UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* DONGHAO CHEN, RICHARD P. BATYCKY, LIOYD JOHNSTON, and JEFFREY MINTZES

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Appeal 2007-4211
Application 10/977,088
Technology Center 1600

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Decided: May 28, 2008

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Before DONALD E. ADAMS, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 14-26, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a method of producing spray dried particles. Claims 14, 25, and 26 are illustrative:

14. A method of producing spray dried particles suitable for inhalation comprising:

a) correlating a dew point value of a drying gas with the resulting tap density, median geometric diameter, and median aerodynamic diameter of the spray dried particles formed by contacting a sprayed liquid feed with the drying gas over a range of drying gas dew point values;

b) selecting a dew point value of a drying gas from the range of dew point values of step (a) that corresponds to a targeted median geometric diameter, a targeted median aerodynamic diameter and a targeted tap density of spray-dried particles;

c) generating a drying gas having said selected dew point; and

d) contacting the sprayed liquid feed with the drying gas having said selected dew point thereby producing particles having the targeted median aerodynamic diameter, targeted tap density and targeted median geometric diameter, wherein said particles are suitable for inhalation.

25. A method of producing spray dried particles formed by contacting a sprayed liquid feed with a drying gas comprising the steps of:

a) correlating a dew point of a drying gas to a level selected to form spray dried particles having a median aerodynamic diameter of less than about 5 μm, a tap density of less than about 0.4 g/cm$^3$ and a geometric diameter of less than about 30 μm of particles;

b) generating a nitrogen drying gas having the correlated dew point of step (a); and

c) contacting the sprayed liquid feed with the nitrogen drying gas having said selected dew point thereby producing particles having a median aerodynamic diameter of less than about 5 μm, a tap density of less than about 0.4 g/cm$^3$ and a geometric diameter of less than about 30 μm, wherein said particles are suitable for inhalation.

26. The method of Claim 25 further comprising the step of maintaining the temperature of the dew point of the drying gas to an accuracy of at least 1° C.

The Examiner relies on the following prior art references to show unpatentability:

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| Lukas et al. | WO 97/39747 | Oct. 30, 1997 |
| Edwards et al. | US 5,985,309 | Nov. 16, 1999 |
| Campbell et al. | WO 01/23821 A1 | Apr. 5, 2001 |

Jeffrey D. Mintzes, *The Pennsylvania State University Scholars Program,* The Spray Drying of Large Porous Particles for Aerosol Drug Delivery to the Lung, The Pennsylvania State University Scholars Program, Department of Chemical Engineering pp. 1-36, (1998).

The rejections as presented by the Examiner are as follows:

1. Claims 14 and 18-23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lukas.
2. Claims 14-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Edwards.
3. Claims 14-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mintzes.
4. Claim 26 stands rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Edwards or Mintzes taken with Lukas.

We reverse.

## DISCUSSION

*Claim Construction*:

*Claim 14*:

Claim 14 is drawn to a method of producing spray dried particles suitable for inhalation. The claimed method comprises four steps.

Step a) requires that a:

1. sprayed liquid feed is contacted with the drying gas over a range of drying gas dew point values; and

2. dew point value of a drying gas is correlated with the resulting tap density, median geometric diameter, and median aerodynamic diameter of the spray dried particles formed.

Step b) requires that a dew point value of a drying gas is selected from the range of dew point values of step (a) that corresponds to a targeted median geometric diameter, a targeted median aerodynamic diameter and a targeted tap density of spray-dried particles.

Step c) requires that generating a drying gas is generated that has the selected dew point.

Step d) requires that the sprayed liquid feed is contacted with the drying gas having the selected dew point to produce particles that are suitable for inhalation and have the targeted median aerodynamic diameter, targeted tap density and targeted median geometric diameter.

*Claim 25*:

Claim 25 is drawn to a method of producing spray dried particles formed by contacting a sprayed liquid feed with a drying gas. The claimed method comprises three steps.

Step a) requires that a dew point of a drying gas is correlated to a level that is selected to form spray dried particles having a median aerodynamic diameter of less than about 5 μm, a tap density of less than about 0.4 g/cm$^3$ and a geometric diameter of less than about 30 μm of particles.

Step b) requires that a nitrogen drying gas having the correlated dew point of step (a) is generated.

Step c) requires that the sprayed liquid feed is contacted with the nitrogen drying gas having the selected dew point to produce particles that are suitable for inhalation and have a median aerodynamic diameter of less than about 5 µm, a tap density of less than about 0.4 g/cm$^3$ and a geometric diameter of less than about 30 µm.

*Claim 26*:

Claim 26 depends from and further limits the method of claim 25 to require that the temperature of the dew point of the drying gas is maintained to an accuracy of at least 1ºC.

*Anticipation*:

1. Claims 14 and 18-23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lukas.

Claim 14 is discussed above. Claims 18-23 depend from claim 14.

The Examiner finds that Lukas teaches the use of "a drying gas (air) with a dew point of less than 0 degrees Celsius" to spray dry pharmaceutical compositions (Ans. 3). The Examiner finds that Lukas teaches a "drying gas exhibiting a low dew point aids in the production of a substantially continuous coating" (*id.*). In addition, the Examiner finds that Lukas teaches that "controlling the process parameters including temperature, solvent concentration, spray drier capacity, atomizing air pressure, droplet size, and total air pressure in the system allows for a range of coats from dense, continuous, and non-porous" (*id.*). From this the Examiner reasons that Lukas selects "a dew point value of a drying gas and other parameters to provide a desired property" (Ans. 9). In this regard, the Examiner finds that Lukas "discloses controlling parameters, including the dew point of the

drying gas, provide different coats ranging from dense to porous" (Ans. 10). According to the Examiner "the coating of the particle affects the density of the particle. For instance, the denser the coating, the heavier the particle. Similarly, a porous coating provides for lighter particles, i.e., particles with lighter density" (*id.*). Therefore, the Examiner concludes that Lukas "inherently 'correlates' the parameters to provide for certain properties" (*id.*).

In response, Appellants assert that Lukas "does not disclose or suggest the relationship between the dew point and the desired aerodynamic properties of spray-dried particles" as set forth in the claimed invention (App. Br. 4). To the contrary, Appellants assert that Lukas "describes that a drying gas exhibiting a low dew point aids in the formation of a substantially continuous coating on the resulting particles" (App. Br. 4-5). According to Appellants Lukas teaches that other process parameters are controlled "for the purposes of forming a range of coats on particles and does not disclose or suggest that correlating the dew point of the drying gas to one or more particular aerodynamic features of the particles and selecting the dew point associated with the targeted particle characteristics" (App. Br. 5). We agree.

According to Lukas,

> [t]he utilisation of a drying gas exhibiting a low dew point aids the production of a substantially continuous coating. It has also been found that the presence of a solvent during the drying step slows the evaporation rate of the solvent such that a substantially continuous coat exhibiting reduced permeability is produced . . . Thus the higher the drying gas dew point, the higher the solvent vapour pressure required in the system to give a substantially continuous coat.

(Lukas 11: 3-9.)

Lukas teaches that "the formation of a range of coats, ranging from dense, continuous, non-porous coats through to more porous particle/polymer matrices" results from "[c]ontrolling the process parameters including temperature, solvent concentration, spray dryer capacity, atomising air pressure, droplet size, viscosity, total air pressure in the system and solvent system" (Lukas 11: 21-25).

Anticipation requires the disclosure, expressly or inherently, of all the limitations of a claimed invention in a prior art reference. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). According to Appellants "[i]t is not true that a reference which teaches the selection of the dew point, among other parameters, to achieve an improved coating process will inherently accomplish the step of correlating that dew point with the aerodynamic diameter of the product" (Reply Br. 2). In this regard, Appellants point out that Lukas "makes no mention of particle aerodynamic diameters, or particle tap densities. Contrary to the Examiner's assertions, such limitations are . . . not inherent to the disclosure" (*id.*).

"[I]n an *ex parte* proceeding to obtain a patent, . . . the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." *See In re Wilder*, 429 F.2d 447, 450 (CCPA 1970). On this record, the Examiner simply asserts that the Lukas' process inherently includes the requirements of Appellants' claimed invention. This assertion is not sufficient. Lukas does not teach the claimed correlation step of claim 14 a) involving "contacting a sprayed liquid feed with the drying gas over a range of drying gas dew point values."

Lukas teaches the modification of parameters in addition to dew point to achieve particular results. Lukas does not address the claimed parameters of aerodynamic diameter or particle tap density. The Examiner has failed to identify, and we do not find, a teaching in Lukas that would resolve these deficiencies. Further, given Lukas' express teachings of other relevant process parameters, the Examiner has failed to articulate a reasonable basis to believe that the choice of dew point alone would result in particles having the "targeted" characteristics recited in claimed 14.

For the foregoing reasons, we reverse the rejection of claims 14 18-23 under 35 U.S.C. § 102(b) as being anticipated by Lukas.

2. Claims 14-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Edwards.

Claims 14 and 25 are discussed above. Claims 15-24 depend directly or indirectly from claim 14.

The Examiner finds that Edwards teaches the "preparation of particles for inhalation with a specific tap density, geometric diameter, and median diameter" (Ans. 4; *see also* Edwards, Abstract). The Examiner finds that "Edwards discloses that the inlet and outlet temperature among other factors increases porosity and surface roughness (example 2) and features that contribute to low tap density are irregular surface texture and porous structure" (Ans. 4). The Examiner finds that Edwards teaches "that by varying the composition of the spray dried material and the spray drying parameters, the aerodynamic properties (density and size of the particles) can be controlled. See column 27, lines 12-31."

Edwards teaches that

> by varying the spray drying parameters, the aerodynamic properties of the inhaled particles can be effectively controlled. More specifically, the composition of the spray dried material especially affects the density and shape of the particles while the spray drying parameters have a stronger affect on their size. . . . Decreasing the inlet temperature largely increases the size of the particles without greatly affecting their tap density. Increasing the feed rate and decreasing the pressure of the compressed air both tend to increase the size of the particles without greatly affecting their density.

(Edwards 27:12-31.)

As Appellants point out, Edwards makes no mention of dew point (App. Br. 6). Nevertheless, the Examiner asserts

> that it is implicit that the prior art has 'correlated the dew point' since the selection of the air velocity, pressure, and the inlet air temperature are dependent on the batch size, the dew point of the air, and spray rate. Thus, since Edwards discloses the feed rate, the air velocity and pressure, inlet temperature, and batch size, the selection of the dew point is an implicit step because all these parameters are correlating factors and selection of one factor is dependent on the other factors.

(Ans. 4-5.) In this regard, the Examiner finds that Edwards teaches that "[l]arger particle size can be achieved by lowering the inlet compressed air flow rate, as well as by changing other variables . . . . Porosity and surface roughness can be increased by varying the inlet and outlet temperatures, among other factors" (Ans. 13 (emphasis removed)). From this the Examiner reasons that "Edwards not only discloses that the spray drying parameters affect particle properties, such as tap density and diameter, of the particles produced, but Edwards also discloses that these parameters may be 'optimized' to obtain the desired, or in Appellant's terminology 'targeted', tap density and aerodynamic diameter" (Ans. 13).

However, as Appellants point out "[a] correlation step is not an inherent part of spray drying. Likewise, the step of optimizing inlet temperature, flow rate and the like does not inherently achieve the step of correlating dew point with aerodynamic properties" (Reply Br. 4). The Examiner does not address Appellants' argument. Therefore, we are left with the Examiner's unsupported conjecture that Edwards inherently teaches a process wherein the dew point value of a drying gas is correlated with the resulting tap density, median geometric diameter, and median aerodynamic diameter of the spray dried particles formed as is required by Appellants' claimed invention. We do not find this sufficient. The Examiner failed to demonstrate by a preponderance of the evidence that Edwards teaches a process have a correlation step as required by Appellants' claimed invention.

Accordingly, we reverse the rejection of claims 14-25 under 35 U.S.C. § 102(b) as being anticipated by Edwards.

3. Claims 14-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mintzes.

Claims 14 and 25 are discussed above. Claims 15-24 depend directly or indirectly from claim 14.

The Examiner finds that "Mintzes discloses a method of spray drying particles with mean diameters less than 5 microns for inhalation" (Ans. 5). The Examiner finds that Mintzes "discloses that the particles attained from the spray drying process depend on many variables including flow rate, inlet temperature of the gas drying feed, the solution feed rate, and atomizer rate" (Ans. 5). The Examiner finds that Mintzes teaches "that the inlet temperature of the drying gas has the strongest effect on tap density" (*id.*).

From this the Examiner reasons that "the relative humidity is the water vapor content of the air relative to its content at saturation and dew point is the temperature of the air at which vapor present in the air would cause saturation. Hence, to select the humidity of the drying gas is indirectly selecting the dew point of the gas" (Ans. 5-6).

In response, Appellants assert that "Mintzes does not disclose or suggest that the correlation of a single parameter, the dew point, over a range of dew points achieves the desired characteristics in the manner as is presently claimed" (App. Br. 7). According to Appellants "[t]he Examiner has simply assumed that the correlation step was done as a necessary and implicit step without providing any well reasoned technical discussion as to why this is so" (Reply Br. 4). We agree.

We do not find the Examiner's unsupported conjecture that Mintzes inherently teaches a process wherein the dew point value of a drying gas is correlated with the resulting tap density, median geometric diameter, and median aerodynamic diameter of the spray dried particles formed as is required by Appellants' claimed invention sufficient to support a prima facie case of anticipation. The Examiner failed to demonstrate by a preponderance of the evidence that Mintzes teaches a process have a correlation step as required by Appellants' claimed invention.

Accordingly, we reverse the rejection of claims 14-25 under 35 U.S.C. § 102(b) as being anticipated by Mintzes.

*Obviousness*:

4. Claim 26 stands rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Edwards or Mintzes taken with Campbell.

The Examiner relies on Edwards and Mintzes as discussed above (Ans. 6-7). The Examiner finds that neither Edwards nor Mintzes "teach a system of maintaining the condition of the drying gas" (Ans. 7). Therefore, the Examiner relies on Campbell to teach "a method and system of controlling evaporative drying processes" (Ans. 7). The Examiner finds that Campbell "teaches a system that continuously monitors the parameters associated with evaporative drying processes which is fed to a controller. . . . The reference teaches the parameters such as drying gas temperature, dew point, drying gas flow rate (inlet and outlet temperature), and spray rate influence the type of final product" (Ans. 7). Based on this evidence, the Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Edwards et al. or Mintzes respectively and WO [(Campbell)] and separate the drying gas and utilize a system that maintains the parameters of a drying process" (Ans. 8). We disagree.

In our opinion, Campbell fails to make up for the above identified deficiencies in Edwards and Mintzes. As Appellants explain, Campbell "does not disclose or suggest anything about aerodynamic properties of particles or the desirability of forming particles with aerodynamic properties of particles or the desirability of forming particles with aerodynamic qualities suitable for inhalation as disclosed and claimed in the present invention" (App. Br. 8).

Accordingly, we reverse the rejection of claim 26 under 35 U.S.C. § 103 as being unpatentable over the combination of Edwards or Mintzes taken with Campbell.

## CONCLUSION

In summary, we reverse the rejections of record.

## REVERSED

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