UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

MED-EL Elektromedizinische Geräte Ges.m.b.H.

Petitioner

v.

Sonova AG,

Patent Owner

_____

U.S. Patent No. 6,761,681

Issue Date: July 13, 2004

Title: Percutaneous or transcutaneous access into the body

Inter Partes Review No. IPR2020-00176

_____

PETITION FOR INTER PARTES REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.*

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Exhibit List for *Inter Partes* Review of U.S. Patent No. 6,761,681

Exhibit #	Brief Description
1001	U.S. Patent No. 6,761,681 (Schmid) (filed August 14, 2001; issued July 13, 2004)
1002	Declaration of David L. Trumper, Ph.D.
1003	U.S. Patent No. 4,352,960 to Dormer ("Dormer")
1004	U.S. Patent No. 3,766,928 to Goldberg ("Goldberg")
1005	U.S. Patent No. 4,676,772 to Hooven ("Hooven")
1006	U.S. Patent No. 3,749,853 to Ely et al. ("Ely")
1007	Prosecution History of U.S. Patent No. 6,761,681 (Schmid)
1008	U.S. Patent No. 3,952,726 to Hennig et al. ("Hennig")
1009	U.S. Patent No. 4,726,378 to Kaplan ("Kaplan")
1010	Moskowitz, Lester R., *Permanent Magnet Design and Application Handbook*, Robert E. Krieger Publishing Company, Inc., Reprint edition 1986.
1011	U.S. Pat. No. 5,949,895 to Ball et al.
1012	U.S. Pat. No. 5,041,806 to Enderle et al.
1013	WO97/05673 to Beesley
1014	U.S. Pat. No. 2,483,900 to Hardenberg

Exhibit #	Brief Description
1015	Definition of "conduit," *The American Heritage Dictionary of the English Language*, Third Edition, Houghton Mifflin Company, 1996, p. 394.

I. BACKGROUND

MED-EL Elektromedizinische Geräte Ges.m.b.H. ("Petitioner" or "MED-EL") respectfully petitions for *inter partes* review and cancellation of claims 6-9, 11 and 12 of U.S. Patent No. 6,761,681 ("the '681 patent"). Ex. 1001. As the evidence shows, the challenged claims were taught in the prior art and should have been rejected on the basis of obviousness.

The '681 patent describes implantable medical devices that fall into two broad classes: (1) "percutaneous" devices where there is a physical opening in and through the skin, and (2) "transcutaneous" devices where the skin is intact. The challenged claims of the '681 patent apply to transcutaneous devices.

The use of magnets in transcutaneous medical implant systems was already rich and well-developed at the time that the '681 patent was filed. For electrical systems such as used in cochlear implants, such systems typically have an implanted magnet surrounded by a receiving coil, which lie on the skull bone under the skin. Ex. 1002, ¶35. An external component includes a similarly arranged external magnet surrounded by a transmitter coil, which are configured to lie on the skin over the implanted magnet and receiver coil. *Id.* The magnetic attraction between the implanted and external magnet hold the external components in place. By maintaining the coils opposite one another with the skin in between, this allows electrical signals to be transmitted through the skin

by the process of induction. *Id.* According to induction, electric current in a coil creates a magnetic field which is received by the other coil and causes a corresponding electric signal in that other coil. In this way, electrical signals can be transmitted through the skin transcutaneously. *Id.*

Throughout the substantive examination (Ex. 1007) of the filed claims that ultimately issued in the ’681 patent, the examiner focused on just two earlier patents. One of these earlier patents was a magnetic anus closing arrangement to Hennig et al. attached hereto as Ex. 1008. The other was a hearing implant patent to Kaplan (Ex. 1009), which was overcome because its magnetic poles were arranged for axial engagement *perpendicular* to the skin, rather than *parallel* as claimed. The examiner overlooked and never mentioned teachings of parallel magnetic arrangements on implanted hearing aids and other medical implant devices.

Anyone who has played with magnets would have understood that the north pole of a magnet attracts the south pole of a second magnet. Ex. 1002, ¶36. Standard configurations for magnetization of a magnet are shown below taken from the 1986 reprint of the Moskowitz handbook. Ex. 1010, p.25.

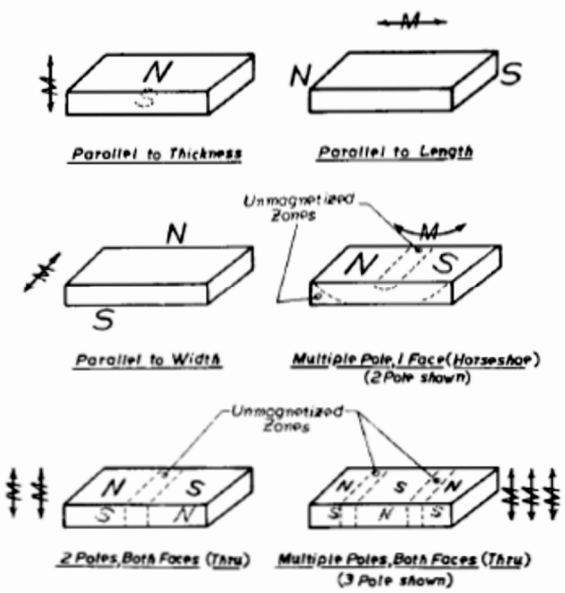


Figure 4-2. Standard magnetizing methods for block, bar, plate, and slab magnets.

Classification by Electrical Properties

In general, magnets based on alloys of pure metals are conductors and magnets based on metal oxides are non-conductors. Since some materials are composites or metals in a nonmetallic matrix, the simple categorical classifications of "conductor" or "insulator" are not always sufficient. More correctly, magnet materials classified by conductivity are:

Good conductors [10]: cerium-copper; chrome steels (all); cobalt steels (all); Cunico; Cunife; P-6 alloy; platinum-cobalt; samarium-cobalt; Vicalloy.

Fair conductors [11]: Alnicos, sintered (all grades); Alnicos, cast (all grades).

Poor conductors [12]: Lodex (all grades).

Insulators [13]: ferrite, bonded (all grades); ferrites sintered (all grades).

Classification by Relative Cost

A cost classification of *basic magnets* is virtually impossible, since the cost of such finished magnets is closely related to their shape, size, quantity, commercial availability, and many other factors. These comparisons are

10. Resistivity of less than 40 micro-ohms/cm/cm^3 at 25°C.
11. Resistivity of 40 to 100 micro-ohms/cm/cm^3 at 25°C.

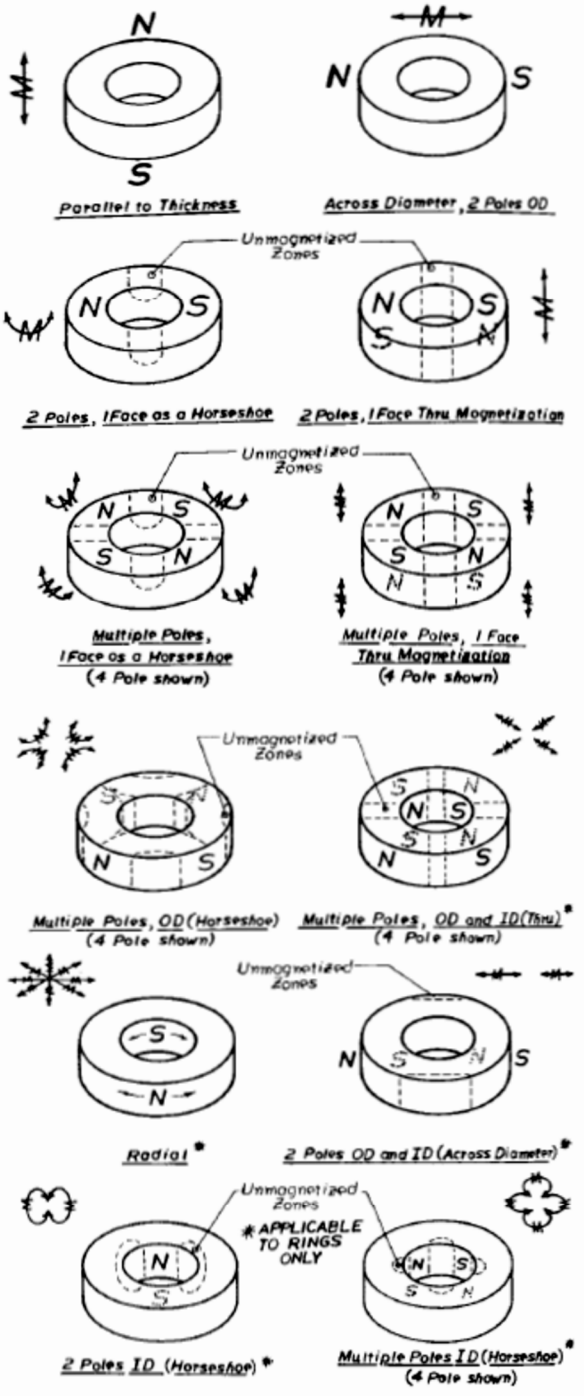


Figure 4-3. Standard magnetizing methods for ring, slug, or disk magnets (ring magnets shown).

The "parallel to thickness" magnets shown above on top of the list attach and attract axially (i.e., in the direction of the magnetization "M") as in Kaplan. Ex.

1002, ¶37. Adjacent to these on top of the above list are the "parallel to length" magnet and the "across diameter" magnet, which can attach and attract in a face to face arrangement with poles extending parallel to an intervening surface (i.e, in the shown direction of magnetization "M"). *Id.* Moskowitz illustrates this known magnetic orientation for a dental implant:

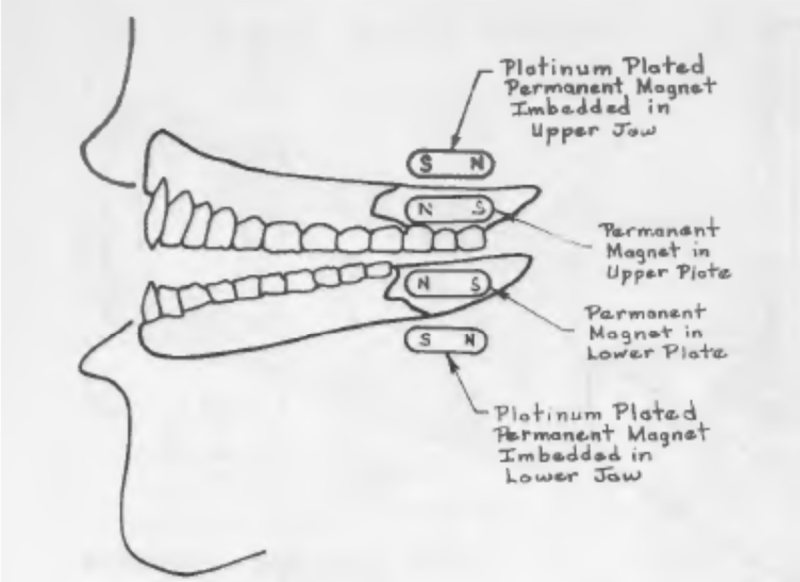


Figure 16-77. Magnets used to improve dental prosthetic device.

Thus, parallel magnetic attachment arrangements for restricted and fixed alignment were well-known.

This knowledge of magnet design has been used to develop implanted transcutaneous connecting devices, but the patent examiner missed the teachings of the prior art. US Patent No. 4,352,960 ("Dormer") (Ex. 1003) taught several magnetic arrangement options for a bio-electronic signal coupling device, such

as a hearing aid. A magnetic north pole and a magnetic south pole are separated from one another on the face of a subcutaneous coupling member to provide a single predetermined alignment for attachment to an external component. Ex. 1002, ¶40. More particularly, the examiner failed to see Dormer's explicit recommendation of "a ring magnet disposed along the periphery of the pot-type core-half." Ex. 1003, col. 7, l. 35-36. A POSITA would have readily understood that using diametric magnetization of the ring magnet parallel to the skin rather than perpendicular magnetization would achieve the single, predetermined alignment as taught by Dormer. Ex. 1002, ¶40. Indeed, US Patent No. 3,766,928 ("Goldberg") (Ex. 1004) illustrates that diametrically magnetizing ring magnets was the known magnetization arrangement for use in implantable devices. Moreover, as to claim 12, US Patent No. 3,749,853 ("Ely") (Ex. 1006) explains the use of an acoustic conduit in the microphone system of a hearing aid. Claims 6-9, 11 and 12 of the '681 patent, therefore add nothing to the prior art and should be found unpatentable for obviousness. Accordingly, Petitioner respectfully requests that the Board institute trial on the grounds set forth herein.

II. NOTICES AND STATEMENTS

A. Notice of Related Matters (37 C.F.R. § 42.8(b)(2))

Petitioner identifies the following related matters. On October 3, 2018, Petitioner, MED-EL Elektromedizinische Geräte Ges.m.b.H. and MED-EL

Corporation, USA. filed suit against Advanced Bionics, L.L.C. ("Advanced Bionics") in the U.S. District Court for the District of Delaware seeking damages for infringement of two MED-EL patents by Advanced Bionics' HiRes Ultra 3D products. See *MED-EL Elektromedizinische Geräte Ges.m.b.H. et al. v. Advanced Bionics et al.*, No. 1:18-cv-01530 (D. Del.). Advanced Bionics, LLC, Sonova AG and Advanced Bionics AG brought a counterclaim on November 28, 2018 for infringement against MED-EL and its subsidiary for various patents including the '681 patent.

B. Real Party-in-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner, MED-EL Elektromedizinische Geräte Ges.m.b.H. and its subsidiary MED-EL Corporation, USA are the real parties-in-interest.

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

MED-EL identifies as lead counsel Robert M. Asher, Reg. No. 30,445, and backup counsel as Kathryn E. Noll, Reg. No. 48,811 and Kerry L. Timbers (*pro hac vice* to be filed) all with Sunstein Kann Murphy and Timbers LLP.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

MED-EL may be served through its counsel, Sunstein Kann Murphy & Timbers LLP, via email to sunsteinip@sunsteinlaw.com, rasher@sunsteinlaw.com, knoll@sunsteinlaw.com, and ktimbers@sunsteinlaw.com, or otherwise to:

Robert M. Asher
Sunstein Kann Murphy & Timbers LLP

125 Summer Street
Boston, MA 02110-1618
617 443 9292 (phone)
617 443 0004 (fax)

E. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner certifies that the '681 patent is available for *inter partes* review and that real parties in interest are not barred or estopped from requesting an *inter partes* review challenging the patent claims on the grounds identified in this Petition.

F. Fees (37 C.F.R. § 42.15(a))

The required fee is paid via Deposit Account No. 19-4972. The Office is authorized to charge fee deficiencies and credit overpayments to the same Deposit Account.

III. STATEMENT OF PRECISE RELIEF REQUESTED

MED-EL respectfully requests cancellation of claims 6-9, 11 and 12 of U.S. Patent No. 6,761,681 ("'681patent" (Ex. 1001)) based on the following grounds of unpatentability, explained in detail in section VIII.

Ground	35 U.S.C.	Claims	References
1	103(a)	6, 7, 8, 9 and 11	U.S. Patent No. 4,352,960 to Dormer ("Dormer") (Ex. 1003) and U.S. Patent No. 3,766,928 to Goldberg ("Goldberg") (Ex. 1004)
2	103(a)	12	Dormer and Goldberg and U.S. Patent No. 3,749,853 to Ely et al. ("Ely")(Ex. 1006)

3	102(b)	9	U.S. Patent No. 4,676,772 to Hooven ("Hooven") (Ex. 1005)

IV. THE '681 PATENT

A. Prosecution History

Applicants Christoph Hans Schmid and Herbert Baechler filed a U.S. patent application in the German language with 15 claims on August 14, 2001. Ex. 1007, p. 6-25. A corresponding English translation was submitted on September 6, 2001. Ex. 1007, p. 27-41. An information disclosure statement was submitted December 21, 2001

A first office action dated January 15, 2003 rejected original claims 1-6, 9-12 and 14 under 35 U.S.C. 102(b) as being anticipated by Hennig et al. (Ex. 1008). Claims 1, 7, 12, 13 and 15 also were rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (Ex. 1009). Original claim 8 was rejected as obvious from Hennig. Ex. 1007, p. 75-84.

Applicant's response argued that Hennig disclosed a device for closing the intestinal opening of a human body rather than a connecting device with a connection through an outer surface of a living being. With regards to the claim rejections based on Kaplan, Applicant argued that "Kaplan does not disclose or

teach that the poles of the permanent magnet extend essential[ly] parallel to the outer surface" as recited in the claims. Ex. 1007, p. 98.

A final office action dated June 30, 2003, allowed new claims 16 and 17. The rejection of Claims 1-3, 6 and 9-12 based on Hennig was maintained. Ex. 1007, p. 102. Applicant filed an after final response.

A further office action dated December 3, 2003 was designated non-final to now reject claim 16 as anticipated by Hennig. Ex. 1007, p. 122. Applicant filed a further response dealing with the remaining issues and further amending claim 16 to include a conduit in the external part so as to distinguish over Hennig's external part. A Notice of Allowance dated March 18, 2004 followed.

B. '681 Connecting Device

The '681 patent relates to a percutaneous or transcutaneous connecting device. The percutaneous device includes an intake/exit conduit 19 in its external part 15. Permanent magnet 17 is magnetized with the south to north direction oriented so that it is parallel to the skin surface when the external part and the subcutaneous part are attached.

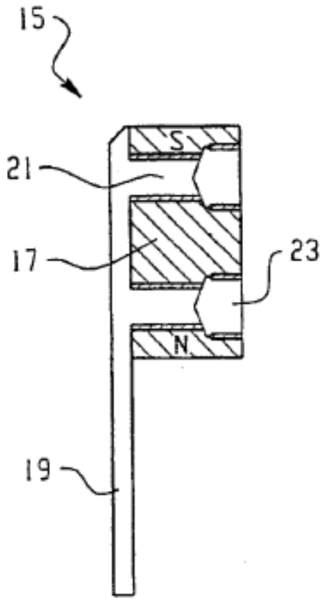


Fig. 1A

Turning now to the transcutaneous device, it includes kidney-shaped parts for placement behind an ear. The permanent magnet is magnetized with the south to north direction oriented so that it is parallel to the skin surface when the external part and the subcutaneous part are attached.

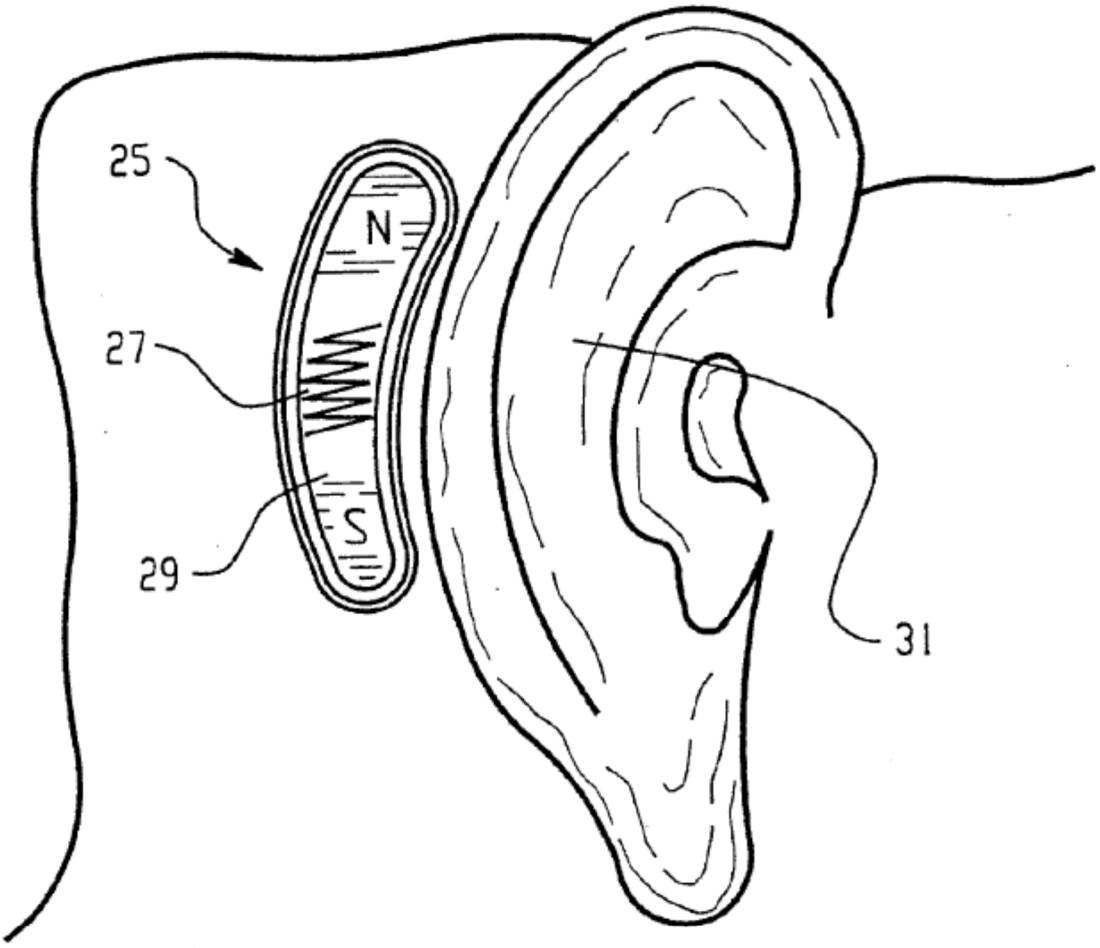


Fig. 3

The ’681 patent sought to distinguish its device from the symmetrical coil aligned with symmetric cylindrical magnet shown below used in devices such as U.S. Pat. No. 5,949,895 (Ex. 1011). (cited at Ex. 1001, col.1, lines 44-49)

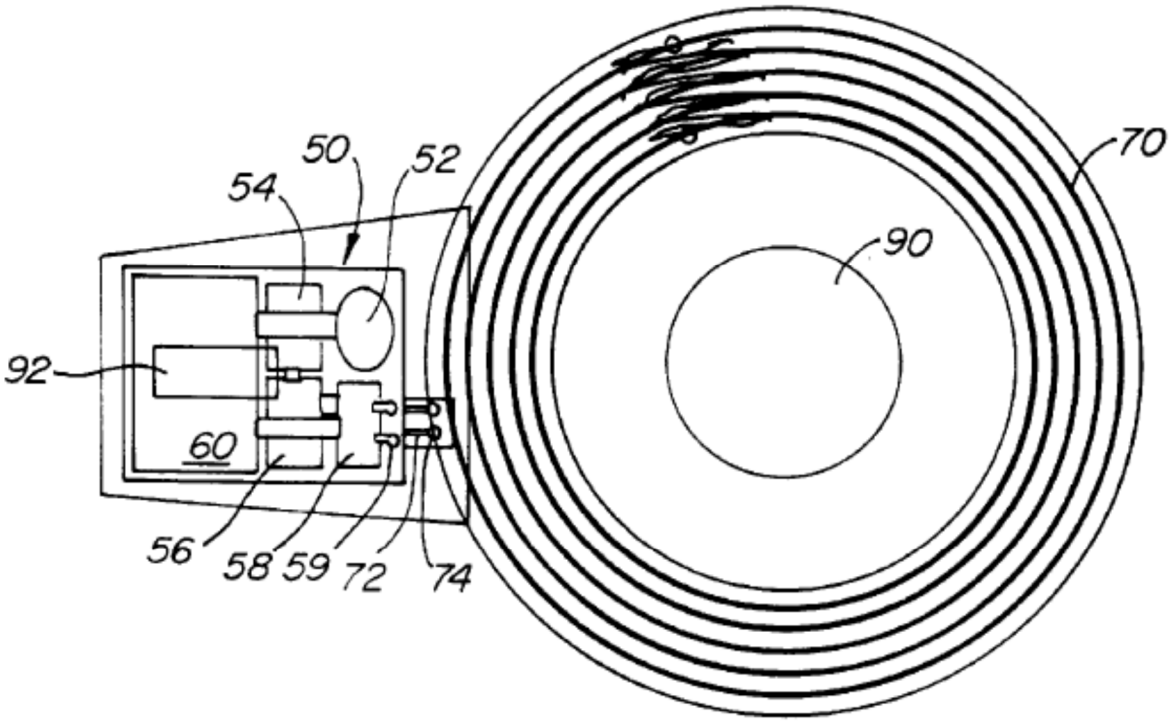


FIG. 6.

The ’681 patent proclaims: “Of particular advantage is a connection between the inside of the body and the external area of the body which is inherently asymmetric.” Ex. 1001, col. 2, lines 3-5. This is useful in a transcutaneous connection that must be aligned with each other. Ex. 1001, col. 2, lines 7-9; Ex. 1002, ¶49.

V. STATE OF THE ART AT THE CLAIMED PRIORITY DATE

A. U.S. Patent No. 4,352,960 (Dormer)

Dormer, Exh. 1003, published October 5, 1982 (more than a year before the '681 patent's earliest priority date), thus making it prior art under pre-AIA 35 U.S.C. § 102(b). Ex. 1003, p. 1; Ex. 1002, ¶50. This reference was before the patent examiner of the '681 patent, but the examiner failed to see its importance to the patentability of the examined claims and never mentioned it. Ex. 1007; Ex. 1002, ¶50.

Like the '681 patent, Dormer is directed to a transcutaneous magnet arrangement for a hearing aid implant system. Dormer describes a "transcutaneous coupling device" [*Abstract*] for a cochlear implant having "an internal, subcutaneously located signal receiving unit" and "an external sound detecting and transmitting unit located outside the skin of the user". Ex. 1003, Col. 1, lines 29-34. An "electrical signal is transferred by electromagnetic induction transcutaneously" from an external coil in a second member to an implanted coil in a first member. Ex. 1003, Col. 2, lines 63-66.

Dormer describes use of magnets associated with each of the first member and the second member "to secure the second member with the first member without significantly adversely affecting the user's skin intervening between the first and second members." [Abstract] In particular, Dormer teaches a laterally separated arrangement of magnetic poles in the embodiment of Fig. 5 to

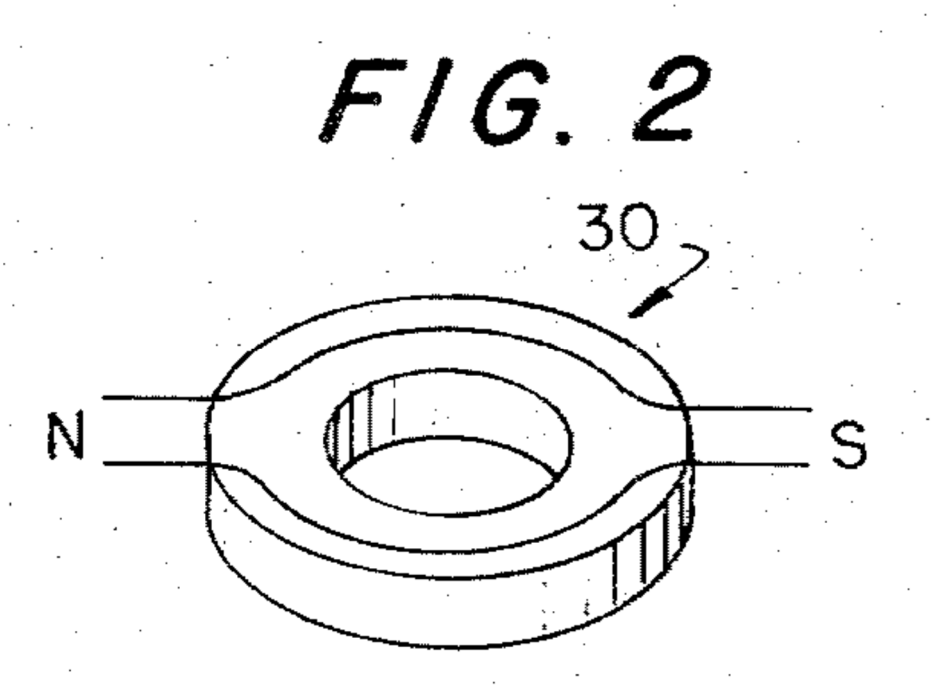
accommodate a need for a single, predetermined alignment. Ex. 1003, col. 6, l. 48-53. The single predetermined alignment is explained as each member having a magnetic north pole and a magnetic south pole for coupling when aligned with the opposite poles on the other member. Ex. 1003, col. 7, lines 1-29.

In addition, Dormer further teaches the use of ring magnets. "Although the specific embodiments described above disclose either a single pair of magnetic slugs in the shape of small disks located in the centers of symmetrical pot-type core halves or two such pairs of magnetic slugs, it is to be noted that other configurations are also feasible. For example, a ring magnet disposed along the periphery of the pot-type core-half could be used." Ex. 1003, Col. 7, lines 29-36.

B. U.S. Patent No. 3,766,928 (Goldberg)

Goldberg published October 23, 1973 (more than a year before the '6¶ patent's earliest priority date) making it prior art against the '681 patent under pre-AIA 35 USC 102 (b). Ex. 1004, p. 1; Ex. 1002, ¶51. Goldberg was not considered during the prosecution of the '681 patent. Ex. 1002, ¶51.

Goldberg describes magnetic coupler arrangements for implanted heart pacer devices. Ex. 1004, Abstract. Specifically, Goldberg describes the use of a ring magnet in such heart pacer devices, which are "diametrically magnetized". Ex. 1004, Abstract.



Goldberg teaches that such a diametrically magnetized ring magnet may be "positioned near a surface of the pacer, and it can be turned by positioning a strong external magnet near the skin of the patient in the vicinity of the pacer magnet." Ex. 1004, Col. 1, line 66-col. 2, line 1.

C. U.S. Patent No. 4,676,772 ("Hooven")

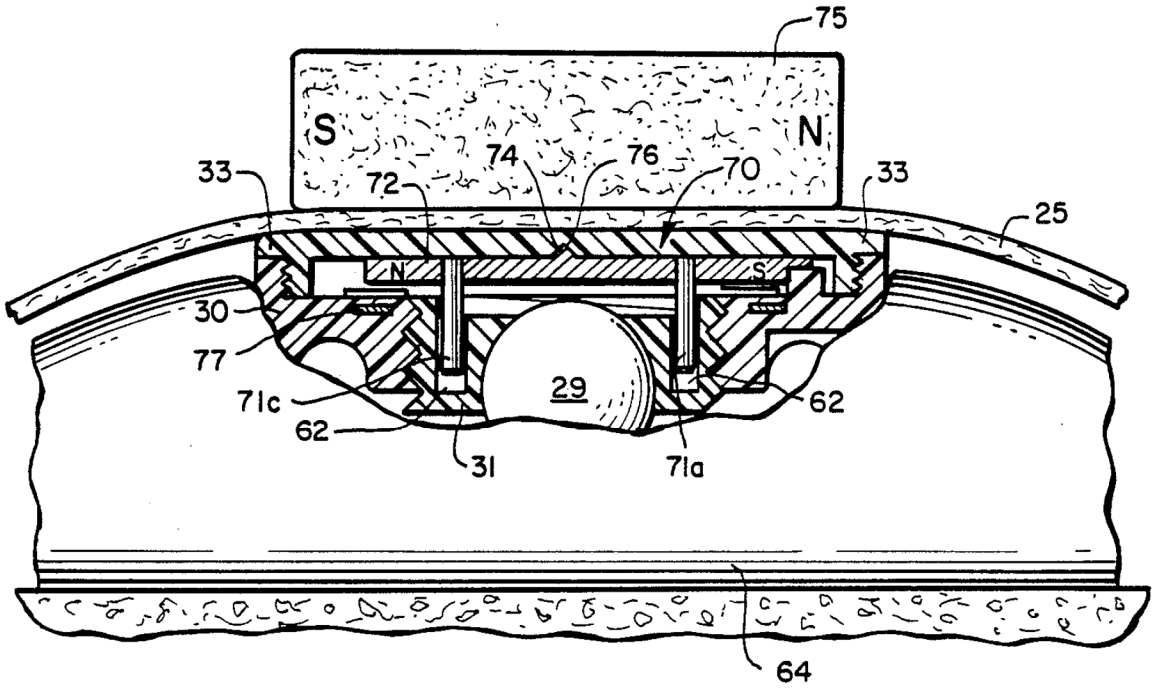
Hooven, Ex. 1005, issued June 30, 1987, more than a year before the '681 patent's earliest priority date, is prior art under pre-AIA 35 U.S.C. § 102(b). It was not in front of the examiner during prosecution. Ex. 1002, ¶52.

Hooven describes the use of a permanent magnet arrangement in an implantable medical device, specifically, a "non-invasively adjustable cerebrospinal fluid pressure relief valve includes a magnetized element which is

positionable, through application of an external magnetic field, to permit post-implantation adjustment" of the valve. Ex. 1005, Abstract.

More specifically, Figure 7 of Hooven shows a transcutaneous connection between an implanted magnetic wrench 70 and an external bar magnet 75 through the skin of scalp 25. When the bar magnet 75 is aligned directly above the magnetic wrench 70 such that the unlike poles (N over S and S over N) are adjacent each other, the magnetic wrench is drawn upwardly. Ex. 1005, col. 6, lines 10-15. The firm transcutaneous magnetic connection allows the bar magnet 75 to effect rotation of the magnetic wrench 70 as the magnet is rotated. Ex. 1005, col. 6, lines 16-21.

FIG. 7



The magnetic wrench 70 of Hooven is a permanent magnet in the form of "an elongate magnetic portion 72 having North and South poles at opposite ends thereof." Ex. 1005, col. 5, lines 57-59. And Figure 7 of Hooven shows that the magnetic wrench 70 and its elongate magnetic portion 72 lie on a line that is parallel to the outer surface of the overlying scalp 25.

D. U.S. Patent No. 3,749,853 ("Ely")

Ely, Ex. 1006, issued July 31, 1973, more than a year before the '681 patent's earliest priority date, is prior art under pre-AIA 35 U.S.C. § 102(b). It was not in front of the examiner during prosecution. Ex. 1002, ¶53.

Ely describes a hearing aid with an improved microphone system. The microphone system includes a microphone casing that defines "a front-to-back acoustic conduit through the hearing aid and a microphone assembly supported in acoustic isolation within the conduit in such a way as to define a sound passageway around the microphone assembly." Ex. 1006, Abstract.

VI. PERSON OF ORDINARY SKILL IN THE ART ("POSITA")

A POSITA is a hypothetical person who is presumed to know the relevant prior art. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). In this case, the art relevant to the '681 patent is the field of percutaneous or transcutaneous connecting devices that provide external access to a patient's body beneath the skin. A POSITA in the field of such connecting devices would have had as of

August 2001, the equivalent of a Bachelor of Science degree in electrical engineering, mechanical engineering or physics or a related discipline with course work in electromagnetics, and two years' experience designing or developing electromagnetic devices. Ex. 1002, ¶24.

VII. CLAIM CONSTRUCTION

Petitioner notes that a claim "shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. §42.100(b).

A. "in the area of the outer surface"

The term "in the area of the outer surface" should be given its ordinary meaning in the context of the claims and the prosecution history. The term "in the area of the outer surface", and even "outer surface," only appears in the claims and the abstract of the '681 patent. In the abstract, "in the area of the outer surface" is followed by "such as the skin." In the claims, claims 1, 6 and 8 include reference numerals 1 and 3 to define the "outer surface." Reference numeral 1 is the epidermis (Ex. 1001, col. 2, line 29), and reference numeral 3 is the bone

underneath the epidermis (Ex. 1001, col. 2, lines 29–30). According to the specification, the permanent magnet 7 that is positioned "in the area of the outer surface" may be positioned "beneath the epidermis 1 in the area of the corium or on a bone 3 underneath the epidermis." Ex. 1001, col. 2, lines 28–30. In the transcutaneous device, the permanent magnet 29 is "implanted underneath the skin." *Id.*, col. 3, line 26.

The prosecution history began with a claim 1 reciting "in the area of the outer surface such as the skin (1, 3)". Ex. 1007, p. 37. The term was broadened in a preliminary amendment by deleting "such as the skin." *Id.*, p. 63. In view of all of the above, the term "in the area of the outer surface" in the claims would be understood by a POSITA as meaning "near the skin or the bone adjacent the skin." Ex. 1002, ¶55.

B. <u>"inductive, capacitive or other passage-free connection adapted to be between inside and outside of the body of a wearer"</u>

The phrase "inductive, capacitive or other passage-free connection(s)" appears in the text of the specification of the '681 patent only at the last sentence. Ex. 1001. The term "passage" is used in the specification to refer to the physical, mechanical passages 9 in the percutaneous embodiment of the connecting device. Ex. 1002, ¶56. The transcutaneous embodiment of Fig. 3 is described "in contrast to percutaneous connections, there is no physical, mechanical passage from inside the body to the outside or from the outside to the inside of the patient." Ex. 1001,

col. 3, lines 27-30. The transfer of electromagnetic energy between an external coil and an implanted coil is called induction and is performed without needing a physical connection. Ex. 1002, ¶56.

In the context of transcutaneous systems, the background section of the '681 patent refers to U.S. Pat. No. 5,949,895 (Ball et al.) (Ex. 1011) as describing a transcutaneous connection in the form of "a pair of flat, symmetrical coils which are aligned with a pair of symmetric, cylindrical permanent magnets." Ex. 1001, col. 1, l. 44-47. From this reference, the POSITA would have understood that the "transcutaneous connection" relates to the pairs of "coils" and "magnets." Ex. 1002, ¶57. The coils or magnets are examples of components that can be placed inside and outside of a body and may interact through energy that does not require a physical passage. *Id.* The discussion of a transcutaneous arrangement in the detailed description of the '681 patent is presented with reference to Figure 3 and similarly is presented in terms of relationships between pairs of implanted and external coils and magnets. For example: "The external part (not shown) of the transcutaneous connection is similarly equipped with a coil for transferring signals or electric energy and with a permanent magnet for positioning and retention purposes." Ex. 1001, col. 3, l. 34-37.

Based on the foregoing, the POSITA would have understood that the claim language "inductive, capacitive or other passage-free connection adapted to be

between inside and outside of the body of a wearer" refers to "a paired relationship between an implanted element interacting via energy with an external element without a physical passage between the inside and outside of the body." Ex. 1002, ¶59.

C. "at least one conduit"

The term conduit in the '681 patent is used in connection with the intake and/or exit of fluids. Ex. 1002, ¶60. The specification states that the conduits "are so designed as to permit the introduction of substances such as medication, nutrients and the like as well as the withdrawal of fluids from inside the body." Ex. 1001, col. 2, lines 53–57. One example for use of the conduits is hemodialysis. *Id.*, col. 2, line 57. An intake/exit conduit 19 is illustrated in Fig. 1A. The conduit consists for example

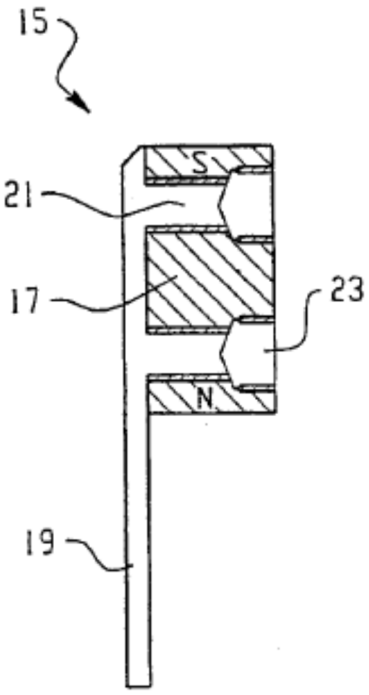


Fig. 1A

of flexible tubing. *Id.*, col. 2, lines 43–44. There is no mention of a conduit in the '681 patent's description of transcutaneous connecting devices. The specification's use of the term conduit makes clear that the conduit is physical or mechanical in nature, like flexible tubing, that conveys substances like medicine or fluids. Ex. 1002, ¶60.

The limitation "at least one conduit extending through the external part" in claim 12 did not appear until the last round of prosecution. Claim 12 (numbered as claim 16 during prosecution) was added as a new claim in the amendment "A" dated April 15, 2003. Ex. 1007, p.86-99. The office action dated Dec. 3, 2003

rejected the claim as anticipated by Hennig (Ex. 1008). Ex. 1007, p. 122. In response, the prosecuting attorney added "at least one conduit extending through the external part" to overcome Hennig, which disclosed a solid external part in Fig. 4. Ex. 1008, Ex. 1007, p. 137-138. The limitation was added to the claim despite the absence of any disclosure in the specification of a transcutaneous connecting device with a conduit in its external part. Ex. 1002, ¶61. Regardless, the claim as amended was allowed over Hennig. Ex. 1007, p. 142. No special meaning was ascribed to "conduit" in the prosecution history.

Consistent with the use of the term "conduit" in the specification, dictionaries define "conduit" as "a pipe or channel for conveying fluids, such as water". Ex. 1015. In view of all the above, "conduit" should receive its ordinary meaning, namely, "a pipe, tube, or the like, for conveying water or other fluid." Ex. 1002, ¶62.

VIII. EXPLANATION OF GROUNDS FOR UNPATENTABILITY

The showing in the following subsections establishes a reasonable likelihood of prevailing as to each ground of invalidity with respect to the challenged claims as to that ground. The showing, accompanied by the Declaration of David Trumper (Ex. 1002), establishes why the challenged claims of the '681patent are unpatentable under the statutory grounds raised, including claim charts specifying

where each element of a challenged claim is met by the prior art. 37 C.F.R. § 42.104(b)(4).

A. Ground 1 – Obviousness of claims 6-9 and 11 based on Dormer and Goldberg

1. Claim 6

All of the elements of claim 6 are disclosed by the connecting device disclosed in the combined teachings of Dormer and Goldberg as shown in the claim chart below. Dormer describes transcutaneous coupling of an implant device having the structural elements required of the connecting device of claim 6 including a permanent ring magnet, except Dormer does not explicitly state the magnetization orientation of the ring magnet. Goldberg teaches the use of diametrically magnetized ring magnets in an implant device thereby orienting the poles of the magnets essentially parallel to the outer surface of a living being. Ex. 1002, ¶63.

CLAIM 6	**DORMER and GOLDBERG**
(6a) 6. A percutaneous or transcutaneous connecting device for providing a connection through an outer surface of a living being characterized by	*Dormer*— Abstract: A "transcutaneous coupling device". Col. 1, lines 29-34: Coupling device is for a cochlear implant having "an internal, subcutaneously located signal receiving unit" and "an external sound detecting and transmitting unit located outside the skin of the user". Col. 2, lines 63-66: An "electrical signal is transferred by electromagnetic induction transcutaneously" between external and implanted coils.

The transcutaneous coupling device described by Dormer provides an electromagnetic connection by induction between external and implanted coils. Ex. 1002, ¶64.

CLAIM 6	**DORMER and GOLDBERG**
(6b) a permanent magnet (7, 29) adapted to be positioned in the area of the outer surface (1,3)	*Dormer*—Col. 2, line 69-col. 3, line 2: "a first rare-earth magnet associated with the first coil of an embodiment of the first member" wherein the first member is "positioned subcutaneously" (col. 2, lines 33-34). Col. 3, lines 3-5—"a second rare-earth magnet associated with an embodiment of the second member" wherein the second member is "positioned supercutaneously (i.e., outside the skin)" (col. 2, lines 34-35). Col. 7, lines 29-36—"Although the specific embodiments described above disclose either a single pair of magnetic slugs in the shape of small disks located in the centers of symmetrical pot-type core halves or two such pairs of magnetic slugs, it is to be noted that other configurations are also feasible. For example, a ring magnet disposed along the periphery of the pot-type core-half could be used."

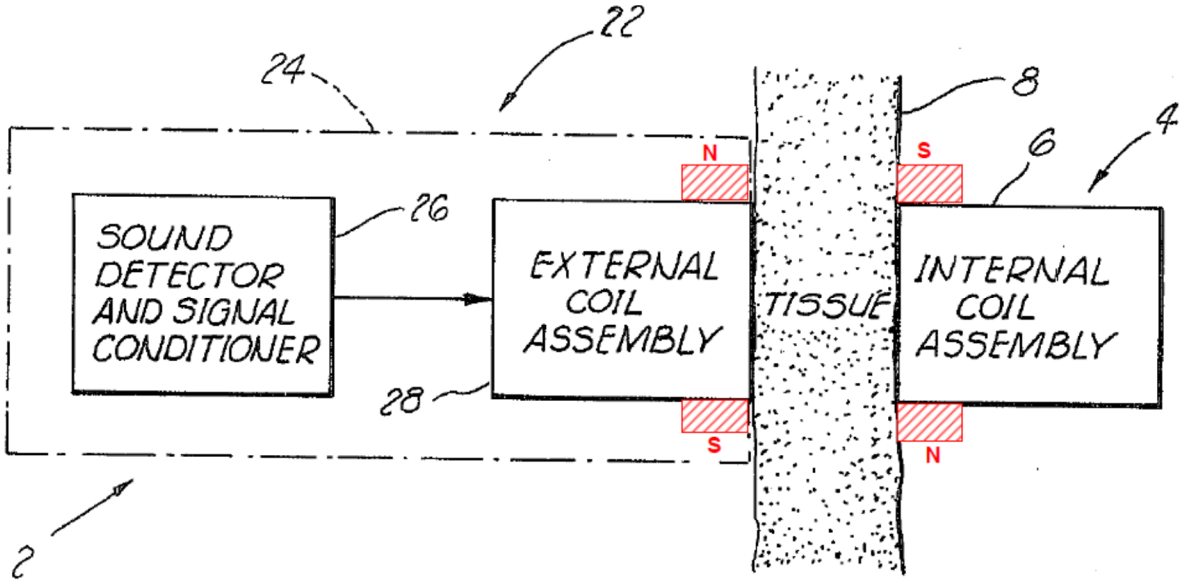
A ceramic pot-type core-half as used in Dormer was a component widely used by POSITAs in magnetic devices. Ex. 1002, ¶65. The core-half is typically formed using a magnetically soft material such as ferrite ceramic. Magnetically soft means the material guides and enhances magnetic flux in the presence of a magnetic field, but does not significantly retain the magnetic flux when the magnetic field is removed. *Id.* The pot-type core is in the shape of a "…pot with a

central rod." Ex. 1014, col. 1, lines 10-11. In a pot core, the annular space between the outer wall of the pot and the central rod provides a location for a wire coil. Ex. 1002, ¶65. Another example of a pot-type core-half is disclosed in U.S. Patent No. 5,041,806 (Enderle et al.) (Ex. 1012).

The rare-earth magnets in Dormer are arranged in the pot-type core-half so as to be positioned adjacent to the skin, i.e., "in the area of the outer surface" when in use on the body. Ex. 1002, ¶66. The magnet or magnets can be located in the central portion of the core-half as shown in Figs. 2 and 5 or about the periphery of the core-half as suggested for a ring magnet. *Id.* In all embodiments, a POSITA would have understood that the magnets are to be arranged in a position near the skin. *Id.* This allows the most efficient coupling across the skin so as to most effectively attract the corresponding opposite pole in the complementary part. *Id.*

CLAIM 6	**DORMER and GOLDBERG**
(6c) with its poles extending essentially parallel thereto, and	*Dormer*: Col. 7, lines 35-36—"a ring magnet disposed along the periphery of the pot-type core-half could be used." *Goldberg*: Col. 3, l.39-42 – "The magnet is …magnetized diametrically. That is, the north and south poles of the magnet are at opposite ends of one of its diameters." See also Fig. 2 and Fig. 5. Col. 2, lines 63-65: "FIG. 5 depicts the face-to-face relationship of the two diametrically magnetized disc magnets utilized in the embodiment of the invention illustrated in FIG. 4."

When the connecting device of Dormer is implemented with diametrically magnetized ring magnets, the magnets are adapted to be attracted to one another when they are parallel as shown in Fig. 5 of Goldberg. Ex. 1002, ¶67. When one ring magnet is implanted in the internal coil assembly 6 of Dormer and the other is in the external coil assembly 28, the skin tissue is sandwiched between the ring magnets. *Id.* The north and south poles at opposite ends of a diameter thereby extend essentially parallel to the skin as illustrated in the modified figure below. *Id.*



The use of diametrically magnetized ring magnets in Dormer thus satisfies the limitations of claim 6. Ex. 1002, ¶67.

CLAIM 6	**DORMER and GOLDBERG**
(6d) at least one inductive, capacitive or other passage-free connection adapted to be between inside and outside of the body of a wearer.	*Dormer*—Col. 4, lines 58: "For the electromagnetically inductive transmission between the first coil 10 and the second coil 29 to be properly achieved" Col. 5, lines 26-27: "the first and second coils 10

	and 29 are positioned for electromagnetically inductive coupling." Col. 3, line 65- col. 4, line 4: "The internal coil assembly 6 is subcutaneously located beneath a layer of tissue 8…the internal coil assembly 6 includes a first electrically conductive coil 10" Col. 4, lines 23-24: "The external coil assembly 28 includes a second electrically conductive coil 29."

Dormer's connecting device includes an inductive connection between a first coil 10 located inside the body and a second coil 29 located outside the body. Ex. 1002, ¶64. Thus, ring magnet embodiment of Dormer diametrically magnetized as shown in Goldberg meets all the limitations of claim 6 rendering the claim unpatentable for obviousness. Ex. 1002, ¶67.

2. Claim 7

CLAIM 7	**DORMER and GOLDBERG**
7. The device as in claim 6, wherein the device provides a transcutaneous connection in the area of an outer ear (31) of a human, incorporating at least one coil (27) in the area of the permanent magnet (29) to receive or transmit electrical signals and/or transfer electrical energy.	*As with claim 6, plus:* *Dormer*— Abstract: A "transcutaneous coupling device". Col. 1, lines 29-34: Coupling device is for a cochlear implant having "an internal, subcutaneously located signal receiving unit" and "an external sound detecting and transmitting unit located outside the skin of the user". Col. 2, lines 63-66: An "electrical signal is transferred by electromagnetic induction transcutaneously" between external and implanted coils. Col. 3, line 55-col. 4, line 1: "The hearing aid 2 includes an internal first member 4 which is designated in FIG. 1 as an internal coil assembly 6. In the preferred embodiment the internal coil assembly 6 is a cochlear implant unit containing

	electronic receiver means for receiving a transmitted signal. … The internal coil assembly 6 is subcutaneously located beneath a layer of tissue 8 which includes the epidermal and dermal layers of the skin of the user of the device when the device is the preferred embodiment hearing aid 2." Col. 5, line 10-13: "a first rare-earth magnet 38 associated with the first coil 10 by being concentrically positioned therewith in the pot-type core-half 20."

In addition to the foregoing discussion of claim 6 as to the combined teachings of Dormer and Goldberg, the transcutaneous coupling device described by Dormer relates to a hearing device such as a "cochlear implant" that is implanted under the skin behind the ear and that uses transmitting and receiving coils to transcutaneously couple signals across the skin. Ex. 1002, ¶68. The receiving coil 10 is concentric with the ring magnet disposed along the periphery of the pot-type core-half and, hence, is "in the area of the permanent magnet." *Id.*

Thus the combination of Dormer and Goldberg teaches all the limitations of claim 7 rendering the claim unpatentable for obviousness. *Id.*

3. Claim 8

CLAIM 8	**DORMER and GOLDBERG**
8. A percutaneous or transcutaneous connecting device for providing a connection through an outer surface of a living being,	*See above element 6a*

characterized by	
a permanent magnet (7, 29) adapted to be positioned in the area of the outer surface (1,3)	*See above element 6b*
with its poles extending essentially parallel thereto,	*See above element 6c*
wherein in the area of the permanent magnet (29) at least one coil (27) is provided for the purpose of receiving or, respectively, sending electrical or electromagnetic signals and/or for transferring electrical energy.	*See above claim 7*

Claim 8 is simply limitations found in claims 6 and 7 combined together in a single independent claim. Thus, the combination of Dormer and Goldberg teaches all the limitations of claim 8 as described above with regards to claims 6 and 7. Ex. 1002, ¶69.

4. <u>Claim 9</u>

All of the elements of claim 9 are disclosed by the connecting device disclosed in the combined teachings of Dormer and Goldberg as shown in the claim chart below. Dormer describes transcutaneous coupling of an implant device having the structural elements required of the connecting device of claim 9 including a permanent ring magnet, except Dormer does not explicitly state the magnetization orientation of the ring magnet. Goldberg teaches the use of

diametrically magnetized ring magnets in an implant device thereby orienting the poles of the magnets essentially parallel to the outer surface of a living being. Ex. 1002, ¶70.

CLAIM 9	**DORMER and GOLDBERG**
9. A method for the transcutaneous or percutaneous introduction or withdrawal of medication, samples, or other substances into or from inside a living being, for transferring, receiving or transmitting electrical signals or electrical energy into or from inside a living being or for placing a measuring probe in the area of an outer surface of a living being, characterized in that,	*Dormer*— Abstract: A "transcutaneous coupling device". Col. 1, lines 29-34: Coupling device is for a cochlear implant having "an internal, subcutaneously located signal receiving unit" and "an external sound detecting and transmitting unit located outside the skin of the user". Col. 2, lines 63-66: An "electrical signal is transferred by electromagnetic induction transcutaneously" between external and implanted coils.

This preamble requires any of three alternatives – (a) the introduction or withdrawal; (b) transferring, receiving or transmitting; or (c) placing. Dormer describes a hearing device such as a "cochlear implant," that is implanted under the skin and uses transmitting and receiving coils to transcutaneously couple electrical signals across the skin. Ex. 1002, ¶71. Hence, Dormer satisfies: "A method …for transferring, receiving or transmitting electrical signals or electrical energy into or from inside a living being."

CLAIM 9	**DORMER and GOLDBERG**
in the area of the outer surface of the living being, a permanent magnet is placed	*See above element 6b*

with its poles extending essentially parallel to that surface,	*See above element 6c*
wherein for the percutaneous or transcutaneous feed-through, transmission or placement, an external functional element is added on the outer surface of the living being which element as well contains an additional magnet and/or a coil,	*Dormer*—Col. 4, lines 16-20: "In addition to the first member 4, the present invention includes a second member 22 which in the preferred embodiment includes signal generating and transmitting means 24 located supercutaneously of the user of the invention." Col. 5, lines 21-32: "In addition to the first rare-earth magnet 38 forming a part of the magnet means of the present invention, there is a second rare-earth magnet associated with the second coil 29 of the second member 22 for magnetically coupling with the first rare-earth magnet 38 so that the first and second coils 10 and 29 are positioned for electromagnetically inductive coupling. The magnetic coupling arises by placing attractive poles of the first and second magnets toward each other so that the magnetic lines of force extend through the intervening tissue 8 to retain the internal and external coil assemblies in alignment adjacent the intervening skin."

In addition to the ring magnet in the implanted portion of the system, Dormer further describes an external member placed on the skin of the user over the implant and containing both an additional magnet and a coil 29. Ex. 1002, ¶72.

CLAIM 9	**DORMER and GOLDBERG**
wherein a magnetic field retains the external functional element adhering to the permanent magnet in the area of the outer surface.	*Dormer* - Col. 4, lines 58-65: "For the electromagnetically inductive transmission between the first coil 10 and the second coil 29 to be properly achieved, it is necessary to provide means for properly securing the external coil assembly 28 (and the sound detector and signal conditioner means 26 if it is unistructurally combined with the external coil assembly 28) with the internal

	assembly 6 without significantly adversely affecting the intervening tissue 8. This is achieved in the present invention with magnet means for magnetically securing the second member 22 with the first member 4." Col. 5, lines 21-32: "In addition to the first rare-earth magnet 38 forming a part of the magnet means of the present invention, there is a second rare-earth magnet associated with the second coil 29 of the second member 22 for magnetically coupling with the first rare-earth magnet 38 so that the first and second coils 10 and 29 are positioned for electromagnetically inductive coupling. The magnetic coupling arises by placing attractive poles of the first and second magnets toward each other so that the magnetic lines of force extend through the intervening tissue 8 to retain the internal and external coil assemblies in alignment adjacent the intervening skin." *Goldberg* – col. 4, lines 63-67: "Magnets 30 and 52 are shown in FIG. 5, and it is apparent that because the north and south poles of different magnets are disposed adjacent to each other the flux lines flow in a loop through the two magnets. If magnet 52 is turned, magnet 30 turns with it."

Dormer further describes that the external member contains a second magnet that cooperates with the magnet in the implanted device that holds the external device over the implanted device with transmitting and receiving coils aligned for transmission of electrical signals across the intervening skin. Ex. 1002, ¶73. Goldberg confirms that alignment is maintained using two diametrically magnetized ring magnets. *Id.*

Thus, the combination of Dormer and Goldberg teaches all the limitations of claim 9 rendering the claim unpatentable for obviousness. *Id.*

5. Claim 11

CLAIM 11	DORMER and GOLDBERG
11. The method as in claim 9, wherein electrical or electromagnetic signals and/or electrical energy are conveyed by passage-free transmission from the external functional element to the permanent magnet, and vice versa, by means of at least one coil positioned in the area of the permanent magnet and, respectively, in the area of the external functional element.	*As with claim 9, plus:* *Dormer*— Abstract: A "transcutaneous coupling device". Col. 1, lines 29-34: Coupling device is for a cochlear implant having "an internal, subcutaneously located signal receiving unit" and "an external sound detecting and transmitting unit located outside the skin of the user". Col. 2, lines 63-66: An "electrical signal is transferred by electromagnetic induction transcutaneously" between external and implanted coils. Col. 3, line 55-col. 4, line 1: "The hearing aid 2 includes an internal first member 4 which is designated in FIG. 1 as an internal coil assembly 6. In the preferred embodiment the internal coil assembly 6 is a cochlear implant unit containing electronic receiver means for receiving a transmitted signal. However, it is to be noted that in other embodiments the internal coil assembly 6 can include means for transmitting a signal or means for both receiving and transmitting signals."

In addition to the foregoing discussion of claim 9 as to the combined teachings of Dormer and Goldberg, Dormer describes providing a transcutaneous coupling device, including a permanent magnet, that uses transmitting and receiving coils to transcutaneously couple signals across the skin in either direction. Ex. 1002, ¶74. Induction transfers the electrical signals between the

internal and external coils without a physical passage between the inside and outside of the body. *Id.*

Thus, the combination of Dormer and Goldberg render claim 11 unpatentable for obviousness.

6. Reasons for combining Dormer and Goldberg

a. Dormer and Goldberg are magnetic devices and implantable devices

Dormer discloses "apparatus for coupling a member implanted in a body with a member located outside the body." Ex. 1003, col. 1, lines 7-9. Dormer achieves coupling with permanent magnets to secure an external assembly to an internal assembly without adversely affecting the intervening skin. Goldberg also discloses an implantable device that utilizes magnetic coupling. Both references fall within the field of transcutaneous connecting devices as identified in the preamble of the '681 patent claims. Furthermore, both references concern magnetic devices and implantable devices. A POSITA working in the field of transcutaneous connecting devices, magnetic devices and/or implantable devices would be presumed to have knowledge of the teachings of Dormer and Goldberg. *In re GPAC*, 57 F.3d at 1579.

b. Parallel magnetization is one of two basic orientations

Dormer teaches all the elements of the transcutaneous connecting device of claims 6-9 and 11 except it leaves open a design need to identify the magnetization direction of its ring magnet. As a practical matter, simple consideration of the available magnetic orientations for the ring magnet of Dormer would include either of perpendicular to the skin or parallel to the skin. Ex. 1002, ¶76. These are the first two magnetizations (M) for a ring magnet listed at the top of Figure 4-3 in the Moskowitz handbook.

Ex. 1010, p. 25. Perhaps even the third configuration with a horseshoe magnetization could have been considered. But a POSITA would have recognized that the simplest configurations, such as in the first row of Moskowitz Figure 4-3 are sufficient to hold one magnet to a second magnet. Ex. 1002, ¶76. Nevertheless, without question there were only a finite number of orientations that would have been considered by a POSITA as a practical matter. *Id.*, Ex. 1010 p. 25. To implement the ring magnet embodiment described by Dormer, one of the magnetization orientations would necessarily be adopted for use in the device.

Goldberg discloses diametrically magnetizing ring magnets which orients the poles of the magnet "essentially parallel" to the intervening skin between the internal part and external part of the connecting device. The two magnets in Goldberg are separated from each other by intervening layer of skin and/or rubber and yet are strongly attracted to one another sufficiently to turn together or even to overcome attraction to a soft unmagnetized magnetic material. Implementing the essentially parallel magnetization in the ring magnet of Dormer would have been one of just a finite number of practical predictable orientations. Ex. 1002, ¶77. The law recognizes that a POSITA has good reason to pursue the known options within his or her technical grasp. Since a POSITA would have known from Goldberg and basic magnetics that the diametrically magnetized ring magnets were a known workable option from among a finite number of predictable solutions, such product design is a straightforward following of the teachings of Dormer and knowledge in the art, not innovation. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.")

c. Predictable use of known magnetic methods applied to Dormer

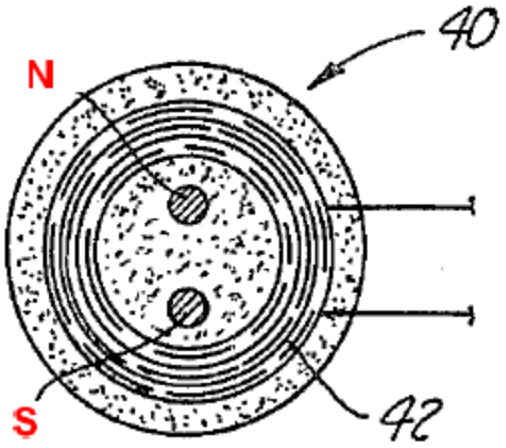
The claimed connecting device and method is merely a combination of prior art elements disclosed by Dormer and Goldberg arranged according to known methods to yield predictable results. Ex. 1002, ¶78. It was well known that when the north pole of a ring magnet approaches a south pole of a second ring magnet as shown in Goldberg, the two would attract one another. *Id.* The use of two magnets arranged with parallel magnetizations as shown by Goldberg was a known configuration for retaining an external member adjacent an implanted internal member. Ex. 1002, ¶79. For example, in the Moskowitz handbook, parallel magnetization was used to retain a dental implant. Ex. 1010, p. 155. And in Beesley WO97/05673 (Ex. 1013), parallel magnetization was used to retain a cochlear implant. Ex. 1002, ¶38, 79.

The ring magnet of Dormer is used with a pot-type core-half. Another example of a pot-type core-half is disclosed in U.S. Patent No. 5,041,806 (Enderle et al.) (Ex. 1012). Enderle shows use of radial magnetization in a permanent ring magnet 19 in conjunction with a pot-type core-half 15 in an electromagnetic holding device. Ex. 1002, ¶80. Thus, parallel magnetization was a known orientation for use with a pot-type core-half. *Id.* "[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the

combination is obvious." *KSR International Co.,* 550 U.S. at 417 (citing *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976).

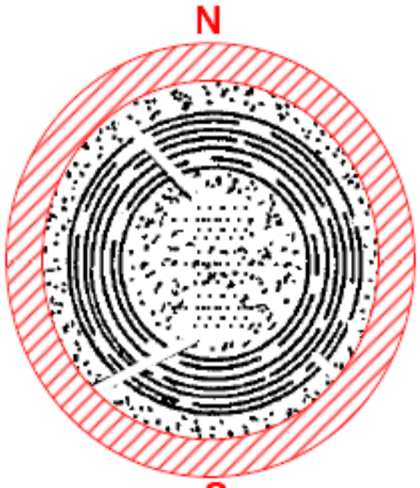
d. Dormer provides motivation for diametric magnetization

As is well known, a south magnetic pole is attracted to a north magnetic pole. Ex. 1002, ¶81. Dormer discloses attaching an internal member to an external member by providing a south pole in one of the members for placement opposite a north pole in the other member. Ex. 1003, col. 5, lines 21-44. Dormer further teaches how to achieve a single, predetermined alignment of the first member with respect to the second member. Ex. 1003, col. 7, lines 1-29. Each member is given a north pole and a south pole for facing the opposite member. This can be done with two laterally separated magnets as shown in Dormer Fig. 5. (Figure modified to show a North pole and a South pole as taught by Dormer.) Ex. 1002, ¶81.

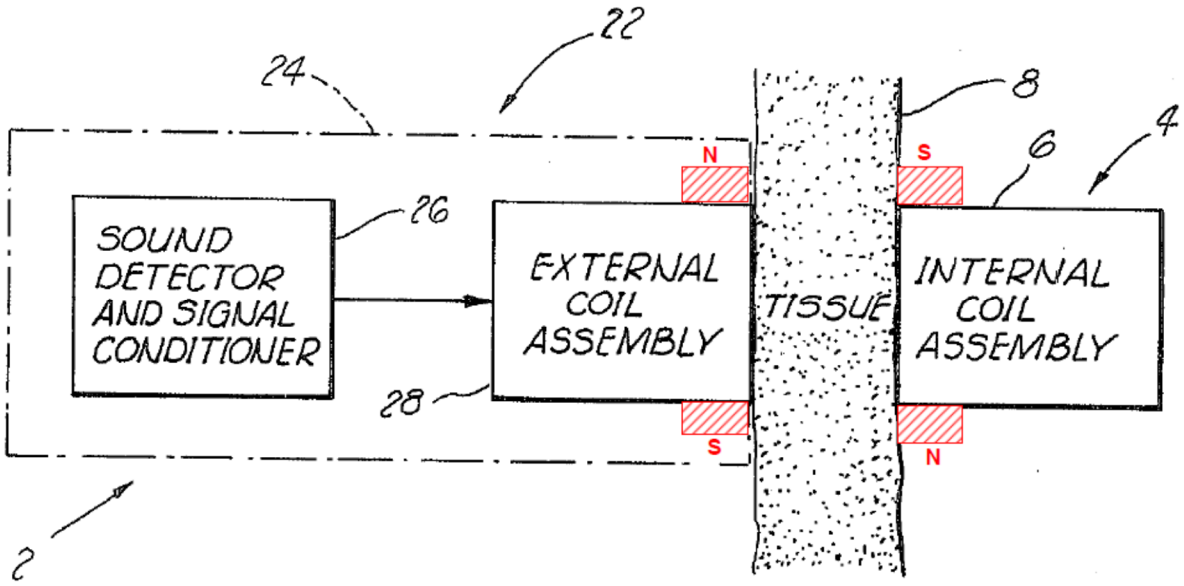


Only when oppositely polarized magnets of the two members are facing each other will the members become magnetically coupled. Ex. 1003, col. 7, lines 1-29. Thus, there is only a single predetermined alignment.

As an alternative to two magnets in each member, Dormer explicitly disclosed other configurations. "For example, a ring magnet disposed along the periphery of the pot-type core half could be used." Ex. 1003, col. 7, lines 34-35. To achieve the single, predetermined alignment with a ring magnet, a north and a south pole are laterally separated along the face of the pot core as taught by Dormer at Fig. 5. Ex. 1002, ¶82. This ring magnet embodiment, in which the two oppositely polarized magnetic slugs are replaced by a ring magnet, is illustrated below:



Ring Embodiment



Ex. 1002, ¶40, 41. In contrast, magnetization perpendicular to the magnet face would not work to achieve the desired single alignment. Ex. 1002, ¶82. Such perpendicular magnetization would provide a single pole across the face of the ring magnet. *Id.*

The diametrically magnetized ring magnet, as taught by Goldberg, is suitable for aligning an exterior magnet with an implanted magnet. Both the north and south poles are laterally separated along the face of the device as called for by Dormer. Ex. 1002, ¶83. Goldberg uses the alignability of the magnets, so that they turn together. A POSITA implementing Dormer would use the alignability of the diametrically magnetized magnets to restrict the connecting device to a single alignment. *Id.* This mimics Dormer which states that to "restrict the alignment between the first and second members to a single predetermined position, the first and third rare-earth magnets 44 and 46 can be disposed in the first member so that

the two polarities facing the second member are opposite." Ex. 1003, col. 7, lines 1-5. Diametrical magnetization provides the two polarities laterally separated on the face of the device as recommended. Ex. 1002, ¶83. When oriented as shown in Fig. 5 of Goldberg, a ring magnet of a first member aligns with a ring magnet of a second member when opposite poles face one another. Ex. 1003, ¶83.

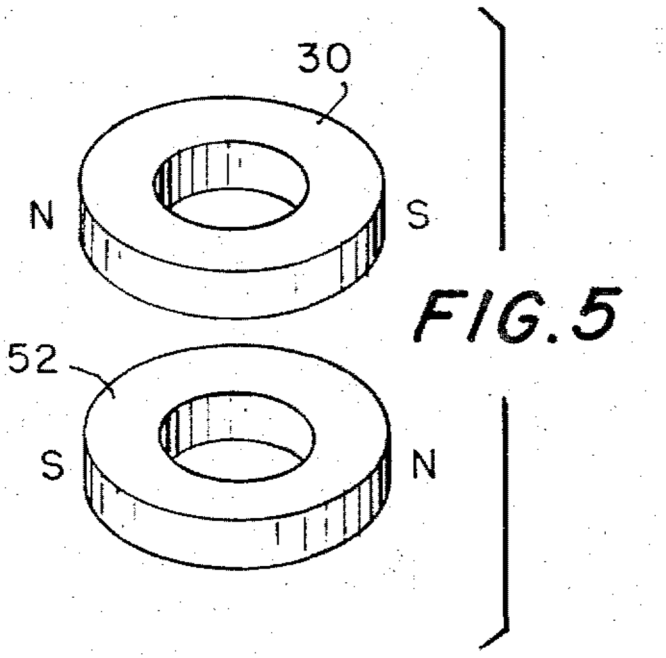


FIG. 5

The teaching is explicit in Dormer for positioning a ring magnet, such as disclosed by Goldberg, about the periphery of the pot-type core-half. Orienting the magnetization as taught by Goldberg is further motivated by Dormer's explanation for achieving a single predetermined alignment. Thus, it would have been obvious for a POSITA to combine Dormer and Goldberg as taught and motivated by the references themselves. Ex. 1003, ¶84.

For any and all of the above enunciated reasons, it would have been obvious to combine the connecting device taught by Dormer with the diametrically magnetized ring magnet taught by Goldberg.

B. **Ground 2 - Claim 12 is Unpatentable for Obviousness over Dormer, Goldberg and Ely**

1. Claim 12

All limitations of claim 12 are disclosed by Dormer, Goldberg and Ely as shown in the below claim chart.

CLAIM 12	**DORMER and GOLDBERG and ELY**
12. A transcutaneous connecting device providing transcutaneous access through a skin surface comprising:	*Dormer*— Abstract: A "transcutaneous coupling device". Col. 1, lines 29-34: Coupling device is for a cochlear implant having "an internal, subcutaneously located signal receiving unit" and "an external sound detecting and transmitting unit located outside the skin of the user". Col. 2, lines 63-66: An "electrical signal is transferred by electromagnetic induction transcutaneously" between external and implanted coils.

CLAIM 12	**DORMER and GOLDBERG and ELY**
an external part and an internal part, the internal part adapted to be implanted beneath the skin surface;	*Dormer*—Col. 3, lines 46-48: "a subcutaneously located first member with a supercutaneously(i.e., outside the skin) positioned second member" Co. 3, lines 55-57 and 65 -68: "an internal first member 4 which is designated in FIG. 1 as an internal coil assembly 6"…"The internal coil

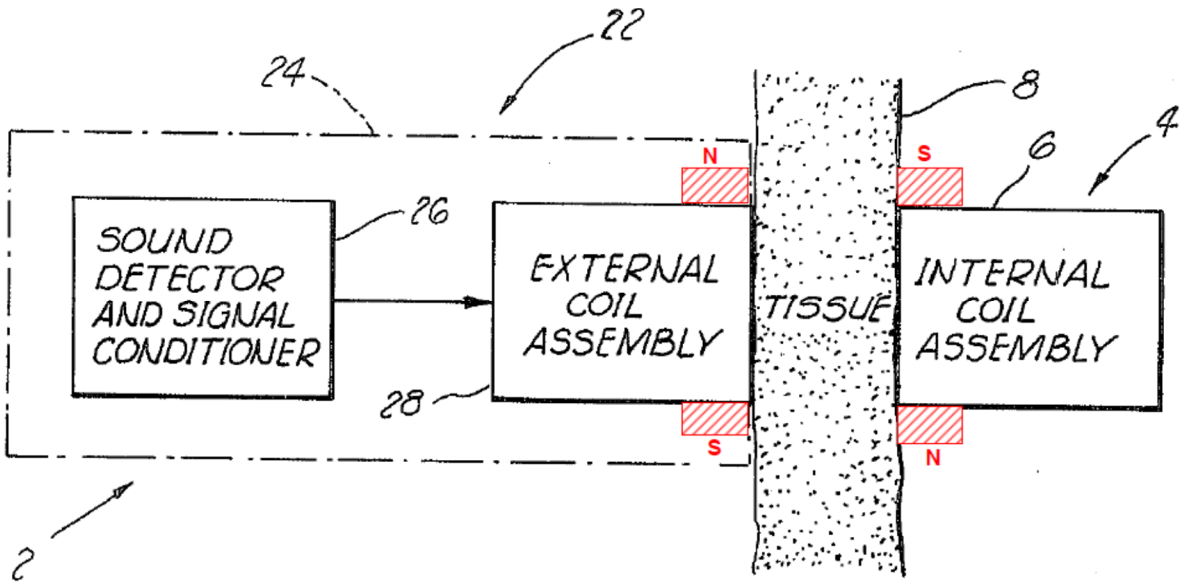
	assembly 6 is subcutaneously located beneath a layer of tissue 8 which includes the epidermal and dermal layers of the skin of the user of the device"

CLAIM 12	**DORMER and GOLDBERG and ELY**
a first magnetic member positioned within the internal part, said first magnetic member having north and south poles adapted to extend parallel to the skin surface; and	*Dormer*— Col. 2, line 69-col. 3, line 2: "a first rare-earth magnet associated with the first coil of an embodiment of the first member" wherein the first member is "positioned subcutaneously" (col. 2, lines 33-34). Col. 7, lines 35-36—"a ring magnet disposed along the periphery of the pot-type core-half could be used." *Goldberg*: Col. 3, l.39-42 – "The magnet is …magnetized diametrically. That is, the north and south poles of the magnet are at opposite ends of one of its diameters." See also Fig. 2 and Fig. 5. Col. 2, lines 63-65: "FIG. 5 depicts the face-to-face relationship of the two diametrically magnetized disc magnets utilized in the embodiment of the invention illustrated in FIG. 4."

CLAIM 12	**DORMER and GOLDBERG**
a second magnetic member positioned within the external part, the second magnetic member having north and south poles adapted to extend	*Dormer*—Col. 5, lines 51-54: "the second member 22, having the second rare-earth magnet associated therewith, is positioned supercutaneously adjacent the outer surface of the user's skin…"

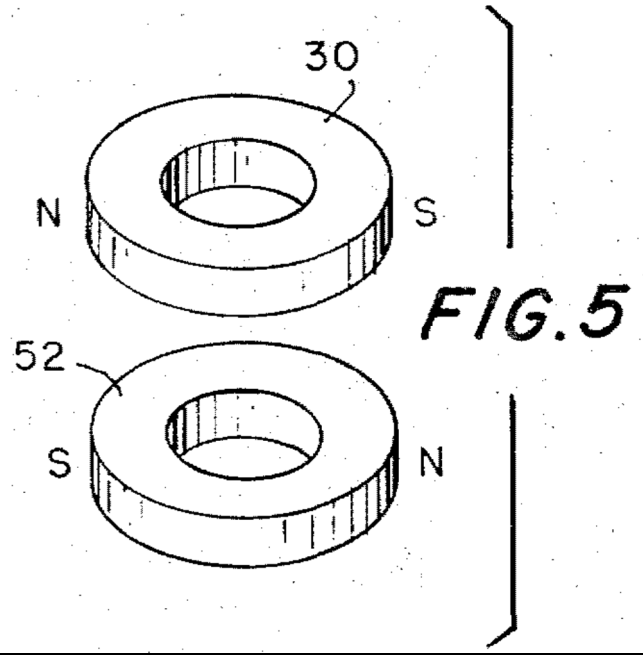
parallel to the skin surface,	Col. 7, lines 35-36—"a ring magnet disposed along the periphery of the pot-type core-half could be used." *Goldberg*: Col. 3, l.39-42 – "The magnet is …magnetized diametrically. That is, the north and south poles of the magnet are at opposite ends of one of its diameters." See also Fig. 2 and Fig. 5. Col. 2, lines 63-65: "FIG. 5 depicts the face-to-face relationship of the two diametrically magnetized disc magnets utilized in the embodiment of the invention illustrated in FIG. 4."

When the connecting device of Dormer is implemented with diametrically magnetized ring magnets, the magnets are adapted to be attracted to one another when they are parallel as shown in Fig. 5 of Goldberg. Ex. 1002, ¶67. When one ring magnet is implanted in the internal coil assembly 6 of Dormer and the other is in the external coil assembly 28, the skin tissue is sandwiched between the ring magnets. *Id.* The north and south poles at opposite ends of a diameter thereby extend essentially parallel to the skin as illustrated below. *Id.*



The use of diametrically magnetized ring magnets in Dormer thus satisfies the limitations of claim 12.

CLAIM 12	**DORMER and GOLDBERG and ELY**
wherein the second magnetic member aligns and magnetically retains in place the external part to the internal part when the second magnet member is positioned on the skin surface proximate to the first magnetic member; and	*Dormer*—Col. 2, lines 36-38: "magnet means for magnetically securing the second member to the first member." Col. 7, lines 1-5: "To restrict the alignment between the first and second members to a single predetermined position, the first and third rare-earth magnets 44 and 46 can be disposed in the first member so that the two polarities facing the second member are opposite." *Goldberg*: Col. 4, lines 63-67: "Magnets 30 and 52 are shown in FIG. 5, and it is apparent that because the north and south poles of different magnets are disposed adjacent to each other, the flux lines flow

	in a loop through the two magnets. If magnet 52 is turned, magnet 30 turns with it."  FIG. 5

CLAIM 12	**DORMER and GOLDBERG and ELY**
at least one conduit extending through the external part.	*Dormer*—Col. 4, lines 40-41: "a microphone 30, for detecting a sound and converting it into a proportional electrical signal." *Ely* – Col. 3, lines 13-16: "acoustic conduit means defining a front-to-back sound conduit 21, here shown as being defined by a microphone casing 24." Col. 5, lines 14-15: "a front-to-back sound conduit through the hearing aid"

Dormer teaches an external part that includes a microphone 30 in a hearing aid. Ex. 1003, col. 2, lines 52-54; col. 3, lines 54-57. Ely teaches the benefits of making the microphone casing in a hearing aid so as to include a sound conduit through the hearing aid. Ex. 1002, ¶86. The combined teachings of Dormer,

Goldberg and Ely thus disclose all of the elements of claim 12 rendering the claim unpatentable for obviousness.

2. Reasons for combining Dormer and Goldberg and Ely

For the reasons set forth above in section VIII.A, there are numerous motivations for a POSITA to implement the Dormer ring magnet embodiment with diametrically magnetized magnets as disclosed in Goldberg. Dormer specifically describes implementing the coupling apparatus in a hearing aid. Fig. 4 of Dormer specifically shows a microphone 30 in the external component of the apparatus. While Dormer only provides a block diagram of the electronic elements, a POSITA would have had available the teachings of Ely for completing the physical embodiment of an external component with a microphone. Ex. 1002, ¶87. Ely teaches, "[t]he microphone system 14 according to this invention comprises a microphone assembly 22 and acoustic conduit means defining a front-to-back sound conduit 21, here shown as being defined by a microphone casing 24." Ex. 1006, col. 3, lines 12-16.

Ely provides explicit motivation to a POSITA for adopting its physical implementation of a microphone assembly. Ex. 1003, ¶88. The hearing aid device as constructed by Ely is highly directional, helping the user to detect the direction from which a sound is emanating. Ex. 1006, col.1, lines 45-47. Ely's hearing aid design is relatively insensitive to external physical interference or obstruction. Ex.

1006, col. 2, lines 30-31. The hearing aid construction is "simple, compact, low cost." *Id*., col. 2, lines 29-30. Thus, there are numerous motivating factors that would lead a POSITA to adopt the sound conduit through the hearing aid as taught by Ely when physically implementing the microphone system of Dormer. Ex. 1002, ¶88. Thus, Dormer, Goldberg and Ely render claim 12 obvious.

Ely establishes that a POSITA would have been aware a front-to-back acoustic conduit through a hearing aid can advantageously contribute to forming a directional microphone system. Ex. 1002, ¶89. Dormer discloses a hearing aid, which necessarily relies upon the hearing aid art to complete its construction. Thus, a POSITA would have known that a front-to-back acoustic conduit as described by Ely was useful to provide directionality to the sound produced for the wearer of a hearing aid. To construct the hearing aid of Dormer with an acoustic conduit would have merely involved constructing a hearing aid with a conduit in accordance with its known function. Ex. 1002, ¶89. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill…[A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR International Co.,* 550 U.S. at 417. In view of Dormer, Goldberg and Ely, the device of claim 12 was constructed

according to the ordinary capabilities of a POSITA. Ex. 1002, ¶89. For this additional reason, claim 12 is unpatentable for obviousness.

C. Ground 3 – Anticipation of claim 9 by Hooven

Claim 9 is anticipated by Hooven, which meets all elements of the claim as shown in the claim chart below.

CLAIM 9	HOOVEN
9. A method for the transcutaneous or percutaneous introduction or withdrawal of medication, samples, or other substances into or from inside a living being, for transferring, receiving or transmitting electrical signals or electrical energy into or from inside a living being or for placing a measuring probe in the area of an outer surface of a living being, characterized in that,	FIG. 1. Col. 3, lines 30-40: "a hydrocephalus system 10 for maintaining a desired predetermined intracranial pressure in a patient 11 is illustrated. As shown, the system includes a non-invasively adjustable intracranial pressure relief valve 12 for maintaining the desired intracranial pressure. Cerebrospinal fluid (CSF) 14 is drained from a ventricle 15 of the brain 16 by means of a ventricular catheter 17. Preferably, catheter 17 is radio-opaque to facilitate its accurate placement within the brain. The distal end 18 of catheter 17 may be provided with a plurality of apertures to permit the passage of CSF therethrough. Opposite distal end 18, the other end of catheter 17 is coupled to an inlet port 20 of valve 12, to provide fluid communication between the valve and the ventricle. An outlet port 21 of the valve is connected to one end of a drain catheter 22, the opposite end of which discharges into an appropriate drainage location in the patient's body, such as, for example, the heart 23 or peritoneal cavity (not shown). The valve 12, together with the extracranial portions of the ventricular catheter 17 and drain catheter 22, is preferably subcutaneously implanted between the patient's skull 24 and scalp 25."

A POSITA would have understood that what Hooven describes relates to an arrangement for draining cerebrospinal fluid from the brain, which involves withdrawal of substances inside a living being. Ex. 1002, ¶91. The claims encompasses both "transcutaneous or percutaneous" thereby reading on Hooven. The cerebrospinal fluid is drained from the brain and discharged into a location in the patient's body, without passing through an opening in the skin. Indeed, the intracranial pressure relief valve 12 is non-invasively adjustable. Hence, Hooven satisfies the "transcutaneous or percutaneous introduction or withdrawal of medication, samples, or other substances into or from inside a living being", the first option listed in the preamble.

CLAIM 9	**HOOVEN**
in the area of the outer surface of the living being, a permanent magnet is placed with its poles extending essentially parallel to that surface,	FIGS. 2 and 7. Col. 5, lines 50-59: "To provide a mechanism for non-invasively adjusting the rotational position of the screw member, the valve includes a magnetic wrench 70 located within the aperture 55 formed in casing top 30. Wrench 70 is generally elongate in form and includes four downwardly projecting cylindrical protrusions 71a 71b, 71c and 71d formed in rectangular formation along the undersurface thereof. The wrench further includes an elongate magnetic portion 72 having North and South poles at opposite ends thereof."

The magnetic wrench 70 in FIG. 2 of Hooven is a permanent magnet in the form of "an elongate magnetic portion 72 having North and South poles at opposite ends thereof." Ex. 1005, col. 5, lines 57-59. FIG. 7 of Hooven shows the magnetic

wrench 70 and its elongate magnetic portion 72 lying on a line that is parallel to the outer surface of the overlying scalp 25.

CLAIM 9	HOOVEN
wherein for the percutaneous or transcutaneous feed-through, transmission or placement, an external functional element is added on the outer surface of the living being which element as well contains an additional magnet and/or a coil,	FIG. 7. Col. 6, lines 6-21: "To permit adjustment of the valve after its implantation beneath the scalp, a tool containing a bar magnet 75 having north and south poles at opposite ends may be positioned above the scalp directly above the implanted valve as shown in FIG. 7. When the magnet is positioned directly above the magnetic wrench such that the unlike poles of each are adjacent one another, the magnetic wrench will be drawn upwardly so that pivot point 74 is received in a suitably positioned recess 76 formed in the interior surface of casing closure cap 33. Pivot point 74 thus allows the magnetic wrench to rotate relative to the interior surface of cap 33 in response to rotational motion of magnet 75. Such rotation of the wrench results in rotation of the screw member 31 and a corresponding change in the contact force existing between ball 29 and shoulder 54."

The bar magnet 75 is an external functional element. Indeed, turning the bar magnet 75 in Hooven causes the implanted magnetic wrench 70 to correspondingly rotate, and thereby adjust the flow regulation of the valve 12 thereby controlling the draining of the cerebrospinal fluid from the brain. Ex. 1002, ¶93.

CLAIM 9	HOOVEN
wherein a magnetic field retains the external functional element adhering to the permanent magnet in the area of the outer surface.	FIG. 7. Col. 6, lines 6-15: "To permit adjustment of the valve after its implantation beneath the scalp, a tool containing a bar magnet 75 having north and south poles at opposite ends may be positioned above the scalp directly above the implanted valve as shown in FIG. 7. When the magnet is positioned directly above the magnetic wrench such that the

	unlike poles of each are adjacent one another, the magnetic wrench will be drawn upwardly so that pivot point 74 is received in a suitably positioned recess 76 formed in the interior surface of casing closure cap 33."

The magnetic field between the implanted magnetic wrench 70 and the bar magnet 75 draws the magnets toward each other thereby maintaining adherence of the bar magnet to the elongate magnetic portion 72 of the magnetic wrench 70. Ex. 1002, ¶94.

Thus, Hooven teaches all the limitations of claim 9, rendering the claim unpatentable for anticipation. Ex. 1002, ¶95.

IX. CONCLUSION

For the reasons detailed above, there is a reasonable likelihood that the Petitioner would prevail against each of claims 6-9, 11 and 12 in the '681patent. Petitioner respectfully requests that a trial be instituted and that claims 6-9, 11 and 12 be canceled as unpatentable.

Dated: November 26, 2019 Respectfully submitted,

/Robert M. Asher, #30,445/
Robert M. Asher, Reg. No. 30,445
Kathryn E. Noll, Reg. No. 48,811
Sunstein Kann Murphy & Timbers LLP

125 Summer Street, 11th Floor
Boston, MA 02110-1618
(617) 443-9292
Counsel for Petitioner

CERTIFICATE OF COMPLIANCE

This petition complies with the word count limits set forth in 37 C.F.R. § 42.24(a)(i), because this Petition contains 10,248 words, excluding the parts of the petition exempted by 37 C.F.R. § 42.24(a), and determined using the word count provided by Microsoft Word, which was used to prepare this Petition.

Dated: November 26, 2019

Respectfully submitted,

/Robert M. Asher, #30,445/
Robert M. Asher
Reg. No. 30,445
Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned certifies service pursuant to 37 C.F.R. §§42.6(e) and 42.105(a) on the Patent Owner by Federal Express of a copy of this Petition for *Inter Partes* Review and supporting materials in its entirety to counsel for Sonova AG at:

Pearne & Gordon LLP
1801 East 9th Street
Suite 1200
Cleveland, OH 44114-3108

and to its litigation counsel at:

Marcus E. Sernel, P.C.
Kirkland & Ellis LLP
300 North LaSalle
Chicago, IL 60654

Dated: November 26, 2019

/Robert M. Asher, #30,445/
Robert M. Asher
Reg. No. 30,445
Counsel for Petitioner