

FRENCH REPUBLIC
In the name of the French People

EXTRACT
of the minutes of the Court Clerk

DEPARTMENTAL COURT
OF
PARIS

EXECUTION COPY

RULING
delivered February 5, 2007

1st chamber
3rd section

N°RG:

03/16755

MINUTES NO.: 3

Writ of summons dated

July 23, 2003

PAYMENT

After appraisal by

Doctors

- Gabriel Sauveur

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75006 PARIS

- Claude Lion

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Brosse

75005 PARIS

PLAINTIFFS

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Dr. Philippe Leclercq

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represented by Mr. Jean Philippe Pin, Attorney at the
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DEFENDANTS

SARL FRIADENT FRANCE

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represented by Ms. Marie-Noëlle Revel-Basuyaux,
Attorney at the Bar of Paris, counsel, Locker no. A 95;
and Mr. Thierry Jove Dejaiffe, Attorney at the Bar of
Melun, litigator

**NOBEL BIOCARE USA, Inc., representing the rights
of STERI-OSS.**

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USA

represented by Mr. Constantin Achillas, Attorney at the
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VOLUNTARY INTERVENOR

**DENTSPLY FRANCE, representing the rights of
FRIADENT FRANCE**

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MEMBERS OF THE TRIBUNAL

Florence Lagémi, Vice-President
Dominique Lefebvre-Ligneul, Vice-President
Catherine Cosson, Vice-President

CLERK OF THE COURT

Karine Nivert, during proceedings
Caroline Gautier, for the ruling

PROCEEDINGS

Hearing of November 13, 2006, held in open court
After proceedings were concluded, notice was given to counsel that the ruling would be delivered on February 5, 2007

RULING

Delivered in open court
After proceedings were concluded
Subject to appeal
Prepared by Catherine Cosson

Drs. Marc Bert and Philippe Leclercq are dental surgeons specializing in surgical implants and prosthetics. Over the course of 1989 and 1990, they acquired Denar cylindrical titanium implants coated with hydroxylapatite (HA) that were manufactured by Steri-Oss and distributed by France Implant. Even though the results achieved were initially satisfactory, starting in 1992, they noticed the first expulsions of implants, on which the HA coating had disappeared. Believing that the product was defective, they summoned France Implant to appear before a summary trial judge to appoint an expert. By a court order dated January 24, 1997, Professor Sauveur was assigned to this task. By a court order dated April 24, 1997, at the request of France Implant, the findings of the expert were made binding against Denar Corporation. Since Denar did not appear, Friatec (formerly France Implant) summonsed Steri-Oss to enforce the findings of the expert against it. A court order to this effect was issued on April 2, 1998.

Since Steri-Oss maintains that the conditions surrounding Prof. Sauveur's filing of a preliminary report were questionable in nature and that the document was biased, the judge charged with monitoring the expert inquiry called for the expert to be replaced.

By a court order dated October 9, 1998, the judge rejected the motion but said that the conclusions of the research laboratory specializing in biocompatible materials directed by Mr. Picard, which was involved in the production and fitting of the two prostheses on the implants at issue, would be excluded from the hearing by the expert and asked the expert to continue performing his duties.

By a court order dated January 3, 2001, the judge supervising the expert inquiry appointed Professor Lyon, a chemist, to form a panel of experts with Dr. Sauveur. Prof. Lyon was also given the task of determining the reasons the failure of osteointegration, with the provision that if it was due to a change in the design or manufacturing of the alloy used in the manufacturing of the implant, he was to give an opinion on the causes of the anomalies observed and, more generally, on all the facts that would enable the court to rule on matters of responsibility. The judge further stated that the two experts would exchange the documents and materials that they deemed necessary to complete their task and would work together to make to carry out their task more efficiently, with the knowledge that they would still be filing separate reports.

Prof. Lyon filed his report on January 11, 2002. By a court order dated April 5, 2002, the supervising judge set compensation at the amount of 13,500.00 euros excluding taxes. On June 16, 2003, in review proceedings initiated by Drs. Bert and Leclercq, the Court of Appeals of Paris overturned the judge's ruling and set compensation at 11,000.00 euros excluding taxes, or 13,156.00 euros all taxes included.

Since Nobel Biocare, which represents the rights of Steri-Oss, demanded the replacement of Prof. Sauveur for the partiality that he allegedly showed when he supposedly refused to respond to the statements being made since 1998 in the preliminary report issued on February 13, 2002, and when he supposedly tried to intervene in the task entrusted to Prof. Lyon, the co-expert whose conclusions he contested, the judge supervising the expert inquiry rejected the motion in a court order dated March 25, 2002, and enjoined the plaintiff to provide an explanation for the origin of the animal tests submitted by its legal counsel in September 2001 and furnish proof that they were used for the Steri-Oss cylindrical implants at issue. He also set the timetable for the conclusion of the expert inquiry.

Upon a motion by Nobel Biocare, who requested that the Court of Appeals use all means that it deemed appropriate to verify whether or not the judge supervising the expert inquiry knew Mr. Bert personally, in a capacity other than that of the expert inquiry and his judicial functions, for several months before the contested order was issued. Subsequently, Nobel Biocare asked that the order be overturned as Dr. Sauveur failed to fulfill the obligations listed in Articles 232 *et seq.* of the New Code of Civil Procedure. The Court of Appeals of Paris, in a decision dated September 20, 2002, declared that the appellant's case lacked sufficient grounds and upheld the contested order in its entirety. The appeal against this decision was rejected on January 6, 2005.

Prof. Sauveur filed his report, which was dated August 10, 2002.

While these proceedings were underway, Ms. C* and Ms. V*, patients of Dr. Leclercq, both summonsed him to appear before a summary trial judge due to the loss of the implants that were placed in them.

By a court order dated February 3, 1999, the summary trial judge of that court, with regard to Ms. C, appointed Prof. Sauveur as an expert. By a court order dated June 4, 1999, this order was extended to include Nobel Biocare. By a court order dated January 4, 2001, the judge supervising the expert inquiry appointed Prof. Genty, an expert in chemistry, to assist Prof. Sauveur in his task, giving the former a task identical to the one entrusted to Prof. Lyon. The expert reports were filed on March 27, 2004, and Ms. C* summonsed Dr. Leclercq to appear before that court to determine compensation for damages, as proceedings were then currently underway. Dr. Leclercq had third-party notice served on Dentsply France (which represents the rights of Friatec Médical France, later Friadent France) and Nobel Biocare USA, Inc.

By a court order dated April 14, 2000, the summary trial judge of that court, with regard to Ms. V* and with Dr. Leclercq, Friatec Médical France, and Nobel Biocare present, appointed Dr. Chavier as an expert. He was later replaced by Dr. Michelet and then Dr. Wautier as a medical expert, and by Prof. Genty as a technical expert. The experts filed their reports, Dr. Wautier on October 14, 2003, and Prof. Genty on November 8, 2005.

By an instrument dated June 13 and July 23, 2003, **Drs. Bert and Leclercq** summonsed Friadent France SARL Nobel Biocare USA, Inc, which represents the rights of Steri-Oss, to appear before that court to seek joint compensation for damages from both companies.

In their summary conclusions, of which notice was given on January 30, 2006, they:

- based their demand on Article 1147 of the Civil Code as understood in light of and according to the objectives of Directive no. 85/374 EEC of July 25, 1985, regarding the harmonization of the legal provisions of Member States in matters of responsibility for defective products,
- can, in their capacity as last purchasers, exercise direct action of a contractual nature against Nobel Biocare USA, and any purchaser may seek recourse in proceedings in matters arising from failure to execute the contract that allowed the product to be used; the producer or supplier must deliver products free of any defect that may endanger people or goods,
- infer from the abovementioned articles the existence on the part of the implant manufacturer of a duty to achieve a result intended to guarantee the safety that any user of the implant may legitimately expect, with the manufacturer being fully responsible for any damages caused by a defect in its product.

They assert that:

- the medical experts concluded that the loss of the implants was not related to the actions of the physicians,
- Steri-Oss marketed implants that had not been sufficiently tested,
- consequently, it failed to perform its duty of care and committed a series of faults when it failed to monitor the effectiveness of the implants at issue,
- the materials vigilance statements were registered by the FDA,
- the evidence of accountability for the loss of the implants constitutes a legal fact that makes it admissible by witness testimony or by serious, precise, and concordant presumptions,
- in this matter, Steri-Oss failed to carry out fundamental research, did not develop the HA coatings to determine which one was the best, and carried out no clinical research,
- since this is a group of contracts, the subsequent purchasers, i.e., physicians, have an action that is of necessity of a contractual nature that they can exercise against both their direct contracting party, Dentsply which represents the rights of France Implants, or the manufacturer, Nobel Biocare, which represents the rights of Steri-Oss.

In response to the arguments by the defendants, they maintain that:

- based on the articles mentioned above, the Court of Cassation has posited the principle of no-fault liability, which transcends the distinction between contractual and tort liability,
- the law has stipulated that the provisions of the Law of May 19, 1998, do not interfere with the rights that the victim may claim with regard to contractual or tort liability or special liability arrangements, thus allowing him to claim the terms of liability provided by law, more specifically, the contractual safety obligation implied by the courts based on Articles 1147 and 1382 of the Civil Code, as clarified by the Directive of July 25, 1985,
- Article 1386-2 of the Civil Code is not a text that applies specifically to consumer rights,
- the professional that experiences the damage because the product is defective and caused damage to something other than the item itself, is a victim who may invoke responsibility because of the defective products,
- the law has extended the obligation of safety to the benefit of professionals since professional status must, in addition, be taken into account with regard to the idea of a professional of the same field of specialty,
- as regards the quality of the implants, physicians are simple ordinary purchasers,
- Articles 1386-1 *et seq.* apply to all damages to goods, not only to damages to goods intended for private consumption, and the only damages excluded are those to the defective product itself.

They add that:

- as part of the expert inquiry, Nobel Biocare does not deny that it distributed implants in France using Friatec Médicale France (at the time, France Implants) as an intermediary and that the implants examined by the experts were Denar implants,

- when the events took place, France Implants was the sole distributor of these implants in France, which was acknowledged during the expert inquiry,
- at the time of the events, they had no obligation of traceability, in particular, they had no obligation to record the lot numbers of the implants in their patients' medical records as, at the time, the implant manufacturers did not put a detachable label on the packaging indicating the lot number and France Implants invoices did not list lot numbers,
- they may not be held liable insofar as the manufacturer must supply dental surgeons with tested products and may not allow them to incur risks by using a new material without their knowledge,
- the defendants must be nonsuited for the demands that they presented pursuant to Article 700 of the New Code of Civil Procedure as well as those related to the awarding of damages with regard to Nobel Biocare.

They seek, under the terms of the provisional enforcement, to have Dentsply France and Nobel Biocare sentenced to:

1) pay them the following amounts:

- for direct material injury: 120,815.00 euros + 70,505.00 euros for Dr. Bert and 211,350.00 euros + 42,685.00 euros for Dr. Leclercq,
 - for direct economic damages related to the loss of patients: 623,820.00 euros for Dr. Bert and 526,200.00 euros for Dr. Leclercq,
 - for moral damages: 150,000.00 euros each,
 - for loss of goodwill: 150,000.00 euros each,
- plus interest at the legal rate starting on the date that notice of the summons is served,
- 30,000.00 euros each for unrecoverable expenses,

2) pay expenses for the compensation of legal experts, which are set at the following amounts:

general expert fees: 11,523.24 euros for Prof. Sauveur and 16,146.00 euros for Prof. Lyon, expert fees for Ms. V* :
1,169.25 euros for Prof. Genty and 831.00 euros for Dr. Wautier, plus interest at the legal rate starting on the date that notification of the conclusions was given, i.e., January 30, 2006.

In addition they demand, under the terms of a provisional enforcement, that the decision be published at the expense of the defendants, which shall include fees for translation into English, in the following periodicals: *L'Information Dentaire*; *la Revue Implants*; *Implandontie*; *JOMI* ; *JHIR Implant Research*.

Under the terms of documents issued on October 9, 2006, **Nobel Biocare USA, Inc.**, maintains that:

- the provisions of the Law of May 19, 1998, are not applicable to the facts of the case, as the implants had been put into circulation nearly 10 years before the law went into effect,
- only the French legal texts applicable at that time, as interpreted in the light of the provisions of the EC directive, may be applied,
- pursuant to traditional French provisions concerning responsibility, the provisions of the EC directive of 1985 as well as legal precedent in matters of product safety obligations, the plaintiffs must furnish proof of damage and a defect and establish causality between the two .

The company believes that:

- the plaintiffs are not victims of recoverable damage as defined by the directive of July 25, 1985, (Art. 9) because they suffered no injuries to their person, nor damage to an object intended for private consumption,
- it has not been sufficiently demonstrated that the great majority of supposedly defective implants were purchased from the distributor Friatec (France Implants),
- concerning the few implants purchased from Friatec (France Implants), it has not been demonstrated that these implants are the ones at issue, as none of the clinical records of the 114 patients affected list the lot numbers of the implants used,
- the claimants cannot seek reparation for future and potential damages related to the “degradation of implant coating that affects all of the 252 implants put in and for which there is currently not any reason for concern but for which the inevitable resorption of the hydroxylapatite may be predicted”,
- sufficient proof has not been given for the alleged damages, as only 5 invoices issued by Friatec for a very small number of Steri-Oss HA implants have been produced,
- no damages are likely to be compensated due to the publication of a ruling, the only useful item being a loss of goodwill, which is not demonstrated.

The company claims that proof of a defect has not been demonstrated because:

- proof of an abnormal rate of failure has not been established,
- the chemistry experts disregarded the design and manufacturing of the implants,
- the state of scientific and technical knowledge at the time the product was put into circulation may not, in any event, indicate the present of a defect that is, in fact, contested,
- other causes of failure exist and were highlighted by Dr. Poitras (a Canadian implantologist), Dr. Wautier (the expert in V’s case), and Dr. Benkiran (the physician who treated Ms. C* after Dr. Leclercq).

The company concludes that proof of a link of causality between a defect and damages has not been demonstrated.

Secondarily, the company cites the faults committed by Drs. Bert and Leclercq, who, besides faults in design or the procedures performed on their patients, accepted a

certain degree of risk when they chose to put in implants that came from a new type of manufacturing process and demands, at the very least, that if the court chooses to impute a share of responsibility to the company, it be strongly mitigated.

As a counterclaim, the company demands that the plaintiffs be sentenced to pay it, under the terms of a provisional enforcement, the amount of 40,000.00 euros for damages, pursuant to the provisions of Article 32-1 of the New Code of Civil Procedure and 40,000.00 euros pursuant to Article 700 of the New Code of Civil Procedure.

By an application to be joined to proceedings dated June 9, 2005, the simplified joint stock company **Dentsply France**, which represents the rights of Friadent, seeks the recall of exhibits 89, 91, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 119, 120, 121, 122, and 123, which was demanded by the plaintiffs in the English language, unless otherwise translated. For the most part, Dentsply France reiterates the arguments made by Nobel Biocare and, in the event that the court should rule against it, demands to be guaranteed by Nobel Biocare. It seeks a joint ruling against Drs. Bert and Leclercq and the payment, under the terms of a provisional enforcement, of 20,000.00 euros, pursuant to Article 700 of the New Code of Civil Procedure.

Proceedings were closed on October 23, 2006.

FOR THESE REASONS

Whereas there were grounds to receive the voluntary third-party intervention from Dentsply France SAS, which represents the rights of Friadent, which was dissolved without liquidation by transfer of all assets and liabilities to the sole partner, Dentsply France SAS, in accordance with the decision of the sole partner on November 28, 2003;

Whereas plaintiffs' exhibits 89 and 122 are in French; and exhibit 119 includes a translation; and exhibits 91, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 120, 121, and 123 were not submitted to the court;

With regard to liability

Whereas the implants at issue were purchased starting in 1989; and Articles 1386-1 *et seq.* of the Civil Code, which came into being due to the Law of May 19, 1998, are not, consequently, applicable to this matter, a point on which all parties agree;

Whereas the combined provisions of Articles 17 and 19 of Council directive 85/374/CEE of July 25, 1985, concerning the harmonization of legislative, regulatory, and administrative provisions of Member States in matters of liability that arise from defective products stipulate that the directive is applicable to products put into circulation at the end of a period of 3 years given to recipient States to transpose the directive; and since the transposition of this text took place with Law 98-389 of

May 19, 1998, it is the responsibility of the court to interpret national law in the light of the directive in question;

Whereas the plaintiffs state that their action is founded on Article 1147 of the Civil Code as understood in light of and according to the objectives of the abovementioned directive; and they rightfully maintain that they can initiate proceedings in matters arising from contractual liability for failure to execute the contract that enabled them to use the product, since the manufacturer or supplier is required to deliver products free of any defect that may be a danger to persons or goods;

Whereas it is the responsibility of the claimants to supply proof of damage and a defect and demonstrate causality between them;

Whereas neither French law nor Directive 85/374/CEE of July 25, 1985, distinguishes the victims that are authorized to act; and a professional that suffers the consequences of a product defect while using it as part of his professional activity may, in accordance with the texts cited above, claim reparations for the economic consequences of bodily injuries caused to third parties by the defect in question; and the final paragraph of Article 9 of the Directive of July 25, 1985, states that it is not detrimental to national provisions with regard to moral prejudices;

Whereas, as regards the alleged defect, it must be remembered that:

- implantology is a recent discipline whose mission it is to replace one or more missing teeth using a two-part system, one intraosseous implant corresponding to a root, and the other a structure over the implant, or prosthesis,
- an implant is a piece of metal most often in the shape of a screw or cylinder, made of titanium or a titanium alloy, and inserted into the bone where a tooth is to be placed,
- the behavior of the implant varies according to the bone in which it is implanted; the bone may react in 4 ways ranging from most (type I) to least (type IV) favorable,
- the long-term success of an endosseous dental implant depends on the quality of osteointegration; this concept, which has been developed based on several animal and clinical experiments, may be defined as the bone tissue's way of adapting to the presence of an implant that is subjected to the forces of chewing; the remodeled bone and implant are not joined together; rather, the permanent physical contact that they have makes it impossible for the artificial pillar at the center of the tooth to move,
- while osteointegration is taking place, the concept of biointegration is being developed; biointegration is the presence of a genuine biochemical bond between the bone and the implant because of the presence of the implant on the surface, which is made of a phosphocalcic bioceramic, the hydroxylapatite called HA, which has advantageous biological properties,
- HA enters the composition of all mineralized tissues; it is the primary component in bone tissue, whose mineral component is 70 % of total bone mass and is comprised mostly of calcium and phosphates;

Whereas, according to several sources, an HA-coated implant is particularly suitable for a low-density bone; and it is, consequently, said to be the ideal implant in high-risk areas such as:

- maxillaries with type IV bones,
- the wide, spongy areas in the back of the jaw,
- wherever the bone does not have good cortical substance;

Whereas Steri-Oss, along with other firms such as Biotech, Calcitek, IMZ, or TBR, has manufactured HA implants (Denar, in this matter) and distributed them since 1988;

Whereas Steri-Oss cylindrical HA implants (Denar) have a tunnel drilled a few millimeters from one end that runs perpendicular to the axis of the implant that joins two diametrically opposed faces, as well as a canal drilled over around half the height of the implant on the two faces perpendicular to the tunnel; and these two features make it possible to recognize these implants by sight with the use of a radiograph;

Whereas Drs. Bert and Leclercq each implanted Denar cylindrical HA implants; that, at first, the results were good, with an initial failure rate lower than titanium implants; and, after 3 to 5 years, they observed difficulties that raised the failure rate to 25% after 7 years, which is an unusual pattern;

Whereas the expert, Prof. Sauveur, selected, with Mr. Délias, the prosthesis representing France-Implant, 11 of Dr. Bert's cases and 8 of Dr. Leclercq's cases; and for each of these 19 cases, the following were provided: a health questionnaire, a preliminary form (diagnostic, treatment plan), an implant implantation protocol sheet, complaint letters from some patients, a complete pre-, per-, and post-operative radiography file, photos taken before and after the procedure, photos of failed implants taken before and after implantation; and the expert examined 7 patients out of 19;

Whereas, based on these studies, he concluded that:

- there were problems at every stage in all cases submitted for examination: implant already expelled, imminent expulsion of the implant with peri-implantitis and suppuration, slight clinical symptoms (pain, mobility) with no obvious radiographic symptoms, radiographic symptoms with no clinical symptoms that reveal a potential failure,
- cases of actual failures had common specific features: problems beginning 3 to 5 years after implantation, perfectly integrated, functional implants with no pain in the first few years, sudden onset of difficulties, rapid changes,
- bone destruction was sometimes located in the crestal level of the implant, more often at the lateral level, and, most oddly, at the apex of the implant (intraosseous extremity of the implant),

- contrary to what normally happens, bone lysis occurs before peri-implantitis,
- that therapy for peri-implantitis was ineffective in the case of HA implants, whereas for non-HA implants, the pathology is reversible after guided bone regeneration;

Whereas the expert listed the causes for the known implant failures and when they occurred:

- immediate: patient- or physician-related (clumsiness, carelessness, technical failure),
- very short term (1 to 8 days): complications from infections,
- short term (1 to 6 months): lack of osteointegration related to infection or technique (heating of bone $> 47^{\circ}$, asepsis failure, or rotation speed of higher than 300 T/min),
- short term (6 to 12 months): related to prosthesis or occlusion (osteitis in the crater, implant fracture, peri-implantitis), tooth/implant joint-related (fistula), etc.
- medium term (2 to 5 years): related to choice of implant type based on shape, surface, length, and diameter criteria,

and believed that, in the cases in question, the failures were not related to the patients, the physicians (capacity, competence, working and technical conditions, i.e., protocol based on the type of implant), or the prostheses (more specifically, the choice of prosthesis type and adjustment of the occlusion);

Whereas, when faced with the criticisms articulated by the Nobel Biocare physician consultants, Drs. Poitras and Wolf, he explained that it must be taken into account that good engineering practices with regard to implantology vary over time; and consequently, for example, the reasons for which it is necessary to have one implant per prosthetic item are unjustified and the concept of deferred weight-bearing is questionable, there being several supporters of immediate implantation;

Whereas it may be added that Dr. Wautier, who examined one of Dr Leclercq's patients, Ms. V, whose Denar Steri-Oss HA implants, which had lost their coating, had to be taken out following a case of peri-implantitis, came to an identical conclusion for that claimant because he indicated that the loss of osteointegration in the maxillary implants could not be blamed on a degradation of the patient's health or a faulty prosthesis implant; and the planned prosthesis appeared to be well founded and thought through and the operating protocol seemed the rules of modern implantology;

Whereas in the cases examined, it may be observed that non-Denar HA implants have also been implanted at the same time as the HA implants, or subsequently, with no short- or medium-term difficulties;

Whereas examination of the expelled implants made it possible to establish that:

- the white HA coating on the new implants disappeared from the surface of the implants irregularly and more or less completely, and the total absence of HA was

most noticeable at the intraosseous end of the implants, then at the neck of the implants,

- that the spaces uncovered after the HA disappeared looked blackish;

Whereas, in general, the HA coatings were not identical; the mechanical, physical, and chemical properties are better when the material is pure, rich in crystals, and dense; and, conversely, an HA coating on an unrefined, impure, porous, and unstable implant lacking in crystals is sensitive to dissolution, be it cell-mediated or via organic fluids; and in 1996, and thus by definition in 1989, industrial standards for HA coatings had yet to be established; and the prevention of infection on the implant site is essential because infection causes a drop in pH and increases HA's vulnerability to resorption;

Whereas HA-coated implants all differ in their chemical composition; and there is a correlation between their biochemical structure and their ability to dissolve;

Whereas, before 1991, Denar HA implants were prepared using a plasma flow technique that was acknowledged to be the most reliable; and this technique made it possible to create a chemical bond between HA and titanium using a high-temperature (30,000° C), ionized gas; and some authors have set forth the hypothesis that states that implants may have defects related to this procedure insofar as the elevation of the implant temperature before overlaying and monitoring the temperature during the emission of HA makes it impossible to tell if the overlaying is being conducted under the same temperature conditions; and the thickness of the coating thus obtained could vary from 40 to 75;

Whereas the technique was modified starting in 1991 to allow for a higher HA density; and, in 1996, M. Hahn was of the opinion that Steri-Oss had a mastery of plasmas that made possible the development of a very pure, crystal-rich coating with optimal resistance to shearing; and it may be inferred from this that in 1991, Steri-Oss's knowledge of plasmas was less developed and the coating was not as rich in crystals;

Whereas Prof. Sauveur concluded that:

- the constraints placed on an ankylosed tooth, and therefore on an osteointegrated implant, created an osseous resorption and a resorption of the HA, a normal physiological phenomenon,

- since bone matter is living tissue, the resorbed portion regenerated whereas HA, an artificial element, did not regenerate after resorption, whence the empty space corresponding to the thickness of the HA that disappeared,

- even though the resorbed bone regenerated, the progression of this phenomenon was prevented by the polluting layer surrounding the implant,

- this process ended up covering the area surrounding the implant and bacteria would penetrate this space, infecting it and lowering the pH conditions that enabled the rest

of the HA to be dissolved in an environment that had become acidic and led to the expulsion of the implant;

Whereas this conclusion did not contradict that of Prof. Lyon, a chemist and co-expert, who, when he compared new implants from the period at issue and new-generation implants, stated that the product was morphologically very different; and the superimpositions of HA layers were almost impossible to take off; and no withdrawal force standard for this type of coating was available; and the resorption of the HA layer on the removed implants was practically 100%, analysis had been extremely difficult;

Whereas he added:

“The method for coating a dental implant was, in comparison with the method for implants currently used in bone surgery, an excellent idea in 1988-1989, as the publications the launch of an HA-coated prototype for dentistry demonstrate. Without knowledge of the specific restrictions of an implant set in a jaw, it turns out that pressures, stresses, and constraints must be different than those of ‘classical’ bone prostheses. As with all material techniques, the involvement of both the manufacturer and any potential users seemed insufficient, in our opinion, for a product ‘implanted’ in a patient, a living, changing system. The behavioral transposition and comparison of a ‘normal’ bone with gums that was made at the beginning perhaps was not able to integrate all parameters. In our opinion, it is this difference between a bone and gums within very different constraints in an equally different environment that could explain the failure of HA in dental implantology with resorption of the HA layer over time. Serious accelerated aging studies on the material cannot be conducted as they normally are, with a new material, because of this specific use. The idea, which is very attractive at first, has demonstrated its limits and posed problems after a period of 3 to 5 years while more traditional systems resist beyond this period. The different appearance of the deposits shows that the deposit technique, even if it is always done with plasma, has evolved over the course of time”;

Whereas the items submitted into evidence establish that other physicians encountered difficulties similar to those described here with Denar HA implants; and several articles reported these problems; and, as a result, a report from the 1996-1997 Cochin Days mentions that the consequence of the high level of solubility of the amorphous HA layer is a more or less accelerated resorption of the implant coating and histological studies show that even if the bone-implant interface is integrated in the short term, a resorption process invariable takes place in the long term; and the article concludes that one should remain very cautious in light of the results announced for HA-coated implants and because it is very difficult to compare statistical studies among themselves (different study protocol, criteria for patient selection, percentage of success aligned over less rigorous criteria, etc.);

Whereas on May 14, 2001, the director general of the French Agency for the Safety of Health Products decided to suspend the marketing, distribution, and use of Steri-Oss HA brand HA-coated cylindrical HA implants marketed by Nobel Biocare for a period of one year (which was not renewed), noting that the HA disappears when it reacts with inflamed bone cells, revealing a surface that is incompatible with good osteo-integration; and it specified that the items submitted by Nobel Biocare did not make it possible to guarantee the lifespan of the implants, in accordance with the state of the art;

Whereas, out of all of these items, it emerges that the implant at issue did not offer the safety that purchasers, in particular physicians, could legitimately expect, knowing that the ordinary life span of an implant is 10 years, with regard to the presentation of the product, which is described as being the answer to several problems;

Whereas Steri-Oss did not conduct animal tests, using those conducted by Calcitek; and however, it turns out that the experiments from before 1991, which were conducted on dogs, did not last for more than 10 months and, consequently, did not allow all matters of long-term implant performance to be evaluated; and Nobel Biocare did not give the reasons that would be compared to the results of the tests that made it possible for the company to sell a product that had the stated features; and this lack of precaution does not authorize it to maintain that the state of scientific and technical knowledge at the time that the product was put on the market could not allow a defect to be revealed; and that, consequently, it cannot be exempted from liability; and it makes no difference that marketing was not covered under specific terms and conditions;

Whereas no blame can be assigned to the physicians for purchasing next-generation implants from a renowned company that presented its product as having exceptional properties (which are partially true) that can resolve problems caused by difficult situations:

Whereas the liability of Nobel Biocare USA Inc and Dentsply will be, consequently, upheld; and the supplier Dentsply will comply with the order to pay the costs imputed to it by Nobel Biocare USA ;

For damages

Direct bodily injury:

Whereas Dr. Leclercq states that he implanted 86 Denar cylindrical HA implants and had to take out 44; and Dr. Bert stated a figure of 252 implants and 64 implants removed; that these physicians added up the additional hours and medical costs thereunto pertaining, which they maintain were at their expense, for a total of 211,350.00 euros for Dr. Leclercq and 120,815.00 euros for Dr. Bert and 42,685.00

euros for Dr. Leclercq and 70,505.00 euros for Dr. Bert regarding the additional hours and medical expenses to be incurred in the future;

Whereas, even though the total of 19 cases examined by the expert correspond effectively to implants from Nobel Biocare, as acknowledged by France Implants, the representative of the distributor in France, it must be emphasized that only 2 invoices addressed to Dr. Leclercq by France Implants and 3 invoices sent to Dr. Bert were submitted into evidence; and two of the latter's invoices were for the professional civil partnership Bert-Lankry, which makes it impossible to determine who used the product; and even though the plaintiffs can be criticized for not keeping the invoices corresponding to the implants they purchased, it is impossible not to notice that this gap is detrimental to the establishment of proof;

Whereas no reliable document submitted into evidence makes it possible to calculate the amounts that the plaintiff physicians paid themselves because they state, without furnishing any proof, that they did not invoice for additional hours; and in particular, the medical files produced make no mention to this effect; and they did not furnish proof of work to be done in the future at their expense; and failing any proof, the demands will be rejected;

For direct economic damages

Whereas Drs. Bert and Leclercq maintain that they suffered economic damages related to the loss of patients, unhappy patients, and that some of their usual correspondents are no longer referring new patients to them;

Whereas, even though these damages appear to be real, as the correspondence submitted reveals, they cannot be quantified for the amounts claimed if they fail to produce any tax and/or accounting document; and, with regard to items in the case, the court will allocate the amount of 25,000.00 euros to each of the plaintiffs, plus interest at the legal rate starting today;

For moral damages

Whereas, even though it is understood that it is difficult, even painful, for a dental surgeon to explain to a patient the failure that has occurred, this situation does not constitute moral damages;

For loss of goodwill

Whereas it is certain that the time that Drs. Bert and Leclercq devoted to their patients because of the difficulties encountered with the Denar HA implants and the time that was necessary for these proceedings, in particular the long and difficult expert investigation conducted by Professors Sauveur and Lyon, prevented them from dedicating themselves to other tasks, be it the treatment of other patients, training, or research; and these damages will be valued, in the absence of tax and accounting

documents, at 25,000.00 euros each, plus interest at the legal rate starting today;

For the publication of the ruling

Whereas the implant at issue is no longer marketed because the manufacturing process was modified in 1991; and the expert stated that, since 1998, the HA coating has been obsolete, not only for the design of the relief surface finishes that were abandoned in favor of the SLA-type crater surface finish, but for HA itself because its stated physical, chemical, and biological properties have been rejected once and for all; and under these conditions, ordering the publication of this ruling does not seem necessary;

For the other demands

Whereas it would not be equitable for Drs. Bert and Leclercq to pay the unrecoverable expenses incurred in this matter without the need to take the expert inquiries for C* and V*, who are separate cases, into account; and that they will each be allotted the amount of 8,000.00 euros each pursuant to Article 700 of the New Code of Civil Procedure;

Whereas a provisional enforcement is compatible with necessary for this type of matter, it will be ordered, except for the compensation payments pursuant to Article 700 of the New Code of Civil Procedure;

Whereas there is no reason that the expenses for Sauveur's and Lyon's expert fees should be included in this matter, and there is no reason for V*'s expert fees to be included in this matter, the defendants shall be jointly responsible for them; and there is no grounds to charge interest on these amounts starting on the date that the defendants are given notice of the conclusions;

Whereas Nobel Biocare USA, Inc., agrees that it will be nonsuited for its demand for damages; and the demands presented by the defendants for their unrecoverable expenses will be rejected;

FOR THESE REASONS

THE COURT

Ruling at a public hearing, in proceedings in which both parties participated and which is subject to appeal,

Pursuant to Article 1147 of the Civil Code interpreted in light of Council directive 85/374/CEE of July 25, 1985, concerning the harmonization of legislative, regulatory, and administrative provisions of Member States in matters of liability that arise from defective products;

Receives the voluntary intervention of Dentsply France, representing the rights of Friadent;

Declares that Nobel Biocare USA, Inc, representing the rights of Steri-Oss, and Dentsply France, representing the rights of Friadent, are jointly responsible with regard to Dr. Marc Bert and Dr. Philippe Leclercq dor damages suffered following the purchase of Denar cylindrical HA implants manufactured prior to 1991, which are defective as defined by the texts cited above;

Sentences Nobel Biocare USA, Inc, representing the rights of Steri-Oss, and Dentsply France, representing the rights of Friadent, jointly to pay:

1) Dr. Marc Bert the amounts of:

- * 50,000.00 (fifty thousand) euros in compensation for damages,
- * 8,000,00 (eight thousand) euros pursuant to Article 700 of the New Code of Civil Procedure, plus interest at the legal rate starting today;

2) Dr. Philippe Leclercq the amounts of:

- * 50,000.00 (fifty thousand) euros in compensation for damages,
- * 8,000,00 (eight thousand) euros pursuant to Article 700 of the New Code of Civil Procedure, plus interest at the legal rate starting today;

Sentences Nobel Biocare USA, Inc, release and hold harmless Dentsply France for all sentences pronounced against it for principal and interest and compensation allocated for unrecoverable and other expenses;

Rejects any larger or contradictory demand by the parties;

Orders provisional enforcement, except for the compensation payments pursuant to Article 700 of the New Code of Civil Procedure;

Jointly sentences Nobel Biocare USA, Inc, and Dentsply France to pay expenses, which shall include legal expert fees incurred by Prof. Sauveur and Prof. Lyon;

Grants Mr. Jean-Philippe Pin the benefit of the provisions of Article 699 of the New Code of Civil Procedure.

Concluded at Paris, February 5, 2007

**In compliance with the rules of doctor-patient confidentiality, the names of the patients have been changed.*