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D E C I S I O N
of 13 December 2001

Case Number: T 0934/98 - 3.2.2

Application Number: 90907633.3

Publication Number: 0423313

IPC: A61C 1/05

Language of the proceedings: EN

Title of invention:

Sterilizable non-lubricated rotary dental and medical
instrument

Patentee:

DEN-TAL-EZ, INC.

Opponent:

Kaltenbach & Voigt GmbH & Co.

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (no)"

Decisions cited:

G 0002/88, T 0181/82

Catchword:

-



Case Number: T 0934/98 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 13 December 2001

Appellant I: Kaltenbach & Voigt GmbH & Co.
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Appellant II: DEN-TAL-EZ, INC.
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office posted 16 July 1998
concerning maintenance of European patent
No. 0 423 313 in amended form.

Composition of the Board:

Chairman: W. D. Weiß
Members: R. Ries
J. C. M. De Preter

Summary of Facts and Submissions

- I. European patent No. 0 423 313 was granted on 28 June 1995 on the basis of European patent application No. 90 907 633.3.
- II. The granted patent was opposed by the present appellant I (KALTENBACH & VOIGT GmbH & Co) on the grounds that its subject matter lacked novelty and did not involve an inventive step (Article 100(a) EPC), that it did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC) and that its subject matter extended beyond the content of the application as filed (Article 100(c) EPC).
- III. With its interlocutory decision posted on 16 July 1998 the opposition division held that, taking into account the amendments made by the patent proprietor (DEN-TAL-EZ INC.) during the opposition procedure, the patent and the invention to which it relates meet the requirements of the EPC.
- IV. Appeals against this decision were filed by the opponent (appellant I) and the by the patentee (appellant II). In the appeal proceedings, inter alia, the following documents were referred to:
- E3: Prospectus "Inside Bearings" MPB Corporation,
vol. 2, No. 1, April 1986, pages 1 to 4
- E8: L. D. Wedeven, T. A. Harris, "Rolling Element",
Machine Design, August 1987, pages 72 to 76
- E9: US-A-4 249 896

E10: JP-A-63-229043 and translation into the English language

Moreover, amongst others the following declarations and Affidavits were considered:

Declarations and Affidavits:

E13a Second Affidavit of Mr Sparks

E17: First Affidavit of Mr Hannoosh

E22: Second Affidavit of Mr Gonser

V. Oral proceedings were held before the Board on 13 December 2001.

- Appellant I (the opponent) requested that the decision under appeal be set aside and the patent be revoked.
- Appellant II (the patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 8 submitted as main request at the oral proceedings or, alternatively, on the basis of one of the two auxiliary requests submitted on 9 November 2001.

Claim 1 of the main request reads:

"1. A powered, high-speed sterilizable medical dental handpiece (10) having a proximal end portion (12) adapted to mount a rotary tool (13) for rotation at high speeds in excess of 300,000 r.p.m. upon or in

proximity with a portion of anatomy and including an anti-friction bearing assembly (18,19) carried in said end portion (12) for rotatably mounting said tool (13) and including an annular inner raceway (19a), an annular outer raceway (19b) and an plurality of rolling elements (19c) and contained between, and cooperating with, said raceways (19a, 19b) for mounting the raceways for motion relative to one another,

characterized in that

said rolling elements are made of silicon nitride sintered under heat and pressure, and in that said bearing assembly is constructed and arranged so that, in use of the apparatus, it is able to withstand repeated periodic sterilization procedures of said handpiece (10) at high temperatures alternating with periods of usage without periodic intervening lubrication either by continuous supply of lubricant during said periods of usage or by lubrication when out of service for general maintenance or for sterilization."

The single claim of the first auxiliary request reads:

"A method of using a powered, high-speed, sterilizable, medical/dental handpiece (10), the handpiece having a proximal end portion (12) adapted to mount a rotary tool (13) and including an anti-friction bearing assembly (18,19) carried in said end portion (12) for rotatably mounting said tool (13), said bearing assembly (18,19) including an annular inner raceway (19a), an annular outer raceway (19b) and a plurality of rolling elements (19c) made of silicon nitride sintered under heat and pressure and contained between, and cooperating with, said raceways (19a, 19b) for mounting the raceways for motion relative to one

another, the method of use involving subjecting the handpiece (10) to repeated periodic sterilization procedures at high temperatures alternating with periods of usage in which the tool is rotated at speeds in excess of 300,000 r.p.m. upon or in close proximity with a portion of anatomy, characterised in that the handpiece is used without periodic lubrication of the bearing assembly either by continuous supply of lubricant to the bearing assembly during said periods of usage or by lubrication of the bearing assembly when the handpiece is out of service for general maintenance or for sterilization."

The single claim of the second auxiliary request reads:

"A method of using a powered, high-speed, sterilizable, medical/dental handpiece (10), having a proximal end portion (12) adapted to mount a rotary tool (13) for use at high speeds in excess of 300,000 r.p.m. upon or in proximity with a portion of anatomy and including a bearing assembly (18,19) carried in said end portion (12) for rotatably mounting said tool (13), said bearing assembly (18,19) including an annular inner raceway (19a), an annular outer raceway (19b) and a plurality of rolling elements (19c) contained between and cooperating with said raceways (19a, 19b) for mounting the raceways for motion relative to one another, at least said rolling elements (19c) being formed of a ceramic material cooperable with said raceways (19a, 19b), whereby the bearing assembly is able to accommodate said high rotational speeds of said tool (13), the method involving subjecting the handpiece (10) to repeated periodic sterilization procedures at high temperatures alternating with periods of use in which the tool is

rotated at speeds in excess of 300,000 r.p.m., characterised in that the bearing assembly accommodates repeated periodic sterilization procedures and alternating periods of use without periodic intervening lubrication either by continuous supply of lubricant during periods of use or by lubrication when out of service for general maintenance or for sterilization."

VI. The opponent (appellant I) argued as follows:

When assessing the obviousness of the apparatus called for in claim 1 of the main request, the technical teaching given in documents E9, E10 and E3 is to be considered. As is set out in the patent specification on page 4, lines 5 to 7, the dental handpiece the patentee started from was of conventional design and construction, as shown in document E9. Apart from minor differences, the side elevational view of the dental handpiece showing the turbine cartridge assembly and the ball bearing assemblies depicted in Figure 2 of the patent complies with those shown in Figure 2 of document E9. The essential structural difference between the claimed handpiece and the disclosure of document E9 resides in that the ball bearing elements which are conventionally made of stainless steel, have been replaced in the claimed dental handpiece by SiN rolling elements sintered under heat and pressure. It is, however, obvious from document E3 to do so, since rolling element bearings made of SiN provide a number of technical advantages vis-à-vis those made of stainless steel. These advantages include a high degree of hardness which remains unaffected by temperatures up to 1000°C, a low coefficient of friction which contributes to the ability of silicon nitride to run - under certain conditions - without lubrication, and a

low density being 40% of that for conventional bearing steel and, therefore, offer the potential for significant improvement in high speed bearing performance. The same conclusion is arrived at when, starting from document E10 as closest prior art, the teaching given in this document is combined with that disclosed in document E3. Document E10 discloses a dental handpiece comprising SiN ball bearing assemblies which are suitable to rotate at very high speed without using a lubricating oil. Even though document E10 fails to mention that the SiN ball bearings have been produced by sintering under heat and pressure, this technology is conventionally resorted to when producing high quality rolling elements, as is apparent from E3, page 1, column 3, lines 1 to 5, page 3, lines 1 to 3 and the Norton Data sheet "NC-132 Hot pressed SiN" mentioned in document E3 on page 4, final paragraph: "References". The subject matter of claim 1 of the main request, therefore, lacks inventive step.

The same objections apply to the single claim of either the first or the second auxiliary request which are directed to a method for using the claimed handpiece without supplying a lubricant to the SiN bearing assembly. The possibility of running SiN roller bearing assemblies - albeit under particular conditions - without lubrication is already envisaged in document E3. The wording "without periodic lubrication" is not construed to mean that the claimed bearing assembly is run absolutely "dry". In this context the patentee himself has admitted during the proceedings that, when assembling the structural parts of the handpiece, the SiN bearings are provided with an "initial" or "basic" lubrication called "lubed-for-life", which is, however, not refreshed when in use or when out of service for

maintenance (see Affidavit of the inventor: E22, pages 2, 3). Therefore, the claims according to the first and second auxiliary request also do not comprise subject-matter which involves an inventive step.

VII. The patentee (appellant II) argued as follows:

The patent refers to a high speed dental handpiece with air driven turbines rotating drills and burrs at velocities in excess of 300,000 or even 400,000 r.p.m (see page 2, lines 21 to 22 of the patent). In particular, such a handpiece must be capable of surviving 2000 hours of life cycle testing according to the conditions set out on page 2, lines 34 to 48 of the patent specification and of resisting repeated sterilization in the so-called "dryclave procedure" at temperatures as high as 375°F (190°C).

Document E10 discloses a dental handpiece including ball bearing components composed primarily of silicon nitride or SIALON, but it does not teach the use of SiN bearing elements which are "sintered under heat and pressure". Hence, the dental handpiece defined in claim 1 of the main request is novel over the disclosure in document E10. Moreover, it is inherent that the apparatus described in E10 includes means for providing a continuous air and water mist lubrication which is emphasized as being essential rather than merely optional, as alleged by the opponent. It is, therefore, contrary to the teaching given in E10 and, hence, by no means obvious to modify this known dental handpiece in order to eliminate the structural components for delivering the air and water mist lubricant and thus to dispense with the mist-air lubrication when operating the device. In the claimed dental handpiece, however, a means for supplying any

form of lubrication is actually unnecessary, since no intervening lubrication - either by continuous supply of a lubricant during periods of usage or periodically when out of service for general maintenance or for sterilization - needs to be provided. Furthermore, the handpiece disclosed in document E10 does not represent a commercially workable and satisfactory structure which is capable of rotating at comparable velocities and of surviving 2000 hours of life cycle testing, as does the claimed handpiece. As has been shown in the Second Affidavit of Mr Sparks (E13a), the structure given in E10 failed after 25 hours. Having regard to document E3, the skilled worker has no indication to turn to this document, and if he did, he would not be led to try an apparatus by omitting the means for providing conventional periodic lubrication which is said to be essential according to E10. Even though document E3 mentions the ability of SiN bearings to run unlubricated "in some conditions", for example when used in a vacuum equipment (under low load and low revolutions) where lubrication contaminates the system, this finding cannot be extrapolated for the bearings to work without lubrication on the extreme edge of mechanical engineering i.e. at speeds in excess of 300,000 r.p.m.. On the contrary, in the light of the prevailing teaching in the technical literature which emphasizes the need for lubrication, (see e.g. document E8), there is nothing in E3 to suggest that a person skilled in the art would in 1989 have seriously contemplated to eliminate any periodic lubrication in a high speed dental handpiece by the mere substitution of silicon nitride for stainless steel rolling elements. The opponent's allegations on this point are, therefore, the purest kind of hindsight. The same conclusion results when starting from document E9 as

closest prior art which represents a dental handpiece of conventional design and combining it with the teaching given document E3. There is no reason to do so as has been previously shown. The subject matter of claim 1 of the main request, therefore involves an inventive step.

The single claim of the first and second auxiliary requests, respectively, is directed to a method of using the dental handpiece claimed according to the main request. Such a change of category is permissible according to the principles laid down in the decision G 2/88. Again, there is no indication in the prior art to encourage the worker in 1989 to attempt to run hybrid ceramic bearings without lubrication in a high-speed dental handpiece. Hence, also the subject matter of these claims is novel and involves an inventive step.

Reasons for the Decision

1. The appeals comply with Rule 65(1) EPC and are, therefore, admissible.

2. *The closest prior art*

According to the patent specification on page 3, line 6 and on page 4, lines 5 to 40, a dental handpiece of conventional design and construction was relied upon as a starting device. The structure, assembly and operation of such a conventional handpiece is described in detail in document E9 (the Kerfoot patent). Accordingly, the design of the claimed turbine driven handpiece depicted in Figure 2 of the patent in suit

essentially complies with that of the known handpiece depicted in Figure 2 of document E9. This conventional handpiece generally comprises upper and lower anti-friction bearing assemblies 18 and 19 (E9: Figure 2, reference signs 38; 39) which are made of stainless steel and lubricated either periodically during maintenance or continuously by supplying a lubricant to the air driving the turbine. Therefore, the technical background describing a typical handpiece and contained in the patent in the form of document E9 represents, in the Board's view, technically the most realistic starting point, i.e. the closest prior art.

3. *The problem to be solved*

The lubrication of the bearing assemblies in the dental handpiece involves many drawbacks. If the handpiece was lubricated after sterilization, contaminants contained in the lubricant could endanger the sterility.

Moreover, repeated sterilization procedures on the handpiece in a high temperature hostile environment exacerbate the corrosive impact of the moisture and chemicals on the bearing assemblies and thereby accelerate their degradation. Last but not least, the lubrication oil that is unavoidably carried into the patient's mouth by the air flow driving the turbine may cause discomfort to the patient.

Consequently, in the light of the closest prior art according to document E9, the technical problem underlying the patent at issue consists in providing a dental handpiece comprising bearing assemblies which are capable of resisting the corrosive attack by the high temperature sterilization procedure and of operating without the need for any lubrication after

being sterilized.

4. *Inventive step; main request*

4.1 A skilled person searching for a solution to the stated technical problem, therefore, would have paid particular attention to such prior art which specifically deals with ball bearing assemblies which are prone to require less maintenance than stainless steel bearings. In his search, the expert would turn to document E3 dealing with higher developed ceramic rolling element bearings which are of small size and suitable to operate at the required high speed of more than 300,000 r.p.m. and which are reported to exhibit an improved chemical stability and corrosion protection during sterilization and are considered suitable to operating unlubricated with no sacrifice in the bearing performance. More specifically, these rolling elements are made of hot pressed silicon nitride which exhibits a plethora of interesting properties capable of overcoming at least in part the limitations set by conventional stainless steel roller bearings. (cf. E3, page 4, column 3, lines 2 and 3). First, SiN is twice as hard as conventional bearing steel, and the hardness is not affected by temperature up to 1000°C (cf. E3, page 1, column 3, second paragraph). Second, SiN is virtually chemically inert and thus offers outstanding corrosion resistance (cf. E3, page 2, column 1). Third, due to its very low coefficient of friction, SiN is extremely wear resistant and - under certain conditions - allows unlubricated contact with itself or with stainless steel M-50 (cf. E3, page 2, column 1, penultimate paragraph; page 4, column 2, second full paragraph). Fourth, since the density of SiN is about 40% of that of conventional steel and the ball

centrifugal loading is directly proportional to the density, the high speed bearing performance is expected to be significantly improved (cf. E3, page 2, column 2). Moreover, other parts of document E3 state that miniature ceramic bearings offer innovative solutions to difficult application problems, and a close engineering cooperation between the customer and the manufacturers is recommended (cf. e.g. E3, page 3, column 1, first paragraph and column 3, last paragraph).

These encouraging technical aspects and the fact that SiN roller bearing elements in suitable dimensions were commercially available advocated at least testing SiN bearings in replacement for stainless steel bearing assemblies when trying to solve the technical problem of the patent in suit. The patent proprietor confirmed that SiN-hybrid roller bearings consisting of Noralide NC-132 and referred to in document E3 eventually have been used in the claimed dental handpiece. He referred i.a. to the First Affidavit of Mr Hannoosh (cf. document E17, points 4.4; 6.3; 6.4) who endorsed this statement at the oral proceedings.

- 4.2 The Board is also not convinced by the argument that there is no technical link between documents E9 and E3 and, that therefore, the skilled worker would not have combined them. In the proprietor's view, the ceramic bearing assemblies proposed in E3 were still untested in practice and no indication was given to run them unlubricated at ultra-high rotational speeds of more than 300,000 r.p.m. (see E3, page 3, column 3, second paragraph; page 4, column 3, paragraph 1).

Document E10 indicates clearly, however, that this

argument reflects the reality and that the skilled practitioner considered SiN as a candidate material for roller bearing in dental handpieces.

- 4.3 The patentee regarded the unforeseeable possibility to operate the claimed dental handpiece without supplying any form of oil or water air-mist lubrication to the bearings as an indication of the presence of an inventive step. The necessity of properly lubricating the ceramic roller bearing assemblies was evident to the expert from document E8, page 73, column 3, penultimate paragraph so that he could not have expected any reasonable success when running the bearings without lubrication.

However, following the principles outlined in the established case law at the EPO, this so-called "extra effect" has no bearing on the matter. If, as has been shown previously, it would have been obvious to the expert to arrive at something falling within the terms of the claim because one or more advantageous effects could be expected to result from the combined teaching of the prior art documents, an extra and possibly unforeseen ("bonus") effect does not justify such a claim as involving an inventive step (cf. T 181/82).

- 4.4 It is, therefore, concluded that the subject matter of claim 1 of the main request lacks an inventive step.

5. *First and second auxiliary request*

The claims of the first and second auxiliary request relate to a "method of using a dental handpiece (as defined in the apparatus claim 1 of main request)... without periodical lubrication of the bearing assembly"

rather than to the apparatus per se. Consequently, a change of category has been made in the first and second auxiliary request.

However, the same reasoning brought forward with respect to claim 1 of the main request also applies to the single claim of the first and second auxiliary requests, respectively. Therefore, these claims are not allowable either, since the method claimed according to the first and second auxiliary request equally does not involve an inventive step.

6. Since the claims of the auxiliary requests are not allowable for other reasons, the question whether or not the amended wording of the claims according to the first and second auxiliary request meets the requirements of Article 123(2) and (3) EPC need not be decided.

It has, however, to be noted that the allowability of the claims of the auxiliary requests cannot be based on the decision G 2/88 of the Enlarged Board of Appeal in which the question of whether a change of category could be permissible was considered. There it held that a change of category of granted claims is not open to objection under Article 123(3) EPC if it does not result in an extension of the protection conferred by the claims as a whole. Moreover, the Board stated that:

...in general terms, determination of the "extent of protection conferred" by the patent under Article 69(1) EPC is a determination of what is protected by the claims in terms of category plus technical features;

The Enlarged Board decided that a granted claim to a

product could be amended to a claim to the use of that product for a particular purpose (cf. G 2/88, OJ EPO 1990, 093, Order).

In the present case, the claims according to the first and second auxiliary request are, however, not "use claims" in the sense used in this decision since they are not directed to the use of an apparatus **for a specific purpose**. Rather, these claims are construed to define a "method of operating" the dental handpiece (as defined in main request) and further include a "negative" process feature ("without periodic lubrication"). The change of category of claim in the present case can, therefore, not be justified merely by referring to G 2/88 but would have to be considered separately.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß