



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/058,769	03/14/2011	Tillmann Roehrich	148500	3565
25944	7590	01/30/2019	EXAMINER	
OLIFF PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850			GOTFREDSON, GAREN	
			ART UNIT	PAPER NUMBER
			1619	
			NOTIFICATION DATE	DELIVERY MODE
			01/30/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

OfficeAction25944@oliff.com
jarmstrong@oliff.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TILLMANN ROEHRICH

Appeal 2017-005495
Application 13/058,769¹
Technology Center 1600

Before DEBORAH KATZ, RACHEL H. TOWNSEND, and DAVID
COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims directed to a method for producing a nicotine-containing granulate. The Examiner rejected the claims on appeal under 35 U.S.C. § 103(a) as obvious.

We reverse.

¹ According to Appellant, the real party in interest is Siegfried Ltd. App. Br. 1.

STATEMENT OF THE CASE

Claims 9–27 are on appeal. Claim 9 is illustrative and reads as follows:

9. A method for producing a nicotine-containing granulate, the method comprising the steps of:
- (a) mixing nicotine or a pharmaceutically acceptable nicotine derivative with an excipient;
 - (b) compacting the mixture obtained in step (a) in a roller compactor to produce granules; and
 - (c) screening the granules obtained in step (b) to remove granules that have a particle size smaller than 250 μm , wherein the granulate has a bulk density of at least 0.5 g/ml.

Claim App'x. A-1.

The claims stand rejected as follows.

Claims 9, 11–14, and 16–27 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Irwin,² Gereg,³ Liu,⁴ and Hansson.⁵

Claim 10 was rejected under 35 U.S.C. § 103(a) as obvious over the combination of Irwin, Gereg, Liu, Hansson, and Hafermann.⁶

² Irwin, FR 2 792 200, published Oct. 20, 2000 (“Irwin”). Irwin is written in French. All citations to Irwin are to the certified translation provided by Appellant.

³ Gereg et al., *Roller Compaction Feasibility for New Drug Candidates, Laboratory to Production Scale*, PHARMACEUTICAL TECHNOLOGY TABLETING & GRANULATION (2002) (“Gereg”).

⁴ Liu et al, *Effect of Particle Properties on the Flowability of Ibuprofene Powders*, 362 INTERNATIONAL JOURNAL OF PHARMACEUTICS 109–117 (2008) (“Liu”).

⁵ Hansson, US Patent Publication No. 2004/0191322 A1, published Sep. 30, 2004 (“Hansson”).

⁶ Hafermann et al., US Patent Publication No. 2001/0019763, published Sep. 6, 2001 (“Hafermann”).

Claim 15 was rejected under 35 U.S.C. § 103(a) as obvious over the combination of Irwin, Gereg, Liu, Hansson, and Baker.⁷

ANALYSIS

The same issue is dispositive with respect to all three obviousness rejections. Accordingly, we address all of the rejections together.

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992): “[T]he examiner bears the initial burden ... of presenting a *prima facie* case of unpatentability.” Appellant has persuaded us that the Examiner has not carried the burden of establishing that the claimed invention would have been obvious over the cited art.

Irwin discloses the following procedure for making compressed nicotine tablets:

First, the nicotine salt was granulated by mixing in a rotating drum with the Keltrol F, the green dye and the aspartame, was passed through a sieve of 250 μm and was collected in a further clean and dry drum. The solid base in powder form, the silicon dioxide and the flavoring materials were then added to the new drum that was sealed and agitated on rolls. After about 10 minutes, the icing sugar and the other excipients for tablet formation were added and continuously mixed during another 10 to 15 minutes. Tablets were formed by compression in a tableting machine and were packed in sealed polyethylene containers that may have an internal vapor resistant lining.

Irwin 3 (emphasis added).

Liu discloses that for pharmaceutical powders, “[i]t is generally accepted that the larger the particles, the better the flow” and that “[p]articles larger than 250 μm are usually free-flowing” while “powders become

⁷ Baker et al., US Patent No. 5,135,753, issued Aug. 4, 1992 (“Baker”).

cohesive and flow problems are likely to occur” when particle size “falls below 100 μm .” Liu 109.

The Examiner found that the cited art disclosed the requirement of claim 9 to remove granules that have a particle size smaller than 250 μm based on the combined disclosures of Irwin and Liu. The Examiner explained:

[I]t would have been prima facie obvious to . . . improve flowability of the powder [disclosed in Irwin] by optimizing the size of the sieve used to screen the granules in order to arrive at the step of removing particles smaller than 250 microns or 500 microns, or larger than 2000 microns, since the particle size is a result effective variable that will affect the flowability of the particles as taught by Liu and Liu expressly teaches that it is generally accepted that flowability can be improved by using particles having a particle size of greater than 250 microns.

Final Act.⁸ 6. The Examiner also noted that Liu teaches that particle size is a result effective variable and that, in the absence of an explanation in Irwin as to why it screens particles, the skilled artisan would have optimized particle size in a manner consistent with Liu’s teaching that, generally speaking, larger particles have better flowability than smaller ones. Ans. 3.

Appellant argues that Irwin describes the removal of particles with a size greater than 250 μm and that this is the opposite of what is recited in the claims. App. Br. 6. Appellant contends that Liu would not have motivated the ordinary artisan to remove particles smaller than 250 μm when Irwin teaches to do the opposite and remove particles greater than 250 μm . *Id.* at 7.

⁸ Office Action mailed March 11, 2016 (“Final Act.”).

This case turns on whether Irwin does, in fact, disclose removing particles with a size greater than 250 μm . Simply put, the Examiner's position that it would have been obvious to optimize particle size selection in Irwin's process by retaining particles larger than 250 μm is not persuasive if Irwin does exactly the opposite.

There can be no dispute that Irwin discloses using a 250 μm sieve to screen nicotine salt. The question is whether Irwin uses the material that passes through the sieve — i.e. particles smaller than 250 μm — to make nicotine tablets or whether Irwin instead uses the material retained by the sieve to make nicotine tablets. Appellant contends that Irwin uses the material that has passed through the sieve to make nicotine tablets. App. Br. 6. The Examiner contends that Irwin “uses a size selection process that retains particles of greater than 250 microns.” Ans. 3.⁹

We find that Irwin's disclosure is ambiguous. The relevant sentence from Irwin reads as follows:

First, *the nicotine salt* was granulated by mixing in a rotating drum with the Keltrol F, the green dye and the aspartame, *was passed through* a sieve of 250 μm and was collected in a further clean and dry drum.

Irwin 3 (emphasis added). At oral argument, Appellant asserted that the language “passed through” applied to the nicotine salt and, in order to pass

⁹ The Examiner's has taken various positions on whether Irwin discloses removing particles smaller than 250 μm . *Compare* Ans. 3 (quoted above), *with* Final Act 4 (conceding that Irwin “does not . . . expressly disclose . . . that the sieve screening step results in the removal of particles that are smaller than 250 microns . . .”), and Ans. 4 (suggesting that the skilled artisan would optimize by “retaining additional particles that are smaller than the 250 microns retained by Irwin, but larger than the 100 micron size below which Liu suggests may cause flowability problems”).

through the sieve, the nicotine salt must be smaller than 250 μm . According to Appellant, this makes clear that Irwin is collecting rather than excluding particles smaller than 250 μm . On the other hand, Irwin discloses that the mixture of nicotine and excipients is “a free flowing mixture.” Irwin 2. When this is read in connection with Liu, which teaches that “[p]articles larger than 250 μm are usually free-flowing,” (Liu 109) it suggests that Irwin’s sieving process retains nicotine particles larger than 250 μm . This suggestion, however, is somewhat diminished by Liu’s teaching that “the effect of particle size . . . on . . . flowability is . . . material specific.” *Id.* Absent any explanation as to why Irwin sieved particles, we find the evidence inconclusive. It is not clear whether Irwin used its sieve to collect particles that are larger than 250 μm or to collect particles that are smaller than 250 μm .

As discussed above, the Examiner’s position that it would have been obvious to optimize particle size selection in Irwin’s process by retaining particles larger than 250 μm is not persuasive if Irwin’s process does exactly the opposite. Because the evidence is inconclusive as to whether Irwin retains or excludes particles larger than 250 μm , the preponderance of the evidence does not show that the Examiner has carried the burden of showing that the claimed method would have been obvious. Accordingly, we reverse all three of the Examiner’s obviousness rejections.

SUMMARY

In summary, we reverse the Examiner’s rejection of claims 9, 11–14, and 16–27 under 35 U.S.C. § 103(a) as obvious over the combination of Irwin, Gereg, Liu, and Hansson.

Appeal 2017-005495
Application 13/058,769

We reverse the Examiner's rejection of claim 10 under 35 U.S.C. § 103(a) as obvious over the combination of Irwin, Gereg, Liu, Hansson, and Hafermann.

We reverse the Examiner's rejection of claim 15 under 35 U.S.C. § 103(a) as obvious over the combination of Irwin, Gereg, Liu, Hansson, and Baker.

REVERSED