

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 42

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte HARRISON M. LAZARUS

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Appeal No. 2000-1759  
Application No. 08/748,637

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HEARD: July 9, 2002

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Before COHEN, ABRAMS, and FRANKFORT, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 39 through 42, which are all of the claims remaining in this application. Claims 1 through 38 have been canceled.

Appellant's invention relates to a minimally invasive method for repairing a diseased portion of a corporeal lumen of a patient's vasculature. Independent claims 39 and 42 are

Appeal No. 2000-1759  
Application No. 08/748,637

representative of the subject matter on appeal and a copy of those claims may be found in the Appendix to appellant's brief.

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

Choudhury	4,140,126	Feb. 20, 1979
Kononov	SU 660689	May 5, 1979
(Russian Inventor's Certificate) <sup>1</sup>		

Claims 39 through 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Choudhury in view of Kononov.

Rather than reiterate the examiner's full statement of the above-noted rejection and the conflicting viewpoints advanced by the examiner and appellant regarding the rejection, we make reference to the examiner's answer (Paper No. 31, mailed May 19, 2000) for the reasoning in support of the rejection, and to appellant's brief (Paper No. 29, filed March 2, 2000) and reply brief (Paper No. 34, filed July 27, 2000) for the arguments thereagainst.

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<sup>1</sup> Our understanding of this foreign language document is based on a translation apparently submitted by appellant.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellant's specification and claims, to the applied prior art references, to the declarations filed by Morton J. Thoshinsky, M.D., and to the respective positions articulated by appellant and the examiner. As a consequence of our review, we have made the determination that the examiner's above-noted rejection will not be sustained. Our reasons follow.

In evaluating the prior art applied by the examiner, we note that Choudhury discloses a method and device for permitting intraluminal repair of an aneurysm (20) in a patient's aorta (10). A primary object of the invention in Choudhury (col. 1, lines 30-34) is to provide a method and article for performing an aneurysm repair "which does not require major surgery and may therefore be used on higher risk patients than conventional excisional aneurysm surgery." More specifically, Choudhury teaches a method of repairing a diseased portion (20) of a first corporeal lumen (aorta 10) comprising the steps of: intraluminally inserting a repair device (22) into a second corporeal lumen (femoral artery 48) at a location remote from the

first corporeal lumen, wherein the second corporeal lumen branches from the first corporeal lumen; and using a catheter (34) having a mechanical expanding means thereon to advance the repair device (22) from the entry point in the second corporeal lumen to the first corporeal lumen, the repair device being carried in a collapsed form on the exterior of the catheter and in association with the mechanical expanding means. Once the repair device is properly positioned in the first corporeal lumen at the site needing repair (Fig. 1), the mechanical expanding means is operated to cause expansion of the collapsed repair device and to cause the anchoring pins (28) at each end of the repair device to pierce the healthy artery wall (18) on opposite ends of the aneurysm, thus anchoring the repair device in place (Figs. 2 and 4). Choudhury notes that his invention is intended to provide a more favorable mortality rate as a result of the less severe surgical technique involved therein.

In contrast to Choudhury, Kononov discloses a highly invasive, major form of surgery and an aneurysm repair device for use therein. As noted on page 2 of the translation, the surgery begins by uncovering the bifurcation of the aorta on the left, starting from a retroperitoneal entrance at the patient's back,

Appeal No. 2000-1759  
Application No. 08/748,637

placing the aorta on a tourniquet and transversely cutting the aorta. A resilient tubular casing (1) housing the repair device (3), which device is wound onto and carried by a prosthesis-fitting means (5) having inflatable bulb structures (6), is inserted into the open end of the aorta formed by the transverse cut. Once properly positioned in the aorta, a pump (7) supplies a physiological solution through the rubber pipes (8) to the resilient bulbs (6) which, with the help of the spring-operated carriage (10) and the flexible linkages (11), guide the repair device in the radial direction until it is fully in contact with the inner wall of the aorta, where the splints or pins on the brackets (4) at each end of the repair device are thrust into the walls of the aorta by the force generated by the bulbs (6) inflated with physiological solution. Subsequently, the physiological solution is drawn off and the resilient bulbs (6) return to their original deflated position. The flexible linkages (11) which held the repair device in a collapsed position on the prosthesis-fitting means (5) are then cut and the placement mechanism for the repair device is extracted from the aorta and the aorta sewn up by the usual method. Likewise, the retroperitoneal entrance would be closed by the usual method.

Appeal No. 2000-1759  
Application No. 08/748,637

The examiner urges (answer, page 4) that it would have been obvious to one of ordinary skill in the art at the time of appellant's invention (circa 1983) "to have utilized the inflatable portion of Kononov with the method of Choudhury such that the repair device could be securely implanted into the lumen by the highly controllable expansion force generated by the inflatable portion." For a variety of reasons set forth in the brief, reply brief and declarations by Dr. Thoshinsky, appellant argues that the examiner's conclusion of obviousness is improper because, in the relevant time frame, there would have been no motivation to modify Choudhury's method to use Kononov's step of balloon expansion.

After a careful assessment of all of the evidence before us, we agree with appellant that one of ordinary skill in the art at the time of appellant's invention would have found no motivation in the references applied in the rejection before us on appeal for making the combination urged by the examiner (i.e., for taking the balloon expansion portion and associated expansion step in Kononov and attempting to employ them in the particular repair device and minimally invasive surgical method disclosed in Choudhury).

Appeal No. 2000-1759  
Application No. 08/748,637

Like appellant, we find that, in the relevant time frame (circa 1983), a person of ordinary skill in the art would not have looked to the invasive, aortic surgical repair method of Kononov and a device like that of Kononov, wherein the device is sized to be inserted directly into an opening formed in the aorta itself, to modify a minimally-invasive repair method like that in Choudhury where the repair device is inserted at a location remote from the aorta, such as the smaller femoral artery in a patient's leg, and then fed through the patient's vasculature to the point in the aorta where repair is needed. In that regard, we note that the examiner has essentially provided no response to the evidence and arguments presented by appellant in the declarations by Dr. Thoshinsky and the brief and reply brief. More specifically, the declarations by Dr. Thoshinsky, who practiced in the field of vascular surgery for 38 years and during the relevant time frame of 1979 through 1983, set forth numerous reasons why one of ordinary skill in the art at the time of appellant's invention would have found no motivation in the references applied by the examiner for making the combination urged in the rejection on appeal, and instead would have found many disincentives in those references for attempting to make such a combination. In the face of appellant's evidence setting

Appeal No. 2000-1759  
Application No. 08/748,637

forth why Kononov's balloon expansion step would have been incompatible with Choudhury's method, the examiner stands silent, having provided no response to the declaration evidence.

Moreover, like appellant, we find that the examiner's specific rationale for the combination, i.e., to obtain a "highly controllable expansion force generated by the inflatable portion," is without foundation in the references themselves and appears to be based on pure speculation and conjecture on the examiner's part. Again, the examiner has provided no cogent response to appellant's arguments and evidence to the effect that substituting the inflatable expansion system of Kononov in the system and method in Choudhury would actually have the undesirable effect of sacrificing control.

In the final analysis, we agree with appellant that the examiner has failed to establish a *prima facie* case of obviousness. Since the combined teachings of the applied references to Choudhury and Kononov would not have rendered the subject matter of appellant's claims on appeal obvious to one of ordinary skill in the art at the time appellant's invention was made, we will not sustain the examiner's rejection of claims 39

Appeal No. 2000-1759  
Application No. 08/748,637

through 42 under 35 U.S.C. § 103. Thus, the decision of the examiner is reversed.

REMAND TO THE EXAMINER

In addition to the foregoing, we REMAND this application to the examiner for a full consideration of the teachings in the declaration by Dr. Stanley N. Carson, cited by appellant in the Information Disclosure Statement filed September 22, 2000 (Paper No. 33). More particularly, we direct the examiner's attention to the disclosure therein at paragraphs 5 through 10, which would appear to teach or suggest a method of stent placement and stent expansion utilizing a catheter with a radially expandable portion exactly like that set forth in appellant's claims 39 through 42 on appeal. This declaration states (paragraph 6) that the concept of a permanently expandable metal stent that could be inserted over an angioplasty balloon and delivered percutaneously to the point of vessel blockage and then inflated to open up the vessel and thereafter deflated and withdrawn leaving the stent in place in the vessel to keep it open was conceived of by Dr. Carson during the latter part of 1979 and pursued into the early 1980's, a time frame before the earliest date established by appellant for his invention (i.e., as indicated in appellant's

Appeal No. 2000-1759  
Application No. 08/748,637

declaration under 37 CFR § 131 (Paper No. 13, filed May 20, 1998), "prior to September 29, 1983"). The examiner should make a determination on the record as to whether or not the disclosure in the declaration by Dr. Carson constitutes knowledge or use which was accessible to the public and therefore would be available as prior art under 35 U.S.C. §§ 102(a) or 102(b).

REVERSED & REMANDED

IRWIN CHARLES COHEN	)	
Administrative Patent Judge	)	
	)	
	)	
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	)	BOARD OF PATENT
NEAL E. ABRAMS	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
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CHARLES E. FRANKFORT	)	
Administrative Patent Judge	)	

CEF/LBG

Appeal No. 2000-1759  
Application No. 08/748,637

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