 27 and 31/27 as being unpatentable over Edwards in view of Madsen

The appellants do not dispute the examiner's finding (see page 8 in the answer) that Edwards meets all of the limitations in independent claim 27 except for the one requiring the agglomerate-forming sieve to have the form of a U-shaped trough. The examiner's reliance on Madsen to overcome this deficiency is unsound.

[3] Upon return of the application to the technology center, the examiner may wish to reconsider the patentability of claim 24 in light of Edwards' disclosure that lactose can be used as an inert solid diluent with form X for administration by inhalation (see Edwards at page 3, lines 30 through 34).

Madsen discloses a V or U-shaped filter tray 3 (a sieve filter) which functions in conjunction with a filter mat 4 to remove dirt from a cleaning liquid. The purpose of this filter tray is far removed from that of the agglomerate-forming sieve disclosed by Edwards. In short, there is nothing in the disparate teachings of these references which would have suggested making Edward's sieve in the form of a U-shaped trough as required by claim 27.

Therefore, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 27, and claims 25, 26 and 31/27 which depend therefrom, as being unpatentable over Edwards in view of Madsen.

XI. The 35 U.S.C. § 103(a) rejection of claims 25 through 28 and 31/27 as being unpatentable over Edwards in view of Edmonds

Acknowledging that Edwards does not meet the limitation in claim 27 requiring the agglomerate-forming sieve to have the form of a U-shaped trough, the examiner (see page 9 in the answer) advances Edmonds' sieve element (enclosure 16 having fenestrated side walls 18) as a U-shaped trough. As discussed above, however, the Edmonds sieve element is conical. This

conical sieve does not constitute, and would not have suggested, a sieve in the form of a U-shaped trough.

Thus, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 27, and claims 25, 26, 28 and 31/27 which depend therefrom, as being unpatentable over Edwards in view of Edmonds.

XII. The 35 U.S.C. § 103(a) rejection of claims 25 through 27 and 31/27 as being unpatentable over Sipos in view of Madsen

Sipos does not meet the limitation in claim 27 requiring the agglomerate-forming sieve to have the form of a U-shaped trough, and Madsen does not overcome this deficiency for the reasons expressed above.

Accordingly, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 27, and claims 25, 26 and 31/27 which depend therefrom, as being unpatentable over Sipos in view of Madsen.

XIII. The 35 U.S.C. § 103(a) rejection of claims 25 through 28 and 31/27 as being unpatentable over Sipos in view of Edmonds

For the reasons explained above, Edmonds does not cure the failure of Sipos to meet the limitation in claim 27 requiring

the agglomerate-forming sieve to have the form of a U-shaped trough.

Hence, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 27, and claims 25, 26, 28 and 31/27 which depend therefrom, as being unpatentable over Sipos in view of Edmonds.

XIV. The 35 U.S.C. § 103(a) rejection of claim 29 as being unpatentable over Sipos in view of Edmonds and Good

The basic combination of Sipos and Edmonds is not responsive to the limitation in claim 29 requiring the agglomerate-forming sieve to have the form of a U-shaped trough. Good, applied for its alleged disclosure of multiple spheronizing steps, does not remedy this situation.

Therefore, we shall not sustain the standing 35 U.S.C. § 103(a) rejection of claim 29 as being unpatentable over Sipos in view of Edmonds and Good.

SUMMARY

In accordance with the above treatment of the various rejections on appeal, the decision of the examiner to reject claims 1 through 8, 12 through 15, 24 through 29 and 31 is

affirmed with respect to claims 1 through 8, 12 through 15 and 31/1, and reversed with respect to claims 24 through 29 and 31/27.

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

AFFIRMED-IN-PART

IRWIN CHARLES COHEN Administrative Patent Judge	)	
NEAL E. ABRAMS Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
JOHN P. McQUADE Administrative Patent Judge	)	

JPM/gjh

JANIS K. FRASER
FISH AND RICHARDSON
225 FRANKLIN STREET
BOSTON, MA 02110-2804

GJH

Appeal No. 1999-0400
Application No. 08/316,938

APJ McQUADE

APJ COHEN

APJ ABRAMS

AFFIRMED-IN-PART

Heard Case; 2 person conference

May 21, 2002