



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

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
11/303.818 12/15/2005 Eamonn Hobbs 121693-00051/P-30CIP 8363

76147 7590 02/23/2016
KBSO Law / ANGIO
100 Matawan Road, Ste 120
Matawan, NJ 07747

Table with 1 column: EXAMINER

LIPITZ, JEFFREY BRIAN

Table with 2 columns: ART UNIT, PAPER NUMBER

3769

Table with 2 columns: NOTIFICATION DATE, DELIVERY MODE

02/23/2016

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):

docketing@kbsolaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

*Ex parte* EAMONN HOBBS and WILLIAM M. APPLING

---

Appeal 2013-006660  
Application 11/303,818  
Technology Center 3700

---

Before LINDA E. HORNER, LISA M. GUIJT, and MICHAEL L. WOODS,  
*Administrative Patent Judges.*

HORNER, *Administrative Patent Judge.*

DECISION ON REHEARING

STATEMENT OF THE CASE

Eamonn Hobbs and William M. Appling (Appellants) request that we reconsider our decision of November 6, 2015 (“Decision”), in which we affirmed<sup>1</sup> the Examiner’s decision rejecting claims 13, 14, and 31 and entered a new ground of rejection of claims 1, 2, 5, 7, 8, 10, 11, 15–28, 30, and 33–40 under 35 U.S.C. § 103(a) as being unpatentable over Appling (US 5,267,979, issued December 7, 1993), Lary (US 2003/0120256 A1, published June 26, 2003), and Goldman (US 2001/0016739 A1, published

---

<sup>1</sup> We designated our affirmance as a new ground of rejection pursuant to 37 C.F.R. § 41.50.

August 23, 2001).<sup>2</sup> Decision 5–8. 37 C.F.R. § 41.50(b)(2) provides that when the Board enters a new ground of rejection, an appellant may request rehearing to address the new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection. In this case, Appellants request rehearing to address the new ground of rejection.

Specifically, Appellants argue that the Decision hinges upon an erroneous determination that one of ordinary skill in the art would have been led to combine the teachings of Appling, Lary, and Goldman in the manner claimed despite the fact that “none of the cited references address the issue of preventing sclerosing agent migration into the deep venous system without using an occluding balloon.” Req. for Reh’g 7; *id.* at 8 (arguing that only Lary recognizes the danger presented by sclerosing agent entering the deep venous system, and that despite the fact that the vein has been exsanguinated, Lary teaches to use an occluding balloon to ensure against migration of the sclerosing agent into the deep venous system). We agree with Appellants that the Record on appeal lacked adequate evidentiary support for the determination that one having ordinary skill in the art would have been led to use the device of Appling to deliver a sclerosing agent without the use of an occlusion balloon. As such, we grant Appellants’ request for rehearing to reconsider our Decision.

We vacate the original Decision in its entirety and substitute the following decision in its place. As a result of this rehearing, we reverse the

---

<sup>2</sup> We also reversed the rejection of claims 1, 2, 5, 7, 8, 10, 11, 15–28, 30, and 33–40 under 35 U.S.C. § 103(a) as unpatentable over Appling and Lary. Decision 3–5.

Examiner's rejections of claims 1, 2, 5, 7, 8, 10, 11, 13–28, 30, 31, and 33–40 under 35 U.S.C. § 103(a). The decision that follows replaces the Board's Decision of November 6, 2015.

#### CLAIMED SUBJECT MATTER

Appellants' claimed subject matter relates to “[treatment of] varicose veins using [a] catheter and [a] sclerosing agent.” Spec. para. 2. Claims 1, 27, 28, 34, and 40 are independent. Claims 1, 27, 28, and 40 are directed to methods, and claim 34 is directed to an apparatus. Claim 1 is illustrative of the subject matter on appeal and is reproduced below.

1. The method of treating a vascular disease comprising:

inserting into a body vessel a catheter having a lumen, an end hole and a plurality of exits longitudinally disposed along the sidewall of said lumen, said end hole having a proximal opening and a distal opening,

inserting through said catheter an occluding wire having an occluding element having a larger size than the size of said end hole so as to occlude the proximal opening of said end hole, and

delivering a sclerosant fluid into said lumen under pressure to provide jets of said fluid through said exits that impinge on the wall of the body vessel without using an occlusion balloon and while said end hole is occluded by said occluding element to close the body vessel.

#### REJECTIONS

Appellants appeal from the Final Action dated August 12, 2011, which includes the following rejections:

1. Claims 1, 2, 5, 7, 8, 10, 11, 15–28, 30, and 33–40 under 35 U.S.C. § 103(a) as unpatentable over Appling and Lary.

2. Claims 13, 14, and 31 under 35 U.S.C. § 103(a) as unpatentable over Appling, Lary, and Goldman.

#### ANALYSIS

##### *First Ground of Rejection*

Appellants argue that the Examiner erred in rejecting the claims subject to the first ground of rejection because the rejection “relies on classic hindsight bias to discount the value of the new combination of elements found in [the rejected] claims.” Br. 11. In particular, Appellants argue that the claimed invention “provides the benefit that the delivered sclerosant will be ejected with enough force against the vessel walls to prevent material dilution by the blood, without the requirement of a distal protection device, such as an occlusion balloon.” *Id.* (citing Spec. para. 54). Appellants contend that Lary “teaches the required use of an occlusion balloon when delivering the sclerosant agent,” and thus, “if Appling were to be modified by Lary, the most logical and sensible combination would clearly use an occlusion balloon.” *Id.* at 12 (citing Lary, para. 74).

The Examiner found that Appling discloses a catheter and occluding wire as called for claim 1, but that it does not disclose using the catheter for delivering a sclerosant fluid. Final Act. 3. The Examiner found that Lary discloses treating a vessel wall with a sclerosant, and determined that it would have been obvious to deliver a sclerosant using Appling’s catheter and occluding wire, because “Appling’s invention is intended to be used with any fluid” and “a sclerosant [was known in the art to be] used to treat varicose veins.” *Id.* (citing Lary, Abstract, para. 10). The Examiner has failed to articulate adequate reasoning with rational underpinning to explain why one having ordinary skill in the art would have been led to use

Appling's catheter to deliver a sclerosant fluid in view of the teachings of Lary.

Lary teaches that “[w]hen a larger vein is injected with a sclerosing agent, the sclerosing agent is quickly diluted by the substantially larger volume of blood which is not present in smaller veins.” Lary, para. 10. Lary teaches that to treat varicose veins, an occluding balloon is inflated until it totally occludes the vessel, and then sclerosing agent is infused. *Id.* at paras. 31, 65–67. Lary discloses that a benefit of the invention is that “[t]he occlusion balloon prevents the sclerosing agent from entering the deep venous system via the saphenofemoral or saphenopopliteal junctions.” *Id.* at para. 74. Based on these disclosures, we understand Lary to use the occluding balloon to both minimize the volume of blood in the larger veins so that the sclerosing agent is not diluted and prevent the sclerosing agent from entering the deep venous system.

Appling discloses a catheter for use in the vascular system formed with pressure responsive valves. Appling, col. 1, ll. 10–13. Appling discloses that one use of the catheter is to more efficiently and quickly dissolve blood clots in the vascular system using a lytic agent that is delivered to the clot at high velocity using a forceful injection. *Id.* at col. 2, ll. 46–50. Appling discloses that “[f]or optimal lysing, the lytic agent should be delivered at an even flow rate at the desired high pressure required for high velocity impact from exits provided along a predetermined length of [the] catheter.” *Id.* at col. 2, ll. 51–54. Appling discloses the use of occluding ball 38 to seal distal end hole 22c of catheter 10 so that all fluid flow is from slits 26. *Id.* at col. 4, ll. 49–55; *see also id.* at Figs. 1 and 16.

Appling discloses that the lytic agents are “delivered at low volumes and high velocities.” *Id.* at col. 4, ll. 14–15.

It is not clear from the disclosure provided in Lary that one having ordinary skill in the art would have been led to use Appling’s catheter to deliver a sclerosing fluid without the use of an occlusion balloon or other means to occlude the blood flow through the vein being treated. Although Appling teaches that the catheter can be used to dispense lytic agents at high velocities, there is insufficient evidence presented in the first ground of rejection on which to find that one having ordinary skill in the art would have recognized that dispensing a sclerosing fluid through the Appling catheter at equally high velocities, and in the absence of an occluding balloon or other occluding means deployed in the vessel, would be sufficient to prevent rapid dilution of the sclerosing fluid and entry of the sclerosing agent into the deep venous system. As such, we find that the Examiner has failed to articulate adequate reasoning based on rational underpinnings to explain why a person having ordinary skill in the art would have been led to use Appling’s catheter to deliver a sclerosant fluid, as taught in Lary, for treatment of vascular disease in the absence of an occluding balloon or other means to occlude the vessel being treated. For these reasons, we do not sustain the first ground of rejection of claims 1, 2, 5, 7, 8, 10, 11, 15–28, 30, and 33–40 as articulated by the Examiner based on the combined teachings of Appling and Lary.

*Second Ground of Rejection*

In the second ground of rejection of claims 13, 14, and 31, the Examiner found that Goldman teaches, “providing a sclerosant for the treatment of vessels,” and also teaches, “providing a tumescent, such as

epinephrine before delivering the sclerosant.” Final Act. 4–5 (citing Goldman, paras. 17, 18, 25, 91). The Examiner determined that it would have been obvious to modify the method of treating vessels to deliver epinephrine, as disclosed in Goldman. *Id.* at 5 (citing Goldman, para. 91). We are persuaded by Appellants’ argument in the Request for Rehearing that this rejection is not sustainable because Goldman does not cure the deficiency in the combination of Appling and Lary. Req. for Reh’g. 7–8. In particular, we agree with Appellants that Goldman “offers no solution to preventing the sclerosing agent from migrating away from the treatment site and entering the deep venous system.” *Id.* at 8. For this reason, we do not sustain the second ground of rejection of claims 13, 14, and 31 based on the combined teachings of Appling, Lary, and Goldman.

#### DECISION

We GRANT the Request for Rehearing, REVERSE the decision of the Examiner to reject claims 1, 2, 5, 7, 8, 10, 11, 15–28, 30, and 33–40 under 35 U.S.C. § 103(a) as unpatentable over Appling and Lary, and REVERSE the decision of the Examiner to reject claims 13, 14, and 31 under 35 U.S.C. § 103(a) as unpatentable over Appling, Lary, and Goldman.

GRANTED; REVERSED