

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte J. BRADLEY PHIPPS  
and GARY A. LATTIN

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Appeal No. 98-2769  
Application 08/485,960<sup>1</sup>

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ON BRIEF

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Before CALVERT, FRANKFORT and CRAWFORD, 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 27, all the claims pending in the application.

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<sup>1</sup> Application for patent filed June 7, 1995.

Appellants' invention relates to a method for delivering a therapeutic agent through a body surface (i.e., the human skin) utilizing adjustable electrotransport, and to an electrotransport device or system capable of such use. As noted in the paragraph bridging pages 8 and 9 of the specification,

“[t]he present invention is characterized by an ability to vary drug delivery rate utilizing a fixed output electronic controller and multiple drug-containing units in an electrotransport system. The system permits a physician to alter drug dosages for a patient without the need to replace the controller, instead, the physician simply prescribes a new class of drug-containing units for use with the same controller. In this manner, the controller output can be set or programmed at the factory or by a pharmacist, e.g., when the controller is first dispensed. The system provides less expensive electrotransport drug delivery regimens because (1) the controller has no patient adjustable electric current/voltage output features, and (2) the controller is reusable, i.e., it is adapted to be used with a plurality of similar or different drug-containing units. Adjusting the drug delivery (i.e., dosing) rates is achieved through a novel combination of physical and chemical features.”

Independent claims 1, 6, 11 and 21 are representative of the subject matter on appeal and a copy of those claims, as reproduced from the Appendix to appellants' brief, is attached to this decision.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Phipps et al. (Phipps '894)	5,125,894	June 30, 1992
Sibalis et al. (Sibalis '479)	5,135,479	Aug. 4, 1992
Chien et al. (Chien)	5,250,022	Oct. 5, 1993

Claims 9 and 19 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a

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non-enabling disclosure.

Claim 1 through 27 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim that which appellants regard as their invention.

Claims 1, 2, 5 through 8, 10 through 18 and 20 through 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sibalis '479.

Claims 1 through 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by Phipps '894.

Claims 3 and 4 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sibalis '479 in view of Chien.

Claims 9 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sibalis '479 in view of Phipps '894.

Rather than reiterate the examiner's full statement of the above-noted rejections and the

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conflicting viewpoints advanced by the examiner and appellants regarding those rejections, we make reference to the examiner's answer (Paper No. 14, mailed March 17, 1998) for the examiner's reasoning in support of the rejections, and to appellants' brief (Paper No. 13, filed December 8, 1997) for appellants' arguments thereagainst.

### OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determinations which follow.

We turn first to the examiner's rejection of claims 9 and 19 under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure. It is by now well-established law that the test for compliance with the enablement requirement in the first paragraph of 35 U.S.C. § 112 is whether the disclosure, as filed, is sufficiently complete to enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation. In re Moore, 439 F.2d 1232; 1235, 169 USPQ 236, 238 (CCPA 1971). See also In re Scarborough, 500 F.2d 560, 566, 182 USPQ 298, 303

(CCPA 1974). Moreover, in rejecting a claim for lack of enablement, it is also well settled that the examiner has the initial burden of advancing acceptable reasoning inconsistent with enablement in order to substantiate the rejection. See In re Strahilevitz, 668 F.2d 1229, 1232, 212 USPQ 561, 563-64 (CCPA 1982); In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Once this is done, the burden shifts to appellant to rebut this conclusion by presenting evidence to prove that the disclosure in the specification is enabling. See In re Doyle, 482 F.2d 1385, 179 USPQ 227 (CCPA 1973); In re Eynde, 480 F.2d 1364, 1371, 178 USPQ 470, 474-75 (CCPA 1973).

In the case before us, after reviewing the disclosure on page 13, lines 1-19, of appellants' specification and the Phipps patent incorporated therein by reference, we are of the opinion that the examiner has not met his burden of advancing acceptable reasoning inconsistent with enablement. While the examiner seems to be of the view that the secondary electrode referred to in claims 9 and 19 on appeal is of the exact same structure and operation in each of the plurality of drug-containing units of claim 9 and in each of the plurality of "different classes of therapeutic agent sources" of claim 19 on appeal (i.e., that the secondary electrode in each of the drug-containing units or therapeutic agent sources generates exactly the same amount of competitive co-ions), our understanding of appellants' disclosure leads us to a contrary conclusion. Even if the structure of the secondary electrode in each of appellants' drug-containing units or therapeutic agent sources is generally the same, in our opinion, it

would have been clear to one of ordinary skill in the art that each of the secondary electrodes would be operated in such a manner as to generate different amounts of competitive co-ions in each of the drug-containing units or therapeutic agent sources so as to maintain the recited different drug or therapeutic agent delivery rates or dosages associated with each of appellants' drug-containing units or therapeutic agent sources.

Method claim 9 and article claim 19 each relate to an embodiment of appellants' invention wherein a second electrode is used in the drug-containing reservoir for generating or adding competitive co-ions to the reservoir as a means for controlling drug delivery rate by varying the ratio of drug ion concentration to co-ion concentration. In our view, the examiner has advanced no reason why what appears to be a relatively simple mechanism for maintaining selected control over the delivery rate of a target species (i.e., a drug or therapeutic agent) in Phipps (U.S. Patent No. 5,125,894) would require undue experimentation on the part of one skilled in the art in order to implement the same such control in the context of appellants' invention.

After a careful consideration of appellants' disclosure and of the arguments on both sides, it is our opinion that the level of skill in this art is sufficiently high that the ordinarily skilled artisan would have been able to make and use appellants' claimed invention as set forth in claims 9 and 19 on appeal,

based on appellants' disclosure, without the exercise of undue experimentation.

For the above reasons, we will not sustain the examiner's rejection of claims 9 and 19 under 35 U.S.C. § 112, first paragraph, as being directed to a non-enabling disclosure.

The next rejection for our review is that of claims 1 through 27 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim that which appellants regard as their invention. Looking first at method claims 1 through 10, we note that independent claim 1 on appeal purports to relate to “a method for delivering a therapeutic agent through a body surface from an electrotransport assembly of the type which includes a controller component and a detachable therapeutic agent source” wherein the method comprises the step of

“adjusting the rate of therapeutic agent delivery by providing a plurality of therapeutic agent sources in which a single parameter or a series of parameters has been varied so that in conjunction with said assembly agent delivery rate is selectively controlled.”

Independent claim 6 sets forth “[a] method for varying drug delivery rate of a therapeutic agent through a body surface from an electrotransport assembly of the type which includes an

electronic controller and a detachable drug-containing unit having an active electrode” wherein the

method comprises the step of “providing, one at a time, a plurality of drug-containing units, each drug-containing units [sic] having a specific dose different from the others of said plurality.”

Like the examiner, we are at a loss to understand how merely “providing a plurality of therapeutic agent sources” as set forth in claim 1 on appeal would in any way adjust the rate of therapeutic agent delivery as required in claim 1. Likewise, we fail to understand how merely “providing, one at a time, a plurality of drug-containing units” would vary the drug delivery rate as set forth in claim 6 on appeal. As is made clear in appellants’ specification (e.g., page 10, line 24, *et seq.*), when the dosing rate needs to be changed, the drug-containing unit that is presently in use is disconnected from the controller and replaced with a new drug-containing unit having a different drug composition and delivery rate, thus, requiring that one of the plurality of provided drug-containing units actually be used along with the controller before any desired variation in drug delivery rate can be achieved. Since the method as set forth in appellants’ claim 1 does not deliver a therapeutic agent or adjust the rate of therapeutic agent delivery as set forth therein, we agree with the examiner that the scope of this claim is indefinite. Similarly, since the

method of claim 6 on appeal does not vary the drug delivery rate as required therein, the scope of that

claim is also indefinite. It follows that claims 2 through 5 which depend from claim 1 and claims 7 through 10 which depend from claim 6 are also indefinite.

Regarding independent claim 11, directed to “[a]n electrotransport device,” it is indicated that the device includes a controller which operates “at a predetermined, fixed electrical output” and which is adapted to be detachably connected, one at a time, to a plurality of therapeutic agent sources. In addition, claim 11 requires that the device include or have

“a plurality of different classes of therapeutic agent sources in which a parameter in each said different classes has been varied so that the electrotransport agent delivery rate from the controller with one class of therapeutic agent sources is substantially different from the controller with another of said classes of therapeutic agent sources.”

In this instance, we are at a loss to see how the claimed “electrotransport device” can be said to include “a plurality of different classes of therapeutic agent sources” when the device, in use, is disclosed as including only a single therapeutic agent source at a time, not a plurality. Given this ambiguity, we agree with the examiner that claim 11 is also indefinite. In addition, it follows that claims 12 through 20 which depend from claim 11 are also indefinite.

As for independent claim 21, we view this “system” claim as being essentially a “kit” claim, wherein the system or kit includes an electrotransport device of the nature set forth in the claim and a plurality of different therapeutic agent sources that can be selectively used, one at a time, in the device to vary the therapeutic agent delivery rate. Thus, we view the scope and content of the subject matter embraced by claim 21 on appeal as being reasonably clear and definite, and as fulfilling the requirement of 35 U.S.C. § 112, second paragraph, that it provide those who would endeavor, in future enterprise, to approach the area circumscribed by the claim, with the adequate notice demanded by due process of law, so that they may more readily and accurately determine the boundaries of protection involved and evaluate the possibility of infringement and dominance. *See, In re Hammack*, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970). Given the foregoing, we will not sustain the examiner's rejection of appellants' claim 21 under 35 U.S.C. § 112, second paragraph, or that of claims 22 through 27 which depend therefrom.

We next look to the examiner's prior art rejections of the appealed claims, turning first to the rejections of claims 1, 2, 5 through 8, 10 through 18 and 20 through 27 under 35 U.S.C. § 102(b) as being anticipated by Sibalis '479, and claims 1 through 27 as being anticipated by Phipps '894. Given our determinations above concerning the indeterminate scope and content of claims 1 through 20 on appeal under 35 U.S.C. § 112, second paragraph, we find that it is not possible to apply

the prior art relied upon by the examiner to these claims in deciding the question of either anticipation under 35 U.S.C. § 102(b) or obviousness under 35 U.S.C. § 103 without resorting to considerable speculation and conjecture as to the exact scope and content of these claims. This being the case, we are constrained to reverse the examiner's rejection of claims 1, 2, 5 through 8, 10 through 18 and 20 under 35 U.S.C. § 102(b) based on Sibalis '479, the rejection of claims 1 through 20 under 35 U.S.C. § 102(b) based on Phipps '894, and the rejections of claims 3, 4, 9 and 19 under 35 U.S.C. § 103, in light of the holding in In re Steele, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962). We hasten to add that this reversal of the examiner's rejections is not based on the merits of the rejections, but only on technical grounds relating to the indefiniteness of the appealed claims.

This leaves for our further consideration on appeal only the examiner's rejections of claims 21 through 27 under 35 U.S.C. § 102(b) based on Sibalis '479 and Phipps '894. Independent claim 21 on appeal specifies that the controller therein operates at a predetermined, substantially fixed electrical output and that it is "adapted to be detachably connected to a plurality of therapeutic agent sources." Since we find no disclosure in Phipps '894 that the controller therein is adapted to be detachably connected to a plurality of therapeutic agent sources, we will not sustain the examiner's rejection of claim 21, or claims 22 through 27 which depend therefrom, under 35 U.S.C. § 102(b) based on Phipps '894. Simply stated, we can not agree with the examiner's position (answer, pages 6-7) that

“Phipps is considered as inherently conveying to the reader the claimed invention.”

However, we will sustain the examiner’s rejection of claims 21 through 27 under 35 U.S.C. § 102(b) based on Sibalis ‘479. Sibalis ‘479 discloses an electrotransport delivery “system” that comprises an electrotransport device for delivering a therapeutic agent through a body surface, wherein the device (e.g., Figs. 17 or 19) includes a controller (e.g., 280) that is programmable to operate at a predetermined, substantially fixed electrical output (see, e.g., col. 11, lines 46-52) and is adapted to be detachably connected to a plurality of replaceable therapeutic agent sources (e.g., 264B). Sibalis ‘479 makes clear (e.g., col 7, lines 60-61) that different drugs can be incorporated into the various replaceable therapeutic agent sources for particular applications depending on the medical needs of the patient, thus providing a plurality of different therapeutic agent sources and a situation where the electrotransport agent delivery rate of the system with one of said sources would be substantially different from the electrotransport agent delivery rate of the system with another one of said sources.

Appellants’ argument (brief, pages 11-12) that Sibalis ‘479 fails to disclose a controller component of an electrotransport device which is adapted to be detachably connected, one at a time, to a plurality of therapeutic agent sources, is not agreed with. In contrast with appellants’ argument regarding the embodiment seen in Figure 17 of Sibalis ‘479, we note that the controller is adapted to be

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detachably connected, one at a time, to a plurality of therapeutic agent sources (226B1, 226B2, 226B3) via the drug reservoir selector switch (230). Note also the detachable and replaceable patch or therapeutic agent source (248B) of Sibalis '479 Figure 19 and the disclosure regarding the alternate connector device of Figure 20 of Sibalis '479 for removably securing the disposable therapeutic agent source (248B) to the controller therein.

In light of the foregoing, we will sustain the examiner's rejection of claim 21 under 35 U.S.C. § 102(b) based on Sibalis '479. Given the lack of any specific argument directed at the examiner's rejection of dependent claims 22 through 27 under 35 U.S.C. § 102(b), we view these claims as falling with independent claim 21.

To summarize our decision, we note that 1) the examiner's rejection of claims 9 and 19 under 35 U.S.C. § 112, first paragraph, has not been sustained; 2) the examiner's rejection of claims 1 through 27 under 35 U.S.C. § 112, second paragraph, has been sustained with regard to claims 1 through 20, but not with regard to claims 21 through 27; 3) the examiner's rejection of claims 1 through 27 under 35 U.S.C. § 102(b) based on Phipps '894 has not been sustained; 4) the examiner's rejection of appealed claims 1, 2, 5 through 8, 10 through 18 and 20 through 27 under 35 U.S.C. § 102(b) as being anticipated by Sibalis '479 has been sustained with regard to claims 21 through 27 on

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appeal, but not with regard to claims 1, 2, 5 through 8, 10 through 18 and 20; and 5) that the examiner's rejections of claims 3, 4, 9 and 19 under 35 U.S.C. § 103 have also not been sustained.

Since at least one rejection of each of the claims on appeal has been sustained, it follows that the decision of the examiner rejecting claims 1 through 27 on appeal is affirmed.

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

AFFIRMED

IAN A. CALVERT )  
Administrative Patent Judge )  
)  
)  
) BOARD OF PATENT  
CHARLES E. FRANKFORT )  
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APPENDIX

1. In a method for delivering a therapeutic agent through a body surface from an electrotransport assembly of the type which includes a controller component and a detachable therapeutic agent source, the controller component operating at a predetermined electrical output, the therapeutic agent source including means for varying drug delivery rate at said substantially predetermined controller output, the method comprising the step of:

adjusting the rate of therapeutic agent delivery by providing a plurality of therapeutic agent sources in which a single parameter or a series of parameters has been varied so that in conjunction with said assembly agent delivery rate is selectively controlled.

6. A method for varying drug delivery rate of a therapeutic agent through a body surface from an electrotransport assembly of the type which includes an electronic controller component and a detachable drug-containing unit having an active electrode, the controller component operating at a fixed output, the method comprising the step of:

providing, one at a time, a plurality of drug-containing units, each drug-containing units having a specific dose different from the others of said plurality.

11. An electrotransport device for delivering a therapeutic agent through a body surface, the device including a controller which operates at a predetermined, fixed electrical output, the controller being adapted to be detachably connected, one at a time, to a plurality of therapeutic agent sources, the device having:

a plurality of different classes of the therapeutic agent sources in which a parameter in each said different classes has been varied so that the electrotransport agent delivery rate from the controller with one class of therapeutic agent sources is substantially different from the controller with another of said classes of therapeutic agent sources.

21. An electrotransport delivery system comprising:

an electrotransport device for delivering a therapeutic agent through a body surface, the device including a controller which operates at a predetermined, substantially fixed electrical output, the controller being adapted to be detachably connected to a plurality of therapeutic agent sources; and

a plurality of different therapeutic agent sources in which a parameter in each said different sources has been varied so that electrotransport agent delivery rate from the system with one of said sources is substantially different from the electrotransport agent delivery rate from the system with another of said sources.