

PTO/SB/57 (02-01)

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(Also referred to as FORM PTO - 1465)

REQUEST FOR *EX PARTE* REEXAMINATION TRANSMITTAL FORM

66548 U.S. PT

90/006558



03/06/03

Address to:

Assistant Commissioner for Patents
Box Reexam
Washington, D.C. 20231

Attorney Docket No. 10436.280288

Date: March 6, 2003

1. ☒ This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 5,053,036 issued Oct. 1, 1991. The request is made by:

☐ patent owner. ☒ third party requester.

2. ☒ The name and address of the person requesting reexamination is:

Smith & Nephew, Inc.

1450 Brooks Rd.

Memphis, TN 38116

3. ☒ a. A check in the amount of \$2,520.00 is enclosed to cover the reexamination fee, 37 CFR 1.20(c)(i); or
☐ b. The Commissioner is hereby authorized to charge the fee as set forth in 37 CFR 1.20(c)(i) to Deposit Account No. 501458; or
☐ c. Payment by credit card. Form PTO-2038 is attached.
4. ☒ Any refund should be made by ☐ check or ☒ credit to Deposit Account No. 501458. 37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.
5. ☒ A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.510(b)(4)
6. ☐ CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table
7. ☐ Nucleotide and/or Amino Acid Sequence Submission
If applicable, all of the following are necessary
a. ☐ Computer Readable Form (CRF)
b. Specification Sequence Listing on:
i ☐ CD-ROM (2 copies) or CD-R (2 copies); or
ii ☐ paper
c. Statements verifying identity of above copies
8. ☐ A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.
9. ☒ Reexamination of claim(s) 1-15 is requested.
10. ☒ A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO-1449.
11. ☒ An English language translation of all necessary and pertinent non-English language patents or printed publications is included.

[Page 1 of 2]

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Reexam, Washington, DC 20231.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

12. ☒ The attached detailed request includes at least the following items:
- a. A statement identifying each substantial new question of patentability based on prior patents and printed publication. 37 CFR 1.510(b)(1)
 - b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited prior art to every claim for which reexamination is requested. 37 CFR 1.510(b)(2)

13. ☐ A proposed amendment is included (only where the patent owner is the requester). 37 CFR 1.510(e)

14. ☒ a. It is certified that a copy of this request (if filed by other than the patent owner) has been served in its entirety on the patent owner as provided in 37 CFR 1.33(c).

The name and address of the party served and the date of service are:

Service by Federal Express to:

Caspar Carl Schneider, Jr., Fish & Richardson, 45 Rockefeller Plaza, New York NY 10111

Synthes (U.S.A.), 1690 Russell Road, Paoli, PA 19301

Brian M. Poissant, Pennie & Edmonds LLP, 1155 Avenue of the Americas, New York, NY 10036

Date of Service: Mar. 6, 2003; or

- ☐ b. A duplicate copy is enclosed since service on patent owner was not possible.

15. ☐ Correspondence Address : Direct all communication about the reexamination to:

- ☒ Customer Number

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27310

- ☐ Firm or
Individual Name

PATENT TRADEMARK OFFICE

Address (line 1)

Address (line 2)

City

State

Zip

Country

Telephone

Fax

16. ☒ The patent is currently the subject of the following concurrent proceeding(s):

- ☐ a. Copending reissue application Serial No. _____.

- ☐ b. Copending reexamination Control No. _____.

- ☐ c. Copending Interference No. _____.

- ☒ d. Copending litigation styled:

Synthes (U.S.A.) v. Smith & Nephew, Inc., Civil Action No. 03-0084 (E.D. Pa.)

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

John Ball #44,433

Authorized Signature

☐ For Patent Owner Requester

March 6, 2003

☒ For Third Party Requester

Date

CERTIFICATE OF SERVICE

I hereby certify that on March 6, 2003, a copy of the Request for Ex Parte

Reexamination of U.S. Patent No. 5,053,036, has been served upon the parties

identified below by Federal Express.

Attorney of record (pursuant to PTO records for USP 5,053,036):

Caspar Carl Schneider, Jr.

FISH & RICHARDSON

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Attorney of record for Synthes (U.S.A.)

Synthes (U.S.A.) v. Smith & Nephew, Inc., Civil Action No. 03-0084 (E.D. Pa.)

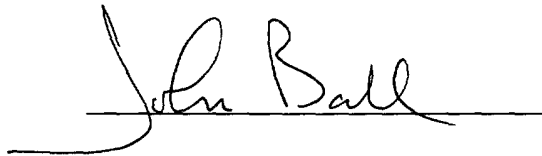
Brian M. Poissant, Esq.

PENNIE & EDMONDS LLP

1155 Avenue of the Americas

New York, New York 10036

Telephone: (212) 790-6301

A handwritten signature in dark ink, appearing to read "John Ball", is written over a horizontal line.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:
Perren et al.

Art Unit: **To Be Assigned**
Examiner: **To Be Assigned**

Patent No.: **5,053,036**
Serial No.: **07/492,403**

Issued: **Oct. 1, 1991**
Filed: **Mar. 8, 1990**

For: **POINT CONTACT BONE COMPRESSION PLATE**

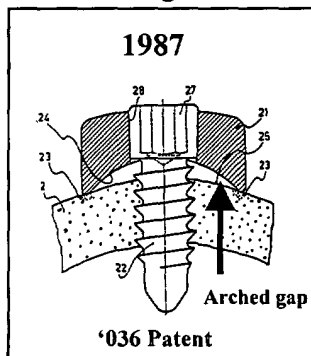
REQUEST FOR REEXAMINATION

Box REEXAM
Assistant Commissioner for Patents
Washington, D.C. 20231

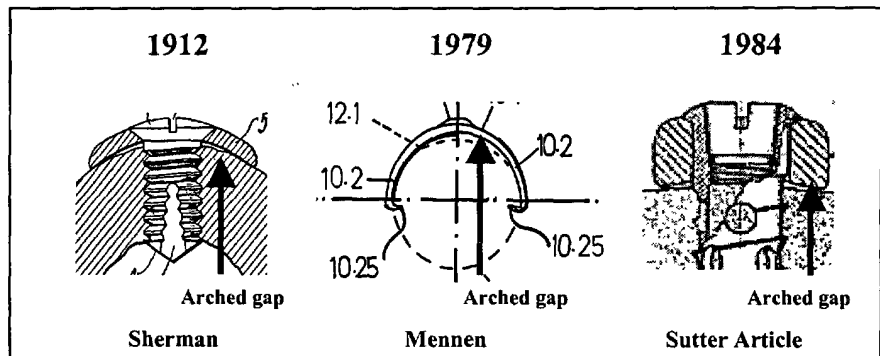
Sir:

Reexamination of Claims 1-15 of United States Patent No. 5,053,036 ("the '036 patent") is requested pursuant to 35 U.S.C. §§ 302-307 and 37 C.F.R. § 1.510 in light of several newly uncovered references, for example: USP 1,105,105 ("Sherman") (issued 1914, filed 1912); USP 4,364,382 ("Mennen") (issued 1982, filed 1979); the Sutter article ("Sutter Article") dated 1984; and the Vattolo dissertation ("Vattolo") dated 1986. Far from being novel, reduced contact bone plates were well known in the art as evidenced below.

Challenged Patent



Uncovered Prior Art



A. Introduction

In obtaining the '036 patent, the patentee asserted that existing bone plates lie flat against the bone and that designing plates with arches to improve blood flow to the bone surface therefore is novel.

'036 Patent, Figs. 2 and 3. However, this design was well known in the art since at least 1912 as is evident in Sherman. *Sherman Fig. 7; Pg. 1, lines 81-86.*

'036 Patent

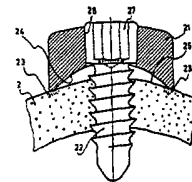
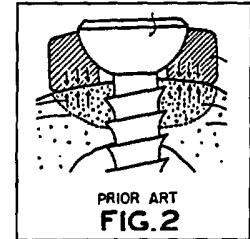
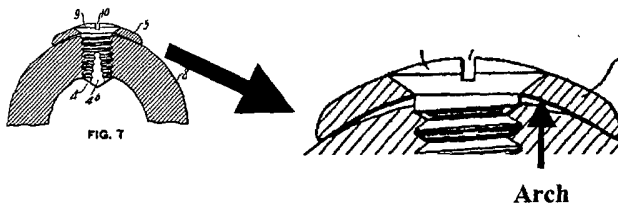


FIG. 3

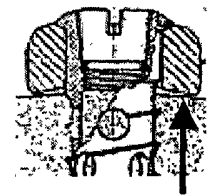
Sherman



The curvature of the concave inner surface of the bone plate is preferably of a smaller radius than that of the bone, 8 to which it is applied, so that when in place the marginal side edges of the bone plate will bear against the outer surface of the bone.

Additionally, the newly uncovered Sutter Article, which was co-authored by one of the '036 inventors three years prior to the '036 filing, also reveals that the use of arches was known in the art.

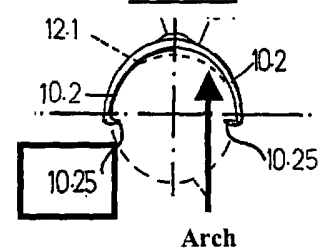
Sutter Article



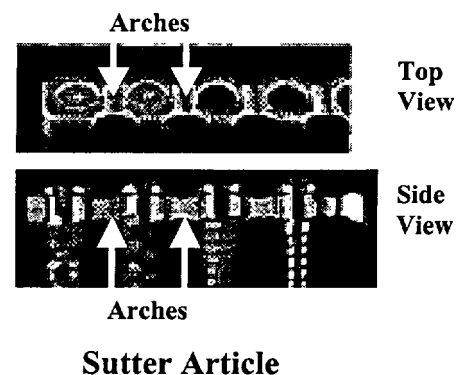
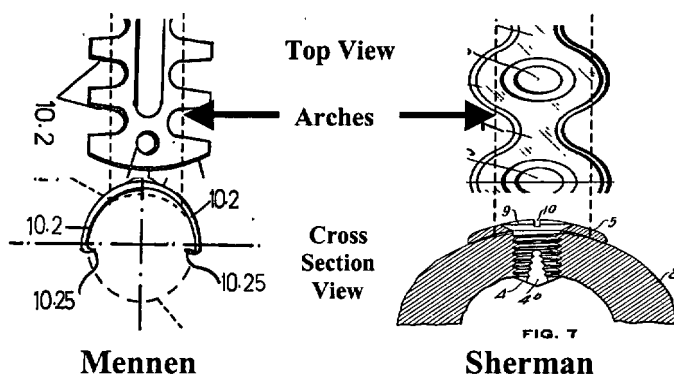
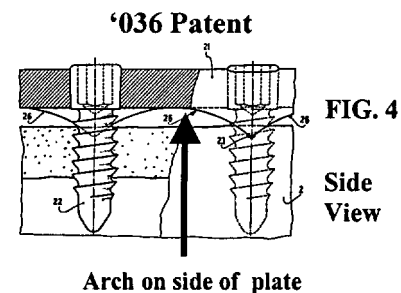
Arch

Mennen also shows the use of arches and explains the resulting benefits on blood flow. *Mennen Fig. 2; Col. 4, lines 27-30* ("The plate is designed so that **only in the immediate vicinity** where each fastening formation **10.25** is inserted ... is **periosteal circulation impaired.**") (*emphasis added*).

Mennen

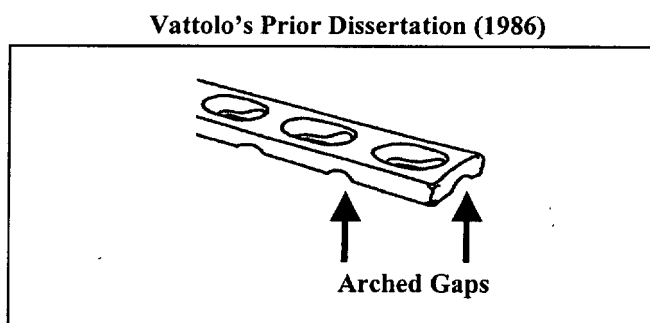
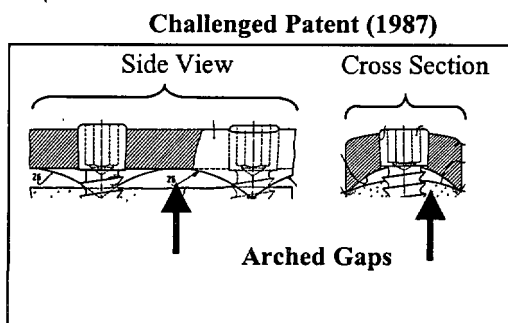


The '036 patentee further asserted the novelty of placing arches along the sides, between the screw holes. '036 Patent Fig. 4; Col. 2, lines 64-68. This approach, too, was well known in the art as shown by Sherman, Mennen, and the Sutter Article.



The Sutter Article explains, "On the titanium reconstruction plate ... grooves which were radial on all sides were machined in between the cylindrical 4.5 mm borings [screw holes]." Sutter Article, p.5, lines 21-23 (emphasis added).

Moreover, in his dissertation, Mauro Vattolo establishes that it was well known in the art to improve blood circulation by combining the use of a central longitudinal groove with transverse grooves between the screw holes.



[illegible]

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The Vattolo dissertation was completed in Switzerland, the residence of the '036 inventors. The dissertation is supported by an affidavit from the Swiss National Library stating that the dissertation was received by the library nearly a year before the '036 patent filing and was indexed in the published Swiss National Bibliography ten months prior to the filing date (a copy of the affidavit and the pertinent pages of the Swiss National Bibliography are submitted with this request). Federal regulations bar the '036 patent owner from establishing a date of invention earlier than the filing date. *See* 37 C.F.R. §1.131 ("...Prior invention may not be established ... before January 1, 1996, in a WTO country [e.g., Switzerland]...").

B. Claims-to-Reference Grid

References	'036 Patent Claims														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Sherman	√	√			√	√									
Vattolo	√	√		√	√	√			√					√	
Mennen	√				√	√								√	
Sutter Art.	√				√	√								√	
Judet															√
Sutter Art. & Sherman		√													
Sherman & Vattolo	√	√			√	√			√				√	√	
Sherman & Raveh Art. 83 or 84														√	
Mennen & Vattolo	√				√	√			√					√	
Mennen & Raveh Art. 83 or 84														√	
Mennen & Sutter		√	√												
Sherman & Sutter			√												
Sherman & Allgower				√											
Mennen & Allgower				√											
Sutter Art. & Allgower				√											
Sherman & Kummer							√	√							
Mennen & Kummer							√	√							
Sutter Art. & Kummer							√	√							
Judet & Mennen															√
Mennen & Vattolo & Sutter		√	√							√	√	√			
Sherman & Vattolo & Sutter			√							√	√	√			
Sherman & Vattolo & Allgower				√											
Mennen & Vattolo & Allgower				√											
Sherman & Vattolo & Kummer							√	√							
Mennen & Vattolo & Kummer							√	√							

Mennen & Vattolo & Sherman													√		
Judet & Mennen & Vattolo															√

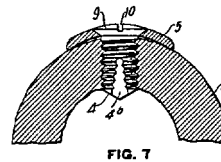
The above rejections are based primarily on stand-alone, anticipatory references. For those that involve a combination of references, all of the references pertain directly to the bone plate art; therefore, one skilled in the art would have been aware of the collective teaching of the references.

C. Statement of New Questions of Patentability.

This request raises substantial new questions of patentability based on the prior art references that are detailed below. Form PTO-1449, which lists the references, is attached.

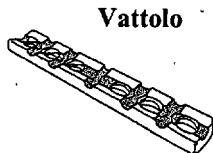
Claims 1-15 are unpatentable for at least the following reasons:

Claims 1, 2, 5, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 1,105,105 (Sherman).

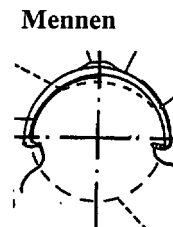


Sherman

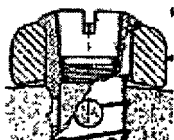
Claims 1, 2, 4, 5, 6, 9, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the Vattolo dissertation (Vattolo).



Claims 1, 5, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,364,382 (Mennen).



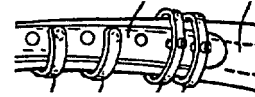
Sutter Article



Claims 1, 5, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the Sutter article dated 1984 (Sutter Article).

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,263,904 ("Judet").

Judet



Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter Article in view of Sherman.

Claims 1, 2, 5, 6, 9, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of the Vattolo dissertation dated 1986 (Vattolo).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of the Raveh article dated 1983 (Raveh Art. 83) or the Raveh article dated 1984 (Raveh Art. 84).

Claims 1, 5, 6, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Raveh Art. 83 or Raveh Art. 84.

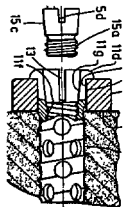
Raveh Art. 84



Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of USP 4,484,570 ("Sutter").

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Sutter.

Sutter



Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of USP Re. 31,628 ("Allgower").

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Allgower.

Allgower

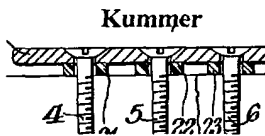


Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter Article in view of Allgower.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of USP 4,338,926 ("Kummer").

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Mennen in view of Kummer.



Claims 7 and 8 are rejected under 35 U.S.C. 103(a)

as being unpatentable over Sutter Article in view of

Kummer.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Judet in view of Mennen.

Claims 2, 3, 10, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo as applied to claims 1 and 9, and further in view of Sutter.

Claims 3, 10, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Vattolo as applied to claims 1, 2, and 9, and further in view of Sutter.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Vattolo as applied to claim 1 and further in view of Allgower.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo as applied to claim 1 and further in view of Allgower.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Vattolo and further in view of Kummer.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo and further in view of Kummer.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo as applied to claim 9 and further in view of Sherman.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Judet in view of Mennen and further in view of Vattolo.

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D. Detailed Explanation of Pertinency and Manner of Applying the Cited Prior Art.

Claims 1, 2, 5, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 1,105,105 ("Sherman").

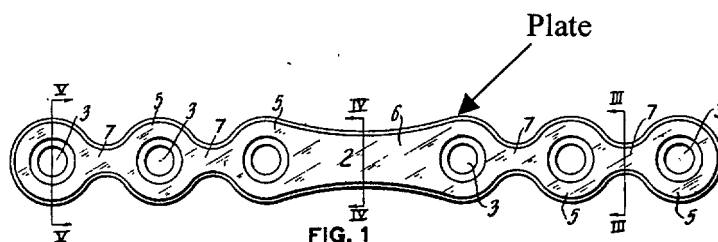
Claim 1

Sherman

"A compression plate for osteosynthesis,"

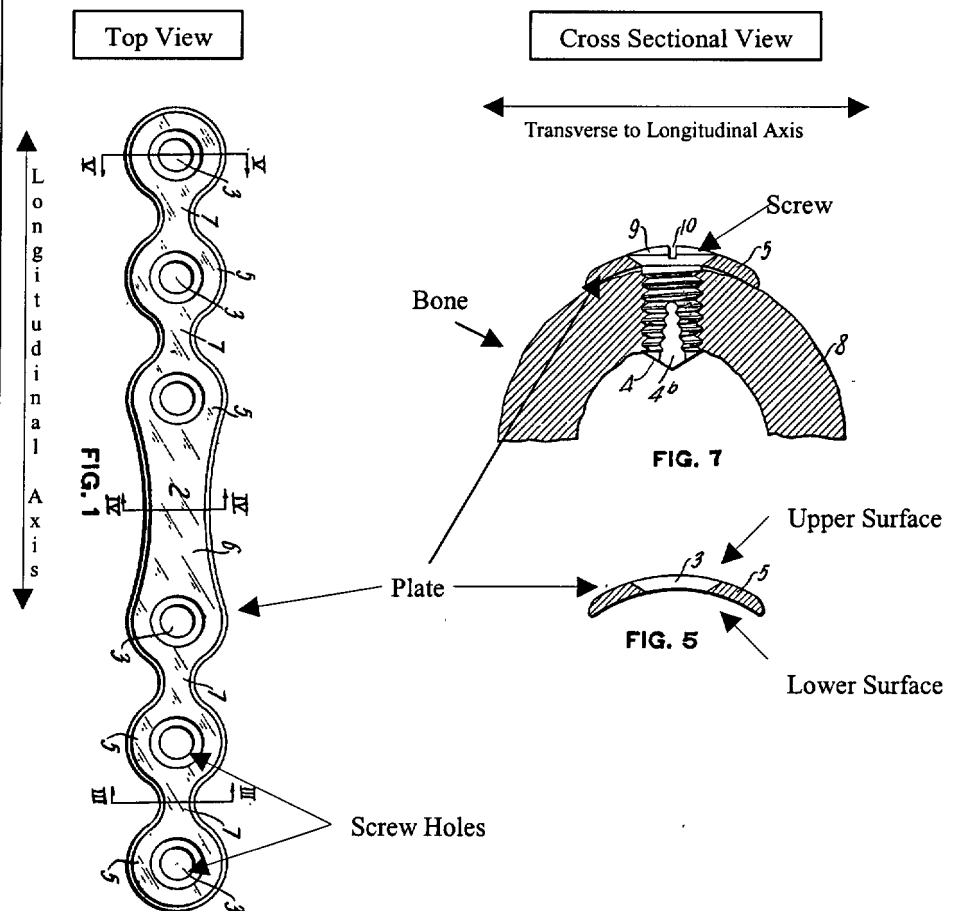
Sherman shows a **plate** (Fig. 1, item 2) for **osteosynthesis**. *See Page 1, lines 21-27 and 79-82* ("Another object of the invention is to provide ... a **bone plate** [for] **maintaining the fractured bone** in alined (sic) position." "...Figure 1 [shows] a **bone plate**..."") (emphasis added).

It should be noted that for at least two reasons, the term "compression" in the preamble, is non-limiting. First, it merely recites the intended use of a structure because nothing in the body of the claim relies on it for completeness, but rather the limitations in the body are able to stand alone. *MPEP 211.02; In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976)*. Second, under the doctrine of claim differentiation, if "compression" is to be given weight (i.e., that there are self-compressing screw holes), then dependent claim 4 (requiring a screw hole to be a self-compressing screw hole) is superfluous. An interpretation that renders the dependent claim superfluous is "presumptively unreasonable." *See Beachcombers, International, inc v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1161 (Fed. Cir. 1994)*. Accordingly, "compression" is nonlimiting.



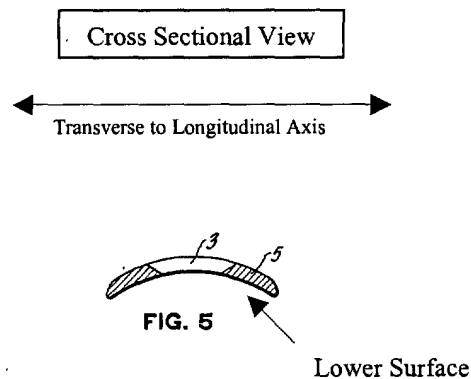
“said plate having a longitudinal axis, an upper surface, a lower surface and a plurality of screw holes spaced in the direction of the longitudinal axis,”

Sherman shows the plate (Fig. 1, item 2) having a longitudinal axis (Fig. 1, lengthwise dimension), an upper surface (Fig. 5, outer surface of plate), a lower surface (Fig. 5, surface toward bone) and a plurality of screw holes (Fig. 1, item 3) spaced in the direction of the longitudinal axis. *See page 1, lines 54-59* (“[T]he bone plate 2 ... is provided with a series of holes 3, in which the screws are countersunk on the outer face of the plate... .”) (emphasis added).



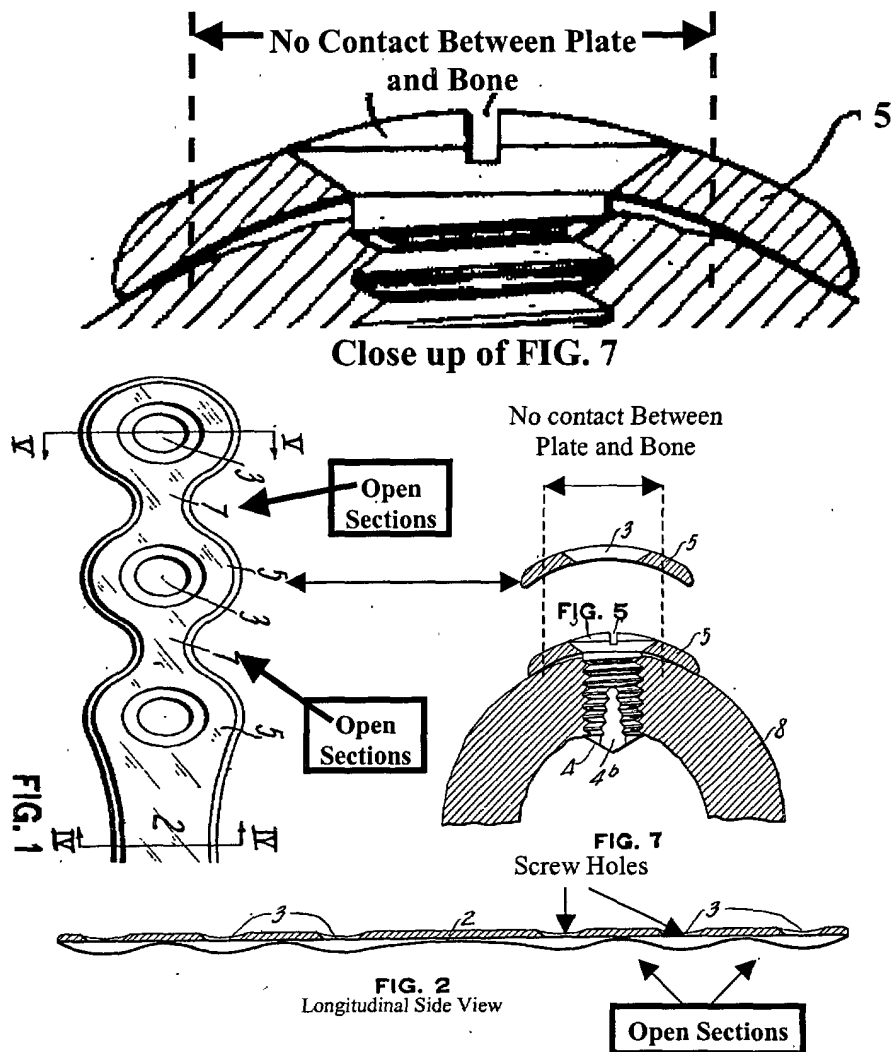
“said lower surface
being arched concavely
transversely to the
longitudinal axis of the
plate,”

Sherman shows the lower surface (Fig. 5) being arched concavely transversely to the longitudinal axis of the plate. *See p. 1, lines 34-39 and 72-73; lines 81-86* (“Fig. 5 is a [**transverse** section of the bone plate] on the line V-V of Fig. 1.” “In cross section the **plates are concave on the inner surface** thereof... .” “The curvature of the **concave inner surface of the bone plate** is preferably of a smaller radius than that of the bone 8 to which it is applied, so that when in place **the marginal side edges of the bone plate will bear against the outer surface of the bone... .**”) (emphasis added).



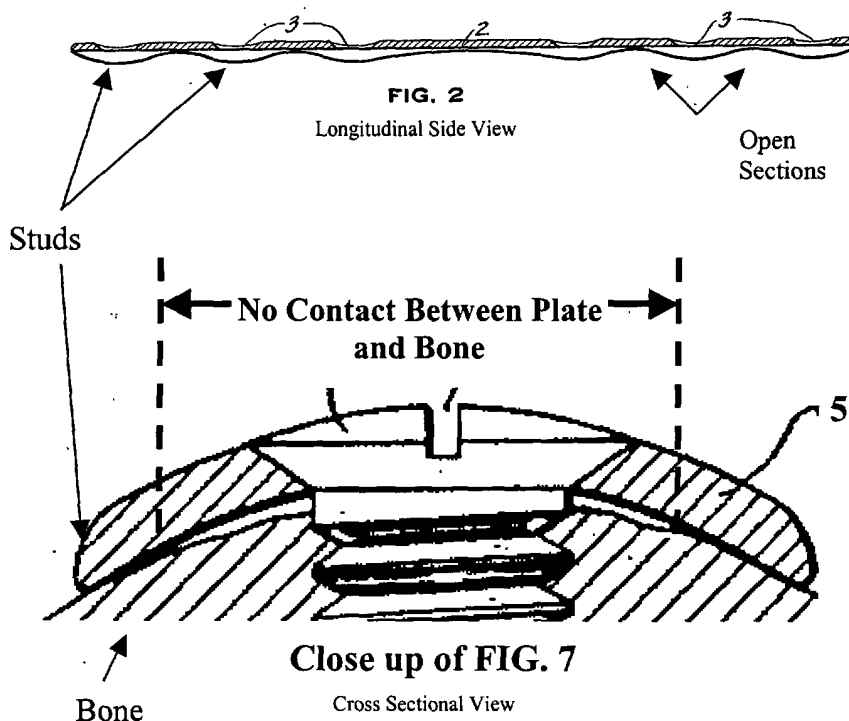
“in combination with
open sections along the
 side edges of the plate
 between the screw
 holes,”

Sherman shows the transverse arched concave lower surface of the plate in combination with open sections (Fig. 1, item 7) along the side edges of the plate between the screw holes (Fig. 1, item 3). (The concave plate with narrow width sections 7 results in open sections 7 along the side edges of the plate. See also Fig. 2. Further, the width of the narrow width section 7 is less than the diameter of the screw holes 3, therefore no contact exists with the bone at the open sections 7.) (Note: the term “open sections” is not explained, nor does it appear in the specification of the ‘036 patent.



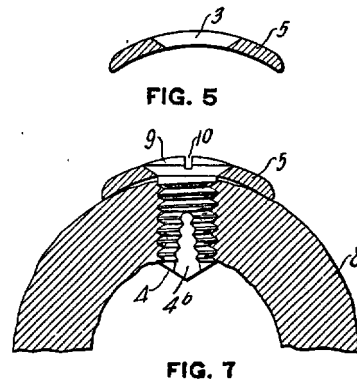
“said open sections, with the concave lower surface of the plate, forming **studs along the side edges of the lower surface for contact with a bone.**”

Sherman shows the open sections (Fig. 2, between screw holes 3), with the concave lower surface of the plate, forming studs along the side edges of the lower surface for contact with a bone (Fig. 7, the side edge of the concave plate in between the open sections projects down to contact the bone.) *See p. 1, lines 81-86* (“The curvature of the concave inner surface of the bone plate is preferably of a smaller radius than that of the bone 8 to which it is applied, so that when in place **the marginal side edges of the bone plate will bear against the outer surface of the bone...**”) (emphasis added).



"A compression plate according to claim 1 wherein said screw holes are conical and traverse said plate between said upper and lower surfaces such that the narrow end of the cone is towards the lower surface, said **holes adapted to receive screws having conical heads of a predetermined cone angle**, such that the plate will not slide down the heads of the screws."

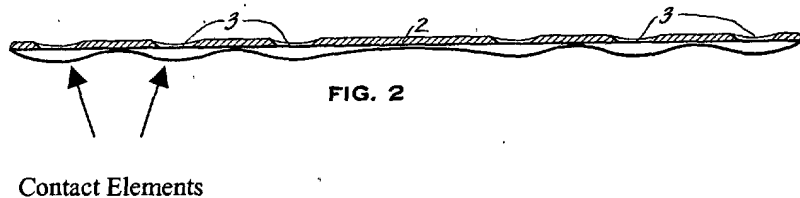
Sherman shows a plate (Fig. 5) according to claim 1 wherein the screw holes (Fig. 5, item 3) are conical and traverse said plate between said upper and lower surfaces such that the narrow end of the cone is towards the lower surface, said holes adapted to receive screws having conical heads of a predetermined cone angle, such that the plate will not slide down the heads of the screws. *See p. 1, lines 54-64* ("[T]he bone plate ... is provided with a series of holes 3, in which the screws are countersunk on the outer face of the plate and **the screws 4 are provided with countersunk heads of the same degree of angularity** so as to insure a neat fit between the contacting surfaces of the bone plate and the screws.") (emphasis added).



Claim 5**Sherman**

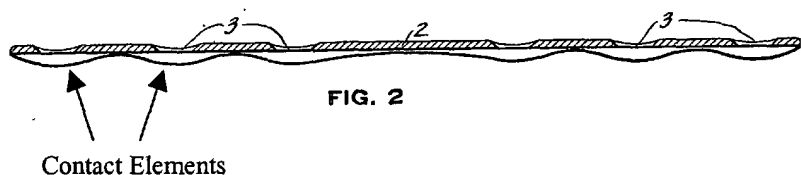
"A bone plate according to claim 1 wherein the **contact elements are less than 5% of the total area** of the lower surface of the plate."

Sherman shows a bone plate (Figs. 2) according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate. *See p. 1, lines 84-86, and p. 2, lines 52-54* ("[W]hen in place the **marginal side edges** of the bone plate will **bear against the outer surface of the bone.**" "The **length and width and the degree of curvature** in cross section of the plates **may be varied.**") (emphasis added).

**Claim 6****Sherman**

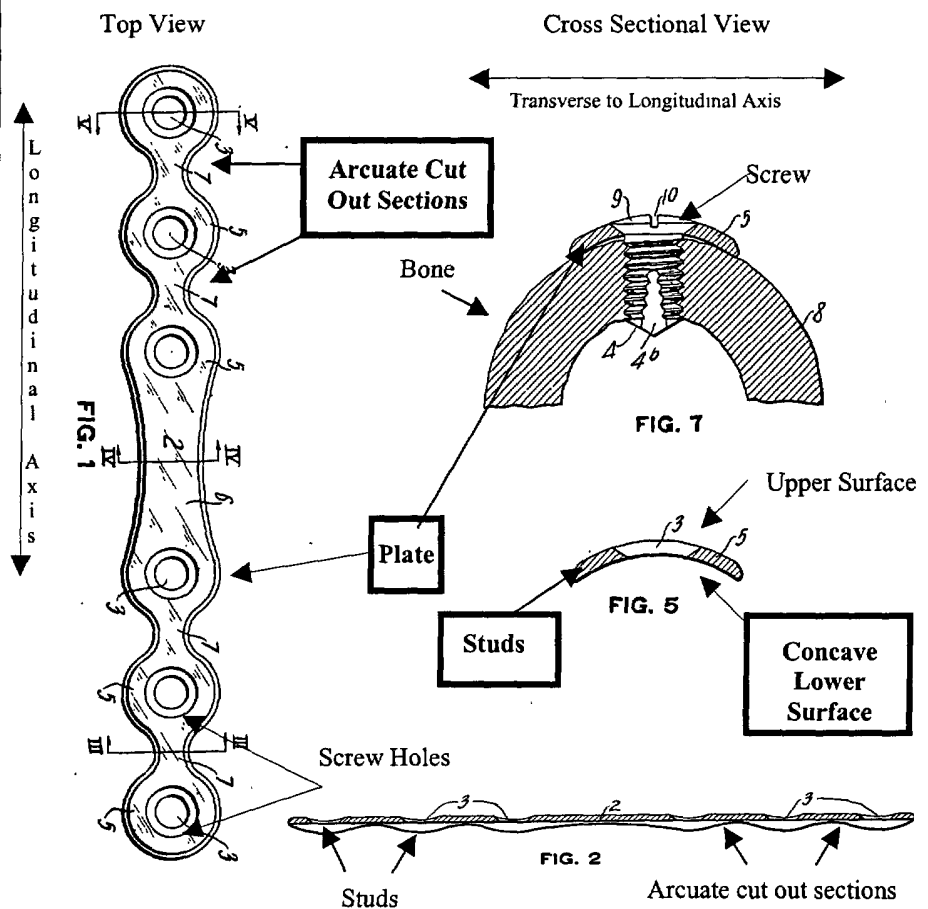
"A bone plate according to claim 1 wherein the **contact elements are less than 2% of the total area** of the lower surface of the plate."

Sherman shows a bone plate (Figs. 2) according to claim 1 wherein the contact elements are less than 2% of the total area of the lower surface of the plate. . *See p. 1, lines 84-86, and p. 2, lines 52-54* ("[W]hen in place the **marginal side edges** of the bone plate will **bear against the outer surface of the bone.**" "The **length and width and the degree of curvature** in cross section of the plates **may be varied.**") (emphasis added).



A compression plate for osteosynthesis, said **plate** having a longitudinal axis, an upper surface, a lower surface and a plurality of **screw holes** spaced in the direction of the longitudinal axis, said **lower surface being arched concavely, transversely to the longitudinal axis of the plate**, in combination with **arcuate cut out sections between the holes**, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming **studs for bone contact.**"

As detailed above, Sherman shows a plate (2) for osteosynthesis, said plate having a longitudinal axis, an upper surface, a lower surface and a plurality of screw holes (3) spaced in the direction of the longitudinal axis, said lower surface being arched concavely, transversely to the longitudinal axis of the plate, in combination with arcuate cut out sections between the holes, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming studs for bone contact. The word "compression" in the preamble is merely a statement of intended use, and therefore not limiting.



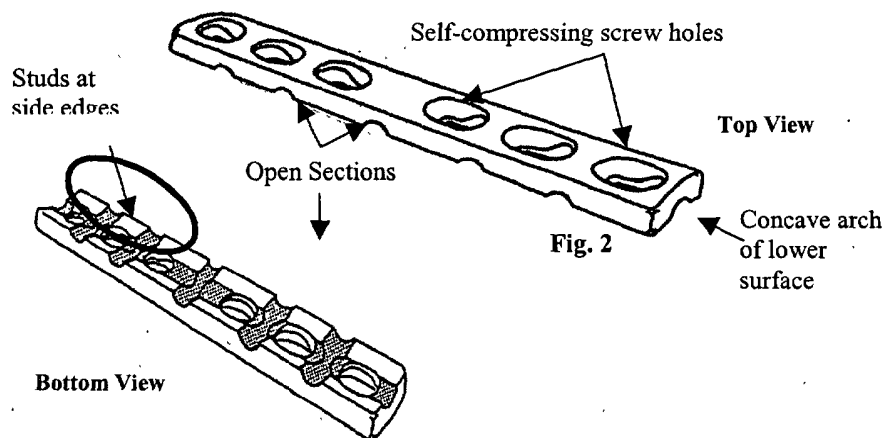
Claims 1, 2, 4, 5, 6, 9, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the Vattolo Dissertation ("Vattolo").

Claim 1

Sherman

"A **compression plate** for **osteosynthesis**, said plate having a longitudinal axis, an upper surface, a lower surface and a **plurality of screw holes** spaced in the direction of the longitudinal axis, said **lower surface being arched concavely transversely** to the longitudinal axis of the plate, in combination with **open sections** along the side edges of the plate between the screw holes, said open sections, with the concave lower surface of the plate, forming **studs along the side edges of the lower surface for contact with a bone.**"

Vattolo shows a **compression plate** (see Fig. 2) for osteosynthesis. *See title, cover page* ("The Effect of Grooves in **Osteosynthesis Plates** on the Restructuring of the **Corticalis**") (emphasis added). *See Fig. 2* (self-compressing screw holes). Vattolo shows the lower surface being **arched concavely** in combination with **open sections** along the sides between the screw holes, forming studs for contact with the bone. *See p.6, line 23 to p.7, line 21* ("Jorger ... shows that by **reducing the contact surface between plate and bone** the circulatory disruption can be decreased ... The grooved plates studied by Jorger ... were originally designed by Brunner ... for mechanical reasons... By **putting grooves between the screw holes**, Brunner achieved equal rigidity over the whole plate. **With an additional groove along the axis of the screw holes**, the contact area between the plate and the bone can be further reduced ... Through the greatest (sic) possible **reduction in the contact surface of the plate, the blood supply of the corticalis is affected most favorably...**") (emphasis added).

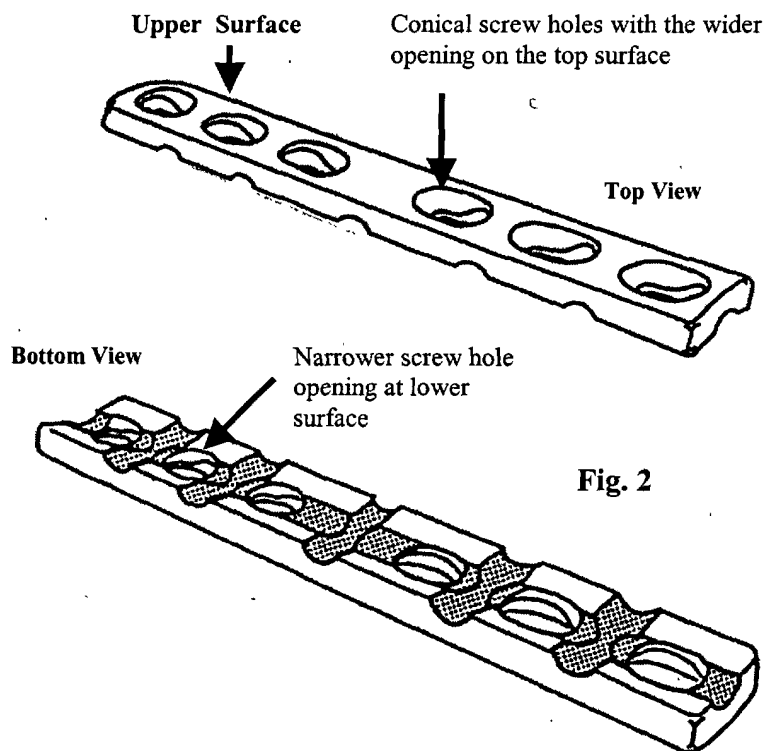


Claim 2

“A compression plate according to claim 1 wherein said screw holes are conical and traverse said plate between said upper and lower surfaces such that the narrow end of the cone is towards the lower surface, said holes adapted to receive screws having conical heads of a predetermined cone angle, such that the plate will not slide down the heads of the screws.”

Vattolo

Vattolo shows a compression plate (Fig. 2) according to claim 1 wherein the screw holes are **conical** and traverse said plate between said upper and lower surfaces such that the **narrow end of the cone is towards the lower surface**, the holes adapted to receive screws having conical heads of a predetermined cone angle, such that the plate will not slide down the heads of the screws.

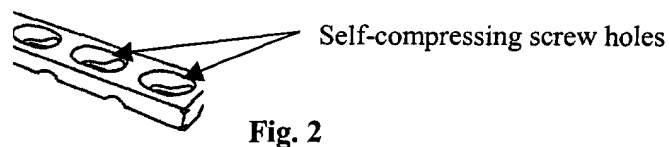


Claim 4

“A bone plate according to claim 1, wherein one screw hole is a **self-compressing screw hole**.”

Vattolo

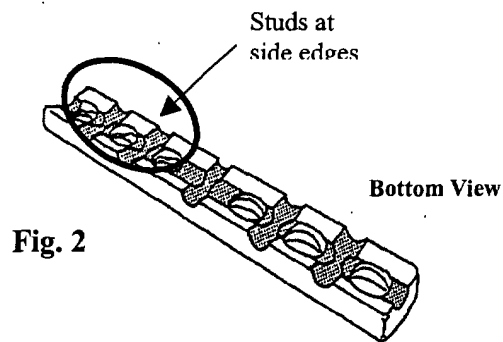
Vattolo shows a **self-compressing screw hole**. See Fig. 2.



Claim 5**Vattolo**

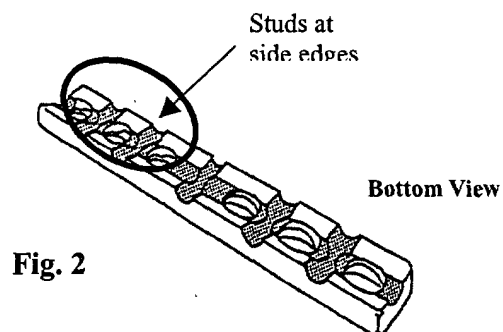
"A bone plate according to claim 1 wherein the **contact elements are less than 5% of the total area of the lower surface of the plate.**"

Vattolo shows a bone plate (Fig. 2) according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate. *See p. 7, lines 18-21. Through the greates (sic) possible reduction in the contact surface of the plate, the blood supply of the corticalis is affected most favorably...*" (emphasis added).

**Claim 6****Vattolo**

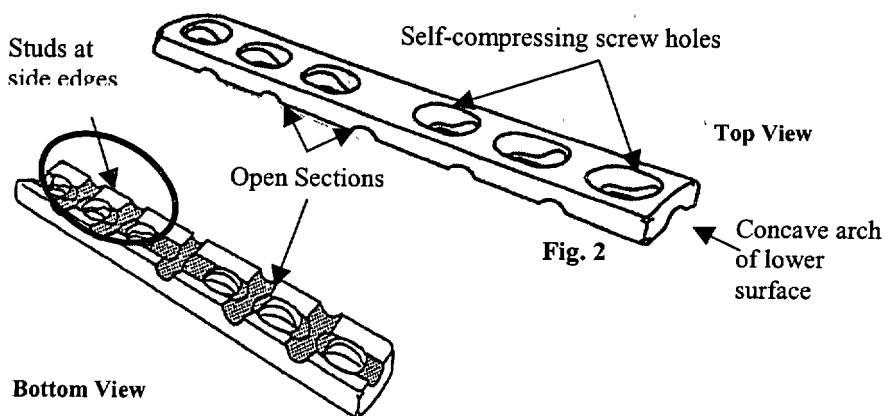
"A bone plate according to claim 1 wherein the **contact elements are less than 2% of the total area of the lower surface of the plate.**"

Vattolo shows a bone plate (Fig. 2) according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate. *See p. 7, lines 18-21. Through the greates (sic) possible reduction in the contact surface of the plate, the blood supply of the corticalis is affected most favorably...*" (emphasis added).



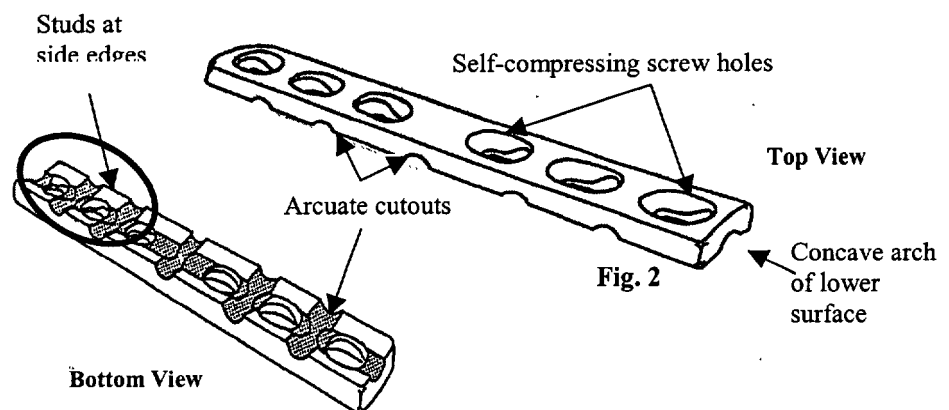
“A bone plate assembly comprising a compression **bone plate** and a plurality of bone screws for attaching said plate to a bone, said plate having a longitudinal axis, an upper surface, a lower surface and a plurality of screw holes for receiving said screws, spaced in the direction of the longitudinal axis, said lower surface being arched concavely transversely to the longitudinal axis of the plate, in combination with open sections along the side edges of the plate between the screw holes, said open sections, with the **concave undersurface** of the plate, forming **studs** for bone contact along the side edges of the lower surface of the plate.”

As detailed above, Vattolo shows a bone plate assembly comprising a **compression bone plate** and a plurality of bone screws for attaching the plate to a bone, the plate having a longitudinal axis, an upper surface, a lower surface and a plurality of screw holes for receiving the screws, spaced in the direction of the longitudinal axis, the **lower surface being arched concavely** transversely to the longitudinal axis of the plate, in combination with **open sections along the side edges** of the plate between the screw holes, the open sections, with the concave undersurface of the plate, **forming studs** for bone contact along the side edges of the lower surface of the plate. See p.6, line 23 to p.7, line 21 (“Jorger ... shows that by **reducing the contact surface between plate and bone** the circulatory disruption can be decreased ... The grooved plates studied by Jorger ... were originally designed by Brunner ... for mechanical reasons... By **putting grooves between the screw holes**, Brunner achieved equal rigidity over the whole plate. **With an additional groove along the axis of the screw holes**, the contact area between the plate and the bone can be further reduced ... Through the greatest (sic) possible **reduction in the contact surface of the plate, the blood supply of the corticalis is affected most favorably...**”; p. 8, line 18-19 (“We used ... corticalis screws ...”) (emphasis added).



A compression plate for osteosynthesis, said **plate** having a longitudinal axis, an upper surface, a lower surface and a plurality of **screw holes** spaced in the direction of the longitudinal axis, said **lower surface being arched concavely**, transversely to the longitudinal axis of the plate, in combination with **arcuate cut out sections between the holes**, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming **studs for bone contact**."

As detailed above, Vattolo shows a **compression plate for osteosynthesis**, the plate having a longitudinal axis, an upper surface, a lower surface and a plurality of screw holes spaced in the direction of the longitudinal axis, the **lower surface being arched concavely**, transversely to the longitudinal axis of the plate, in combination with **arcuate cut out sections between the holes**, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming **studs** for bone contact.. See p.6, line 23 to p.7, line 21 ("Jorger ... shows that by **reducing the contact surface between plate and bone** the circulatory disruption can be decreased ... The grooved plates studied by Jorger ... were originally designed by Brunner ... for mechanical reasons... By **putting grooves between the screw holes**, Brunner achieved equal rigidity over the whole plate. **With an additional groove along the axis of the screw holes**, the contact area between the plate and the bone can be further reduced ... Through the greatest (sic) possible **reduction in the contact surface of the plate**, the blood supply of the corticalis is affected most favorably..." (emphasis added).



Claims 1, 5, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 4,364,382 ("Mennen")

Claim 1

Mennen

"A compression plate for osteosynthesis,"

Mennen shows a plate for osteosynthesis (Fig. 1, item 10). *See col. 1, lines 34-35* ("According to the invention there is provided an internal fixation device for a bone fracture, the device comprising a metallic plate.... ." (emphasis added).

It should be noted that for at least two reasons, the term "compression" in the preamble, is non-limiting. First, it merely recites the intended use of a structure because nothing in the body of the claim relies on it for completeness, but rather the limitations in the body are able to stand alone. *MPEP 211.02; In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976)*. Second, under the doctrine of claim differentiation, if "compression" is to be given weight (i.e., that there are self-compressing screw holes), then dependent claim 4 (requiring a screw hole to be a self-compressing screw hole) is superfluous. An interpretation that renders the dependent claim superfluous is "presumptively unreasonable." *See Beachcombers, International, inc v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1161 (Fed. Cir. 1994)*. Accordingly, "compression" is nonlimiting.

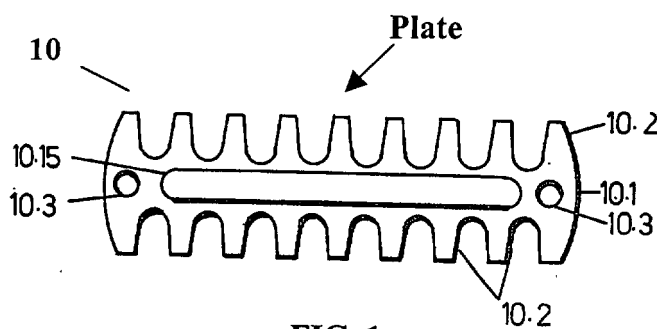



FIG. 1

	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	2101	2102	2103	2104	2105	2106	2107	2108	2109	2110	2111	2112	2113	2114	2115	2116	2117	2118	2119	2120	2121	2122	2123	2124	2125	2126	2127	2128	2129	2130	2131	2132	2133	2134	2135	2136	2137	2138	2139	2140	2141	2142	2143	2144	2145	2146	2147	2148	2149	2150	2151	2152	2153	2154	2155	2156	2157	2158	2159	2160	2161	2162	2163	2164	2165	2166	2167	2168	2169	2170	2171	2172	2173	2174	2175	2176	2177	2178	2179	2180	2181	2182	2183	2184	2185	2186	2187	2188	2189	2190	2191	2192	2193	2194	2195	2196	2197	2198	2199	2200	2201	2202	2203	2204	2205	2206	2207	2208	2209	2210	2211	2212	2213	2214	2215	2216	2217	2218	2219	2220	2221	2222	2223	2224	2225	2226	2227	2228	2229	2230	2231	2232	2233	2234	2235	2236	2237	2238	2239	2240	2241	2242	2243	2244	2245	2246	2247	2248	2249	2250	2251	2252	2253	2254	2255	2256	2257	2258	2259	2260	2261	2262	2263	2264	2265	2266	2267	2268	2269	2270	2271	2272	2273	2274	2275	2276	2277	2278	2279	2280	2281	2282	2283	2284	2285	2286	2287	2288	2289	2290	2291	2292	2293	2294	2295	2296	2297	2298	2299	2300	2301	2302	2303	2304	2305	2306	2307	2308	2309	2310	2311	2312	2313	2314	2315	2316	2317	2318	2319	2320	2321	2322	2323	2324	2325	2326	2327	2328	2329	2330	2331	2332	2333	2334	2335	2336	2337	2338	2339	2340	2341	2342	2343	2344	2345	2346	2347	2348	2349	2350	2351	2352	2353	2354	2355	2356	2357	2358	2359	2360	2361	2362	2363	2364	2365	2366	2367	2368	2369	2370	2371	2372	2373	2374	2375	2376	2377	2378	2379	2380	2381	2382	2383	2384	2385	2386	2387	2388	2389	2390	2391	2392	2393	2394	2395	2396	2397	2398	2399	2400	2401	2402	2403	2404	2405	2406	2407	2408	2409	2410	2411	2412	2413	2414	2415	2416	2417	2418	2419	2420	2421	2422	2
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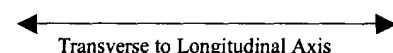
Top View



Transverse to Longitudinal Axis

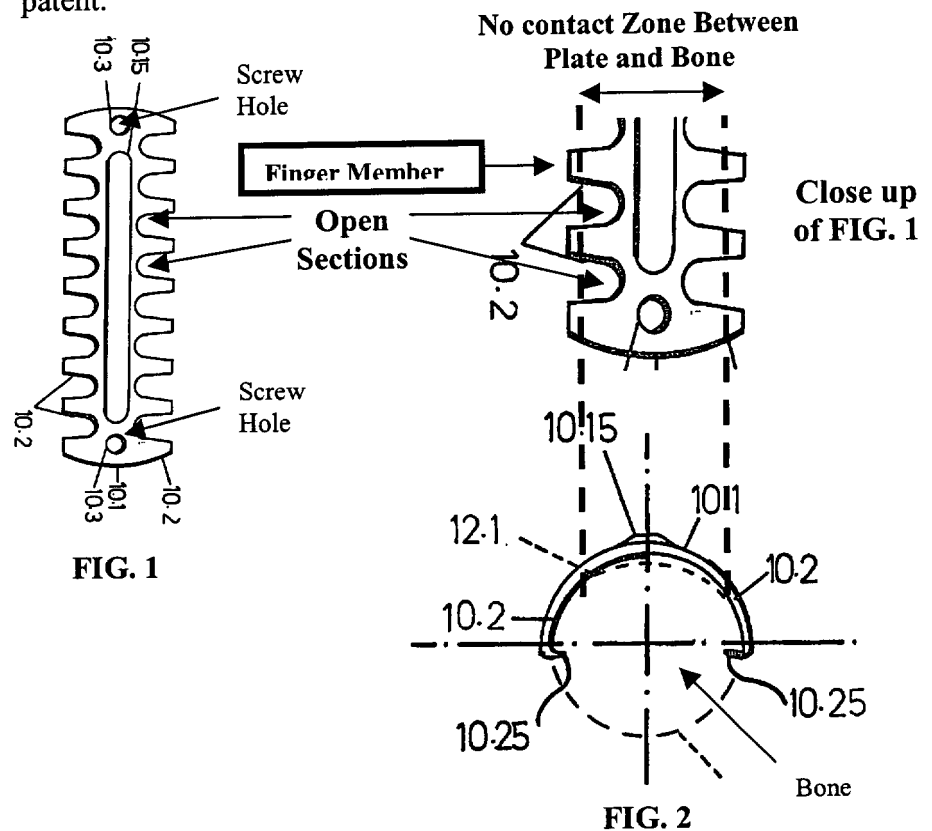
[illegible]

Cross Sectional View



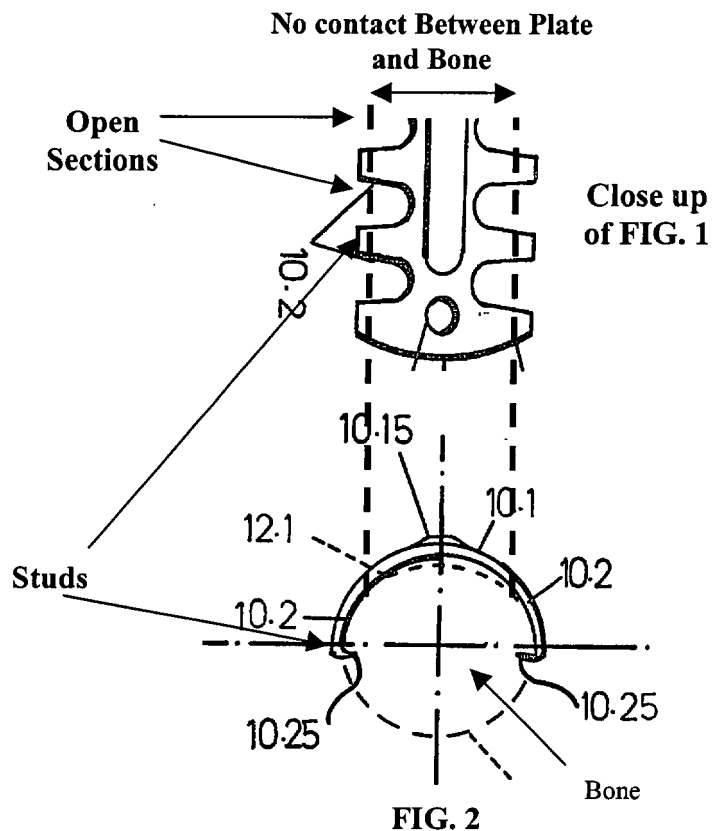
“in combination with
open sections along the
side edges of the plate
between the screw
holes,”

Mennen shows the transverse arched concave lower surface of the plate (Fig. 2) in combination with open sections along the side edges of the plate between the screw holes (Fig. 1, items 10.3). (The concave plate has narrow width sections between finger members (Fig. 1, items 10.2) that **results in open sections** along the side edges of the plate. *See col. 1, lines 62-62* (“[E]ach finger member having an edge fastening formation at the extremity thereof.”) (emphasis added). (Note: the term “open sections” is not explained, nor does it appear in the specification of the ‘036 patent.



“said open sections, with the concave lower surface of the plate, forming studs along the side edges of the lower surface for contact with a bone.”

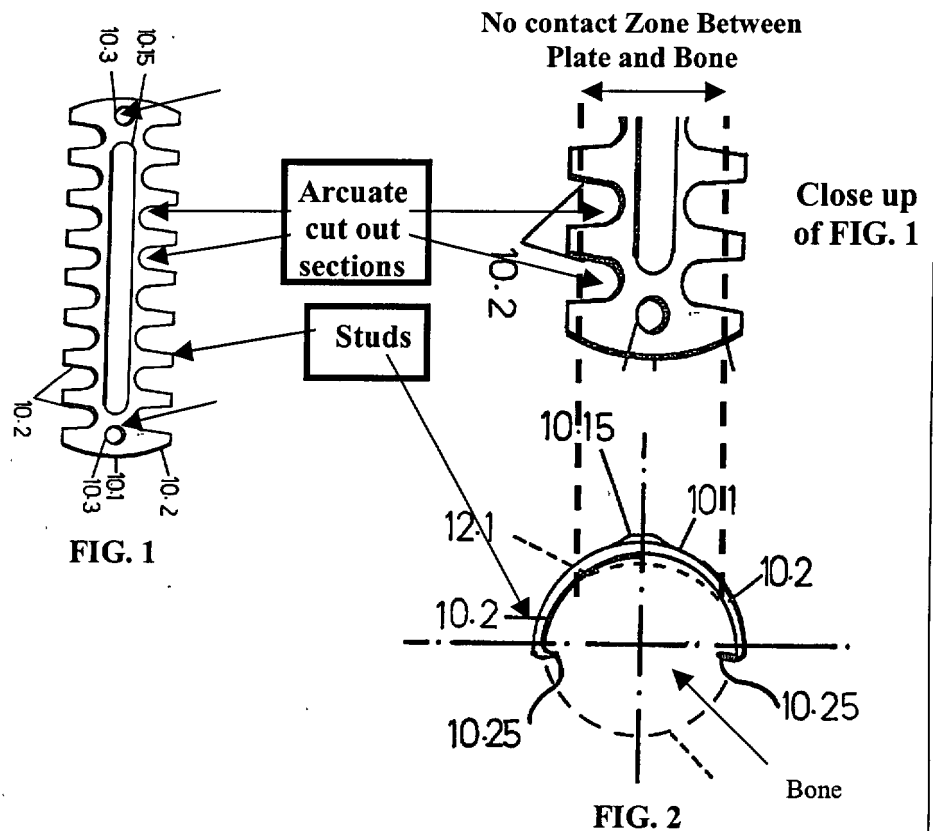
Mennen shows the open sections (Fig. 1), with the concave lower surface of the plate (Fig. 1), forming studs along the side edges of the lower surface for contact with a bone. *See col. 1, lines 62-62; col. 2, lines 65-68* (“[E]ach finger member having an edge fastening formation at the extremity thereof.”) (“The **extremity of each finger member 10.2 is bent inwardly** to provide a sharpened fastening formation 10.25 pointing inwardly... .”) (emphasis added).



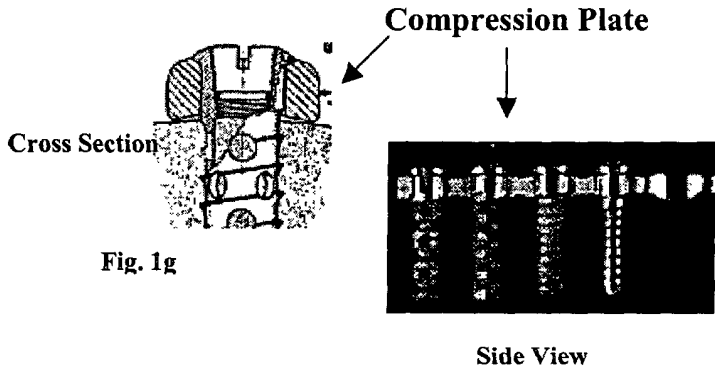
Claim 5	Mennen
<p>“A bone plate according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate.”</p>	<p>Mennen shows a bone plate according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate. <i>See col. 1, lines 62-62; col. 4, lines 27-30</i> (“[E]ach finger member having an edge fastening formation at the extremity thereof.”) (“The plate is designed so that only the immediate vicinity where the fastening formation 10.25 is inserted and penetrates into the bone, is periosteal circulation impaired...”) (emphasis added).</p>
Claim 6	Mennen
<p>“A bone plate according to claim 1 wherein the contact elements are less than 2% of the total area of the lower surface of the plate.”</p>	<p>Mennen shows a bone plate according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate. <i>See col. 1, lines 62-62; col. 4, lines 27-30</i> (“[E]ach finger member having an edge fastening formation at the extremity thereof.”) (“The plate is designed so that only the immediate vicinity where the fastening formation 10.25 is inserted and penetrates into the bone, is periosteal circulation impaired...”) (emphasis added).</p>

“A compression **plate** for osteosynthesis, said plate having a longitudinal axis, an upper surface, a lower surface and a plurality of **screw holes** spaced in the direction of the longitudinal axis, said **lower surface being arched concavely**, transversely to the longitudinal axis of the plate, in combination with **arcuate cut out sections between the holes**, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming **studs** for bone contact.”

As detained above, Mennen shows a plate for osteosynthesis, the plate (Figs. 1 and 2) having a longitudinal axis, an upper surface, a lower surface and a plurality of screw holes (10.3) spaced in the direction of the longitudinal axis, said lower surface being arched concavely, transversely to the longitudinal axis of the plate, in combination with arcuate cut out sections between the holes, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming studs for bone contact. The word “compression” in the preamble is merely a statement of intended use, and therefore not limiting.



Claims 1, 5, 6, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by the Sutter article dated 1984 ("Sutter Article").

Claim 1	Sutter Article
<p>"A compression plate for osteosynthesis,"</p>	<p>The Sutter Article shows a plate for osteosynthesis (Fig. 1g, Fig. 6, Fig. 7). <i>See p. 5, line 15</i> ("The reconstruction plate") (emphasis added).</p> <p>It should be noted that for at least two reasons, the term "compression" in the preamble, is non-limiting. First, it merely recites the intended use of a structure because nothing in the body of the claim relies on it for completeness, but rather the limitations in the body are able to stand alone. <i>MPEP 211.02; In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976)</i>. Second, under the doctrine of claim differentiation, if "compression" is to be given weight (i.e., that there are self-compressing screw holes), then dependent claim 4 (requiring a screw hole to be a self-compressing screw hole) is superfluous. An interpretation that renders the dependent claim superfluous is "presumptively unreasonable." <i>See Beachcombers, International, inc v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1161 (Fed. Cir. 1994)</i>. Accordingly, "compression" is nonlimiting.</p> <div data-bbox="646 1360 1446 1724">  <p data-bbox="646 1486 797 1514">Cross Section</p> <p data-bbox="743 1604 821 1631">Fig. 1g</p> <p data-bbox="1377 1562 1446 1589">Fig. 6</p> <p data-bbox="1117 1703 1230 1730">Side View</p> </div>

“said plate having a longitudinal axis, an upper surface, a lower surface and a **plurality of screw holes** spaced in the direction of the longitudinal axis,”

The Sutter Article shows the plate having a longitudinal axis (Fig. 6), an upper surface, a lower surface and a plurality of screw holes spaced in the direction of the longitudinal axis. See p.5, line 10 (“...[S]olid screw types may be used (Fig. 6: C,D).”) (emphasis added).

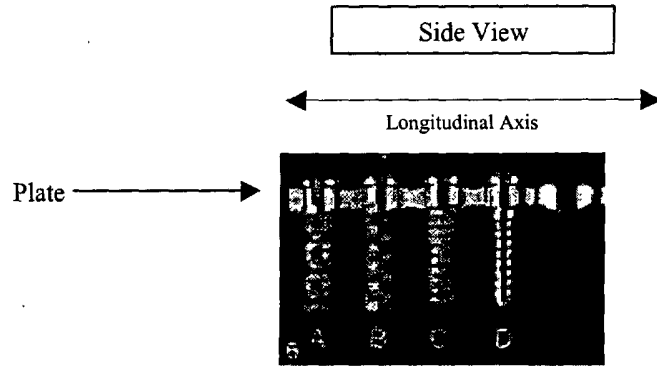


FIG. 6

said lower surface being **arched concavely** transversely to the longitudinal axis of the plate,”

The Sutter Article shows the lower surface being **arched concavely transversely** to the longitudinal axis of the plate (Fig. 1g).

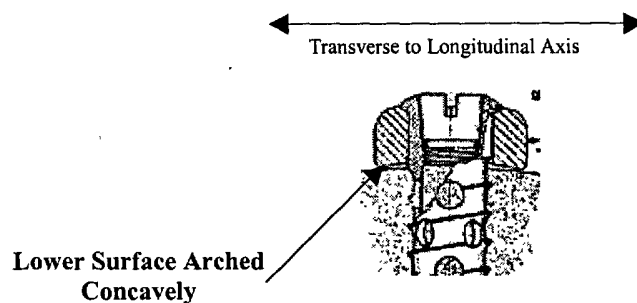


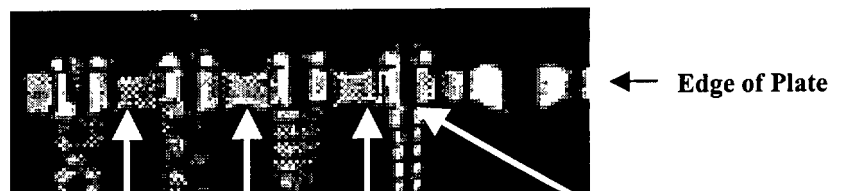
FIG. 1g

“in combination with **open sections** along the side edges of the plate **between the screw holes**, said open sections, with the concave lower surface of the plate, forming **studs along the side edges of the lower surface for contact with a bone.**”

The Sutter Article shows the transverse arched concave lower surface of the plate (Fig. 1g) in combination with open sections along the side edges of the plate between the screw holes (Fig. 6). See p.5, lines 21-23 (“On the titanium reconstruction plate ... **grooves which were radial** on all sides were **machined in between the cylindrical 4.5 mm borings** [screw holes]”) (emphasis added). (Note: the term “open sections” is not explained, nor does it appear in the specification of the ‘036 patent.) The Sutter Article further shows the open sections, with the concave lower surface of the plate, forming studs along the side edges of the lower surface for contact with a bone (Fig. 1g).

Side View

Fig. 6



Open Sections Between Screw Holes

Studs Contact the Bone

Cross Section

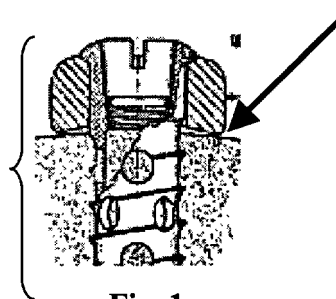
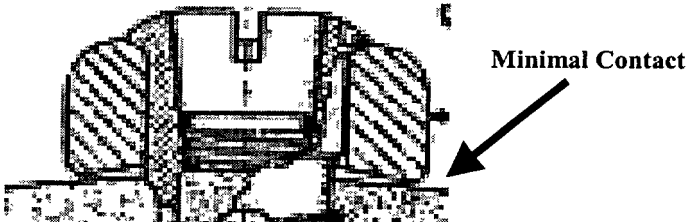
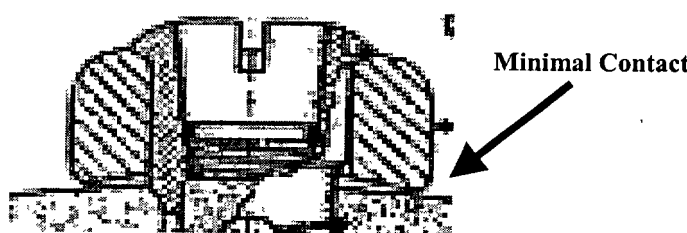


Fig. 1g

Claim 5	Sutter Article
<p>“A bone plate according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate.”</p>	<p>The Sutter Article shows a bone plate according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate. <i>See Fig. 1g, p.5, line 25</i> (“The radius of the grooves was made as large as possible ...”) (emphasis added).</p> 
Claim 6	Sutter Article
<p>“A bone plate according to claim 1 wherein the contact elements are less than 2% of the total area of the lower surface of the plate.”</p>	<p>The Sutter Article shows a bone plate according to claim 1 wherein the contact elements are less than 5% of the total area of the lower surface of the plate. <i>See Fig. 1g, p.5, line 25</i> (“The radius of the grooves was made as large as possible ...”) (emphasis added).</p> 

Claim 14

Sutter Article

“A compression **plate for osteosynthesis**, said plate having a longitudinal axis, an upper surface, a lower surface and a plurality of **screw holes** spaced in the direction of the longitudinal axis, said **lower surface being arched concavely**, transversely to the longitudinal axis of the plate, in combination with **arcuate cut out sections between the holes**, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming **studs** for bone contact.”

As detailed above, the Sutter Article shows a **plate for osteosynthesis**, the plate having a longitudinal axis, an upper surface, a lower surface and a plurality of screw holes spaced in the direction of the longitudinal axis (Fig. 6), the lower surface being arched concavely, transversely to the longitudinal axis of the plate (Fig. 1g), in combination with arcuate cut out sections between the holes, the intersection of surfaces formed by said cut out sections and the concave lower surface of the plate forming studs for bone contact. *See p.5, lines 21-23* (“On the titanium reconstruction **plate ... grooves which were radial on all sides were machined in between the cylindrical 4.5 mm borings [screw holes]**”) (emphasis added). The word “compression” in the preamble is merely a statement of intended use, and therefore not limiting.

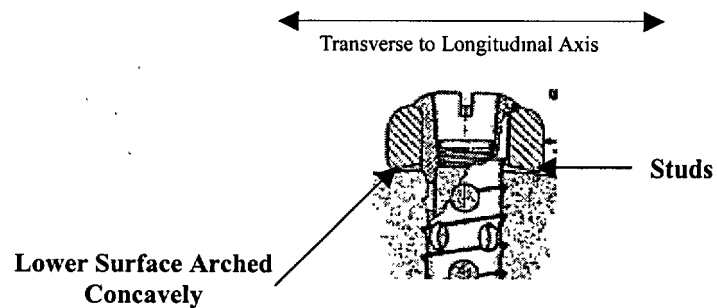


FIG. 1g

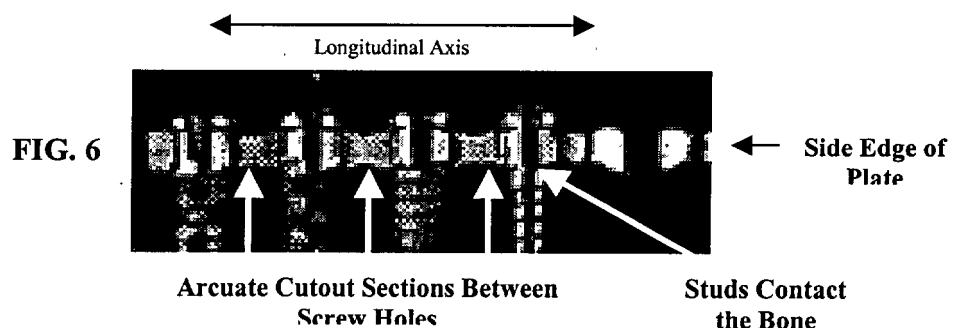


FIG. 6

**Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by
USP 4,263,904 ("Judet").**

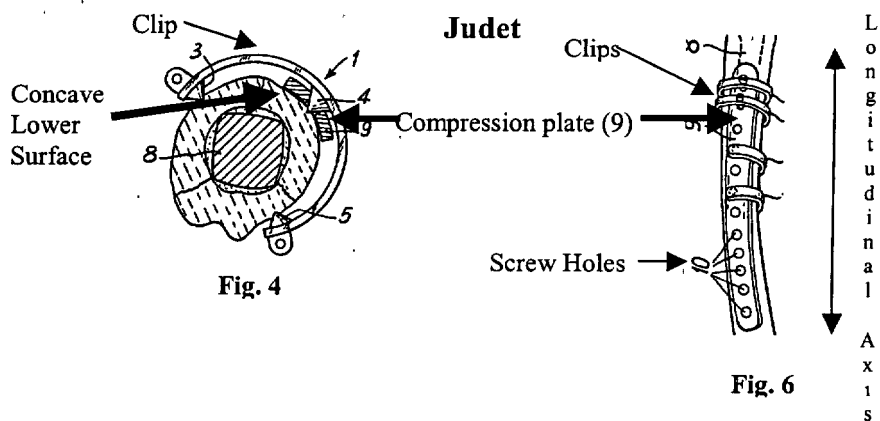
Claim 15

Judet

"A compression **plate** for osteosynthesis, said plate having a longitudinal axis, an upper surface, a concave lower surface, side walls joining said upper and lower surfaces and a plurality of **screw holes** spaced in the direction of said longitudinal axis, in combination with a plurality of **clips** removably attached to said plate and spaced along the length of said plate, "

Judet shows a **plate (9)** for osteosynthesis, the plate having a longitudinal axis, an upper surface, a concave lower surface (**Fig. 4**), side walls joining the upper and lower surfaces and a plurality of screw holes (**10**) spaced in the direction of the longitudinal axis, in combination with a plurality of clips (**1**) removably attached to the plate and spaced along the length of the plate.

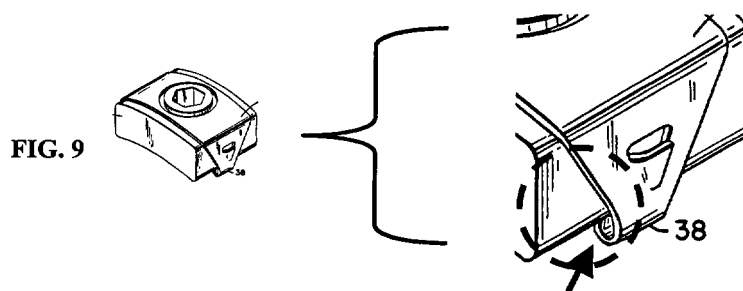
It should be noted that for at least two reasons, the term "compression" in the preamble, is non-limiting. First, it merely recites the intended use of a structure because nothing in the body of the claim relies on it for completeness, but rather the limitations in the body are able to stand alone. *MPEP 211.02; In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976)*. Second, under the doctrine of claim differentiation, if "compression" is to be given weight (i.e., that there are self-compressing screw holes), then dependent claim 4 (requiring a screw hole to be a self-compressing screw hole) is superfluous. An interpretation that renders the dependent claim superfluous is "presumptively unreasonable." See *Beachcombers, International, inc v. WildeWood Creative Products, Inc.*, 31 F.3d 1154, 1161 (Fed. Cir. 1994). Accordingly, "compression" is nonlimiting.



“each of said clips extending across the upper surface of the plate, down the side walls thereof and having elements extending below the lower surface of said plate to provide a limited area of bone contact.”

Judet shows each of the clips extending across the upper surface of the plate, down the side walls thereof. It should be noted that the ‘036 Patent does not discuss “down the side walls” except for what is shown in Fig. 9. Fig. 9 shows the clip extending downward but away from the side wall. Judet shows a clip curving down past the side walls (Fig. 4). Judet also shows elements (3,4,5) extending below the lower surface of said plate to provide a limited area of bone contact.

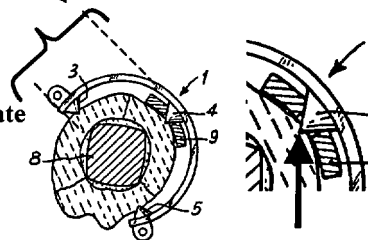
The ‘036 Patent



‘036 Patent clips project down and away from the side wall. Judet clips project down & away also.

Portion of clip extending down side wall of plate

Fig. 4



Contact element extends below plate into bone

Judet

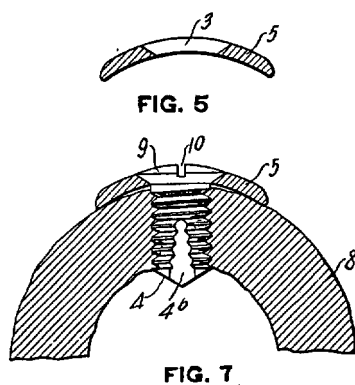
Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter Article in view of Sherman.

Claim 2

Sutter Article and Sherman

“A compression plate according to claim 1 wherein said screw holes are **conical** and traverse said plate between said upper and lower surfaces such that the **narrow end of the cone is towards the lower surface**, said holes adapted to receive screws having conical heads of a predetermined cone angle, such that the plate will not slide down the heads of the screws.”

The Sutter Article shows the plate according to claim 1. Sherman teaches screw holes (Fig. 5, item 3) being conical and traverse the plate between the upper and lower surfaces such that the narrow end of the cone is towards the lower surface, the holes adapted to receive screws having conical heads of a predetermined cone angle, such that the plate will not slide down the heads of the screws. *See p. 1, lines 54-64* (“[T]he bone plate ... is provided with a series of holes 3, in which the screws are countersunk on the outer face of the plate and **the screws 4 are provided with countersunk heads of the same degree of angularity** so as to insure a neat fit between the contacting surfaces of the bone plate and the screws.”) (emphasis added). It would have been obvious to one of ordinary skill in the art to use screws with conical heads as taught by Sherman to securely attach the plate to the bone.

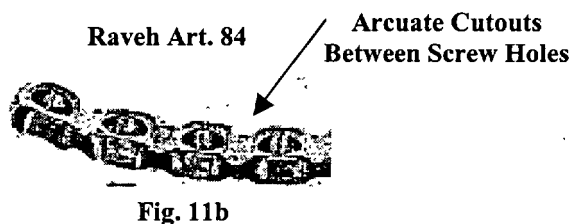


Claims 1, 2, 5, 6, 9, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of the Vattolo dissertation dated 1986 ("Vattolo").

As detailed above, Sherman shows all the elements of claims 1, 2, 5, 6, 9, 13, and 14. Vattolo teaches that it was well known in the art that **compression plates** for osteosynthesis having reduced bone contact were previously designed that way for mechanical reasons, but the design also resulted in increased blood circulation to the bone. Vattolo also teaches that it was well known in the art to place a cut out section along the longitudinal axis of the plate in combination with cut out sections made transversely between the screw holes to increase blood circulation. *See Vattolo, p.6, line 23 to 7, line 21* ("Jorger ... shows that by reducing the contact surface between plate and bone the circulatory disruption can be decreased ... The grooved plates studied by Jorger ... were originally designed by Brunner ... for mechanical reasons... **By putting grooves between the screw holes**, Brunner achieved equal rigidity over the whole plate. **With an additional groove along the axis of the screw holes**, the contact area between the plate and the bone can be further reduced ... Through the greatest (sic) possible **reduction in the contact surface of the plate**, the blood supply of the corticalis is affected **most favorably...**") (emphasis added).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of the Raveh article dated 1983 (Raveh Art. 83) or the Raveh article dated 1984 (Raveh Art. 84).

As detailed above, Sherman shows all the elements of claim 14. Raveh Art. 83 (Fig. 3) and Raveh Art. 84 (Fig. 1 and Fig. 11b) each further teaches arcuate cutouts made between the screw holes. It would have been obvious to one of ordinary skill in the art to combine these teachings such that the cutouts are between the screw holes and not directly altering the screw holes.

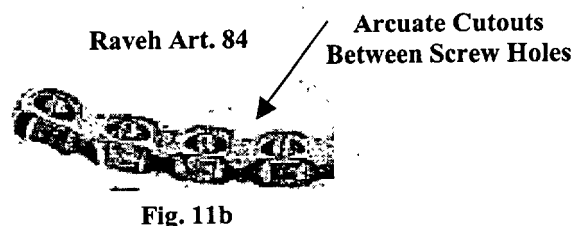


Claims 1, 5, 6, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo.

As detailed above, Mennen shows all the elements of claims 1, 5, 6, 9, and 14. Vattolo teaches that it was well known in the art that **compression plates** for osteosynthesis having reduced bone contact were previously designed that way for mechanical reasons, but the design also resulted in increased blood circulation to the bone. Vattolo also teaches that it was well known in the art to place a cut out section along the longitudinal axis of the plate in combination with cut out sections made transversely between the screw holes to increase blood circulation. *See Vattolo, p.6, line 23 to 7, line 21* ("Jorger ... shows that by reducing the contact surface between plate and bone the circulatory disruption can be decreased ... The grooved plates studied by Jorger ... were originally designed by Brunner ... for mechanical reasons... By **putting grooves between the screw holes**, Brunner achieved equal rigidity over the whole plate. **With an additional groove along the axis of the screw holes**, the contact area between the plate and the bone can be further reduced ... Through the greatest (sic) possible **reduction in the contact surface of the plate**, the blood supply of the corticalis is affected most **favorably...**") (emphasis added).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Raveh Art. 83 or Raveh Art. 84.

As detailed above, Mennen shows all the elements of claim 14. Raveh Art. 83 (Fig. 3) and Raveh Art. 84 (Fig. 1 and Fig. 11b) each further teaches arcuate cutouts made between the screw holes. It would have been obvious to one of ordinary skill in the art to combine these teachings such that the cutouts are between the screw holes and not directly altering the screw holes.



Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of USP 4,484,570 ("Sutter")

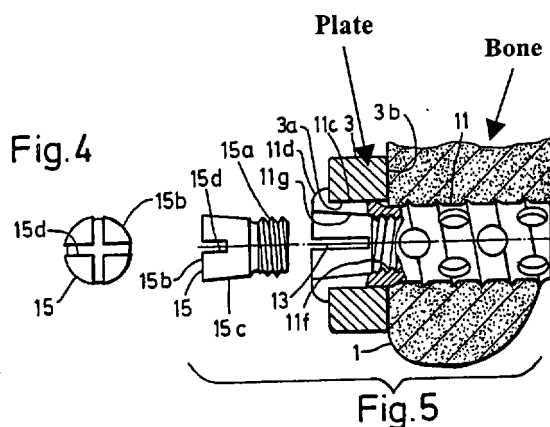
Claim 2

Sutter

"A compression plate according to claim 1 wherein said screw holes are **conical** and traverse said plate between said upper and lower surfaces such that the **narrow end of the cone is towards the lower surface**, said holes adapted to receive screws having conical heads of a predetermined cone angle, such that the plate will not slide down the heads of the screws."

As detailed above, Mennen shows a plate according to claim 1 wherein the screw holes (10.3) traverse the plate between the upper and lower surfaces. Sutter teaches the screw holes (11g) being conical and traversing the plate between the upper and lower surfaces such that the narrow end of the cone is towards the lower surface, the holes adapted to receive screws having conical heads (15c) of a predetermined cone angle, such that the plate will not slide down the heads of the screws. *See col. 5, lines 46-50* ("The **diameter of the conical surface 11g gradually decreases** from the head end face toward the tail end of the screw") (emphasis added). It would have been obvious to one of ordinary skill in the art to use screws with conical heads as taught by Sutter to securely attach the plate to the bone.

Sutter



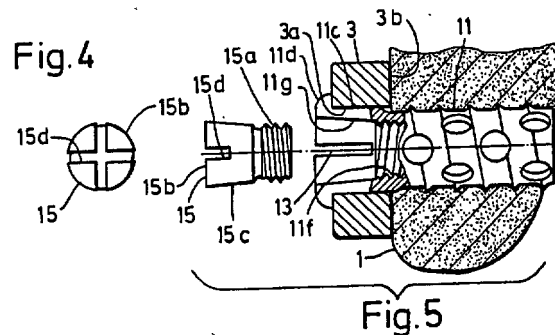
Claim 3

Sutter

“A bone plate according to claim 2 wherein the taper of the **conic section is in the range of 1:5 to 1:20.**”

As detailed above, Mennen shows the elements of claim 1 and Mennen in view of Sutter makes obvious the elements of claim 2. Sutter further teaches using a taper in the range of 1:5 to 1:20 for conical screw heads used in the bone plate art (a taper of 1:5 to 1:20 correlates roughly to a taper range of 3° to 11°). *See col. 5, lines 46-50* (“The diameter of the conical surface 11g gradually decreases from the head end face toward the tail end of the screw. **The angle enclosed between the screw axis 13 and the conical surface 11g is less than 10° for example 5°.**”) (emphasis added). Use of conical screw heads within the range of 1:5 to 1:20 (3° to 11°) is well within the level of ordinary skill in the screw art, as well as the bone plate art, as evidenced in Sutter.

Sutter



Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Sutter.

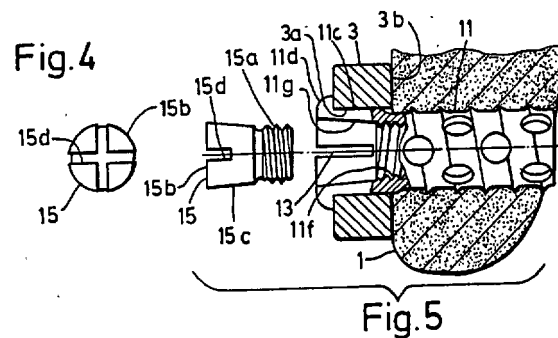
Claim 3

Sutter

"A bone plate according to claim 2 wherein the taper of the **conic section is in the range of 1:5 to 1:20.**"

As detailed above, Sherman shows the elements of claim 1 and 2. Sutter teaches using a taper in the range of 1:5 to 1:20 for conical screw heads used in the bone plate art (a taper of 1:5 to 1:20 correlates roughly to a taper range of 3° to 11°). *See col. 5, lines 46-50* ("The diameter of the conical surface 11g gradually decreases from the head end face toward the tail end of the screw. **The angle enclosed between the screw axis 13 and the conical surface 11g is less than 10° for example 5°.**") (emphasis added). Use of conical screw heads within the range of 1:5 to 1:20 (3° to 11°) is well within the level of ordinary skill in the screw art, as well as the bone plate art, as evidenced in Sutter.

Sutter



Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of USP Re. 31,628 ("Allgower").

Claim 4

Allgower

"A bone plate according to claim 1 wherein one screw hole is a self-compressing hole."

As detailed above, Sherman shows the elements of claim 1. Allgower teaches using self compressing screw holes in bone plates. The '036 Patent admits that self-compressing screw holes are known in the art and explicitly refers to Allgower for an enabling disclosure. *See Col. 4, lines 13-15* ("The plate may be constructed with one or more self-compressing screw holes of the type described in U.S. Pat. No. Re. 31,628.").

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of USP Re. 31,628 ("Allgower").

Claim 4

Allgower

"A bone plate according to claim 1 wherein one screw hole is a self-compressing hole."

As detailed above, Mennen shows the elements of claim 1. Allgower teaches using self compressing screw holes in bone plates. The '036 Patent admits that self-compressing screw holes are known in the art and explicitly refers to Allgower for an enabling disclosure. *See Col. 4, lines 13-15* ("The plate may be constructed with one or more self-compressing screw holes of the type described in U.S. Pat. No. Re. 31,628.").

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter Article in view of Allgower.

Claim 4

Allgower

"A bone plate according to claim 1 wherein one screw hole is a self-compressing hole."

As detailed above, the Sutter Article shows the elements of claim 1. Allgower teaches using self compressing screw holes in bone plates. The '036 Patent admits that self-compressing screw holes are known in the art and explicitly refers to Allgower for an enabling disclosure. *See Col. 4, lines 13-15* ("The plate may be constructed with one or more self-compressing screw holes of the type described in U.S. Pat. No. Re. 31,628.").

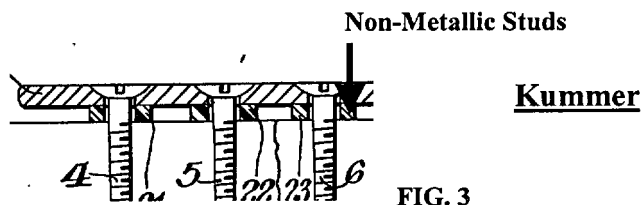
Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Kummer.

Claim 7

Kummer

"A **metallic** compression plate for osteosynthesis, said plate having a longitudinal axis, an upper surface, a lower surface, side walls joining said upper and lower surfaces and a plurality of screw holes spaced in the direction of said longitudinal axis, in combination with a plurality of individual, **non-metallic, support studs** attached to the lower surface of the plate at the sides of said lower surface and longitudinally spaced in the direction of said axis, said studs providing bone contact, at selected points along the sides of said plate, and spacing the central portion of the lower surface of said plate along the longitudinal axis from the bone."

As detailed above, Sherman shows a **metallic** plate for osteosynthesis ("compression" in preamble non-limiting), the plate having a longitudinal axis, an upper surface, a lower surface, side walls joining said upper and lower surfaces and a plurality of screw holes spaced in the direction of the longitudinal axis, in combination with a plurality of individual studs at the sides of the lower surface and longitudinally spaced in the direction of the axis, the studs providing bone contact, at selected points along the sides of the plate, and spacing the central portion of the lower surface of the plate along the longitudinal axis from the bone. *See Sherman, p. 1, lines 54-56* ("[T]he bone plate ... formed of vanadium **steel** alloy...") (emphasis added). Kummer teaches attaching non-metallic support studs to a metallic bone plate. *See Kummer, Fig. 3; Col. 2, lines 16-26; lines 8-12* ("The structural member is preferably made of **metal** ... The **biologically absorbable element** is preferably made of synthetic polymeric material ... The structural member of the novel prosthesis of the invention may be, e.g., a **bone plate** ...") ("[The] biologically absorbable element [is] adapted to be **held under compression against said structural member** ... so that stress is transmitted through said element to said structural member.") (emphasis added)" It would have been obvious to one of ordinary skill in the art to use non-metallic support studs instead of metallic studs as taught by Kummer to minimize the problems of stress-shielding. *Kummer, Col. 1, lines 14-17.*

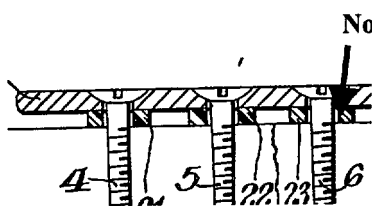


Claim 8**Kummer**

“A bone plate according to claim 7 wherein the contact elements comprise studs made of **material which is resorbable or dissolvable in body fluids.**”

As detailed above, Sherman in view of Kummer renders the elements of claim 7 obvious to one of ordinary skill in the art. Kummer further teaches the contact elements comprising studs made of material which is resorbable or dissolvable in body fluids. See Kummer, Col. 3, lines 44-49 (“As time passes after implantation ... element 3 is gradually **absorbed by the bodily fluids** and is thus **gradually weakened.**”)(emphasis added).

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Kummer.

Claim 7	Kummer
<p>“A metallic compression plate for osteosynthesis, said plate having a longitudinal axis, an upper surface, a lower surface, side walls joining said upper and lower surfaces and a plurality of screw holes spaced in the direction of said longitudinal axis, in combination with a plurality of individual, non-metallic, support studs attached to the lower surface of the plate at the sides of said lower surface and longitudinally spaced in the direction of said axis, said studs providing bone contact, at selected points along the sides of said plate, and spacing the central portion of the lower surface of said plate along the longitudinal axis from the bone.”</p>	<p>As detailed above, Mennen shows a metallic plate for osteosynthesis (“compression” in preamble non-limiting), the plate having a longitudinal axis, an upper surface, a lower surface, side walls joining said upper and lower surfaces and a plurality of screw holes spaced in the direction of the longitudinal axis, in combination with a plurality of individual studs at the sides of the lower surface and longitudinally spaced in the direction of the axis, the studs providing bone contact, at selected points along the sides of the plate, and spacing the central portion of the lower surface of the plate along the longitudinal axis from the bone. <i>See Mennen, Col. 1, lines 35-36</i> (“[T]he device comprises a metallic plate...”) (emphasis added). Kummer teaches attaching non-metallic support studs to a metallic bone plate. <i>See Kummer, Fig. 3; Col. 2, lines 16-26; lines 8-12</i> (“The structural member is preferably made of metal ... The biologically absorbable element is preferably made of synthetic polymeric material ... The structural member of the novel prosthesis of the invention may be, e.g., a bone plate ...”) (“[The] biologically absorbable element [is] adapted to be held under compression against said structural member ... so that stress is transmitted through said element to said structural member.”) (emphasis added)” It would have been obvious to one of ordinary skill in the art to use non-metallic support studs instead of metallic studs as taught by Kummer to minimize the problems of stress-shielding. <i>Kummer, Col. 1, lines 14-17.</i></p> <div data-bbox="678 1591 1312 1837">  <p style="text-align: right;">Kummer</p> </div>

Claim 8	Kummer
<p>“A bone plate according to claim 7 wherein the contact elements comprise studs made of material which is resorbable or dissolvable in body fluids.”</p>	<p>As detailed above, Mennen in view of Kummer renders the elements of claim 7 obvious to one of ordinary skill in the art. Kummer further teaches the contact elements comprising studs made of material which is resorbable or dissolvable in body fluids. See Kummer, Col. 3, lines 44-49 (“As time passes after implantation ... element 3 is gradually absorbed by the bodily fluids and is thus gradually weakened.”)(emphasis added).</p>

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Sutter Article in view of Kummer.

Claim 7

Kummer

"A **metallic** compression plate for osteosynthesis, said plate having a longitudinal axis, an upper surface, a lower surface, side walls joining said upper and lower surfaces and a plurality of screw holes spaced in the direction of said longitudinal axis, in combination with a plurality of individual, **non-metallic, support studs** attached to the lower surface of the plate at the sides of said lower surface and longitudinally spaced in the direction of said axis, said studs providing bone contact, at selected points along the sides of said plate, and spacing the central portion of the lower surface of said plate along the longitudinal axis from the bone."

As detailed above, the Sutter Article shows a **metallic** plate for osteosynthesis ("compression" in preamble non-limiting), the plate having a longitudinal axis, an upper surface, a lower surface, side walls joining said upper and lower surfaces and a plurality of screw holes spaced in the direction of the longitudinal axis, in combination with a plurality of individual studs at the sides of the lower surface and longitudinally spaced in the direction of the axis, the studs providing bone contact, at selected points along the sides of the plate, and spacing the central portion of the lower surface of the plate along the longitudinal axis from the bone. *See Sutter Article, p.5, line 21* ("[T]he **titanium reconstruction plate** ...") (emphasis added). Kummer teaches attaching non-metallic support studs to a metallic bone plate. *See Kummer, Fig. 3; Col. 2, lines 16-26; lines 8-12* ("The structural member is preferably made of **metal** ... The **biologically absorbable element** is preferably made of synthetic polymeric material ... The structural member of the novel prosthesis of the invention may be, e.g., a **bone plate** ...") ("[The] biologically absorbable element [is] adapted to be **held under compression against said structural member** ... so that stress is transmitted through said element to said structural member.") (emphasis added)" It would have been obvious to one of ordinary skill in the art to use non-metallic support studs instead of metallic studs as taught by Kummer to minimize the problems of stress-shielding. *Kummer, Col.*

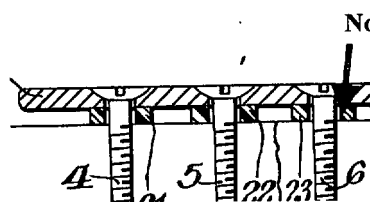


FIG. 3

Kummer

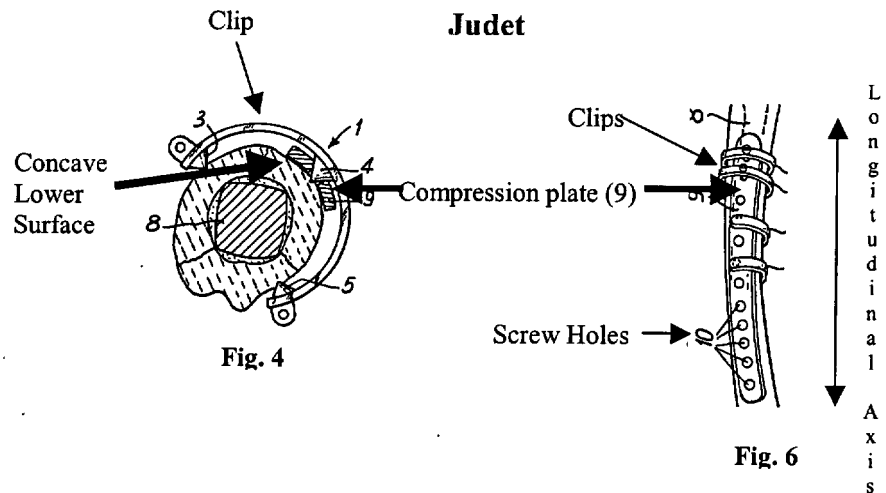
Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 4,263,904 ("Judet") in view of Mennen.

Claim 15

Judet and Mennen

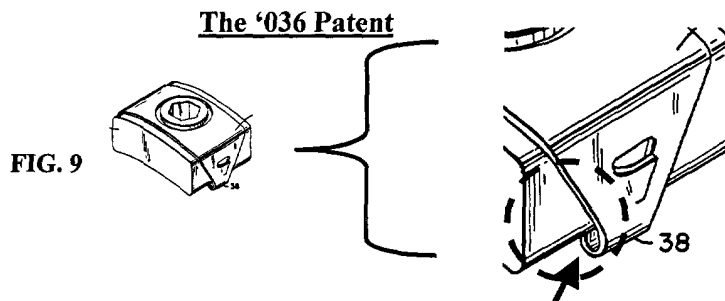
"A compression **plate** for osteosynthesis, said plate having a longitudinal axis, an upper surface, a concave lower surface, side walls joining said upper and lower surfaces and a plurality of **screw holes** spaced in the direction of said longitudinal axis, in combination with a **plurality of clips** **removably attached** to said plate and spaced along the length of said plate, "

Judet shows a plate (9) for osteosynthesis ("compression" in preamble non-limiting), the plate having a longitudinal axis, an upper surface, a concave lower surface (Fig. 4), side walls joining the upper and lower surfaces and a plurality of screw holes (10) spaced in the direction of the longitudinal axis, in combination with a plurality of clips (1) removably attached to the plate and spaced along the length of the plate.

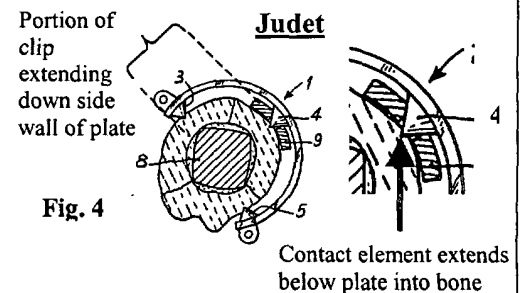
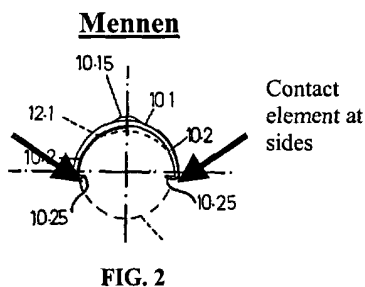


“each of said clips extending across the upper surface of the plate, down the side walls thereof and having elements extending below the lower surface of said plate to provide a limited area of bone contact.”

Judet shows each of the clips extending across the upper surface of the plate, down the side walls thereof. It should be noted that the ‘036 Patent does not discuss “down the side walls” except for what is shown in Fig. 9. Fig. 9 shows the clip extending downward but away from the side wall. Judet shows a clip curving down past the side walls (Fig. 4). Judet also shows elements (3,4,5) extending below the lower surface of said plate to provide a limited area of bone contact. Mennen teaches that plates of various widths may be used depending on the bone fracture. *Mennen, Col. 3, lines 5-7*. The wider the plate, the closer the clip will extend down the side walls of the plate. Further, Mennen teaches an embodiment that may be a clip-like plate device (*Mennen, Col. 2, lines 1-2*) with contact elements (Mennen, Fig. 2, item 10.25) at the side walls. Judet shows all of the claimed elements. It would have also been obvious to one of ordinary skill in the art to combine Mennen with Judet because both address increasing blood flow by minimizing contact surfaces. (Judet, col. 1, lines 53-57).



‘036 Patent clips project down and away from the side wall. Judet clips project down & away also.



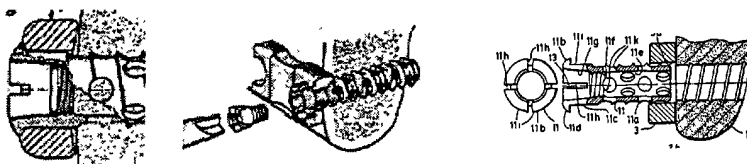
Rejections Incorporating Vattolo

Claims 2, 3, 10, 11, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo as applied to claims 1 & 9, and further in view of Sutter or Sutter Art.

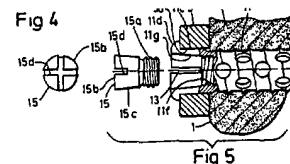
Claims 3, 10, 11, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Vattolo as applied to claims 1, 2, and 9, and further in view of Sutter or Sutter Art.

Regarding the rejections of claims 10, 11, and 12 noted above, Vattolo shows the bone plate assembly of claim 9. Sutter teaches using screws (11) having heads (11b) which are expandable by means of a body (15) inserted to the head. *See col. 5, lines 64-67; col. 6, lines 24-27; col. 3, lines 13-17.* It would have been obvious for one of ordinary skill in the art to use screws with expandable heads as taught by Sutter for securely connecting the plate to the bone. Sutter further teaches a body (11) fitted into the screw hole, the body being expandable by a conical screw head (15) which has a cone angle smaller than the resulting friction angle. *See col. 5, lines 64-66; lines 24-27; lines 46-50* ("The diameter of the conical surface 11g **gradually decreases** from the head end face toward the tail end of the screw. The angle enclosed between the screw axis 13 and the conical surface 11g is **less than 10° for example 5°.**"). It would have been obvious for one of ordinary skill in the art to use a body that is expandable by a conical screw head which has a cone angle smaller than the resulting friction angle as taught by Sutter for securely connecting the plate to the bone. Sutter teaches using a taper in the range of 1:5 to 1:20 for conical screw heads used in the bone plate (a taper of 1:5 to 1:20 correlates roughly to a taper range of 3° to 11°). *See col. 5, lines 46-50.* Use of conical screw heads within the range of 1:5 to 1:20 (3° to 11°) is well within the level of ordinary skill in the screw art, as well as the bone plate art, as evidenced in Sutter. The Sutter Article similarly teaches these features.

Sutter Art.



Sutter



Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Vattolo as applied to claim 1 and further in view of Allgower.

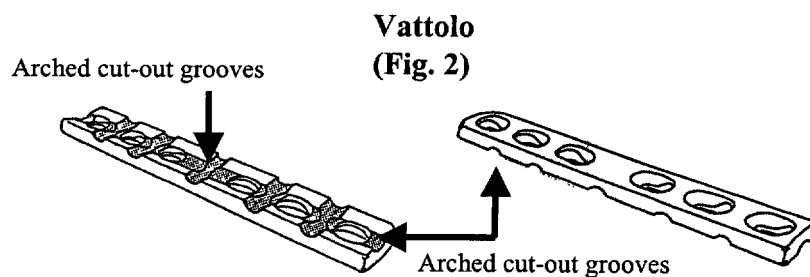
Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman in view of Vattolo and further in view of Kummer.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo and further in view of Kummer.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mennen in view of Vattolo as applied to claim 9 and further in view of Sherman.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Judet in view of Mennen and further in view of Vattolo.

All the above references have been discussed in detail. These rejections merely include Vattolo's teachings to serve as a further basis for rejecting the claims. Vattolo teaches that it was well known in the art to place a grooved section along the longitudinal axis of a **compression plate** in combination with grooved sections made transversely between the screw holes to increase blood circulation to the bone. See *Vattolo*, p.6, line 23 to 7, line 21 ("Jorger ... shows that by reducing the contact surface between plate and bone the circulatory disruption can be decreased ... The grooved plates studied by Jorger ... were originally designed by Brunner ... for mechanical reasons... By **putting grooves between the screw holes**, Brunner achieved equal rigidity over the whole plate. **With an additional groove along the axis of the screw holes**, the contact area between the plate and the bone can be further reduced ... Through the greatest (sic) possible **reduction in the contact surface of the plate, the blood supply of the corticalis is affected most favorably...**") (emphasis added).



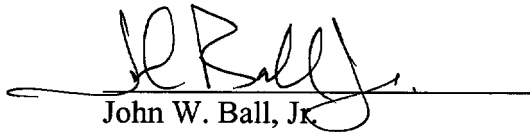
Conclusion

It is respectfully submitted that this request for reexamination of the '036 patent be granted and claims 1-15 be found invalid in their current form. If there are any questions, the representative of the requestor may be contacted at the below listed phone number.

Respectfully submitted,

Date:

March 6, 2003


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Declaration

I researched the dissertation entitled "The Effect of Grooves in Osteosynthesis Plates on the Restructuring of the Corticalis" by Mauro Vattolo dated 1986, and provide the following:

The dissertation is located at two libraries: 1) The City and University Library of the University of Bern, and 2) the Swiss National Library.

Handwritten in the dissertation copy of the Swiss National Library is a notation that it was approved on November 3, 1986.

The Swiss National Library received the dissertation on November 11, 1986.

I have not determined when the dissertation was received at the City and University Library.

The dissertation was indexed in the published Swiss National Bibliography dated January 1, 1987.

I hereby declare the above statements are true.


Simone Bleuler

27 February 2003
Date

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Reissigl, Hans. — Die Bluttransfusion / Hans Reissigl, Diether Schönitzer. — Basel [etc.] : S. Karger, 1986. — IX, 210 S. : Ill. ; 25 cm
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Inhalt: (Teil 1) Organisation und Spendervorsorge / H. Reissigl. (Teil 2) Prätransfusions-
nelle Untersuchungen / D. Schönitzer. — Literaturangaben. — ISBN 3-8055-4491-X
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E: Schönitzer

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The role of cyclic nucleic acid adducts in carcinogenesis and mutagenesis : proceedings of a meeting organized by the IARC ..., held in Lyon, 17—19 September 1984 / ed. : B. Singer, H. Bartsch. — Lyon : International Agency for Research on Cancer ; [Geneva] : World Health Organization, 1986. — XVI, 467 S. : Fig. ; 25 cm. — (IARC scientific publications, ISSN 0300-5085 ; no. 70) SP 499^m
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E: Bartsch; Singer; Centre international de recherche sur le cancer; Organisation mondiale de la santé

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Roulet, Jean-François. — Degradation of dental polymers / Jean-François Roulet. — Basel [etc.] : S. Karger, 1987, XII, 228 S. : 183 Ill. ; 25 cm
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Nb 39625

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E: Titel; Institut; Fakultäre Instanz

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Hb 13903

Diss. med. dent. Zürich (kein Austausch)

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Sommer, Jürg H. — Economie et efficacité du système suisse de santé : résultats du Programme national de recherche n° 8 / Jürg H. Sommer, Felix Gutzwiller ; version française établie par B. Eggmann et F. Paccaud. — Berne [etc.] : H. Huber, cop. 1986. — 251 p. : fig. ; 23 cm
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Trad. de : Wirtschaftlichkeit und Wirksamkeit im schweizerischen Gesundheitswesen. — ISBN 3-456-81542-5 (br.) : Fr. 44.—

E: Gutzwiller; titre: Programme

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Sommer, Jürg H. — Wirtschaftlichkeit und Wirksamkeit im schweizerischen Gesundheitswesen : Ergebnisse des Nationalen Forschungsprogrammes Nr. 8 / Jürg H. Sommer, Felix Gutzwiller. — Bern [etc.] : H. Huber, 1986. — 259 S. : graph. Darst. ; 23 cm
ISBN 3-456-81510-7 (br.) : Fr. 44.—
N 181522

E: Gutzwiller; Titel; Nationales Forschungsprogramm

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Stadler, Boda M. — Biological and biochemical studies on interleukin-2 / Boda M. Stadler. — 1986. — [48] Bl. (getr. Zählungen) : Fig. ; 30 cm
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P 31447^a

Literaturangaben. — ISBN 0-8247-7536-8

E: Weiner; Frishman

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Udapa, K. N. — Natürliche Heilkräfte : Früchte, Beeren, Gemüse, Gewürze / Text: K. N. Udapa, S. N. Tripathi ; [Übers. aus dem Engl. : Martin Fürst, Michael Feichtinger] ; Konzept und Fotos: Norma Schwitter-Hamilton ; Diätartikel: Arno Sollmann. — [2. Aufl.]. — Zug : F. P. Schwitter, 1983. — 200 S. : zahlr. Ill. (farbig) ; 30 cm
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80 Bildtafeln sind dem Heilkräuterbuch «Herbarium Blackwellianum» entnommen. — ISBN 3-284-00011-9

E: Tripathi

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Literaturangaben. — ISBN 0-8247-7636-4

E: Kawamura; Kare; International Symposium on Umami (1 ; 1985 ; Hawaii)

636

Vattolo, Mauro. — Der Einfluss von Rillen in Osteosyntheseplatten auf den Umbau der Kortikalis / von Mauro Vattolo. — 1986. — 89 Bl. : 41 Abb. ; 30 cm
Hq 7838

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Würmli, Regula. — Untersuchungen zur Regulation der Chloridhomöostase bei alimentärem Chlorid-Mangel / von Regula Würmli. — 1986. — 54 S. : 6 Abb. ; 21 cm
Fth 13911

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