UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
WEST PALM BEACH DIVISION

JACK T. KRAUSER, D.M.D., an individual, Plaintiff, v. BIOHORIZONS, INC., a Delaware corporation, BIOLOK INTERNATIONAL, INC., a Delaware corporation, and BIOHORIZONS IMPLANT SYSTEMS, INC., a Delaware corporation, Defendants.	CASE NO.: 9:10 CV 80454-MARRA

DECLARATION OF DR. CLARK STANFORD IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

I, DR. CLARK STANFORD, hereby declare as follows:

1. I submit this declaration in support of Defendants: BioHorizons, Inc., Biolok International, Inc. and BioHorizons Implant Systems, Inc.'s (collectively "BioHorizons") motion for summary judgment.

2. I am a Centennial Fund Professor of Clinical and Translational Research and an Associate Dean for Research at the University of Iowa, College of Dentistry's Dows Institute for Dental Research and Department of Prosthodontics. Prosthodontics is the branch of dentistry that specializes in the replacement of missing teeth and related mouth or jaw structures, such as bridges, dentures, dental implants, and other artificial devices.

3. I am also a Professor at the Department of Biomedical Engineering, College of Engineering, University of Iowa, and a Professor in the Department of Orthopedic Surgery, College of Medicine, University of Iowa.

4. I received my D.D.S. degree from the University of Iowa in 1987, and was awarded a post-graduate certificate in Prosthodontics from the University of Iowa in 1992. Since 1987, I have practiced dentistry, including implant dentistry, with a focus on Prosthodontics. My Ph.D. (University of Iowa, 1992) addressed tissue response to dental implant materials and design aspects of medical device designs.

5. I am a member of the Dental Products Panel of the Medical Devices Advisory Committee of the U.S. Food and Drug Administration (FDA), where I participate in reviewing 510(k) regulatory permission applications from dental implant manufacturers, among other responsibilities.

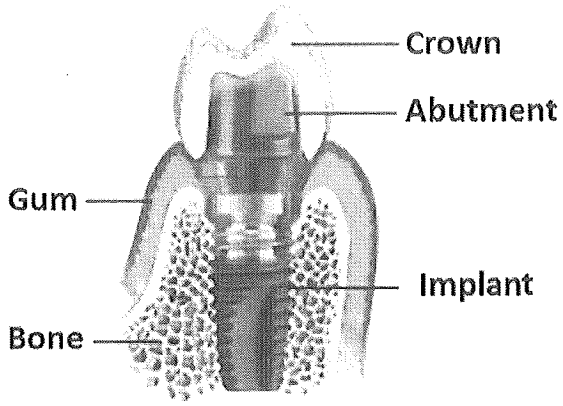
6. My background and qualifications are fully set forth in my curriculum vitae attached as Exhibit A.

I. BACKGROUND OF DENTAL IMPLANT TECHNOLOGY

A. Development of Endosseous Dental Implants

7. When a patient loses a tooth or multiple teeth, the ability to replace the missing teeth with predictably good results is very important, especially when the front teeth are involved. Groundbreaking research in the 1950's establishing the ability of bone to "bond" with titanium laid the foundation for the development of what are known as "endosseous" dental implants -- that is, dental implants that are implanted into and are surrounded by living bone of the jaw and have the potential to bond with the bone. All of the dental implants at issue in this case are endosseous dental implants.

8. Endosseous dental implant systems generally consist of three main components: (i) the implant (which is implanted into the jawbone), (ii) the abutment (which attaches to the implant and provides a platform for the prosthesis, and (iii) the prosthesis, or crown (the artificial tooth) itself. These components are depicted in the diagram below:



9. In the early 1980's, the development of endosseous dental implants and, equally importantly, the demonstration of their reliability, revolutionized oral rehabilitation . Prior to the widespread introduction of endosseous dental implants in North America in early 1980's, the dental implants commonly in use (e.g., blades, plates and subperiosteal devices) had generally unsatisfactory results because these antecedent implant designs were technique sensitive and required significant surgical interventions and clinical skill to accomplish reasonable clinical outcomes.

10. By approximately 1988, endosseous dental implant systems were on the market that were demonstrated to last for at least 5 - 10 years. By that time, these endosseous dental implants were clearly established as superior to existing alternative designs (e.g. blades, plates and subperiosteal devices), which often appeared to work well for a while but would then begin to develop bone loss and inflammation which in turn led to loss of the supporting bone around the implant body.

B. Distinguishing Features of Dental Implants

11. Endosseous dental implant designs included a variety of distinguishing features, including threaded/threadless, internal/external abutment connection, and whether or not they

included "grooves" to block growth of gum tissue epithelium down along the bone interface of the healed oral implant.

1. Threaded vs. Threadless Implants

12. "Threaded" implants are designed with a thread on the body of the implant and are screwed into the bone of the jaw (much like standard wood screws) providing what is called "primary stability" until the bone has time to heal and bond with the implant (at which point this bond provides what is called "secondary stability" to the implant). Stability is important because lack of stability can lead to implant loss.

13. "Threadless" implants are literally threadless (meaning they do not have a thread on the external body of the implant) and typically have a cylindrical design that relies upon compression between the bone and the implant for primary stability (as opposed to being screwed into the bone of the jaw in the manner that threaded implants are). Threadless designs were typically "press-fit," which means that the clinician prepares a hole smaller in diameter than the implant, and then hammers the cylindrically shaped dental implant device (which itself may contain various surface coatings) into place.

14. While threaded and threadless designs were each initially thought to have advantages, threadless implants were ultimately found to suffer from significant problems and subsequently fell out of favor. Today, virtually all dental implants are threaded designs.

2. External vs. Internal Hex Connections

15. In general, there are two principle types of interconnection between an implant and an abutment: (i) an external hex connection, and (ii) an internal connection. Each has advantages and disadvantages.

16. An external hex connection is one in which the top of the implant has an external male hex-shaped protrusion that mates with an internal hex-shaped cavity on the bottom of the abutment. An example of an external hex connection is shown below:



17. The external hex connection on the top of the implant body was first developed in the 1960's and advocated especially by PI Brånemark' s group in Goteborg, Sweden, and was seen to have certain advantages. One such advantage is that it facilitated placement of the implant using an implant driver and allowed sufficient precision for implant manufacturers to provide milled implants based on the precision and machining tolerances of the 1960's when these were first developed. By the mid-1980's, the external hex was used as a means to connect a dental crown or bridge to the external hex implant(s).

18. In the mid-to-late 1980's, a number of dental implant systems started to move away from the Brånemark external-type hex connection toward a combination of internal hex configurations, conical interfaces and a range of "abutment-to-implant" configurations to reduce micromotion between the abutment and the body of the implant.

19. Internal hex designs were developed to address leakage and micromotion issues that affected the external hex connection.

3. Use of "grooves" to block apical migration of epithelium on implant

20. An early concern with dental implants was the apical migration of epithelium (gum tissue) down the side of the dental implant following loss of bone around the implant. This

migration of gum tissue blocks regrowth of bone, leading to a loosening and potential loss of the implant. This undesirable growth of epithelium was referred to as "marsupialization," and was recognized as a significant cause of implant failure. Avoidance of marsupialization was a long-standing goal of implant design.

21. While there are multiple causes of bone loss, significant attention has been paid to micromotion, which is thought to promote inflammation and bone loss as well as downward migration of epithelium, as the body attempted to establish a more stable seal on the head of the non-moving dental implant secured in the bone.

22. As developed in the 1960-70's, many of the dental implant designs used a two piece abutment in which a butt-joint crown abutment was fixed to the dental implant by way of an abutment screw (the screw passing through the abutment and screwed in the body of the implant positioned down in the bone tissue). Due partly to the limitations of machining technology at the time, implant parts often did not fit together as tightly as desired, amplifying micromotion.

23. As a result, there was a need to develop implant designs that would block migration of the soft tissues down on to the implant body.

24. I understand that Dr. Krauser is claiming ownership of dental implants that have the "Laser-Lok" grooves to block and/or control epithelial growth. The development of those grooves is generally credited to the work of Dr. Ricci and his colleagues. I am aware that Dr. Ricci is a consultant to Defendant BioHorizons. I am very familiar with Dr. Ricci and his work. Dr. Ricci and his group found that, when applied to a dental implant, very small groove sizes (in the range of about 2 to about 25 microns) coupled with specific groove shapes and patterns could be used to provide preferential control of cell growth. The "microgeometric" groove patterns, formed by laser etching the collar of the implant (conventionally a polished area on the upper portion of the implant body

where it exits from the bony tissue), were found to be superior in controlling epithelial downgrowth than the much larger V -shaped grooves known at the time. Dr. Ricci's work formed the basis for Defendants' Laser-Lok microgroove technology. Dr. Ricci published his work extensively and obtained several patents on it.

II. THE BIOHORIZONS DENTAL IMPLANT SYSTEMS THAT DR. KRAUSER CLAIMS TO OWN AND THE MINIMATIC 1996 DENTAL IMPLANT SYSTEM ARE SIGNIFICANTLY DIFFERENT SYSTEMS

25. I understand that Dr. Krauser bases his ownership claims on the October 1996 Settlement Agreement (OSA) and his assertion that the 2012 BioHorizons dental implant products are somehow based on the earlier Minimatic 1996 dental implant products and drawings. I have compared the technical aspects of the Minimatic 1996 dental implant systems (which are no longer marketed) and drawings to the 2012 BioHorizons Dental Implant Products.

26. I have reviewed the 510(k)s, technical drawings and product catalog relating to the Minimatic dental implant system as it existed in October 1996. I have also inspected and reviewed the 510(k)s and product catalogs for the 2012 BioHorizons products that Dr. Krauser claims to own. In my opinion, the BioHorizons Dental Implant Products are very different from the 1996 Minimatic dental implant systems and Minimatic drawings.

A. The Minimatic 1996 Dental Implant System

27. In 1996, Minimatic had four types of dental implant products: one type of threaded screw implant (with an external hex top) and three types of threadless cylindrical implants (one with an external hex top and two with bevel tops having a sloping interface). These implants are depicted in the 1996 Minimatic Catalog that was attached as Exhibit B to the October 1996 Settlement Agreement:

Implant Type	510(k) Number
Threaded External Hex Top Implant	K9047078
Threadless Cylindrical Hex Top Implant	K904705/A
Threadless Cylindrical Bevel Top HA	K902928/A
Threadless Cylindrical Bevel Top (Titanium Plasma Spray)	K911776

B. The BioHorizons Dental Implant Products Are Significantly Different From The Four Products Showing In The 1996 Minimatic Catalog

28. In my opinion, the BioHorizons dental implants at issue are significantly different from the Minimatic dental implant systems shown in the 1996 Minimatic catalog. Unlike the 1996 Minimatic implant systems, the 2012 BioHorizons products have several distinguishing features: (1) they are all threaded, (2) they have micro-etching of specifically sized horizontal grooves on the upper portions of the implant to control epithelial and bone growth and differentiation, (3) they have a tapered profile, and (4) they have combine a threaded body to an internal rather than an external hex connection for the abutment interface.

29. First, three out of the four implant lines identified in the 1996 Minimatic Catalog are threadless cylindrical implants. BioHorizons does not make or sell any threadless cylindrical implants, and never has. I am also informed that although Minimatic/BioLok once sold threadless cylindrical implants, it discontinued making and selling them well before BioLok became an affiliate of BioHorizons.

30. Second, the 1996 Minimatic implants do not have micro-etching. BioHorizons has adapted a technology with a very specific micro-etching texturing, which it markets under the trade name "Laser-Lok." Laser-Lok is a significant characteristic of the BioHorizons implant families referenced above because it achieves significant improvements in product performance, showing minimal bone loss and minimal inflammation. These are important and desirable clinical outcomes.

Clearly, Laser-Lok is a significant attribute of the BioHorizons implant families referenced above and does not appear in the 1996 Minimatic catalog.

31. Third, the implants of the Tapered Internal product line all have (as their name implies) a substantially tapered body. This tapering allows significant flexibility in implant placement, such as in extraction sockets, tight spaces between two adjacent teeth, and areas of thin bone to reduce the need for bone grafting. In contrast, the only threaded implant shown in the 1996 Minimatic catalog is a parallel-walled implant that does not show substantial tapering and would not provide the flexibility of use of the tapered implant. The use of substantially tapered dental implants has been widely accepted in the dental community (virtually all of the major dental implant manufacturers now market a substantially tapered implant as a distinct product line), and I am informed that the BioHorizons Tapered Internal Implant is the largest and fastest growing implant family within the BioHorizons product line.

32. Fourth, the only threaded implant in the 1996 Minimatic Product Catalog has both an external hex connection with a buttress thread. None of the BioHorizons implant families have this combination. The only such implant having a buttress thread is the Tapered Internal Implant, which is both substantially tapered and has an internal connection that is completely different from the external hex connection on the 1996 Minimatic implant.

33. Fifth, BioHorizons' dental implants are marketed under BioHorizons' own 510(k) regulatory clearances. None of the Minimatic 510(k)s in existence in 1996 are used to market any of BioHorizons' products.

III. THE OCTOBER 1996 SETTLEMENT AGREEMENT (OSA) DOES NOT CONFER OWNERSHIP OF BIOHORIZONS IMPLANTS TO DR. KRAUSER

34. The October 1996 Settlement Agreement ("OSA") makes clear that Dr. Krauser cannot assert ownership of the BioHorizons implants, because paragraph 8 of the OSA limits Dr. Krauser to seeking a declaration of dental implants "currently being manufactured" by Minimatic in

1996, which excludes the later-developed and significantly different BioHorizons dental implant systems.

35. I understand that, as part of the OSA entered by the Bankruptcy Court, Dr. Krauser released his ownership claims, with a limited right set forth in Paragraph 8 to seek "a declaration of his rights in and to the dental implant system currently being manufactured by Debtors [Minimatic]." This paragraph thus does not itself confer ownership on Dr. Krauser, but simply gives him a (limited) right to seek a declaration of what his ownership interest is. Since Dr. Krauser never owned the Minimatic implant system, those rights are zero.

36. In addition, paragraph 8 of the OSA expressly limits Dr. Krauser's right to seek a declaration of ownership to "the dental implant system currently being manufactured" by Minimatic. A reasonable dentist would understand this to refer to the dental implants described in Minimatic's product catalog as of the date of the agreement (that is, Minimatic's 1996 product catalog). This is confirmed by the fact that the OSA attaches (as Exhibit B) the 1996 Minimatic Product Catalog as "the Debtors' current product catalog." Paragraph 8 of the OSA thus limits Dr. Krauser to seeking a declaration of ownership only of those products described in the Minimatic 1996 product catalog.

37. The BioHorizons implant systems Dr. Krauser now seeks to own are different from those 1996 Minimatic products: they are sold under different regulatory clearances (that is, different 510(k) clearances), and have different design features than those shown in the Minimatic 1996 Product Catalog.

I declare under penalty of perjury that the foregoing is true and correct.

May 7, 2012

Dr. Clark Stanford DDS, Ph.D.