

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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 KEITH E. JASPERSON, THOMAS J. VALINE  
and FREDERIC J. R. WAHLQUIST

Appeal No. 2006-3056  
Application No. 10/278,769

HEARD: NOVEMBER 14, 2006

Before FRANKFORT, OWENS and 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 1 through 24. Claims 25 through 35, the only other claims remaining in the application, have been withdrawn from consideration.

As noted on page 1 of the specification, appellants' invention relates to a drug infusion system that is programmable by a medical professional and which provides a simple external means to select

dosage amounts and intervals from a wide range of possible doses and intervals, and verify that a desired change has been made. Independent claim 1 is representative of the subject matter on appeal and reads as follows:

1. A drug infusion system capable of delivering a fluid medication to a patient under direction of a medical professional, comprising:

a drug delivery module capable of delivering said fluid medication to said patient continually at a basal rate and capable of delivering said fluid medication at an interval rate in each of a plurality of time slots over a specified period of time, said interval rate being different from said basal rate;

controller, programmable by said medical professional, operatively coupled to said drug delivery module to control said basal rate and said interval rate at which said fluid medication is delivered to said patient; and

wherein said controller, upon being programmed by said medical professional to deliver an interval rate for at least one of said plurality of time slots, determines a total dose of said fluid medication to be delivered to said patient over said period of time based on said basal rate and said interval rate for each of said plurality of time slots, compares said total dose against a maximum dose and adjusts said basal rate, if necessary, so that said total dose does not exceed said maximum dose.

The sole prior art reference of record relied upon by the examiner in rejecting the appealed claims is:

Fischell                    4,731,051                    Mar. 15, 1988

Claims 1 through 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Fischell.

Rather than reiterate the examiner's commentary regarding the above-noted anticipation rejection and the conflicting viewpoints advanced by the examiner and appellants regarding that rejection, we make reference to the examiner's answer (mailed March 13, 2006) for the reasoning in support of the rejection, and to appellants' brief (filed December 28, 2005) and reply brief (filed May 15, 2006) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification<sup>1</sup> and claims, to the Fischell

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<sup>1</sup> The examiner and appellants should review pages 8-11 of the specification with an eye towards correcting the inaccurate information conveyed in Table II (page 8) and in paragraph [47] on page 11. It appears that the last entry in Table II for the two hour time frame of 22:00-24:00 hours should be 70, not 105 as shown. This would make the total for the 24-hour time period shown in Table II 575 mg, not 610 mg as now indicated in paragraph [47] on page 11. Appellants should also explain why the adjustment of the basal rate noted in the last sentence of

patent, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determination that the examiner's above-noted rejection under 35 U.S.C. § 102(b) will not be sustained. Our reasons follow.

The examiner's position concerning the rejection of claims 1 through 24 under 35 U.S.C. § 102(b) is set forth on page 3 of the answer, wherein the examiner urges that

Fischell shows an implantable drug delivery module 10 that is capable of delivering a fluid medication continually at a basal rate and capable of delivering a fluid medication at an interval rate where the interval rate is different from the basal rate. Fischell also shows a controller 35 that is programmable by a medical professional and operatively coupled to the drug delivery module. See Figures 1-22 and col. 1, line 64 through col. 4, line 49.

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paragraph [47] is calculated based on 15 hours instead of the entire 24 hours of the time period. In that regard, Figure 3 of the application appears to show the basal rate as constant over the 24-hour period, which is exactly what appellants have argued in the paragraph bridging pages 8 and 9 of their brief and also on pages 15 and 16 thereof.

While we agree with the examiner that the drug infusion system in Fischell includes a drug delivery module (10) that is fully capable of delivering a fluid medication to a patient in the manner required in the first clause of claim 1 on appeal, and also includes a controller that is programmable by a medical professional to deliver an interval rate for at least one of the plurality of time slots making up the specified period of time set forth in the first clause of claim 1, we find nothing in the applied Fischell patent which teaches a controller that then determines a total dose of said fluid medication to be delivered to the patient over said specified period of time based on said basal rate and said interval rate for each of said plurality of time slots, compares said total dose against a maximum dose, and adjusts said basal rate, if necessary, so that said total dose does not exceed said maximum dose, as required in appellants' claim 1.

In contrast to the examiner's apparent position, we do not view the determining, comparing and adjusting recitations of claim 1 on appeal to be merely "intended use of the claimed invention" (answer, page 5). In our opinion, such limitations serve to positively define structural characteristics of the controller set forth in appellants' claim 1 which is specifically programmed and/or constructed to carry out the determining, comparing and adjusting operations once the medical professional enters an appropriate continuing basal rate of delivery and the desired additional interval rates. No such special purpose controller is found in Fischell.

The examiner's reliance on the disclosure of Fischell at col. 31, lines 40-52, and Figure 21 as teaching a controller that determines the total dose to be delivered over the specified time period based on the assigned basal and interval rates, compares the total dose to be delivered to the maximum dose, and then, if necessary, adjusts the basal rate to prevent exceeding the maximum dose, appears to be misplaced. The 3-hour and 24-hour integral rate limiting software means of Fischell is described in some detail in column 18 of the patent and in the disclosure bridging columns 30 and 31. From that disclosure, it is clear to us that the controller in Fischell determines the number of pump actuations which have occurred over the last eleven quarter-hour periods (called SUM 11) and over the last twenty-three hour periods (called SUM 23), and then compares those quantities that have already been delivered respectively to the 3-hour dosage limit and 24-hour dosage limit so as to arrive at a quarter-hour limit which is the smaller of [(3-hour limit)-(SUM 11)] and [(24-hour limit)-(SUM 23)]. The quarter-hour limit tells the controller how many pump actuations will be allowed in the next quarter-hour. Pump activity is suspended when the number of pump actuations occurring during the next quarter-hour equals the quarter-hour limit. Such activity is exactly what has occurred toward the end of the 3-hour window shown at (362) in Figure 21 of Fischell, where the last two supplemental (358, 359) and

two basal (360, 361) shots of medication scheduled for delivery to the patient during the quarter-hour periods at the end of the 3-hour window were prevented from being delivered.

Thus, it is clear from the foregoing that the controller in Fischell looks back to the previous pump actuations and determines a quarter-hour limit based on the previous totals, which limit can not be exceeded in the next quarter-hour period of time making up the sliding 3-hour and 24-hour time windows. The controller in Fischell does not determine a total dose of said fluid medication to be delivered to the patient over said specified period of time (e.g., the 3-hour or 24-hour time window) based on said basal rate and said interval rate for each of said plurality of time slots, does not compare such total dose against a maximum dose, and does not then adjust said basal rate, if necessary, so that said total dose does not exceed said maximum dose, as is required in appellants' claim 1. Moreover, it is not at all clear to us that the controller in Fischell even has the capability of carrying out the particular determining, comparing and adjusting functions set forth in appellants' claim 1. Nor has the examiner explained exactly how such activity, in fact, is within the capability of the controller in Fischell.

Like appellants, we find that the examiner has failed to establish a *prima facie* case of anticipation with regard to the subject matter of independent claim 1 on appeal. For that

reason, the examiner's rejection of claim 1, and of claims 2 through 12 which depend therefrom, will not be sustained.

We now turn to independent claim 13. This claim differs from claim 1 in that it has no comparison function associated with the controller, i.e., wherein a total dose to be delivered for the prescribed time period is determined on the basis of the basal rate and interval rates, and then compared to a maximum dose for the prescribed time period programmed by the medical professional. As written, claim 13 determines a total dose of fluid medication to be delivered over the prescribed time period based on the basal rate and interval rates, and then anomalously "adjusts said basal rate to maintain said total dose." The basis upon which said adjustment is made is not clear from the claim. Dependent claim 14 sets forth the requirement that said total dose in claim 13 "equals said maximum dose," but there is no antecedent basis in claim 13 for a "maximum dose." Thus, in our view, claim 13 and the claims which depend therefrom are indefinite. For that reason, we enter a NEW GROUND of rejection under 35 U.S.C. § 112, second paragraph.

As for the examiner's rejection of claims 13 through 24 under 35 U.S.C. § 102(b), we emphasize again that those claims contain language which renders the subject matter thereof vague and indefinite. Thus, we find that it is not reasonably possible to apply the prior art relied upon by the examiner to those claims in deciding the question of

anticipation under 35 U.S.C. § 102(b) without resorting to considerable speculation and conjecture as to exactly what the claims on appeal actually cover and thus the boundaries of what might constitute infringement of those claims. This being the case, we are constrained to reverse the examiner's rejection of appealed claims 13 through 24 under 35 U.S.C. § 102(b) in light of the holding in In re Steele, 305 F.3d 859, 134 USPQ 292 (CCPA 1962). We hasten to add that this reversal of the examiner's rejection is not based on the merits of the rejection, but only on technical grounds relating to the indefiniteness of the appealed claims.

In Summary: since we have not sustained the rejection of claims 1 through 24 put forth by the examiner under 35 U.S.C.

§ 102(b), it follows that the decision of the examiner is reversed.

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provide that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED AND NEW GROUND OF REJECTION

CHARLES E. FRANKFORT	)
Administrative Patent Judge	)
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	)
	) BOARD OF PATENT
TERRY J. OWENS	) APPEALS
Administrative Patent Judge	) AND
	) INTERFERENCES
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	)
JENNIFER D. BAHR	)

Administrative Patent Judge )

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