APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERAMTEC GMBH,
Appellant

v.

COORSTEK BIOCERAMICS LLC, FKA C5 MEDICAL WERKS, LLC,
Appellee

2023-1502

Appeal from the United States Patent and Trademark Office, Trademark Trial and Appeal Board in Nos. 92058781, 92058796.

Decided: January 3, 2024

JESSICA LYNN ELLSWORTH, Hogan Lovells US LLP, Washington, DC, argued for appellant. Also represented by ANNA KURIAN SHAW, REEDY SWANSON; KATHERINE BOOTH WELLINGTON, Boston, MA; JOHANNAH CASSEL-WALKER, SAN FRANCISCO, CA.

STEVEN J. HOROWITZ, Sidley Austin LLP, Chicago, IL, argued for appellee. Also represented by CAROLINE A. WONG; DIANA RUTOWSKI, Orrick, Herrington & Sutcliffe LLP, Menlo Park, CA.

Before LOURIE, TARANTO, AND STARK, Circuit Judges.

LOURIE, Circuit Judge.

CeramTec GmbH ("CeramTec") appeals from a decision of the United States Trademark Trial and Appeal Board ("the Board") cancelling its trademarks which claim protection for the pink color of ceramic hip components. Coorstek Bioceramics LLC f/k/a C5 Medical Werks, LLC v. CeramTec GmbH, Nos. 92058781 & 92058796, 2022 WL 17547263 (T.T.A.B. Dec. 6, 2022) ("Decision"). For the reasons discussed below, we affirm.

BACKGROUND

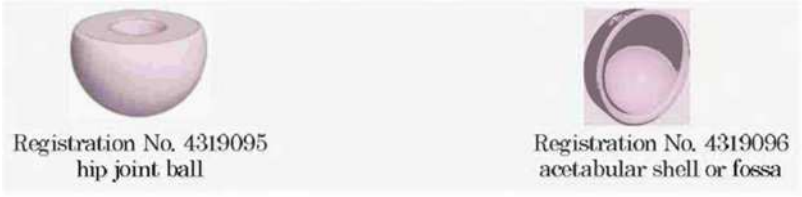
CeramTec manufactures artificial hip components used to replace damaged bone and cartilage in hip replacement procedures. The hip components are made from a zirconia-toughened alumina ("ZTA") ceramic originally developed for use in cutting tools. The ZTA ceramic contains, among other things, chromium oxide (chromia). CeramTec markets the hip components under the name, "Biolox Delta." Decision at *15.

Biolox Delta's chemical composition, including the addition of chromia, was the subject of CeramTec's U.S. Patent 5,830,816 ("the '816 patent") until January 2013, when the patent expired. J.A. 1230. Claim element 3(e) of the '816 patent is illustrative, claiming "the molar ratio between the [zirconia] . . . and the [chromia] amounting to 1,000:1 to 20:1." '816 patent col. 10, ll. 31–33. The '816 patent's specification

and prosecution history discuss how adding chromia enables the claimed composition to obtain unprecedented levels of hardness. '816 patent col. 3, ll. 62– 63 (the addition of chromia "makes it possible for the first time to achieve hardness values such as have not previously been achieved"); J.A. 1628 ('816 patent prosecution history: similar)). Increased hardness levels enable the ZTA hip component to maintain its shape and resist deformation. Decision at *13.

The amount of chromia in the ZTA ceramic affects its coloring. In fact, the range of chromia claimed in the '816 patent can produce ZTA ceramics in a variety of colors, such as pink, red, purple, yellow, black, gray, and white. Biolox Delta contains chromia at a 0.33 weight percentage (0.33%), which makes it pink. Decision at *16, *56. CeramTec has also applied for and received other patents that spoke to chromia's impact on ZTA ceramic hardness.

In January 2012, CeramTec applied for two trademarks claiming protection for the color pink used in ceramic hip components. In April 2013, the marks were registered on the Supplemental Register.



Registration No. 4319095
hip joint ball

Registration No. 4319096
acetabular shell or fossa

Decision at *14; see also J.A. 107–10 (Supplemental Registration Nos. 4319095 and 4319096).

CoorsTek Bioceramics LLC, formerly known as C5 Medical Werks, LLC ("CoorsTek"), is a competitor to CeramTec in the medical-implant market. CoorsTek manufactures two ZTA ceramic materials for hip implants: (1) CeraSurf-p, which contains chromia, rendering it pink, and (2) CeraSurf-w, which does not contain chromia, rendering it white.

On March 3, 2014, CoorsTek filed a lawsuit in the District of Colorado and a cancellation petition with the Board, both seeking to cancel CeramTec's trademarks on the ground that the color pink claimed was functional. J.A. 491–500.[1] In response, at the Board, CeramTec argued that although it had once believed that adding chromia provided material benefits to ZTA ceramics, that belief was mistaken and has since been disproven.

The Board found in favor of CoorsTek and concluded that the color pink was functional as it relates to ceramic hip components. *Decision* at *57. The Board analyzed the functionality of the marks under the four factors discussed in *In re Morton–Norwich Products, Inc.*, 671 F.2d 1332, 1340–41 (C.C.P.A. 1982), and also considered experimental

[1] The district court proceeding was ultimately resolved on procedural grounds. *C5 MedicalWerks, LLC vs. CeramTec GmbH*, 937 F.3d 1319, 1323 (10th Cir. 2019) (vacating the district court decision based on a lack of personal jurisdiction).

testing conducted in a related German litigation, suggesting that chromia has no effect on the material properties of ZTA ceramic hip components. *Id.* at *48–57.

Applying the *Morton–Norwich* factors, the Board found that CeramTec's patents and public communications disclosed that the addition of chromia provides material benefits to ZTA ceramics, and therefore weighed in favor of functionality. *Id.* at *49–54. Because there was no probative evidence as to whether Biolox Delta would work as well if made in colors apart from pink, the Board found this factor to be neutral with respect to functionality. *Id.* at *54. And because there was conflicting evidence as to whether chromia decreases the cost of manufacturing ceramic hip components, the Board also found this factor neutral. *Id.* at *55.

As for the testing suggesting that chromia had no effect on the material properties of ZTA ceramics, the Board found the experiments to be methodologically flawed, and therefore chose not to factor the results into its functionality determination. *Id.* at *55–56.

Lastly, the Board rejected CeramTec's unclean hands defense, in which CeramTec argued that CoorsTek should be precluded from petitioning to cancel its trademarks on functionality grounds because CoorsTek had previously contended that chromia provided no material benefits to ZTA ceramics. *Id.* at *57–58.

In sum, the Board cancelled the marks based on its conclusion that the marks are in fact functional.

CeramTec appeals the Board's decision. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(B) and 15 U.S.C. § 1071(a)(1).

DISCUSSION

A trademark is not registrable or is cancellable if the design described is functional. *See Valu Eng'g, Inc. v. Rexnord Corp.*, 278 F.3d 1268, 1273 (Fed. Cir. 2002). As the Supreme Court explained in *Qualitex Co. v. Jacobson Prods. Co.*:

> The functionality doctrine prevents trademark law, which seeks to promote competition by protecting a firm's reputation, from instead inhibiting legitimate competition by allowing a producer to control a useful product feature. It is the province of patent law, not trademark law, to encourage invention by granting inventors a monopoly over new product designs or functions for a limited time, 35 U.S.C. §§ 154, 173, after which competitors are free to use the innovation. If a product's functional features could be used as trademarks, however, a monopoly over such features could be obtained without regard to whether they qualify as patents and could be extended forever (because trademarks may be renewed in perpetuity).

514 U.S. 159, 164–65 (1995).

Legal conclusions of the Board are reviewed *de novo*, and the factual findings of the Board are upheld when they are supported by substantial evidence. *In re Pacer Tech.*, 338 F.3d 1348, 1349 (Fed. Cir. 2003). A finding is supported by substantial evidence if a

reasonable mind might accept the evidence as adequate to support the finding. *In re GO & Assocs., LLC*, 90 F.4th 1354, 1357 (Fed. Cir. 2024). The functionality of a mark is a question of fact. *In re Becton, Dickinson & Co.*, 675 F.3d 1368, 1372 (Fed. Cir. 2012); *Morton–Norwich*, 671 F.2d at 1340–41 (C.C.P.A. 1982) (establishing the *Morton–Norwich* factors for evaluating trademark functionality).

CeramTec raises two main arguments on appeal: (1) that the Board's finding that its trademarks are functional was infected by legal error and unsupported by substantial evidence, and (2) that the Board erred by categorically precluding the defense of unclean hands in cancellation proceedings involving functionality.

I

CeramTec first challenges the Board's finding that its trademarks are functional. CeramTec asserts that the Board's analysis with respect to the first *Morton–Norwich* factor was both factually and legally flawed and that the Board's findings with respect to the third and fourth factors were not supported by substantial evidence. CeramTec also asserts that the Board's findings as to the experimental testing were not supported by substantial evidence. And last, CeramTec contends that the Board erroneously placed the burden on it to prove that its trademarks were not functional. We address each argument in turn.

A

As noted, the Board analyzed the functionality of CeramTec's trademarks in part under the four factors set out in *Morton–Norwich*, 671 F.2d at 1340–41:

> (1) the existence of a utility patent disclosing the utilitarian advantages of the design;
>
> (2) advertising materials in which the originator of the design touts the design's utilitarian advantages;
>
> (3) the availability to competitors of functionally equivalent designs; and
>
> (4) facts indicating that the design results in a comparatively simple or cheap method of manufacturing the product.

1

The Board concluded that CeramTec's patents were "strong evidence that the color pink for ceramic hip implant components is functional" under the first *Morton–Norwich* factor. *Decision* at *52. In analyzing the first factor, the Board read the claims, specification, and prosecution history of the '816 patent to disclose the "functional benefits of chromia with respect to the toughness, hardness, stability and suppression of brittleness of the ZTA ceramic." *Id.* at *51. The Board also considered CeramTec's other patents and applications, *e.g.*, U.S. Patent 9,237,955 ("the '955 patent") and U.S. Patent Application 2012/0142237 ("the '237 application"), which it found disclosed that chromia increases the hardness and toughness of ZTA ceramics and makes ZTA ceramics suitable for medical applications. *Id.* And last, the Board considered CeramTec's concessions that the

addition of chromia causes ZTA ceramics to become pink and that Biolox Delta practices at least one claim of the '816 patent. *Id.*

CeramTec makes two arguments challenging the Board's analysis under the first *Morton–Norwich* factor: (1) that the Board erred in reading the patents to attribute functional benefits to the addition of chromia other than hardness, and (2) that the Board improperly applied the Supreme Court's decision in *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23 (2001) to the facts of this case.

CeramTec contends that it was error for the Board to find that the patents disclose that chromia provides utilitarian advantages to ZTA ceramics in addition to increasing hardness. Although the patents mention other material benefits (toughness, stability, and suppression of brittleness), CeramTec asserts that the patents attribute them to other elements of ZTA ceramics (*e.g.*, zirconia). CeramTec, however, admits that the Board correctly read the '816 patent to attribute increased hardness levels of ZTA ceramics to the addition of chromia. CeramTec Br. at 10 (the "['816] patent, reflecting the understanding at the time, suggests that chromia in the amounts claimed contributes to the overall hardness of the ZTA ceramic"). We therefore need not consider whether the Board may have partially erred in its reading of the patents because the Board's analysis is equally supported whether the patents state that chromia accounts for only one or several material benefits.

As for *TrafFix*, CeramTec acknowledges that that case holds that utility patents can be "strong evidence" that the features therein claimed are functional, thus precluding trademark protection. However, CeramTec argues that *TrafFix* only applies when two threshold requirements are met. First, according to CeramTec, the utility patent must explicitly claim a design feature that the patent owner later seeks to trademark, and second, the goods for which trademark protection is sought must be the "central advance" of the patent—*i.e.*, the same goods mentioned in the patent. CeramTec asserts neither requirement is met here because the patents do not explicitly disclose material benefits for pink ZTA ceramics and do not discuss hip components, only cutting tools.

CeramTec supports its reading of *TrafFix* by pointing to the policy underlying the functionality doctrine. According to CeramTec, the reason patented design features weigh in favor of finding a trademark functional is "because the public should be 'free to use' those features after the patent's terms have ended." Reply Br. at 12 (quoting *Qualitex*, 514 U.S. at 164). And here, CeramTec contends that the public is free to use CeramTec's patents, so long as it does not "produc[e] a pink product." Reply Br. at 12. We disagree with CeramTec's reading of *TrafFix*.

In *TrafFix*, the Supreme Court explained that because utility patents are granted for "unique and useful" inventions, they are "strong evidence that the features therein claimed are functional." *TrafFix*, 532 U.S. at 29, 31. Accordingly, "if trade[mark] protection

is sought for those features[,]" the patent "great[ly] weigh[s]" in favor of finding the trademark functional. *Id.* at 29–30. *TrafFix* also explained that the functionality inquiry can be "aided by . . . examining the patent [specification] and its prosecution history to see if the feature in question is shown as a useful part of the invention." *Id.* at 34. But nowhere does *TrafFix* hold that for a patent to be evidence of a claimed feature's functionality, the patent must explicitly disclose that the claimed feature is functional. Nor does *TrafFix* state that for a trademark to be subject to a *TrafFix* analysis it must be used for the goods described in the patent. Rather, the "central advance" language was used by the *TrafFix* Court to illustrate why the patent in that case was particularly strong evidence that the design feature at issue was functional. *See id.* at 30.

The Board correctly applied *TrafFix* here. Recall CeramTec's two concessions: (1) the addition of chromia causes a ZTA ceramic to become pink, and (2) that Biolox Delta practices at least one claim of the '816 patent. *Decision* at *51. These concessions establish that the '816 patent claims a "feature[]," the color pink, which CeramTec has trademarked. *TrafFix*, 532 U.S. at 30. The Board also considered the specifications and prosecution history of the '816 patent, which state that the addition of chromia increases ZTA ceramic hardness. *Decision* at *51; '816 patent col. 3, ll. 61–63 (the addition of chromia "makes it possible for the first time to achieve hardness values such as have not previously been achieved"); J.A. 1628 ('816 patent prosecution history: similar). And the

Board supported its conclusion with CeramTec's other patents, which also disclose that chromia increases ZTA ceramic hardness. '955 patent col. 7. ll 33–35 ("[T]he chromium addition counteracts any drop in the hardness values when the proportion of zirconium dioxide rises."); *see also* '237 application, Abstract, (the addition of chromia to a ZTA ceramic is "particularly suitable for medi[c]al application").

CeramTec's policy argument is likewise unpersuasive. The functionality doctrine is premised on the public being "free to use the innovation" after a patent has expired—not merely a part of the innovation. *Qualitex*, 514 U.S. at 164. That CeramTec only seeks to prevent the public (*i.e.*, CoorsTek) from practicing the narrow portion of its patents that claim a pink ZTA ceramic is beside the point. Permitting the public to use that innovation weighs in favor of finding functionality.

The Board therefore did not err in evaluating the first factor.

2

The Board found that the second *Morton–Norwich* factor—advertising materials in which the originator of the design touts the design's utilitarian advantages—also "constitute[s] strong evidence of functionality." *Decision* at *54. In coming to this conclusion, the Board considered promotional and technical literature, as well as submissions made to the FDA, in which CeramTec stated that chromia provides various functional benefits to ZTA ceramics. *Id.* at 52–53.

CeramTec does not challenge the Board's finding with respect to factor two. We accordingly need not review that ruling and turn to the Board's analysis of the third factor.

3

The Board found the third factor—the availability of functionally equivalent designs—to be neutral with respect to functionality. *Id.* at 54. That finding was supported by substantial evidence.

As the Board recognized, there was no "probative evidence" that different-colored ceramic hip components were "equivalent in desired ceramic mechanical properties to those of [Biolox Delta]." *Id.* That lack of evidence was critical—for the third factor to weigh in favor of non-functionality, there must be evidence of actual or potential alternative designs "that work equally well" to the trademarked design. *Valu Eng'g*, 278 F.3d at 1276 (citation omitted).

CeramTec contends that the Board's neutral determination was erroneous because the Board overlooked undisputed evidence of actual and potential ceramic hip components that are at least functionally equivalent to Biolox Delta: (1) statements made by CoorsTek that CeraSurf-w (CoorsTek's white ceramic hip component) was functionally better than Biolox Delta, and (2) the '816 patent, which can produce ZTA ceramics in a variety of colors in addition to pink. CeramTec mischaracterizes both the evidence and the Board's analysis.

First, the evidence did not undisputedly provide that CeraSurf-w was functionally better than Biolox

Delta. CoorsTek's employee proffered that CeraSurf-w "is not as hard" as CeraSurf-p (CoorsTek's pink ceramic), and thus not functionally better than Biolox Delta. *Decision* at *40; J.A. 4911.

Second, as for the '816 patent, the Board began its analysis of the third factor by stating, "because of the technical challenges involved[,] there are only a few companies" capable of producing ceramic hip components. *Decision* at *54. That suggests to us that the Board simply discounted all potential alternative designs because they are too theoretical. CeramTec's argument thus amounts to a disagreement with the weight the Board assigned to the evidence, which we see no reason to disturb. *See GO & Assocs.*, 90 F.4th at 1357 ("reweighing the evidence is not the role of this court") (internal quotation marks and citation omitted).

The Board's determination that the third factor was neutral was therefore supported by substantial evidence.

4

The Board also found the fourth *Morton–Norwich* factor—whether the design results in a comparatively simple or cheap method of manufacturing the product—to be neutral. *Decision* at *55.

As with the third factor, CeramTec again argues that the Board overlooked undisputed evidence providing that chromia makes Biolox Delta more expensive to manufacture, and therefore reversibly erred in not finding the fourth factor to weigh in favor of non-functionality. Once again, however, CeramTec

mischaracterizes the evidence as undisputed. As the Board noted, CoorsTek proffered evidence that the cost of producing CeraSurf-p was "pretty similar" to its white components. *Id.* at 55; J.A. 13527. Accordingly, in light of the conflicting evidence, the Board reasonably found the factor to not weigh for or against functionality. *See GO & Assocs.*, 90 F.4th at 1357.

The Board's determination that the fourth factor was neutral was therefore supported by substantial evidence.

B

Next, the Board properly considered and rejected the results of several experiments conducted in a related German litigation in which a government-sponsored research agency found that the addition of chromia at various levels (0.0, 0.1, 0.3, and 0.5% by weight) had no effect on Biolox Delta's hardness or wear resistance. *Id.* at *39, *55–56.

The Board decided not to factor the results into its functionality determination for two reasons. First, the Board explained that it found CoorsTek's expert's criticisms of the testing's methodology to be "persuasive." *Id.* at *55. And second, the Board found that the independent testing was incomplete because it did not address the full range of chromia that produces pink ZTA ceramics as claimed by the '816 patent. *Id.* The Board based the second critique on an internal CeramTec experiment demonstrating that chromia at levels above 0.5% by weight causes ZTA ceramics to become the pink color claimed in

CeramTec's trademarks whereas the German-based testing did not evaluate levels above 0.5% by weight. *Id.*

CeramTec takes issue with both reasons the Board gave for discounting the results of the testing. With regard to the Board's statement that it found CoorsTek's expert persuasive, CeramTec argues that explanation was inadequate because it did not give the findings of the testing the "close attention" they deserved and ignored CeramTec's expert's rebuttal report, which provided a "point-for-point accounting" explaining why CoorsTek's expert's criticisms were misguided. CeramTec Br. at 44, 46. This, however, overlooks that the Board devoted an entire section of its opinion to discussing the methodology of the testing and both parties' expert's opinions of the testing. Decision at *39. CeramTec's argument thus again amounts to a disagreement with the weight the Board assigned to results of the independent testing, a finding which we have no basis to disturb. *See GO & Assocs.*, 90 F.4th at 1357.

CeramTec next contends that the Board's criticism of the independent testing was inapposite because CoorsTek's functionality challenge is to the exact amount of chromia used to produce Biolox Delta, 0.33% by weight, within the range of added chromia analyzed in the independent testing. That argument is misguided: the issue before the Board was whether the color pink claimed in CeramTec's trademarks is functional. The trademarks are not tied to a specific amount of chromia. *Decision* at *1 ("The sole claim for protection in each registration is for the color pink

only."). CeramTec's own internal experiment demonstrated that the pink color of ZTA ceramics claimed in its trademarks could be obtained at weight percentages above 0.5%. *Decision* at *56; J.A. 10624. The Board therefore acted in accord with its role as factfinder in deciding to discount the results of the independent testing as incomplete.

C

CeramTec's last argument regarding the Board's functionality determination is that the Board erroneously required it, the trademark owner, to prove that its trademarks were not functional. In support of its position, CeramTec points to the Board's emphasis on certain language in its discussion of the Supreme Court's decision in *TrafFix*. *E.g.*, *Decision* at *50 ("Where the expired patent claimed the features in question, one who seeks to establish trade dress protection *must carry the heavy burden of showing that the feature is not functional*[.]") (quoting *TrafFix*, 532 U.S. at 29–30 (emphasis added by the Board)).

We are unpersuaded. The Board stated that "[CoorsTek] bears the burden of proving its Trademark Act Section 23(c) functionality claim by a preponderance of the evidence." *Decision* at *2. After considering the evidence, the Board concluded that CoorsTek "ha[d] carried [its] burden" of proving that CeramTec's trademarks are functional. *Id.* It correctly applied the burden of proof.

We accordingly see no reason to disturb the Board's findings based on CeramTec's burden shifting argument.

* * *

In sum, because substantial evidence supports the Board's factual findings, we affirm the Board's conclusion that CeramTec's trademarks are functional.

II

We last consider the unclean hands issue. The doctrine of unclean hands "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant." *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945)).

CeramTec argued to the Board that CoorsTek should be precluded from asserting that CeramTec's trademarks are functional because CoorsTek had long expressed the opposite: that chromia provides no material benefits for ZTA ceramics. J.A. 617–21. The Board disagreed, "hold[ing] . . . the unclean hands defense is unavailable in Board functionality proceedings in view of the prevailing public interest in removing registrations of functional marks from the register" and "find[ing] [CeramTec's] unclean hands defense inapplicable." *Decision* at *58.

CeramTec contends that the Board erred, necessitating remand, by "refus[ing] to even consider the equitable circumstances" and "adopt[ing] a categorical rule" precluding the unclean hands

defense in functionality proceedings. CeramTec Br. at 61.

We agree that the Board spoke too strongly by suggesting that the unclean hands defense was categorically unavailable in functionality proceedings. The Board's rules explicitly provide that the defendant, in cancellation proceedings before the Board, may "includ[e] the affirmative defense[] of unclean hands." 37 C.F.R. § 2.114(b)(2). It is not clear that the Board intended to announce a broad policy, as its conclusion is preceded by reference to its "discretion," which is generally exercised case-by-case, and the Board did not designate its decision as precedential. If, however, the Board intended to bar an unclean hands defense from all functionality proceedings, that would be error. Any such error was harmless here because the Board adequately considered whether the unclean hands defense was available in this case, as illustrated by its statement that it was "exercis[ing its] discretion" in view of the "strong public policy interest in" cancelling ineligible marks. *Decision* at *58 (citing *Loglan Inst., Inc. v. Logical Language Grp., Inc.*, 962 F.2d 1038, 1042 (Fed. Cir. 1992) ("The Board did not err in declining to apply [equitable] defenses [in a cancellation proceeding], as the public interest . . . to rid the register of [an ineligible mark] transcends them.")).

CONCLUSION

We have considered CeramTec's remaining arguments and find them unpersuasive. For the

foregoing reasons, we affirm the final decision of the Board.

AFFIRMED

APPENDIX B

This Opinion is Not a Precedent of the TTAB

Hearing Date: February 22, 2022
Mailed: December 6, 2022

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UNITED STATES PATENT AND TRADEMARK OFFICE

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Trademark Trial and Appeal Board

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CoorsTek Bioceramics LLC
f/k/a C5 Medical Werks, LLC
v.
CeramTec GmbH

_____

Cancellation Nos. 92058781 and 92058796

_____

Diana Rutowski, Peter D. Vogl and Briggs M. Wright of Orrick, Herrington & Sutcliffe LLP
for CoorsTek Bioceramics LLC f/k/a C5 Medical Werks, LLC.

Anna Kurian Shaw, Katherine Bastian Phillips, Lauren Cury, Ryan Stephenson and Brendan Quinn of Hogan Lovells US L.L.P.
for CeramTec GmbH.

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Before Goodman, Lynch and Hudis,
Administrative Trademark Judges.

Opinion by Hudis, Administrative Trademark Judge:

I. Background

This pair of cancellation proceedings is another chapter in the parties' eight-year odyssey to decide whether the color pink as applied to a composition for hip joint implant parts is functional. CeramTec GmbH ("Respondent") is the owner of record of two registrations on the Supplemental Register for the following marks and goods:

Mark	**Mark Description**	**Appln. No. Appln Filing Date Reg. No. Reg. Date**	**Goods**
	The color(s) pink is/are claimed as a feature of the mark. The mark consists of the color pink applied to the goods. The configuration of a hip joint ball is shown in dotted lines in the drawing. **The matter shown in broken lines indicates placement of the mark on the goods and neither the matter shown in broken lines nor the configuration of the goods are**	85521237 filed Jan. 20, 2012 4319095 issued Apr. 9, 2013 First use and first use in commerce alleged: Mar. 16, 2000	Hip joint implants and their parts made of artificial materials, namely, hip joint balls, in International Class 10

	claimed as a feature of the mark. (emphasis added).		
	The color(s) pink is/are claimed as a feature of the mark. The mark consists of the color pink applied to the entire surface of the goods. **The matter shown in broken lines indicates placement of the mark on the goods and neither the matter shown in the broken lines nor the configuration of the goods is claimed as a feature of the mark.** (emphasis added).	85521240 filed Jan. 20, 2012 4319096 issued Apr. 9, 2013 First use and first use in commerce alleged: Mar. 16, 2000	Hip joint implants and their parts made of artificial materials, namely, acetabular shell, acetabular fossa, in International Class 10

To be clear, in neither registration does Respondent claim protection for the configuration of the goods. The sole claim for protection in each registration is for the color pink only.[1]

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[1] Because of the size of the reproductions of the registration drawings above, the broken lines are difficult to discern. According to convention for color marks, in the

In each Petition for Cancellation, both filed on March 3, 2014,[2] C5 Medical Werks, LLC, which by change of name is now known as CoorsTek Bioceramics LLC ("Petitioner"), seeks cancellation of Respondent's registrations under Trademark Act Section 23(c), 15 U.S.C. § 1091(c), on the grounds that the color pink, as applied to the goods identified in the registrations, is functional; and that Respondent committed fraud on the U.S. Patent and Trademark Office ("USPTO") in obtaining the registrations. The Board has updated the case caption to identify CoorsTek Bioceramics LLC as the petitioner and party-plaintiff.

In its Orders of May 8 and May 10, 2014, the Board suspended both proceedings,[3] pending the resolution of a then-pending civil action between the parties in

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drawings, the entire configurations appear in broken lines, "inform[ing] the viewer where and how color is used on the product . . ., while at the same time making it clear that the shape of the product . . . is not claimed as part of the mark." TRADEMARK MANUAL OF EXAMINING PROCEDURE (TMEP) § 1202.05(d)(i) (2022).

[2] Cancellation Nos. 92058781 and 92058796; each petition for cancellation is located at 1 TTABVUE. References to the pleadings, the evidence of record and the parties' briefs refer to the Board's TTABVUE docket system. Coming before the designation TTABVUE is the docket entry number; and coming after this designation are the page and paragraph references, if applicable.

[3] Board Order of May 8, 2014 in Cancellation No. 92058781, 8 TTABVUE; Board Order of May 10, 2014 in Cancellation No. 92058796, 8 TTABVUE.

the U.S. District Court for the District Court of Colorado (the "Colorado Litigation"). We address the Colorado Litigation below, following the Summary of proceedings.

On February 4, 2016 in Cancellation No. 92058796, Respondent moved without Petitioner's consent to amend the date of first use claimed in Registration No. 4319096 from March 16, 2000 to March 20, 2001.[4] Because, in its response, Petitioner did not provide its unequivocal consent to the amendment,[5] Respondent's motion was deferred until final disposition.[6]

In its Order issued February 14, 2017, the Board consolidated the two cancellation proceedings, with Cancellation No. 92058781 being designated the parent case.[7] Unless otherwise stated, from this point forward our citations to the evidentiary record and the parties' briefs shall be to the parent proceeding.

Following a final determination of the Colorado Litigation, on June 29, 2020 the Board resumed the cancellation proceedings. [8] In its Answers filed separately in each of these proceedings, Respondent

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[4] 12 TTABVUE in Cancellation No. 92058796.

[5] 14 TTABVUE in Cancellation No. 92058796.

[6] Board Order of June 21, 2016 in Cancellation No. 92058796, 15 TTABVUE.

[7] Board Order February 14, 2017 in Cancellation No. 92058781, 16 TTABVUE; and in Cancellation No. 92058796, 20 TTABVUE.

[8] Board Order of January 29, 2020, 26 TTABVUE.

denied the salient allegations of the Petitions for Cancellation and asserted the affirmative defense of unclean hands.[9]

The consolidated cases are fully briefed. The parties participated in an oral hearing on February 22, 2022.[10]

II. Summary

Petitioner bears the burden of proving its Trademark Act Section 23(c) functionality claim by a preponderance of the evidence. *See Poly-America, L.P. v. Ill. Tool Works Inc.*, 124 USPQ2d 1508, 1520 (TTAB 2017) ("We conclude, based on the preponderance of the evidence, that Respondent's registered configurations are functional."). Having considered the evidentiary record, the parties' arguments and applicable authorities, as explained below, we find that Petitioner has carried this burden, and grant the cancellation sought in each proceeding.

Because we find Respondent's marks to be functional, we need not reach Petitioner's additional claim regarding Respondent's alleged fraud upon the USPTO. *Fuji Medical Instr. Mfg. Co., Ltd. v. Am.*

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[9] Answer in in Cancellation No. 92058781, 28 TTABVUE; Answer in Cancellation No. 92058796, 22 TTABVUE.

[10] The day before the hearing, Respondent moved to strike unspecified visual aids submitted by Petitioner, and to prevent these visual aids from being used at the hearing. *See* 166 TTABVUE. No such visual aids were presented at the hearing, nor did we rely on them in this decision. Respondent's motion, therefore, is denied as moot.

Crocodile Int'l Grp., Inc., 2021 USPQ2d 831, at *38 n. 69 (TTAB 2021) (citing *Multisorb Techs., Inc. v. Pactiv Corp.*, 109 USPQ2d 1170, 1171 (TTAB 2013) ("[T]he Board . . . generally use[s] its discretion to decide only those claims necessary to enter judgment and dispose of the case. . . . More specifically, the Board's determination of registrability does not require, in every instance, decision on every pleaded claim.")).

As explained in further detail below, we also find Respondent's affirmative defense of unclean hands inapplicable to these proceedings. Finally, we deny as moot Respondent's motion filed in Cancellation No. 92058796 to amend the claimed date of first use in Registration No. 4319096.

III. The Colorado Litigation

Simultaneous with its filing of these cancellation proceedings, Petitioner initiated the Colorado Litigation, through which Petitioner sought cancellation of Respondent's trademark registrations now before us, and a declaratory judgment that it did not infringe the mark in either registration. Respondent (a German company) moved to dismiss Petitioner's lawsuit on the ground that the Colorado district court lacked personal jurisdiction over it. *C5 Med. Werks, LLC v. CeramTec GmbH,* 112 USPQ2d 1857, 1858-59 (D. Colo. 2014) ("*CeramTec I*"). Finding that it had jurisdiction, the district court denied Respondent's motion. *Id.*, 112 USPQ2d at 1861.

Two years later, the parties proceeded to a bench trial, extending from August through October 2016. In April 2017, the district court issued its opinion (with

a final judgment to follow) that Respondent's registered trademarks for the composition of its pink-colored ceramic hip implant components were functional and thus unenforceable, noted that Respondent's trademark registrations would be cancelled, and granted Petitioner judgment in its favor as to Respondent's counterclaims for trademark infringement and unfair competition under federal and Colorado state law. *C5 Med. Werks, LLC v. CeramTec GmbH*, 249 F. Supp. 3d 1210, 1212 and 1223 (D. Colo. 2017) ("*CeramTec II*").

On appeal, the U.S. Court of Appeals for the Tenth Circuit held that the Colorado district court did not possess personal jurisdiction over Respondent, *C5 Med. Werks, LLC v. CeramTec GmbH*, 937 F.3d 1319, 2019 USPQ2d 339846, at *1 (10th Cir. 2019) ("*CeramTec III*"), thus reversing the district court's denial of Respondent's motion to dismiss for lack of personal jurisdiction, and remanded the case to the district court with instructions that the case be dismissed. *Id.*, 2019 USPQ2d 339846, at *5. The district court entered its amended final judgment, dismissing the case without prejudice for lack of personal jurisdiction, on November 12, 2019.[11]

As noted, these consolidated proceedings resumed on June 29, 2020, at which time the parties submitted their stipulated protective order and stipulation

[11] The District Court Amended Final Judgment was submitted as an attachment to Respondent's Notice to Board of Disposition of Civil Action on December 10, 2019. 24 TTABVUE 5.

regarding discovery. [12] The Board approved and entered these stipulations into the record by its Order dated August 25, 2020.[13]

IV. The Evidentiary Record

The record includes the pleadings and, by operation of Trademark Rule 2.122(b), 37 C.F.R. § 2.122(b), the files of Respondent's involved registrations. In addition, the parties stipulated to or otherwise introduced the following evidence:

A. The Parties' Stipulations

The parties entered into numerous stipulations regarding the evidence obtained during the Colorado Litigation and these proceedings, which they filed during the parties' testimony periods before the Board. [14] Thus, the parties stipulated to the

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[12] Board Order resuming proceedings, 26 TTABVUE; stipulated protective order, 30 TTABVUE; stipulation regarding discovery 31 TTABVUE.

[13] Board Order approving stipulations, 32 TTABVUE.

[14] *See* Stipulation Regarding Discovery (31 TTABVUE, June 29, 2020). The parties' stipulation of 31 TTABVUE was approved and entered into the record on August 25, 2020. 32 TTABVUE. Stipulation for Presentation of Certain Trial Testimony and Exhibits (67 TTABVUE, July 1, 2021). Stipulation for Admission of Federal Court Evidence via Notice of Reliance and for Filing of Confidential Material (68 TTABVUE, April 21, 2021). The parties' stipulations of 67 and 68 TTABVUE were approved and entered into the record on July 12, 2021. 69 TTABVUE. Trial Testimony and Exhibits (132 TTABVUE, August 18, 2021). The parties'

introduction under Notices of Reliance of many materials not otherwise admissible when submitted in this form.[15]

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stipulation of 132 TTABVUE was approved and entered into the record on September 7, 2021. 142 TTABVUE.

On April 21, 2021, Respondent filed the parties' joint stipulation regarding the admission of certain trial testimony and trial exhibits in Cancellation No. 92058796, the child proceeding. 25 TTABVUE in Cancellation No. 92058796. Inasmuch as these proceedings were consolidated in 2017, 16 TTABVUE, the stipulation should have been filed in the parent proceeding only. For purposes of efficiency, the then-assigned Interlocutory Attorney noted the April 21, 2021 stipulation and placed a copy in the parent proceeding. 68 TTABVUE.

[15] Submission of non-conforming materials under Notices of Reliance is normally impermissible under the Board's Rules of Practice. However, the parties stipulated to this method of introduction here. *See Target Brands Inc. v. Hughes*, 85 USPQ2d 1676, 1678 (TTAB 2007) (parties stipulated to the entire record in the case including business records, public records, government documents, marketing materials, Internet materials, and numerous factual matters); *Blackhorse v. Pro-Football Inc.*, 111 USPQ2d 1080, 1084-85 (TTAB 2014) (parties stipulated that the record of a prior proceeding may be submitted into evidence under notice of reliance, reserving the right to object based on relevance), *aff'd,* 112 F. Supp. 3d 439, 115 USPQ2d 1524 (E.D. Va. 2015), *vacated and remanded*, 709 F. App'x 183 (4th Cir. 2018) (mem.); *See generally* TRADEMARK TRIAL AND APPEAL BOARD MANUAL OF PROCEDURE (TBMP) § 705 (2022) (noting the various ways of stipulating to evidence not otherwise admissible pursuant to the Board's Rules of Practice).

B. Petitioner's Evidence

Petitioner's First Notice of Reliance ("PNOR1") on e-mail correspondence (many with attachments) exchanged among Respondent's personnel (41 TTABVUE).

Petitioner's Second Notice of Reliance ("PNOR2") on excerpts of trial and deposition testimony from the Colorado Litigation (42 TTABVUE).

Petitioner's Third Notice of Reliance ("PNOR3") on U.S. patents issued and patent applications filed in the name of Respondent or its predecessors, portions of patent file histories and Respondent's correspondence with the federal Food and Drug Administration ("FDA") (43 TTABVUE).

Petitioner's Fourth Notice of Reliance ("PNOR4") on Respondent's internal correspondence and memoranda, Respondent's external e-mail correspondence; results of Petitioner's product analyses, technical articles, a data sheet featuring Respondent's product, and reports Respondent filed with the FDA (44 TTABVUE).

Petitioner's Fifth Notice of Reliance ("PNOR5") on promotional materials featuring Respondent's product; Respondent's external and internal e-mail correspondence (some with attachments); technical articles; Petitioner's survey and expert witness report from the Colorado Litigation by Sara Parikh, Ph.D.

("Parikh Lit. Rpt."), Respondent's admissions' responses from the Colorado Litigation; declaration of D. Burkhardt in support of Respondent's motion to dismiss the Colorado Litigation ("Burkhardt Decl.") and trade show agenda and sponsor list (45 TTABVUE).

Petitioner's Sixth Notice of Reliance ("PNOR6") on technical articles and third-party submissions to the FDA (46 TTABVUE).

The testimony declaration and report of Petitioner's survey expert, Sara Parikh, Ph.D. ("Parikh Decl." and "Parikh Rpt.") (47 TTABVUE).

The testimony declaration and initial report of Petitioner's materials expert, William M. Carty, Ph.D. ("Carty Decl." and "Carty Rpt.") (48 TTABVUE (confidential); 60 TTABVUE (public/redacted)).

Petitioner's Seventh Notice of Reliance ("PNOR7") on European Union and U.S. patents issued and patent applications filed in the name of Respondent or its related companies and the Colorado district court's opinion in *CeramTec II* (49 TTABVUE).

Petitioner's Eighth Notice of Reliance ("PNOR8") on technical articles; promotional materials featuring Respondent's product and an article on Master Files by the FDA (50 TTABVUE).

Petitioner's Ninth Notice of Reliance ("PNOR9") on technical articles (51 TTABVUE).

Petitioner's Tenth Notice of Reliance ("PNOR10") on technical articles (52 TTABVUE).

Petitioner's Eleventh Notice of Reliance ("PNOR11") on technical articles (53 TTABVUE).

Petitioner's Twelfth Notice of Reliance ("PNOR12") on Respondent's internal e-mail correspondence (some with attachments), Respondent's marketing materials, Respondent's correspondence with the FDA, Petitioner's evidentiary submissions pursuant to Fed. R. Evid. 1006 of presentations by Respondent, Petitioner's business plan, excerpts from the discovery deposition of Grant Shopoff, Respondent's Commercial Director for the Americas ("Shopoff Depo.") and Respondent's admissions' responses and interrogatory answers from this proceeding (54 TTABVUE (confidential); 61 TTABVUE (public/redacted)).

The testimony declaration and rebuttal report of Petitioner's statistics expert, Arnold Barnett, Ph.D. ("Barnett Decl." and "Barnett Rebuttal Rpt.") (55 TTABVUE (confidential); 56 TTABVUE (public/redacted)).

The testimony declaration of Lucian Strong, Petitioner's Commercial Vice President of the Americas ("Strong Decl.") (57 TTABVUE).

The testimony declaration of Jonathan D. Haftel, Petitioner's Plant Manager ("Haftel Decl.") with exhibits (58 TTABVUE (confidential); 59 TTABVUE (public/redacted)).

C. Respondent's Evidence[16]

Respondent's First Notice of Reliance ("RNOR1") on excerpts of trial testimony from the Colorado litigation, Respondent's internal memoranda, a U.S. patent issued in the name of Respondent's predecessor, a Standard issued by the International Organization for Standardization ("ISO") and technical articles (70 TTABVUE).[17]

Respondent's Second Notice of Reliance ("RNOR2") on Petitioner's engineering report, Petitioner's marketing materials, Respondent's external e-mail correspondence, technical articles and a U.S. patent (with its file history)

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[16] Pursuant to a Notice Respondent filed at 125 TTABVUE, Respondent withdrew its Eighteenth through Twenty-Third and Twenty-Fifth Notices of Reliance, at 88-94 and 96 TTABVUE.

[17] Respondent filed a Corrected First Notice of Reliance at 122 TTABVUE, in which portions of the trial testimony transcript of Respondent's FDA expert, Mark Kramer, were omitted. Since Mr. Kramer's trial testimony was never expressly withdrawn, and we find portions of it helpful, we have considered it.

issued in the name of Respondent's related company (71 TTABVUE).

Respondent's Third Notice of Reliance ("RNOR3") on the file history for a U.S. patent issued in the name of Respondent's predecessor, portions of the initial expert report of Petitioner's materials expert in the Colorado Litigation, G. Fischman, Ph.D., a Standard issued by the ISO, Respondent's internal e-mail correspondence (with English translation), Petitioner's internal e-mail correspondence (many with attachments), U.S. patents issued and patent applications filed in the name of Respondent or its predecessors, portions of a patent file history, and one of Petitioner's trial exhibits (a timeline) from the Colorado Litigation (72 TTABVUE).

Respondent's Fourth Notice of Reliance ("RNOR4") on Petitioner's internal and external e-mail correspondence (many with attachments), Petitioner's engineering report, Petitioner's marketing materials and Petitioner's business plan (73 TTABVUE).

Respondent's Fifth Notice of Reliance ("RNOR5") on the technical file for one of Petitioner's products, and Petitioner's internal e-mail correspondence (one with an attachment) (74 TTABVUE).

Respondent's Sixth Notice of Reliance ("RNOR6") on Petitioner's internal and external e-mail correspondence (some with

attachments), a technical article, Respondent's internal memorandum (entirely in German), Respondent's marketing material and an experimental data spreadsheet (75 TTABVUE).

Respondent's Seventh and Eighth Notices of Reliance ("RNOR7" and "RNOR8") on Respondent's experimental data records (76 and 77 TTABVUE).

Respondent's Ninth Notice of Reliance ("RNOR9") on Respondent's experimental data records, Petitioner's external and internal e-mail correspondence, technical articles, experimental data spreadsheets and records, exhibits to the report of Mark Kramer, Respondent's FDA expert witness, from the Colorado Litigation, photos of Respondent's product development archives, Respondent's lab testing notes, a color swatch and a color board (78 TTABVUE).

Respondent's Tenth and Eleventh Notices of Reliance ("RNOR10" and "RNOR11") on photos of experimental sample discs (79 and 80 TTABVUE).

Respondent's Twelfth Notice of Reliance ("RNOR12") on a U.S. patent issued in the name of Respondent's predecessor, Petitioner's external e-mail correspondence (some with attachments), Petitioner's technical file distribution log, and demonstrative exhibits

used by Respondent's witnesses during the trial in the Colorado Litigation (81 TTABVUE).[18]

Respondent's Thirteenth Notice of Reliance ("RNOR13") on portions of the transcript and certain exhibits from the discovery deposition of Jonathan Haftel ("Haftel Discov. Depo.") (82 TTABVUE (confidential); 129 TTABVUE (public/redacted)).

Respondent's Fourteenth Notice of Reliance ("RNOR14") on Petitioner's interrogatory answers and responses to Respondent's production requests (83 TTABVUE).

The testimony declaration and report of Respondent's survey expert, Robert Klein ("Klein Decl." and "Klein Rpt.") (84 TTABVUE).

The testimony declaration of Grant Shopoff, Respondent's Commercial Director for the Americas ("Shopoff Decl.") (85 TTABVUE).

Respondent's Fifteenth Notice of Reliance ("RNOR15") on Petitioner's admissions responses and interrogatory answers (86 TTABVUE (confidential); 130 TTABVUE (public/redacted)).

Respondent's Sixteenth Notice of Reliance ("RNOR16") on Petitioner's marketing

[18] Respondent filed a Corrected Twelfth Notice of Reliance at 124 TTABVUE, in which the demonstrative exhibits used by Respondent's witnesses during the trial in the Colorado litigation were omitted and expressly withdrawn.

materials and social media postings (87 TTABVUE).

Respondent's Twenty-Fourth Notice of Reliance ("RNOR24") on a technical article (95 TTABVUE).

Respondent's Twenty-Sixth Notice of Reliance ("RNOR26") on portions of the transcript and certain exhibits from the discovery deposition of Lucian Strong, Petitioner's Commercial Vice-President, Americas ("Strong Discov. Depo.") (97 TTABVUE (confidential); 131 TTABVUE (public/redacted)).

The testimony declaration of Dr. Allessandro Alan Porporati, an employee in Respondent's Oxide Department ("Porporati Decl.") with exhibits (98 TTABVUE (confidential); 99 TTABVUE (public/redacted)).

Respondent's Twenty-Seventh Notice of Reliance ("RNOR27") on excerpts of trial testimony from the Colorado Litigation, list of meetings/trainings attended and photos of Respondent's trade show materials (100 TTABVUE).

The testimony declaration of Dr. Meinhard Kuntz, the former Manager of Respondent's Oxide Development and presently the Dean of and professor at Heilbronn University in Germany ("Kuntz Decl.") with exhibits (102 TTABVUE (confidential); 101 TTABVUE (public/redacted)).

The testimony declaration, litigation expert report, litigation rebuttal expert report, TTAB expert report and TTAB rebuttal expert report of Respondent's statistics expert, Joseph B. Kadane, Ph.D. ("Kadane Decl.", "Kadane Lit. Rpt.", "Kadane Lit. Rebuttal Rpt.", "Kadane TTAB Rpt." and "Kadane TTAB Rebuttal Rpt.") with exhibits (103 TTABVUE (confidential); 104 TTABVUE (public/redacted)).

The testimony declaration, litigation expert report, litigation rebuttal expert report, TTAB expert report and TTAB rebuttal expert report of Respondent's materials expert, Dr. John J. Mecholsky, Jr. ("Mecholsky Decl.", "Mecholsky Lit. Rpt.", "Mecholsky Lit. Rebuttal Rpt.", "Mecholsky TTAB Rpt." and "Mecholsky TTAB Rebuttal Rpt.") with exhibits (106-112 TTABVUE (confidential); 105 TTABVUE (public/redacted)).

The testimony declaration of Florence Petkow, Respondent's Director of Marketing and Communications ("Petkow Decl.") with exhibits (113 TTABVUE (confidential); public/redacted (114-120 TTABVUE).

Respondent's Twenty-Eighth Notice of Reliance ("PNOR28") on excerpts of discovery deposition testimony from the Colorado Litigation (121 TTABVUE).

Respondent's Twenty-Ninth Notice of Reliance ("RNOR29") on Petitioner's internal and external e-mail correspondence (some with

attachments), Petitioner's correspondence and reports exchanged with the FDA and Petitioner's marketing materials (123 TTABVUE).

The transcript from the testimony deposition of Angel Abeyta, Petitioner's Market Development Manager in its Medical Division ("Abeyta Testim. Depo.") with exhibits (133 TTABVUE (confidential)).

The transcript from the testimony deposition of Megan Maguire, Petitioner's Senior Marketing Communications Manager ("Maguire Testim. Depo.") with exhibits (134 TTABVUE (confidential)).

The transcript from the testimony deposition of Nicole Stavish, Petitioner's Strategic Marketing Manager for the Americas ("Stavish Testim. Depo.") with exhibits (135 TTABVUE (confidential)).

The transcript from the cross-examination testimony deposition of Jonathan Haftel ("Haftel CX Testim. Depo.") with exhibits (146-147 TTABVUE (confidential)).

The transcript from the cross-examination testimony deposition of Arnold I. Barnett, Ph.D. ("Barnett CX Testim. Depo.") with exhibits (148 TTABVUE (confidential)).

The transcript from the cross-examination testimony deposition of William M. Carty, Ph.D. ("Carty CX Testim. Depo.") with exhibits (149-151 TTABVUE (confidential)).

The transcript from the cross-examination testimony deposition of Sara Parikh, Ph.D. ("Parikh CX Testim. Depo.") with exhibits (149-152 TTABVUE (confidential)).

D. Petitioner's Rebuttal Evidence

Petitioner's Thirteenth Notice of Reliance ("PNOR13") on excerpts of the discovery depositions of Petitioner's former Scientific Consultants who are now Petitioner's Commercial Managers, Rebecca Echols ("Echols Discov. Depo."), with exhibits; ("McCormick Discov. Depo."); and Blake Miller ("Miller Discov. Depo.") (136 TTABVUE (confidential); 154 TTABVUE (public/redacted).

The rebuttal testimony declaration of Jonathan D. Haftel ("Haftel Rebuttal Decl.") with exhibits (137 TTABVUE (confidential); 138 TTABVUE (public/redacted)).

The rebuttal testimony declaration and rebuttal report of Petitioner's statistics expert, Arnold Barnett, Ph.D. ("Barnett Rebuttal Decl." and "Barnett Rebuttal Rpt.") (139 TTABVUE (confidential); 140 TTABVUE (public/redacted)).[19]

The rebuttal testimony declaration and rebuttal report of Petitioner's materials expert, William M. Carty, Ph.D. ("Carty Rebuttal

[19] The confidential and public versions of Dr. Barnett's Rebuttal Report also were filed at 55-56 TTABVUE.

Decl." and "Carty Rebuttal Rpt.") (141 TTABVUE (confidential); 153 TTABVUE (public/redacted)).

The transcript from the cross-examination testimony deposition of Respondent's survey expert, Robert Klein ("Klein CX Testim. Depo.") with exhibits (143 TTABVUE).

The transcript from the cross-examination testimony deposition of Respondent's statistics expert, Joseph B. Kadane, Ph.D. ("Kadane CX Testim. Depo.") with exhibits (144 TTABVUE (confidential); 156 TTABVUE (public/redacted)).

The transcript from the cross-examination testimony deposition of Respondent's materials expert, Dr. John J. Mecholsky, Jr. ("Mecholsky CX Testim. Depo.") with exhibits (145 TTABVUE (confidential); 155 TTABVUE (public/redacted)).

V. Evidentiary Issues

Before proceeding to the merits of the cancellation proceedings, we address a number of evidentiary matters.

A. Applicability of the District Court's Decision in *CeramTec II*

To begin, in an Appendix to its Brief,[20] Respondent "objects to any reliance on or consideration" in these cancellation proceedings of the "now-vacated decision

[20] Respondent's Brief, 160 TTABVUE 55.

in the District of Colorado [action] . . . between the Parties" (that is, the district court's decision in *CeramTec II*). As a retort to Respondent's objection, Petitioner essentially argues that (i) Respondent did not object to the manner in which Petitioner introduced the Colorado district court's decision into evidence in these proceedings, and (ii) none of the evidence introduced in these proceedings which came into being subsequent to the *CeramTec II* trial would have persuaded the Colorado district court to rule any differently.[21] Respondent's objection is sustained.

The vacated decision has been set aside and has no effect. We therefore cite the Colorado district court's opinion solely for procedural context and to explain the sources of the evidence the parties submitted from the Colorado Litigation. We do not rely on it for any of the findings of fact, conclusions of law or the holdings of the district court in *CeramTec II*. The Board's rulings in these proceedings are based upon our own review of the evidence and application of pertinent law.

B. Problems with Large Portions of the Evidentiary Record Labeled as Confidential

The parties over-designated as confidential large portions of the record. Only the particular exhibits, declaration passages or deposition transcript pages that truly disclosed confidential information should have been filed under seal pursuant to a protective

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[21] Petitioner's Reply Brief, 162 TTABVUE 27.

order. *Made in Nature, LLC v. Pharmavite LLC*, 2022 USPQ2d 557, at *12 (TTAB 2022).

If a party over-designates material as confidential, the Board will not be bound by the party's designation, and will treat as confidential only testimony and evidence that is truly confidential and commercially sensitive trade secrets. *See* Trademark Rule 2.116(g), 37 C.F.R. § 2.116(g) ("The Board may treat as not confidential that material which cannot reasonably be considered confidential, notwithstanding a designation as such by a party."). In this decision, in instances where Petitioner or Respondent improperly designated material as confidential, we disregard the designation.[22] *See AT&T Mobility LLC v. Thomann*, 2020 USPQ2d 53785 , at *12 (TTAB 2020) (parties reminded to limit confidential designation to truly confidential or commercially sensitive materials).

C. Needless Duplication of Evidence

We credit the parties for having entered into the numerous stipulations discussed above regarding the entry and admissibility of evidence. However, less helpfully, the parties also elected to file duplicative evidence by different methods of introduction; for example, once (sometimes twice or even thrice) by Notice(s) of Reliance and again by way of exhibit(s) to

[22] Our treatment here of the parties' confidentiality over-designations should not come as a surprise. In the Board's August 25, 2020 order approving and entering the parties' Stipulated Protective Order, 32 TTABVUE, they were warned of the potential consequences of over-designating as confidential materials filed with the Board.

testimony declarations or testimony deposition transcripts. *See Made in Nature*, 2022 USPQ2d 557, at *12 (criticizing the parties for this practice). The parties further paid little attention to Trademark Rules 2.120(k)(7) and 2.122(a), 37 C.F.R. §§ 2.120(k)(7) and 2.122(a), which provide that when evidence has been made of record by one party, it may be referred to by any party for any purpose permitted by the Federal Rules of Evidence.

Whether the parties are unfamiliar with the Board's Rules of Practice or simply disregarded them, the Board's evaluation of the evidentiary record required reviewing some of the same testimony, technical articles, patents, promotional materials and other exhibits numerous times (or at least spending the time to determine whether they were duplicates, if not actually reviewing them in toto). The Board views with disfavor the practice of introducing cumulative evidence at trial. *See Calypso Tech. Inc. v. Calypso Cap. Mgmt. LP*, 100 USPQ2d 1213, 1218 (TTAB 2011). Suffice it to say, testimony and evidence does not become more probative if introduced multiple times.

D. Irrelevant Evidence

Moreover, noticeable portions of the evidentiary record were not pertinent to the functionality claim or unclean hands defense, such that the Board was forced to spend needless time sifting through an inappropriately large record in search of germane proofs. *See, e.g.*, *RxD Media, LLC v. IP Appln. Dev. LLC*, 125 USPQ2d 1801, 1803 (TTAB 2018), *aff'd*, 377

F. Supp. 3d 588 (E.D. Va. 2019), *aff'd*, 986 F.3d 361, 2021 USPQ2d 81 (4th Cir. 2021) ("Simply put, the parties introduced into the record thousands of pages of testimony and other evidence without regard to what they needed to prove, apparently in the hope that in wading through it, we might find something probative. This is not productive. 'Judges are not like pigs, hunting for truffles buried in . . . [the record].' ") (quoting *U.S. v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991).

E. Submission of Entire Discovery Deposition Transcripts

Accompanying submission of the trial testimony of witnesses Messrs. Klein and Haftel, as well as Drs. Kadane, Mecholsky, Barnett and Carty, were the entirety of the transcripts from each of their discovery depositions. These filings were in derogation of Trademark Rules 2.120(k) and 2.122(g), 37 C.F.R. §§ 2.120(k) and 2.122(g).

Of all these witnesses, only Mr. Haftel was a person designated by Petitioner to testify pursuant to Fed. R. Civ. P. 30(b)(6) at the time his discovery deposition was taken; all the others were expert witnesses. We first discuss the introduction of Mr. Haftel's discovery deposition transcript in its entirety as an exhibit to his testimony cross-examination.

Notably, well prior to the submission of Mr. Haftel's testimony deposition transcript and exhibits, Respondent already had introduced by way of Notice of Reliance those portions of Mr. Haftel's discovery deposition transcript and select exhibits on which

Respondent wished to rely, together with a statement of the relevance of those transcript portions and exhibits to the issues in the proceeding pursuant to Trademark Rule 2.122(g).[23]

Thus, refiling the entirety of Mr. Haftel's discovery deposition transcript again as an exhibit to his testimony deposition transcript [24] was not only unnecessarily duplicative, it skirted the requirements of Trademark Rule 2.122(g). We have considered only those portions of Mr. Haftel's discovery deposition transcript that were included with Respondent's applicable Notice of Reliance, or read or used as part of his testimony on cross-examination.

The entire discovery deposition transcripts of third-party expert witnesses, such as Mr. Klein and Drs. Kadane, Mecholsky, Barnett and Carty, should not have been offered in evidence except by stipulation of the parties or by order of the Board on motion under the specific circumstances noted in Trademark Rule 2.120(k)(2). The Rule requires that the party seeking to rely on a discovery deposition of a third-party witness for purposes of trial make an affirmative showing at the time of the proffer of such evidence that circumstances exist that justify acceptance of the evidence, unless the party is invoking "exceptional circumstances," in which case the motion must be filed promptly after the party learns of the circumstances.

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[23] Haftel Discov. Depo., RNOR13, 82 TTABVUE 2-202 (confidential), 129 TTABVUE 2-199 (redacted/non-confidential).

[24] Haftel CX Testim. Depo., 146 TTABVUE 129-537.

Vans, Inc. v. Branded, LLC, 2022 USPQ2d 742, at *7 (TTAB 2022) (citing numerous cases). No such stipulations or motions were filed with respect to these trial witnesses.

As mentioned, Trademark Rule 2.120(k)(6) permits the reading or use of the transcripts from the discovery depositions of Mr. Klein and Drs. Kadane, Mecholsky, Barnett and Carty as part of their cross-examination trial testimony. However, use of these witnesses' discovery deposition transcripts to impeach or otherwise clarify their trial testimony does not automatically make the entire discovery deposition transcripts of record. *Vans*, 2022 USPQ2d 742, at *8. Therefore, only to the extent that portions of these expert witnesses' discovery deposition transcripts were read or used as part of their cross-examination testimony do we consider these witnesses' discovery deposition transcripts. Otherwise, we decline to consider these witnesses' discovery deposition transcripts in their entirety.

F. The Parties' Citations to the Record

Finally, rather than using full TTABVUE citations with the docket entry and electronic page numbers, as recommended, *see* TBMP § 801.03 and *Turdin v. Trilobite, Ltd.*, 109 USPQ2d 1473, 1477 n.6 (TTAB 2014), the parties used their own numbering systems. For exhibits, the parties used the TTABVUE docket number but then cited to exhibits by their assigned exhibit numbers (without specifying the TTABVUE page numbers). For testimony submitted by deposition transcripts, the parties used the page and

line numbers provided by the court reporters rather than the TTABVUE citations with the docket entry and electronic page numbers. For testimony submitted by declarations, the parties used the numbers assigned to each paragraph, but neglected to provide the TTABVUE electronic page numbers at which the text of each of these numbered paragraphs could be found.

Especially with the voluminous record compiled by the parties, this citation practice made it extremely cumbersome to locate the evidence and provide evidentiary references for use in this opinion. In turn, this lengthened the time for review of the record, drafting of the decision and ultimately for issuance of this opinion. *See Made in Nature*, 2022 USPQ2d 557, at *14-15 (criticizing this practice, and encouraging parties in future cases to cite properly to the evidentiary record).

VI.The Parties

Respondent, CeramTec GmbH, is a limited liability company organized under the laws of Germany and headquartered in Germany. Since 1974, Respondent has manufactured ceramic prosthetic implant components for hip, knee and shoulder joint replacements. Respondent sells these products to medical device companies that incorporate those components into their own prosthetic devices. Those medical device companies subsequently sell such

devices to their customers such as, for example, hospitals.[25]

Petitioner was formed in 2005, under its original name C5 Medical Werks, LLC, to become a new entrant to the medical-implant component supply business, initially focusing primarily on hip replacement implant components — recognizing at the outset that Respondent would be its principal major competitor.[26] The original company has since undergone a number of re-organizations and name changes; [27] and today is known as CoorsTek Bioceramics, LLC, a limited liability company of Delaware whose manufacturing facility is located in Grand Junction, Colorado.[28]

VII. Technical Terminology

Our resolution of these proceedings will involve the use of numerous scientific and other technical terms. For the benefit of the reader, we have culled from the record and present here the definitions of

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[25] Burkhardt Decl., 45 TTABVUE 250, ¶ 2; Petkow Decl., 114 TTABVUE 4, ¶¶ 7-9.

[26] Brad Coors Colorado litigation trial testimony ("Brad Coors Lit. Testim."), PNOR2, 42 TTABVUE 129-134; Petitioner's business plan; PNOR12, 54 TTABVUE 475-78, 480, 483, 492-93, 504.

[27] Jonathan Coors Colorado litigation trial testimony ("Jonathan Coors Lit. Testim."), PNOR2, 42 TTABVUE 145-46.

[28] Strong Decl., 57 TTABVUE 2, ¶¶ 3-4; Haftel Decl., 59 TTABVUE 2-3, ¶¶ 4-7.

these terms. Throughout this opinion, for brevity, we include in any citations to technical articles only the principal author(s) and year of publication (unless no author is provided, in which case we recite the article title). We have omitted formal citations to article titles and the publications in which the articles appeared. However, we have included cites to the TTABVUE record, and there the reader can find the formal citations to the article titles.

> A **ceramic** is a compound of a metal and nonmetal element. Nonmetal elements in ceramics can include, among other things, oxygen, nitrogen, and carbides. **Oxide ceramics** include oxygen as the nonmetal element. These oxide ceramics have special properties, and require specialized techniques to properly produce.[29]
>
> **Ion:** An atom or molecule that has lost or gained one or more electrons, resulting in a net positive or negative charge. The net charge, positive or negative, is written with a superscript representing the net charge and whether it is positive or negative. A chromium ion that has given up three electrons (and is thus positively charged), for instance, would be represented as Cr^{3+}.[30]

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[29] Kuntz Decl., 101 TTABVUE 4, ¶ 10.

[30] Carty Rpt., 60 TTABVUE 15, ¶ 33; Mecholsky Lit. Rpt., 105 TTABVUE 51, ¶ 78.

Microstructure: The structure of a material, including a ceramic material, at a microlevel. The microstructure of ceramic materials is composed of small crystals known as "**grains**."[31]

Lattice: The arrangement of atoms in a crystal structure at the microstructural level.[32]

Aluminum/Aluminum Oxide/Alumina: Aluminum (Al) is the elemental metal on the periodic table of elements. Aluminum Oxide (Al_2O_3) or Alumina is the oxide of Aluminum. Chemical names that end with an "a" denote the oxide form.[33]

Chromium/Chromium Oxide/Chromia: Chromium (Cr) is the elemental metal on the periodic table of elements. Chromium Oxide (Cr_2O_3 or presented in its common ionic form Cr^{3+}) or Chromia is the oxide of chromium.[34]

Zirconium/Zirconium Dioxide/Zirconia: Zirconium (Zr) is the elemental metal on the

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[31] Carty Rpt., 60 TTABVUE 15, 21-23, ¶¶ 33, 48, 50, 52; Mecholsky Lit. Rpt., 105 TTABVUE 40, ¶ 59.

[32] Carty Rpt., 60 TTABVUE 15, ¶ 33; Mecholsky Lit. Rpt. (confidential), 106 TTABVUE 108, ¶ 170.

[33] Carty Rpt., 60 TTABVUE 14, ¶ 33; Mecholsky Lit. Rpt., 105 TTABVUE 20, ¶ 20.

[34] Carty Rpt., 60 TTABVUE 14, ¶ 33; Mecholsky Lit. Rpt., 105 TTABVUE 20, ¶ 21.

periodic table of elements. Zirconium dioxide (ZrO_2) or Zirconia is the oxide of Zirconium.[35]

Yttrium/Yttrium Oxide/Yttria: Yttrium (Y) is the elemental metal on the periodic table of elements. Yttrium oxide (Y_2O_3) or Yttria is the oxide of Yttrium.[36]

Zirconia Toughened Alumina ("ZTA"): A composite material composed of Alumina and Zirconia. It also may include other additives including, but not limited to, chromium. [37] Alumina ceramics are well known to be hard and biocompatible. Zirconia, when added to alumina, toughens the material. When strontium aluminate platelets are added to the material, it contributes to higher toughness as well.[38] ZTA ceramics exhibit superior strength and toughness compared to conventional alumina and zirconia.[39]

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[35] Carty Rpt., 60 TTABVUE 16, ¶ 33; Mecholsky Lit. Rpt., 105 TTABVUE 20, ¶ 20.

[36] Carty Rpt., 60 TTABVUE 16, ¶ 33; Mecholsky Lit. Rpt., 105 TTABVUE 20, ¶ 21.

[37] Carty Rpt., 60 TTABVUE 16-17, ¶¶ 33, 36; Mecholsky TTAB Rpt. 105 TTABVUE 197, ¶ 14.

[38] Kuntz Decl., 101 TTABVUE 6, ¶ 15.

[39] Kurtz et al. (2014), PNOR9, Exh. 5, 51 TTABVUE 105-115 at 107.

Doping: The addition of a small amount of a material to a composite to alter the composite's properties.[40]

Sintering: The process of compacting and forming a solid mass of material through exposure to heat and pressure without liquefying the material. Sintering is a common method for manufacturing ceramic materials such as orthopedic ceramics.[41]

In vivo: Within the body.[42]

Hydrothermal ageing: Degradation of material when exposed to temperature and moisture, which increases with increased temperature and humidity, for example when in vivo for extended periods of time.[43]

Autoclaving: Exposure to elevated temperatures and steam pressures to mimic long-term exposure to heated, humid conditions such as those experienced in vivo. Autoclaving previously has been used as a re-sterilization method for orthopedic ceramics, and is an

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[40] Carty Rpt., 60 TTABVUE 14, ¶ 33; Mecholsky Lit. Rpt., 105 TTABVUE 85-86, ¶ 135.

[41] Carty Rpt., 60 TTABVUE 15, 18-19, 22, ¶¶ 33, 41-42, 50; Mecholsky Lit. Rpt., 105 TTABVUE 58, ¶ 92.

[42] Carty Rpt., 60 TTABVUE 15, 64, ¶¶ 33, 140; Mecholsky Lit. Rpt. (confidential), 106 TTABVUE 42, ¶ 65.

[43] Carty Rpt., 60 TTABVUE 15, ¶ 33; Mecholsky Lit. Rpt. (confidential), 106 TTABVUE 68, ¶ 105.

accepted method for accelerated ageing of ZTA material.[44]

Hardness: The resistance of a material to permanent deformation (such as surface impression) after force is applied to the surface from a standardized harder material.[45]

Fracture toughness: The resistance of a material to crack propagation (i.e., the spreading of a crack through the material).[46]

Strength: The ability of a material to withstand a force without cracking or failing. **Flexural strength** is the ability of a material to withstand **bending** without cracking or failing. **Burst strength** is the ability of a material to withstand an exertion of force without bursting.[47]

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[44] Carty Rpt., 60 TTABVUE 14, 19-20, ¶¶ 33, 45-47; Mecholsky Lit. Rpt. (confidential), 106 TTABVUE 76, ¶ 105.

[45] Carty Rpt., 60 TTABVUE 15, 26, ¶¶ 33, 60; Mecholsky Lit. Rpt., 105 TTABVUE 26, ¶ 34; DePuy Synthes brochure (2013), PNOR5, 45 TTABVUE 83; (Green (1998), PNOR9, 51 TTABVUE 163-171 at 166.

[46] Carty Rpt., 60 TTABVUE 15. 24-25, 85, ¶¶ 33, 56, 178; ; Mecholsky Lit. Rpt. 105 TTABVUE 23-24, ¶ 28; DePuy Synthes brochure (2013), PNOR5, 45 TTABVUE 83; (Green (1998), PNOR9, 51 TTABVUE 163-171 at 170.

[47] Carty Rpt., 60 TTABVUE 15, 22-23, ¶¶ 33, 50, 53; Mecholsky Lit. Rpt. 105 TTABVUE 24-25, ¶¶ 30-31; DePuy Synthes brochure (2013), PNOR5, 45 TTABVUE 83.

Wear resistance/Stability: The ability of a material to withstand loss, erosion or displacement of material over time in response to an application of force caused by environmental factors, such as temperature or contact with other material (such as friction between moving surfaces).[48]

Debris: Particles of different material and size shed from the surface of the various parts of an implant due to wear.[49]

Osteolysis: Bone resorption due to biological response to debris that can compromise the bone around a medical implant device and lead to loosening of the prosthesis.[50]

Mechanical property: Physical property that a material exhibits upon the application of force. Mechanical properties include such functional characteristics as hardness, fracture toughness, flexural strength and wear resistance.[51]

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[48] Carty Rpt., 60 TTABVUE 16, 28-29, 66-67, ¶¶ 33, 65, 67, 146; Mecholsky Lit. Rpt. 105 TTABVUE 42, ¶¶ 66; DePuy Synthes brochure (2013), PNOR5, 45 TTABVUE 83; Zagra et al. (2018), PNOR8, Exh. 15, 50 TTABVUE 348-354 at 350.

[49] Zagra et al. (2018), PNOR8, Exh. 15, 50 TTABVUE 348-354 at 350.

[50] Zagra et al. (2018), PNOR8, Exh. 15, 50 TTABVUE 348-354 at 350.

[51] Carty Rpt., 60 TTABVUE 15, 22, ¶ 33, 50; Mecholsky Lit. Rpt. 105 TTABVUE 22, ¶ 25.

> **Biocompatibility:** A material's interaction and compatibility with the human body.[52]
>
> **Phase Stabilization:** For purposes of these proceedings, the **tetragonal** and **monoclinic phases** refer to the stages during which the physical properties of Zirconia may be affected during the heating and cooling of the sintering process. **Phase stabilization** refers to the proper balance that must be maintained between the tetragonal and monoclinic phases of the Zirconia. The phase stability of the Zirconia portion of the ZTA compound in turn affects the toughness and wear performance of the material.[53]

VIII. Trial by Implied Consent

Generally, plaintiffs in proceedings before the Board may not rely on unpleaded matters, and the Board will not consider them. *See P.A.B. Produits et Appareils de Beaute v. Satinine Societa In Nome Collettivo di S.A. e.M. Usellini*, 570 F.2d 328, 196 USPQ 801, 804 (CCPA 1978); *UVeritech, Inc. v. Amax Lighting, Inc.*, 115 USPQ2d 1242, 1244 (TTAB 2015). As an exception to this general rule, the Board will consider matters that have been tried by express or implied consent of the parties. Fed. R. Civ. P. 15(b)(2); *NT-MDT LLC v. Kozodaeva*, 2021 USPQ2d 433, at *14-15 (TTAB 2021). Matters will be found as having

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[52] Mecholsky Lit. Rpt. 105 TTABVUE 43, ¶ 68.

[53] Porporati Decl., 99 TTABVUE 6, ¶¶ 15-16; Chevalier/Gremillard (2009), PNOR10, 52 TTABVUE 7-8.

been tried by implied consent when, even if not expressly raised in the pleadings, the parties introduce evidence regarding the unpled matters without objection and discuss the issues relating thereto in their briefs. *Conolty v. Conolty O'Connor NYC LLC*, 111 USPQ2d 1302, 1305 (TTAB 2014).

In its Petitions for Cancellation, Petitioner asserts that the color pink as applied to the chemical composition of ceramic hip implant components is functional because, when chromium oxide is added to the composition, it naturally appears in that color. Moreover, Petitioner alleges, chromium oxide (chromia) is added for the hardening effect it provides.[54] However, the parties did not limit their functionality evidence and arguments solely to the hardening effects of chromia. Both parties also presented evidence and arguments regarding chromia's contributions (or not) to other mechanical properties, such as the fracture toughness, flexural/burst strength, wear/aging resistance and phase stabilization properties of ZTA.[55] We therefore

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[54] Petition for Cancellation, 1 TTABVUE 4, 6, 10-11, ¶¶ 7-8, 15, 28-32 in Cancellation No. 92058781; Petition for Cancellation, 1 TTABVUE 4, 6, 10-11, ¶¶ 7-8, 15, 28-32 in Cancellation No. 92058796.

[55] Petitioner's factual materials and expert opinions summarized in Carty Decl. and Carty Rpt., 48/60 TTABVUE, Carty Rebuttal Decl. and Carty Rebuttal Rpt., 141/153 TTABVUE; Respondent's factual materials and expert opinions summarized in Mecholsky Decl., Mecholsky Lit. Rpt., Mecholsky Lit. Rebuttal Rpt., Mecholsky TTAB Rpt. and Mecholsky TTAB Rebuttal Rpt., 105/106-116

deem the pleadings amended to conform to the evidence and arguments of the parties pursuant to Fed. R. Civ. P. 15(b).

IX. How the Parties' Products are Used within a Hip Replacement System

We reproduce here the drawings of the color pink as applied to Respondent's goods, as depicted in Respondent's registrations:

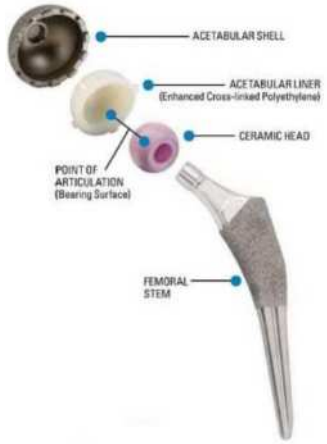
Registration No.
4319095
hip joint ball

Registration No.
4319096
acetabular shell or fossa

As used within a hip replacement system, the products appear and function as shown below:

TTABVUE. See respective arguments made in Petitioner's Brief, 157/158 TTABVUE 17-20; and Respondent's Brief, 159/160 TTABVUE 11-16.

56



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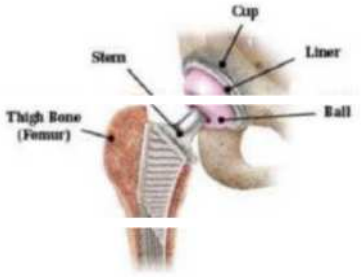
[56] Stavish Testim. Depo., Exh. 6, 135 TTABVUE 258.

[57] Pektow Decl., Exh. 17, 116 TTABVUE 46.

58



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As can be seen from the above diagrams, a hip joint "ball" is also referred to as a "head"; an acetabular shell or fossa is also referred to as a "cup" or a "liner," depending upon the overall construction of the total hip replacement system.

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[58] Abeyta Testim. Depo., Exh. 133 TTABVUE 213. "THR" is the acronym for Total Hip Replacement system.

[59] Pektow Decl., Exh 17, 118 TTABVUE 41.

Stating the obvious, the implantation of a hip replacement system into the human body involves major surgery to provide a patient with a substitute for a significantly deteriorating skeletal joint. This is not the type of surgery a patient would want to repeat. Thus, it is undesirable that any part of the replacement system would fail, degrade or cause an adverse bodily reaction in vivo.

The parties agree the development of materials that are highly resistant to impact fracturing and long-term wear has historically been a major challenge in the development of hip implant components. Metal heads and polyethylene inserts have been used, but these systems have created polyethylene wear debris causing osteolysis (bone decay) in patients. Ceramic implant components began replacing metal implants because they produced less polyethylene wear debris, thus reducing osteolysis. However, while ceramics have some favorable characteristics, they also have limited impact resistance and a greater risk of fracturing.[60] At one time, hip replacement systems outfitted with a poorly functioning femoral head implant component (the subject of unacceptably high fracture rates) were

[60] Petition for Cancellation, 1 TTABVUE 4, ¶¶ 4-5 in Cancellation No. 92058781; Answer, 28 TTABVUE 2, ¶¶ 4-5 in Cancellation No. 92058781; Petition for Cancellation, 1 TTABVUE 4, ¶¶ 4-5 in Cancellation No. 92058796; Answer, 22 TTABVUE 3, ¶¶ 4-5 in Cancellation No. 92058796.

subject to a major product recall.[61] Therefore, the processing and manufacture of ceramic femoral heads and acetabular cups with the most efficacious chemical combination, resulting in the optimal mechanical properties, is critically important.

X. The Parties' Ceramic Hip Plant Product Offerings

A. Respondent's Ceramic Hip Implant Components

Respondent began offering ceramic femoral heads and acetabular cups as hip implant components using an alumina chemical composition sold under the name BIOLOX in 1974. The first generation introduced in 1974 was made of highly-pure alumina and was manufactured using a pressureless sintering process. The second generation of the BIOLOX composition was introduced in 1985, containing fewer impurities and featuring a decreased grain size. The third generation chemical composition was introduced under the name BIOLOX forte in 1995, featuring an even smaller grain that was manufactured using hot isostatic pressing (or "H.I.P."). The fourth generation chemical composition was introduced under the name BIOLOX delta in 2003, which is a zirconia-toughened

[61] Mecholsky Lit. Rpt., Ex. 3 - Major Recalls of Organ Replacement Devices, Saint Gobain Desmarquest Hip Implant Recall (2007) Exh. 3, 106 TTABVUE 217-223.

alumina ("ZTA") composite (and which includes chromia that makes the compound pink).[62]

Today, in the United States, Respondent offers ceramic ball head and liner hip implant components made from the BIOLOX forte and BIOLOX delta chemical compositions. The BIOLOX forte composition features pure alumina ceramic, and the BIOLOX delta composition features a ZTA ceramic chemical combination. Respondent asserts that the BIOLOX delta composition has superior material properties - particularly the fracture rate and wear rates - compared to BIOLOX forte, but Respondent claims the BIOLOX forte composition has a higher hardness value.[63]

Whereas BIOLOX forte has an ivory, beige or cream color, BIOLOX delta is decidedly pink:[64]

[62] Petkow Decl., 114 TTABVUE 4, ¶¶ 7-8, Exh. 1, 27-28; *see also* Clark et al. (2007) describing the history of the development of ceramics used for hip replacement system components, PNOR4, 44 TTABVUE 645-655 at 645-646.

[63] Petkow Decl., 114 TTABVUE 4, ¶ 9.

[64] Petkow Decl., 114 TTABVUE 5, ¶ 10; images from Parikh Rpt., 47 TTABVUE 32-33.

BIOLOX forte BIOLOX delta

We find, and the parties do not dispute, that the chemical composition of BIOLOX delta hip joint implant components are pink in color because of the presence of chromia as a material constituent. [65] BIOLOX delta is a ZTA composite ceramic with three main components: alumina, zirconia and strontium aluminate ($SrAl_{12}O_{19}$) platelets. Each of these three components contains other ingredients. Specifically, the alumina portion of the BIOLOX delta composition contains chromia. This chromia is dissolved into the alumina portion of BIOLOX delta material. Similarly, yttria is dissolved into the zirconia portion of the BIOLOX delta material.[66]

The production of the BIOLOX delta composition begins with four raw fine powder materials: alumina, zirconia, yttrium chromite ($YCrO_3$), and strontium zirconate ($SrZrO_3$). After quality control, Respondent's ceramics manufacturing process comprises milling, binder addition, spray drying, powder pressing, green shaping, sintering in a furnace at high temperatures and hard machining. During manufacturing, Respondent uses a technique called "pressure-assisted sintering," or hot isostatic pressing, towards the end of the sintering process to further densify the material and control the grain size of the material. Changes to any of these processes can affect the final

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[65] Kuntz Decl., 101 TTABVUE 5, ¶ 14; Petkow Decl., 114 TTABVUE 5, ¶ 10.

[66] Kuntz Decl., 101 TTABVUE 5-6, ¶¶ 13-15; Dobbs (2010), PNOR4, 44 TTABVUE 785-820 at 787.

properties and performance of the material.[67] As discussed in greater detail below, the parties dispute the contribution of chromia (which turns the product pink), versus the addition of yttrium, better sintering techniques, and control of grain size as contributing to the material performance of the composition.

Today, BIOLOX delta accounts for the vast majority of Respondent's hip implant components sales. This is because, as Respondent claims, components made with the BIOLOX delta compound have a superior mechanical performance and lower fracture rates than components made with the BIOLOX forte compound, although both products meet and exceed the international standards for hip implant components.[68] Petitioner continually opines that Respondent has maintained a dominant (90-95% or greater) share of the ceramic hip implant component market.[69] Respondent has not shown or alleged to the contrary.

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[67] Kuntz Decl., 101 TTABVUE 6, ¶¶ 16-17.

[68] Petkow Decl., 113/114 TTABVUE 5 ¶¶ 10-11. *See* ISO Standard 6474-2, Implants for Surgery - Ceramic Materials (2012), DNOR1 70 TTABVUE 709-726. This ISO Standard sets out prescribed chemical composition and mechanical performance requirements for ZTA material. Mark Kramer Colorado litigation trial testimony ("Kramer Lit. Testim."), DNOR1, 70 TTABVUE 639-44.

[69] Strong Decl., 57 TTABVUE 4, ¶ 9; Abeyta Testim. Depo., Exh. 3, 133 TTABVUE 148, 152; Respondent's Business Plan, PNOR12, Exh. 12, 54 TTABVUE 478; e-mail exchange between Nield and Wanadoo/Biotechni (April 2015), DNOR6,

B. Petitioner's Ceramic Hip Implant Components

Petitioner has developed two ZTA ceramic materials for hip implants: (1) CeraSurf-p, a material that contains chromium oxide, which renders it pink, and (2) CeraSurf-w, a white-colored material that does not contain chromium oxide. The primary difference between the two materials is the presence of chromium oxide in CeraSurf-p. The two products have different technical characteristics.[70] Petitioner's pink CeraSurf-p ceramic femoral head and acetabular cup appear as follows:

[71]

Almost all of Petitioner's customers buy CeraSurf-p instead of CeraSurf-w, because (says Petitioner) CeraSurf-p contains chromium oxide (which Petitioner contends the marketplace understands to improve the performance-related properties of the

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Exh. 6, 75 TTABVUE 37-41 at 38; Petitioner's Brief, 157/158 TTABVUE 7.

[70] Haftel Decl., 59 TTABVUE 5, ¶ 12.

[71] Image from CoorsTek Bioceramics Overview (2018), Stavish Testim. Depo., Exh. 7, 135 TTABVUE 284.

material), while CeraSurf-w does not. Petitioner claims the market demands the current state-of-the-art material, which is a ceramic material that contains chromium oxide. It is Petitioner's understanding that, because of Respondent's education of the market, when surgeons see a pink hip ball, they recognize it as the state-of-the-art ceramic material.[72]

At least as of the close of testimony periods before the Board, Petitioner had not developed any specific marketing materials for its white product, CeraSurf-w,[73] and Petitioner had only one significant customer interested in purchasing CeraSurf-w for use as part of its hip replacement implant system.[74]

C. Customers and Potential Customers for the Parties' Products

The customers and potential customers for the parties' ceramic hip implant components are original equipment manufacturers ("OEMs") - such as Zimmer Biomet, Smith & Nephew, DePuy Synthes and Stryker — that in turn produce total hip replacement implant systems supplied to hospitals, buying associations or surgeons.[75]

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[72] Strong Decl. 57 TTABVUE 5, ¶ 14.

[73] Strong Discov. Depo., RNOP26, 97/131 TTABVUE 99.

[74] Haftel Decl., 58/59 TTABVUE 6, ¶ 16.

[75] Shopoff Decl., 85 TTABVUE 3, ¶¶ 5-6; Petkow Decl., 114 TTABVUE 5, ¶¶ 12-13; Strong Decl. 57 TTABVUE 3, 6, ¶¶ 7, 19; Haftel Decl., 58/59 TTABVUE 6, ¶ 16.

The parties compete in a highly demanding industry, operating under a complex regulatory system requiring assurances that their products comply with applicable requirements imposed by the U.S. Food and Drug Administration ("FDA") for implant grade materials. The OEM customers comprise major medical device companies that are experts in the medical device field and have high standards for their suppliers.[76] They have deep technical knowledge of orthopedic implant products, complete their own internal product and material testing, perform their own clinical testing while working closely with surgeons and other healthcare professionals, and are responsible for obtaining regulatory approval for devices incorporating the parties' components.[77]

XI. Respondent's Relevant Patents and Patent Application

On November 3, 1998, a related company to Respondent[78] was issued U.S. Patent No. 5830816 (the "'816 Patent"), Burger et al., for a chemical composition to be used in the manufacture of cutting tools, titled "Sintered Molding,"[79] the same chemical

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[76] Strong Decl. 57 TTABVUE 3, ¶ 7.

[77] Haftel Decl., 59 TTABVUE 5-6, ¶ 14.

[78] A concise description of Respondent and its related or predecessor companies may be found at Dobbs (2010), PNOR4, 44 TTABVUE 785-820 at 787.

[79] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 5-18; Petition for Cancellation, 1 TTABVUE 4-5, ¶ 9 in

composition presently used in Respondent's BIOLOX delta hip implant components. The '816 patent expired on January 21, 2013.[80] As we discuss below, it is after this date that Respondent began to change its position regarding the contribution of chromia (which turns the compound pink) to the material properties of the composition.

In any event, the Abstract of the '816 patent, in part, states: "[z]irconium dioxide containing 2 to 40

Cancellation No. 92058781; Answer, 28 TTABVUE 4, ¶ 9 in Cancellation No. 92058781; Petition for Cancellation, 1 TTABVUE 5, ¶ 9 in Cancellation No. 92058796; Answer, 22 TTABVUE 4, ¶ 9 in Cancellation No. 92058796.

[80] Under 35 U.S.C. § 154(a)(2), a U.S. patent has "a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under [35 U.S.C. §] 120 . . ., from the date on which the earliest such application was filed." Pursuant to 35 U.S.C. § 120, "[a]n application for patent for an invention . . ., which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application." Here, the filing date of the earliest application from which, through continuations, the '816 issued was January 21, 1993. '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 13, col. 1, lines 3-8. Twenty years from that date is January 21, 2013.

vol. % of stabilizing oxides is embedded in the matrix material of a sintered molding consisting of an aluminum oxide/**chromium oxide** mixed crystal." (emphasis added). Independent Claim 3 of the '816 Patent recites (emphasis added):

> **3.** A sintered molding comprising:
>
> a1) 60 to 98 vol.-% of a matrix material, the latter consisting of
>
> a2) 67.1 to 99.2 vol.-% of an aluminum oxide/**chromium oxide** mixed crystal
>
> a3) 0.8 to 32.9 vol.-% of a mixed crystal of the formula $SrA1_{12-x}$,$\mathbf{Cr_xO_{19}}$, x corresponding to a value of 0.0007 to 0.045,
>
> b) 2 to 40 vol.-% of zirconium dioxide incorporated into the matrix material, which
>
> c) contains as stabilizing oxides more than 10 to 15 mol.-% of one or more of the oxides of cerium, praseodymium and terbium and/or 0.2 to 3.5 mol.-% of yttrium oxide, with respect to the mixture of zirconium dioxide and stabilizing oxides,
>
> d) the added amount of the stabilizing oxides being chosen such that the zirconium dioxide is present predominantly in the tetragonal modification, and

> e) the molar ratio between the zirconium dioxide containing the stabilizing oxide and the **chromium oxide** amounting to 1,000:1 to 20:1,
>
> t) the portions of the components making up 100 vol.-% of the sintered molding, and
>
> g) the zirconium dioxide has a grain size not exceeding 2 μm. (emphasis added).[81]

Respondent concedes that BIOLOX delta chemical combination practices one or more of the inventions described and claimed in the '816 patent.[82] However, nowhere in the '816 patent is the color pink mentioned. The disclosures and discussion within the '816 patent, in relevant part, provide (emphasis added):

> The problem still exists of improving the known materials and to make available sintered moldings which have a high **strength** level and in which good **toughness** is combined with great **hardness**. The invention is aimed at making available a sintered molding which will satisfy these requirements,

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[81] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 17, col. 9, lines 59-67; col. 10, lines 21-37.

[82] Respondent's Admission Response No. 28 from the Colorado litigation, PNOR5, 45 TTABVUE 239; Kuntz Colorado litigation trial testimony ("Kuntz Lit. Testim."), PNOR2, 42 TTABVUE 195-97.

> and due to its range of properties will have greater **resistance to wear**, so that the sintered molding will be suitable as a cutting tool, especially as a cutting insert, and quite especially as a cutting insert for the machining of cast-iron and steel materials, while an additional objective is seen in proposing a sintered molding which can be used as a cutting insert for interrupted cutting.[83]
>
> It has now been found that the solution of the problem in question requires a sintered molding with an entirely special composition. In addition to the transformation **toughening**, which is achieved by embedding in a ceramic matrix a zirconium dioxide containing stabilizing oxides, the invention, in accordance with a first embodiment, provides as the matrix a mixed crystal of aluminum oxide/**chromium oxide**. Furthermore, the invention provides that the zirconium dioxide embedded in the matrix, and the **chromium oxide** forming the mixed crystal with the aluminum oxide, are in a specific molar ratio to one another. This measure makes it possible for the first time to achieve **hardness** values such as have

[83] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 14, col. 3, lines 39-50.

not previously been achieved at such zirconium dioxide contents, even at the relatively high zirconium dioxide contents which may be necessary to obtain an especially good **toughness**. On the other hand, at low zirconium dioxide contents, relatively low **chromium oxide** contents can be present, thereby counteracting the embrittlement of the material.[84]

The statement that the zirconium dioxide and **chromium oxide** containing the stabilizing oxides are to be present in a specific molar ratio necessarily also implies specific ratios for the rest of the components, because for example as the zirconium dioxide content decreases, the contents of the stabilizing oxides also decrease with respect to the sintered moldings, while on the other hand the content of the aluminum oxide increases. **With respect to the aluminum oxide in the sintered molding, the chromium oxide is present in a weight ratio of 0.004 to 6.57% by weight**, but it must not be overlooked that chromium oxide and the zirconium dioxide containing the

[84] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 4, col. 3, lines 51-67 through col. 4, lines 1-2.

> **stabilizing oxides** are in the stated molar ratio. . . .[85]
>
> The term, "mixed crystal," used in the claims and description, . . . means a solid solution of **chromium oxide** in aluminum oxide and in strontium aluminate.[86]
>
> The sintered molding in accordance with the invention is made by pressureless sintering or hot pressing a mixture of aluminum oxide/zirconium dioxide/**chromium oxide** and **stabilizing oxides** or a mixture of these components is used . . .[87]
>
> Applications of the sintered molding preferably lie in its use as a cutting tool for cutting paper, textiles and films, but especially preferred is the use of the sintered molding as a cutting insert for the machining of cast iron or of steel materials, especially interrupted cutting.[88]

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[85] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 14, col. 4, lines 5-16.

[86] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 14, col. 4, lines 53-56.

[87] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 15, col. 6, lines 18-21.

[88] '816 Patent, PNOR3, Exh. 1, 43 TTABVUE 15, col. 6, lines 35-39.

During the prosecution of the underlying application to the '816 patent, in order to overcome a prior art reference to patentability raised by the patent examiner, Respondent's patent counsel at the time, in an Office action response, stated (emphasis added):

> The invention of the present application is not suggested by [the prior art reference]. The solution of the object according to the present invention requires a sintered body with an entirely unique composition. For this purpose, inter alia, **a very specific molar ratio of the zirconium dioxide deposited in the matrix and the chromium oxide which together with the aluminum oxide forms the mixed crystal is required**. Only in this way has it for the first time been possible to obtain **hardness** values, even at higher zirconium dioxide contents, which have heretofore not been achievable with corresponding zirconium dioxide contents. On the other hand, relatively low chromium oxide contents can be present at low zirconium dioxide contents, whereby **a brittleness of the sintered body can be suppressed**. [The prior art reference] does not teach

> or suggest any of these advantages.[89] (emphasis added)

Respondent's materials expert, Dr. John Mecholsky, concedes that "[t]he '816 Patent . . . covers a broad range of chromium, including amounts so low that they would be almost undetectable . . . [f]or example, having .004 wt % chromium (with respect to alumina) . . . [and, o]n the high end, . . . at least 6 wt % chromium, and possibly higher. The '816 Patent also discloses a very broad range of ratios between the zirconia and chromia, from as low as 20:1 to as much as 1,000:1."[90]

That the '816 patent, on its face, is directed to a sintered molding of a particular composition for use as a cutting tool is of no moment. Respondent's internal and sales presentation documents (some of which mention the color pink as being caused by the addition of chromia) disclose that even though the material developed under the name DC25, now produced and sold under the name BIOLOX delta, was conceived in Respondent's industrial division and initially manufactured for cutting tools, it has since been optimized for medical use — specifically for prosthetic

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[89] Patent Appln. Ser. No. 08/674,458, Office Action Response dated April 15, 1997, PNOR3, Exh. 7, 43 TTABVUE 404.

[90] Mecholsky Lit. Rpt., 105 TTABVUE 174, ¶¶ 301-02; *see also* Kuntz Decl., 101 TTABVUE 12, ¶ 36 ("The ['816 P]atent claims a wide range of chromium content.").

hip joint components.[91] The Gottwik memorandum identified in the footnote below explicitly identifies ZTA formulations including chromium oxide as contributing to desired mechanical properties such as hardness, toughness and strength.

Respondent has sought or obtained additional patent protection for compositions claiming the beneficial effects of chromia, the chemical that turns the compound pink. On September 17, 2002, a related company to Respondent was issued U.S. Patent No. 6452957 (the "'957 Patent"), Burger et al., "Sintered Shaped Body Reinforced with Platelets."[92] The '957 patent expired on November 2, 2018.[93] Chromium oxide is noted as a constituent element in nearly all of the claims of this patent.[94]

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[91] Questions and Answers for Respondent's Meeting Discussion (May 2013), PNOR1, 41 TTABVUE 49; Respondent's internal memorandum authored by Lukas Gottwik, (Translated Version, August 2, 2011), PNOR4, Exh. 3, 44 TTABVUE 38-44; CeramTec Sales Questionnaire and FAQs (March 2, 2012), PNOR5, Exh. 5, 45 TTABVUE 91-144 at 95; CeramTec/DePuy Sales Training (August 2013), PNOR12, Exh. 1, 61 TTABVUE 6-105 at 18; Kuntz Lit. Testim., RNOR1, 70 TTABVUE 388-96.

[92] '957 Patent, PNOR6, Exh. 6, 43 TTABVUE 215-222.

[93] The filing date of the earliest application from which the '816 patent issued was the Patent Cooperation Treaty (PCT) application filed on November 2, 1998. '957 Patent, PNOR3, Exh. 6, 43 TTABVUE 216.

[94] '957 Patent, PNOR3, Exh. 6, 43 TTABVUE 221, cols. 9-10.

The disclosures and discussion within the '957 patent, in relevant part, provide (emphasis added):

> The subject-matter of the present invention is a sintered shaped body consisting of a matrix material that contains an aluminum oxide/**chromium oxide** mixed crystal and which is in situ reinforced with platelets.[95]
>
> [T]he invention provides that the matrix contains a mixed crystal of aluminum oxide/**chromium oxide**. Furthermore, the invention provides that the zirconium dioxide, incorporated in the matrix, and the **chromium oxide**, forming the mixed crystal together with the aluminum oxide, are in a specific molar ratio with respect to each other. This measure makes it possible for particular **hardness** values to be attained even in the case of comparatively high proportions of zirconium dioxide that may be required in order to obtain a particularly good level of **fracture toughness**. On the other hand, in the case of low proportions of zirconium dioxide there may even be a comparatively small **chromium-oxide**

[95] '957 Patent, PNOR3, Exh. 6, 43 TTABVUE 217, col. 1, lines 6-9.

> content, inhibiting embrittlement of the material.[96]
>
> In accordance with the invention, the matrix material contains an aluminum oxide/**chromium oxide** mixed crystal and a further mixed crystal in accordance with one of the general formulae . . . One effect that increases the **toughness** results from the zirconium dioxide that is incorporated in the mixed-crystal matrix, whilst the **chromium** addition counteracts any drop in the **hardness** values when the proportion of zirconium dioxide rises.[97]

On January 19, 2016, Respondent was issued U.S. Patent No. 9237955 (the "'955 Patent"), Niess et al., "Intervertebral Disc Endoprosthesis." [98] Chromium oxide is noted as a constituent element in one of the dependent claims of this patent.[99] The disclosures and discussion within the '955 patent, in relevant part, provide (emphasis added):

> The object on which the invention is based is to improve an intervertebral

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[96] '957 Patent, PNOR3, Exh. 6, 43 TTABVUE 218, col. 4, lines 43-56.

[97] '957 Patent, PNOR3, Exh. 6, 43 TTABVUE 219, col. 5, lines 13-15, 41-46.

[98] '955 Patent, PNOR7, Exh. 8, 49 TTABVUE 46-55.

[99] '955 Patent, PNOR7, Exh. 8, 49 TTABVUE 55, col. 12, lines 54-57.

> disc endoprosthesis . . . . [T]he sliding bodies should have extreme **hardness**, so that no abrasion occurs over the entire period of service.[100]
>
> [T]the invention provides that the zirconium dioxide, incorporated in the matrix, and the **chromium oxide**, forming the mixed crystal together with the aluminum oxide, are in a specific molar ratio with respect to each other. This measure makes it possible for the first time for **hardness** values to be attained, even with comparatively high proportions of zirconium dioxide that may be required in order to obtain particularly good **fracture toughness**, that have not been attainable hitherto with corresponding proportions of zirconium dioxide. On the other hand, with low proportions of zirconium dioxide there may even be a relatively small **chromium-oxide** content, which counteracts embrittlement of the material.[101]
>
> [T]he **chromium** addition can counteract any drop in the **hardness**

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[100] '955 Patent, PNOR7, Exh. 8, 49 TTABVUE 50, col. 1, lines 46-52.

[101] '955 Patent, PNOR7, Exh. 8, 49 TTABVUE 50, col. 2, lines 51-63; *see also* 49 TTABVUE 52, col. 6, lines 35-44.

> values due to the proportion of zirconium dioxide.[102]
>
> An effect that increases the **toughness** results from the zirconium dioxide that is incorporated in the mixed crystal matrix, whilst the **chromium** addition counteracts any drop in the **hardness** values when the proportion of zirconium dioxide rises.[103]

On February 14, 2012, Respondent's then-Manager of Oxide Development in its Development Department, Meinhard Kuntz,[104] with others, filed U.S. Patent Application No. 2012/0142237 (the "'237 Application"), Kuntz et al., "Sintered Moulded."[105] The Abstract of the '237 Application describes "[a] sintered molded body consisting of a material that contains aluminum oxide with **chromium** doping, zirconium oxide with Y-stabilization and strontium aluminates with variable **Cr**-doping, which is particularly suitable for medial [sic] application."[106] (emphasis added). Chromium oxide is noted as a constituent

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[102] '955 Patent, PNOR7, Exh. 8, 49 TTABVUE 51, col. 3, lines 38-40.

[103] '955 Patent, PNOR7, Exh. 8, 49 TTABVUE 53, col. 7, lines 31-35.

[104] Kuntz Decl., 101 TTABVUE 3-4, ¶¶ 4, 8-9.

[105] '237 Application, PNOR7, Exh. 7, 49 TTABVUE 42-45.

[106] '237 Application, PNOR7, Exh. 7, 49 TTABVUE 3.

element in all of the published claims of this application.[107]

The disclosures and discussion within the '237 Application, in relevant part, provide:

> The object of the invention is to provide a sintered moulding made of a ceramic material which combines optimum properties such as **hardness**, elasticity and thermal conductivity and is particularly suitable for medical technology applications.[108]

The material composition disclosed in the '237 Application includes "aluminum oxide with **chromium** doping" and "strontium aluminate (with variable **Cr** doping)." (emphasis added).[109]

XII. Technical Literature Regarding the Advantages of Chromia in Chemical Compounds for Industrial and Medical Applications

The parties made of record a wealth of technical literature about the benefits of chromia to the mechanical properties of ceramics compounds comprising or including alumina, particularly

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[107] '237 Application, PNOR7, Exh. 7, 49 TTABVUE 44, second column, to 45, first and second columns.

[108] '237 Application, PNOR7, Exh. 7, 49 TTABVUE 44, first column, paragraph 0002.

[109] '237 Application, PNOR7, Exh. 7, 49 TTABVUE 44, first column, table immediately following paragraph 0003.

hardness, strength and wear resistance, spanning about 54 years,[110] some of which was authored by current or former employees of Respondent (for example, Burger, Kuntz and Porporati). We summarize below pertinent portions from these scientific articles (emphasis added throughout):

> [T]he **enhancement of alumina's hardness, strength, wear resistance, and other mechanical properties** by **chromia** in solid solution is generally accepted . . . . This note describes the variation of the **microhardness** of alumina with **increasing chromia content** in dense, fine-grained solid solutions. [Bradt (1966), PNOR6, Exh. 12, 46 TTABVUE 315-317 at 316].
>
> A positive influence of **Cr_2O_3** was observed for the . . . **grindability** of all samples. . . . [T]he **abrasion resistance** of alumina ceramics increases with increased additions of **chromium oxide**. . . . [T]here is a lack of correlation between the abrasion resistance of

[110] Petitioner and Respondent submitted many of the same technical articles as evidence. Due to the order in which the parties' evidence was presented, if Petitioner made of record a technical article first, we do not recite where the identical article submitted by Respondent appears elsewhere in the record. Further, neither party objected that any of these articles are hearsay or otherwise are inadmissible. We set out below the article excerpts not for their truth, but for what they show on their face at the time of publication, as stated by knowledgeable persons in the scientific community.

alumina ceramics and the porosity increase at all firing temperatures, when **Cr_2O_3** is added. This **increase of hardening and abrasion resistance** of hot-pressed Al_2O_3 with increased **Cr_2O_3** additions has been reported by Bradt and an **increase of the crater wear resistance** of vacuum-pressure-sintered alumina cutting tools alloyed with chromium oxide was observed by Ghate *et* al. This study indicates a **disadvantageous effect** of **Cr_2O_3** on the sintering of alpha-alumina in the presence of a liquid phase. The effect of **chromium oxide** is so significant as to **decrease** the sintered **density** of the alumina ceramics. This is correlated with the influence of **Cr_2O_3** in increasing the dihedral angle. As a result, the distinct **deterioration** of the mechanical properties of alumina ceramics is observed. [Tomaszewksi (1982), PNOR10, Exh. 15, 52 TTABVUE 176-181 at 181. The conclusions in this article appear to be an outlier compared to the other published scientific studies reported herein].

The only positive role of **Cr_2O_3** on sintered Al_2O_3 was the improved grindability, and this was only at a low level of addition (≤ 0.34 mole% **Cr_2O_3**). The **Cr_2O_3 addition**, however, **improved densification** and **hardness** when Al_2O_3 with a little MgO as a grain growth inhibitor was hot-pressed in hydrogen and in vacuum. In the latter, the **Cr_2O_3** exhibited significantly greater **wear resistance** than

the non-alloyed cutting tools. [Cho et al. (1990), PNOR10, Exh. 14, 52 TTABVUE 166-175 at 172].

High **hardness** and **fracture toughness** can be achieved by forming solid solutions. of Al2-x**Crx**O3, and SrAl12-x**Crx**O19. In the system Al_2O_3-**Cr_2O_3**-SrO-ZrO_2-Y_2O_3 the **fracture toughness** reaches 10 MPa$\sqrt{m}$ and in the system Al_2O_3-**Cr_2O_3**-SrO-ZrO_2-CeO_2 15 MPa$\sqrt{m}$. Due to the excellent **hardness, fracture toughness and mechanical strength** of 800 MPa, these platelet- and zirconia toughened (ZPTA-) materials have great potential for future applications. . . . **Chrome oxide** forms a solid solution together with aluminum oxide. The **hardness** can be increased by incorporating **Cr** atoms into the Al_2O_3-grid. . . . [I]t could be proven that an increase in hardness in substance system Al_2O_3-**Cr_2O_3**-ZrO_2-Y_2O_3 can be realized with rather low additions of **chrome oxide**. . . . However, a significant **embrittlement** occurred due to the **chrome oxide** alloying of the matrix. . . . [Burger (1997), English transl.), PNOR11, Exh. 11, 53 TTABVUE 119-123 at 119, 122].

The formation of $SrAl_{12}O_{19}$ platelets in the structure can be achieved with a suitable process with the addition of e.g., SrO to the Al_2O_3-ZrO_2-(:Y_2O_3) matrix. In addition to the suitable process, the ratio of SrO : Al_2O_3 is also important. In such ceramic materials, a

significant increase in toughness can be achieved.

However, **due to the formation of platelets, a significant decrease in hardness** can be found in such ceramics. This has **an adverse effect on the wear resistance**. On a material basis, small amounts of **chromium oxide** can be **added to counteract this effect**. Apart from the formation of a Al_2O_3-$\mathbf{Cr_2O_3}$ solid solution, the solid solution SrAl12-xCrxO19 is also formed. This solid solution exhibits a **significantly increased hardness compared to the chrome-free ternary phase**. . . . The in-situ platelet reinforcement through the deposit of ternary hexagonal aluminates into an alumina matrix or an alumina-zirconia-matrix leads to a significant increase of the mechanical properties. Through the additional formation of solid solutions, due to the **addition of chrome oxide**, the **hardness** may also be kept at a very high level. [Burger (1998, English transl.), PNOR11, Exh. 12, 53 TTABVUE 128-133 at 129, 131].

Reference is made to the five-material system Al_2O_3-$\mathbf{Cr_2O_3}$-SrO-ZrO_2-Y_2O_3 for the production of DC25, hereinafter described. . . . [I]t can be seen that even at high zirconium oxide concentrations, high **hardness** is maintained and facture toughness increases steadily, compared to ZTA materials. . . . The DC25 material is based on an aluminum oxide matrix. "Yttrium-coated" zirconium oxide is

dispersed at a concentration of 25 wt% in this matrix. 0.8 wt% SrO and **0.3 wt% Cr_2O_3** are added as additional components. . . . With this material, it was possible to exceed the excellent mechanical properties of Y-TZP materials for the first time and at the same time, to achieve the **high hardness** of aluminum oxide materials. [Burger (2000), English transl.), PNOR11, Exh. 9, 53 TTABVUE 90-104 at 97-98].

The effects of **Cr_2O_3** addition on the microstructural evolution and the mechanical properties of Al_2O_3 were investigated. . . . The **fracture toughness** and the **flaw tolerance** of Al_2O_3 were improved remarkably by the addition of small amounts (~2 mol %) of **Cr_2O_3**. Crack bridging by the large platelike grains was the main cause for the improvements. The **hardness** and the **elastic modulus** also increased, however, the **fracture strength decreased** by the **Cr_2O_3** additions. [Riu et al. (2000), PNOR11, Exh. 1, 53 TTABVUE 6-13 at 7].

Already in 1977 a composite material, based on an alumina matrix and therein homogeneously dispersed metastable tetragonal zirconia particles, was developed (ZTA). . . . From literature, it is well known that alumina and **chromia** form a solid solution. Experimental investigation has shown that by addition of **chromia** the **hardness** is increased significantly. . . . [H]igh **hardness** is retained

even at high zirconia concentrations by adding small amounts of **chromia**. . . . Wear tests . . . with rings and discs made of Biolox delta have shown extremely **low wear rate**. [Burger and Richter (2001), PNOR4, Exh. 7, 44 TTABVUE 174-179 at 176-77].

[T]he **hardness** [of the ZTA matrix] is recaptured by alloying the material with **chromium oxide** which creates a solid solution with the basic alumina matrix. The distribution of **chromium** inside the alumina atomic lattice activates **a colorizing effect similar to natural ruby**. . . . Matrix hardening [is achieved] . . . by creating a solid solution with **chromium oxide**. . . . The . . . addition of **chromium oxide** as a solid solution in the alumina matrix as a means of **compensating for the drop in hardness** caused by the addition of the lower hardness zirconia particles throughout the microstructure. [Kuntz (2006), PNOR6, Exh. 2, 46 TTABVUE 14-19 at 16].

Additionally to the reinforcing components, there are also stabilizing elements doped to the material. **Chromium** is added which is soluble in the alumina matrix and **increases the hardness** of the composite. The minor amount of **chromium** is the reason for the **pink color** of the material . . . . [Kuntz (2008), PNOR6, Exh. 3, 46 TTABVUE 20-36 at 26].

In order to further reinforce the [BIOLOX delta] components, stabilising elements are also doped to the material. **Chromium** is added, which is soluble in the alumina matrix and **increases the hardness** of the composite. The small amount of chromium is the reason for the **pink colour** of the material. [Pandorf and Kuntz (2009), PNOR6, Exh. 4, 46 TTABVUE 37-41 at 39].

Additionally to the reinforcing components, there are also stabilizing elements doped to the material. **Chromium** is added which is soluble in the alumina matrix. and **increases the hardness** of the composite. The minor amount of chromium [1.4-2.0% by weight according to Table 2] is the reason for the **pink color** of the material. [Kuntz et al. (2009), PNOR6, Exh. 8, 46 TTABVUE 259-282 at 264].

A new alumina-zirconia matrix composite (AMC: Al_2O_3 = 80.5%, ZrO_2= 18 vol%) was introduced in 2000 as a high-strength implant material with virtually double the fatigue resistance of alumina . . . The improvement came from small and well-dispersed zirconia (24%; grains < 0.3 μm) constrained by the alumina matrix. The **chromium** and strontium (1%) platelet distributions (aspect ratio 3–6) combined with the zirconia allowed for **suppression of crack initiation, growth and deflection** while the alumina matrix contributed overall **hardness**. This new bioceramic is known as Biolox-delta (CeramTec

Inc., Plochingen, Germany). [Clark et al. (2009), PNOR11, 53 TTABVUE 105-113 at 106].

BIOLOX delta is an alumina based composite ceramic. . . . Additionally to the reinforcing components, there are also stabilizing elements doped to the material. **Chromium** is added which is soluble in the alumina matrix and increases the hardness of the composite. The minor amount of **chromium** is the reason for the **pink** color of the material . . . . [Kuntz (2010), PNOR4, Exh. 10, 44 TTABVUE 612-637 at 618].

[T]he newest generation of ceramics (named Biolox Delta) . . . incorporate zirconia into the alumina matrix. . . . **Chromium oxide** (0.5%) has been added to improve the **hardness** and **wear characteristics**, and strontium crystals (0.5%) to enhance toughness and diffuse crack energy. The final AMC [alumina matrix composite] material consists of roughly 75% aluminum oxide, 25% zirconia, and less than l % **chromium oxide** and strontium oxide. [Cai and Yan (2010), PNOR5, Exh. 6, 45 TTABVUE 145-152 at 149].

[A]lumina/zirconia composites represent the newest generation of ceramic materials and the most promising candidates for replacing metallic bearing parts in arthroplastic applications. . . . **Cr^{3+}** addition to the composite structure could . . . affect . . . an ability of the

alumina phase [during processing], thus ultimately leading to a different rate in polymorphic transformation in the zirconia phase. Results collected by [other authors] on the phase stability at room temperature of tetragonal zirconia added with **Cr_2O_3 dopant** indeed support this suggestion. According to the findings of those researchers, the observed stabilization . . . resulted from a strong interaction between Cr_2O_3 and the ZrO_2 surface, which prevented the diffusion of oxygen from the atmosphere into the ZrO_2 lattice. . . . [T]his paper . . . suggests a role of **Cr_2O_3** dopant on **thermal stability** and, thus, the possibility of **tailoring environmental performance** through a suitable doping not only of the ZrO_2 phase but also of the Al_2O_3 matrix phase. [Pezzotti, Porporati, et al. (2010), PNOR6, Exh. 1, 46 TTABVUE 5-13 at 6, 12].

Some alumina-zirconia composites are already implanted or developed by companies (Biolox delta by Ceramtec being an improved version of these composites, with SrO and **Cr_2O_3 additions** and alumina grains with platelet-like morphology). As expected, they show **significant improvement in ageing resistance** . . ., and **excellent crack resistance**. [Douillard et al. (2012), PNOR10, Exh. 9, 52 TTABVUE 122-134 at 124].

Additionally to the reinforcing components, there are also stabilising elements doped to the material. **Chromium** is added, which is soluble

in the alumina matrix and which **increases the hardness** of the composite. The minor amount of **chromium** is the reason for the **mauve colour** of the material. [Masson and Kuntz (2013), PNOR6, Exh. 5, 46 TTABVUE 42-51 at 45].

Chromia (**Cr_2O_3**) is one the many additives potentially able to **improve the physical properties** of alumina. . . . The addition of **Cr_2O_3** . . . increases the **hardness**, tensile **strength** and thermal **shock resistance** of alumina (Riu et al., 2000). When a small amount of Cr_2O_3 (~ 2 mol %) is added, the grains become larger and bimodal in size distribution. At the same time, the **fracture toughness** and **flaw tolerance** of alumina are also improved. The **hardness** as well as **elastic modulus** is increased. However, **fracture strength decreases** with the addition of **Cr_2O_3** (Riu et al., 2000). . . . The effects of **Cr_2O_3** addition on the mechanical properties and microstructurc of ZTA were investigated. When a small amount of Cr_2O_3 (~0.6 wt %) was added, the grains becomes larger and acquired a platelike shape. As a result, **fracture toughness was improved** remarkably by the small addition of Cr_2O_3 (~0.6 wt %). [Azhar et al. (2013), PNOR11, Exh. 2, 53 TTABVUE 14-21 at 16, 20].

Th[e] fourth generation of composite ceramics of alumina matrix (BIOLOX Delta, CeramTec

GmbH, Germany) is composed of 82% of alumina and 17% zirconia. **Improved oxidation resistance, hardness and wear** were achieved adding a 0.5% of **chromium oxide** . . . . [Gabarro et al. (2014), PNOR8, Exh. 6, 50 TTTABVUE 47-59 at 49].

Chromium oxide is another additive used in Biolox Delta to **increase the hardness and wear** characteristics . . . [T]he addition of **chromia** is reported to lead to an **increase in toughness** with no change in hardness for ZTA composites with different zirconia and alumina contents. . . . **Chromium oxide** added to the alumina phase is also shown to **slow down the hydrothermal degradation** in the zirconia . . . The addition of **chromia** further enhances [the] . . . **protective effect** [of zirconia from **undergoing phase transformation**]. [Kurtz et al. (2014), PNOR9, Exh. 5, 51 TTABVUE 105-115 at 111.

Biolox Delta, a commercialized product by CeramTec AG, is a ZTA but also **contains small quantities of** SrO and **Cr_2O_3**. These additives react with alumina and form plate-like alumina grains that produce extra **toughening mechanisms** through crack deflection and crack bridging . . . In addition to **enhancing toughness**, the addition of **chromium oxide** in alumina matrix **enhances the hardness, the tensile strength and resistance to corrosion and**

thermal shock . . . In addition to the positive role of **Cr** in the enhancement of **wear resistance**, this dopant also helps **maintain the stability** of zirconia, under a hydrothermal environment. As **Cr** dopant changes the oxygen vacan[c]y concentration it prohibits or delays moisture transfer to zirconia. As a result, oxygen vacancy annihilation and thereby polymorphic phase transformation in a hydrothermal environment is postponed. . . . The enhancement of **density and mechanical properties** (**fracture toughness/**Vickers **hardness**) are achievable by incorporation of a specific amount of Cr_2O_3 and $SrCO_3$. [Bostanchi (2017), PNOR8, Exh. 8, 50 TTABVUE 75-149 at 98, 100, 259, 272].

BIOLOX delta, an example of a fourth-generation ceramic, has even higher grain uniformity and smaller grain size than previous generations. Alumina still makes up a significant portion of the material, but [z]irconium oxide crystals have been added in small amounts to help increase toughness. . . . **[C]hromium oxide** is added to the composite to help increase the **hardness** that was lost by the addition of zirconium. [Gamble et al. (2017), PNOR, Exh. 5, 53 TTABVUE 37-44 at 38].

Nowadays the most commonly used ceramic is the alumina matrix composite (AMC) (Biolox Delta; CeramTec AG, Plochingen, Germany). AMC, introduced in the early 2000s, is the fourth generation of Biolox Ceramics, composed

of 82% alumina and 17% zirconia, with the addition of **chromium oxide** (0.5%) **to enhance hardness** and strontium crystals (0.5%) to diffuse crack energy. [Zagra et al. (2018), PNOR8, Exh. 15, 50 TTABVUE 348-354 at 352].

The Biolox delta ceramic was developed to address some of the drawbacks of the third-generation alumina designs using nano-sized yttria-stabilized zirconia particles (17%), which are dispersed in the alumina matrix (81.6%) along with strontium (1%) in the form of a platelet to inhibit crack propagation, providing more strength. The addition of zirconia greatly increases the fracture toughness; and the addition of **chromium oxide** recaptures the **hardness** of the basic alumina matrix. [Chang et al. (2018), Exh. 3, 53 TTABVUE 22-29 at 26].

[T]he fourth and most recent edition of the ceramic (CeramTec, BIOLOX delta) femoral head has been optimized with zirconia, strontium oxide, and **chromium oxide** to **diffuse crack energy, limit crack propagation, and improve hardness**. This has shown to **further reduce the incidence of ceramic head fractures** . . . . [Robinson, et al. (2019), PNOR8, Exh. 14, 50 TTABVUE 341-347 at 343].

Fourth-generation ceramics are called alumina matrix composites (AMC) and marketed as BIOLOX Delta (CeramTec GmbH, Plochigen;

Germany). They have higher grain uniformity, smaller grain size, and contain about 82% alumina and 17% zirconia which is incorporated as tetragonal, nano-sized yttrium-stabilized particles and this improves the composite's mechanical properties by preventing initiation and propagation of cracks. **Chromium oxide** is added to increase **hardness** while addition of small quantity strontium oxide forms platelets which deflect subcritical cracks, further adding to the toughness. [Tapasvi, et al. (2019), PNOR10, Exh. 4, 52 TTABVUE 60-67 at 61].

The effect of **Cr_2O_3 addition** in different volume ratios (0.5, 1, 5 vol %) on microstructure and mechanical properties of Al_2O_3 were examined to assess as an alternative to the pure Al_2O_3 for ceramic armour applications. . . . 0.5 vol% **Cr_2O_3** addition increased the **flexural strength** 44% by the grain boundary modification of the larger size of the **Cr^{3+}** ions. A 6% and 13% **hardness** increase was achieved because of the combined effect of increasing relative **density** and solid solution formation with 0.5 vol% and 1 vol% **Cr_2O_3 additions**, respectively. Even though the fracture toughness values remained unchanged for all the compositions, the **crack propagation behavior** turned from mostly intergranular to a mixture of intergranular and transgranular with the **Cr_2O_3** addition by the localized compressive stresses that induce the

strengthening of the grain boundary. [Yildiz et al. (2019), PNOR10, Exh. 5, 52 TTABVUE 68-76 at 75].

[T]he fourth and most recent edition of the ceramic (CeramTec, BIOLOX delta) femoral head has been optimized with zirconia, strontium oxide, and chromium oxide to diffuse crack energy, limit crack propagation, and improve hardness. This has shown to further reduce the incidence of ceramic head fractures. [Rankin et al. (2019), PNOR11, 53 TTABVUE 30-36 at 32].

[A] fourth generation of CoC [ceramic on ceramic] bearings . . . incorporates yttria-stabilized tetragonal zirconia (Y-TZP) into alumina matrix. This new generation is marketed as Biolox Delta ceramic bearings and was introduced by CeramTec AG (Plochingen, Germany) in 2004 . . . The aim of this composite is to reduce both the risk of fracture and wear rate, as well as to obtain excellent scratch resistance together with low coefficient of friction . . . This new ceramic consists of 82% alumina, 17% zirconia, and **0.5% chromium oxide to improve hardness and wear characteristics** . . . . [Fernández-Fairén et al. (2020), PNOR8, Exh. 7, 50 TTABVUE 60-74 at 62].

BIOLOX delta represents the latest advancement in alumina ceramic technology due to the addition of zirconium oxide which

> provides the basic hardness and wear resistance, and strontium oxide and **chromium oxide** which provide the **improved mechanical properties**. Compared with pure aluminum oxide, ceramic BIOLOX delta offers **higher mechanical properties including higher fracture toughness** . . . . [Davis et al. (2020), PNOR8, Exh. 13, 50 TTABVUE 338-340 at 339].

XIII. Respondent's Submissions to the U.S. Food and Drug Administration ("FDA")

As explained, in its filings with the FDA, Respondent states that the presence of chromium oxide causes the pink color of the chemical composite.

The FDA is a large agency, organized into centers. For example, there are centers for medical devices, drugs, biologics, veterinary medicines, foods and cosmetics, and tobacco products. The Device Center primarily reviews and approves or clears new medical devices prior to their coming to the market.[111]

The categories of medical devices for which the Device Center has oversight responsibility cut across multiple medical disciplines from orthopedics to cardiovascular and more. The FDA categorizes these devices into classes. The amount of regulatory control applied to a particular class of device is a function of

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[111] Kramer Colorado litigation trial testimony ("Kramer Lit. Testim.") on FDA practices, RNOR1, 70 TTABVUE 611-12. Petitioner did not introduce any testimony of its own expert on FDA practices.

its relative risk and novelty or the extent of information known about the product. Class 1 includes simple devices, some of which do not even require FDA clearance prior to marketing. Class 3 devices carry the highest risk, such as heart valves and pacemakers. Class 2 devices fall in the middle. Orthopedic hip implants are categorized into either Class 2 or Class 3. How a medical device is classified depends on a variety of factors, including the type of surfaces that are articulating or moving against each other. For example, an orthopedic device having a femoral head that is ceramic articulating against a polyethylene acetabular component is a Class 2 device. If the device has two ceramic components articulating against each other, it is a Class 3 device.[112]

If a company wants to sell a new orthopedic device, the documentation it needs to file with the FDA depends on the class in which the device is categorized. If it is a Class 2 device, for example a ceramic component articulating against a polyethylene component, then the company would file a Premarket Notification, commonly referred to as a 510k, from the section of the law where it originated. The premise of a 510k is to demonstrate that one's device is "substantially equivalent" to a "predicate device." For one device to be substantially equivalent to another, the two devices must have the same intended use. A new device does not need to be identical to a predicate device in order to be

[112] Kramer Lit. Testim., RNOR1, 70 TTABVUE 612-13.

substantially equivalent to that predicate device. A predicate device typically is a legally marketed product. The predicate device most often is itself found substantially equivalent to an earlier legally marketed device through the 510k process, and shown to be in the same generic category as the new device. If a company is unsuccessful in convincing the FDA that its Class 2 device is substantially equivalent to a predicate device, then it would be considered a Class 3 device and have to undergo the process for Premarket Approval (or "PMA") used for Class 3 devices.[113]

The FDA found hip-implant systems incorporating components made from the BIOLOX delta composition to be substantially equivalent to hip-implant systems integrating a different ceramic component on at least four separate occasions. The very first 510k for a device incorporating BIOLOX delta components was such an example because there was no prior BIOLOX delta. Yet the FDA still found the devices with and without BIOLOX delta components substantially equivalent because they had the same technological characteristics. That is, BIOLOX delta was (and is), a ZTA-type material and the predicate devices contained components made from alumina and zirconia. Even though there was a change to the material composition, the FDA cleared the medical device incorporating a component made

[113] Kramer Lit. Testim., RNOR1, 70 TTABVUE 614-16.

from the BIOLOX delta composition for marketing and sale in the U.S.[114]

Component parts for medical devices are not subject to being cleared through the 510k clearance process. The FDA reviews or clears and approves finished medical devices, not pieces and parts. So unless for some reason a component is presented as a finished medical device in its own right, it would be approved only in the context of a larger system. A medical device component could be a material, software within a device, an assembly, but not a finished device in its own right.[115]

For some medical devices, the component manufacturer might have information in its possession that is helpful to its customer, the final medical device manufacturer needing to submit a 510k or PMA application to the FDA. In such a case, a method has been set up for a component manufacturer, if it wishes to maintain confidentiality over some of its information, to provide that information directly to the FDA. The form for providing confidential information directly to the FDA is called a "master file." A master file permits a third party, such as a component supplier, to provide information directly to the FDA, confidentially, but the finished-device manufacturer would not have direct access to it. However, the finished-device manufacturer could tell the FDA it knows this master

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[114] Kramer Lit. Testim., RNOR1, 70 TTABVUE 619-23.

[115] Kramer Lit. Testim., RNOR1, 70 TTABVUE 624-25.

file exists, and provide a letter from the master file owner permitting the FDA to access it on the finished-device manufacturer's behalf. Component suppliers are not required to submit master files to the FDA; it is a voluntary process.[116]

Petitioner made of record Respondent's master files (or their amendments) submitted to the FDA in 2004, 2008, 2012, 2013 and 2015, in which Respondent stated that chromium oxide had been added to BIOLOX delta ceramic matrix to increase the hardness of the ceramic, explaining in some, but not all, instances that the addition of chromia is the cause of the pink color of the material (emphasis added):

> The selected Alumina Matrix Composite [BIOLOX delta] makes use of three different principles in order to achieve its excellent properties. These are: [1] [t]ran[s]formation toughening resulting from the addition of the small Zirconia particles homogeneously dispersed in the Alumina Matrix, [2] [platelet reinforcement resulting from the in situ

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[116] Kramer Lit. Testim., RNOR1, 70 TTABVUE 625-26; *see also*, U.S. FDA "Introduction to Master Files for Devices (MAFs)," PNOR8, Exh. 4, 50 TTABVUE 37-40 at 38 ("To help preserve the trade secrets of the ancillary medical device industry and at the same time facilitate the sound scientific evaluation of medical devices, FDA established the device master file system. In addition, a master file may be considered when several applications may be submitted for different products which may use a common material or process, etc. . . . .").

> formation of elongated oxide crystals, [3] [c]omposite **hardening** by the addition of **chromium oxide**. . . . The final mechanism is the addition of **chromium oxide** as a solid solution in the Alumina Matrix composite as a **means of compensating for the drop in hardness** caused by the addition of the lower **hardness** zirconia particles throughout the microstructure. (2004).[117]
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> * * *
>
> [A]n [a]lumina matrix composite of approximately 82% by volume [a]lumina with roughly 17% by volume of zirconia, **chromium oxide** and other oxides presented the ideal base for . . . [improved] material [when compared to BIOLOX forte]. . . . Additionally to the reinforcing components, there are also stabilizing elements doped to the material. **Chromium** is added which is soluble in the alumina matrix and increases the **hardness** of the composite. The minor amount of

[117] Respondent's updated information on Alumina Matrix Composite, BIOLOX delta, into Master File No. 197 for Respondent's ceramic ball heads (April 17, 2004), PNOR3, Exh. 2, 43 TTABVUE 19-59 at 24-25; Exh. 5, 43 TTABVUE 173-193 at 178-79.

> **chromium** is the reason for the **pink** color of the material. . . . (2008).[118]
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> * * *
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> The intention of this submission is to assure that our future customers' filings for their hip replacement products incorporating BIOLOX delta or BIOLOX forte ceramic ball heads will refer to accurate and recent data with respect to CeramTec's manufacturing processes and quality systems data. . . . Description of BIOLOX delta[:] . . . BIOLOX delta is an alumina based composite ceramic. Approximately 80 vol.-% of the matrix consist[s] of fine grained high purity alumina which is very similar to the well[-]known material BIOLOX forte. . . . Additionally to the reinforcing components, there are also stabilizing elements doped to the material. **Chromium** is added which is soluble in the alumina matrix and increases the **hardness** of the composite. The minor amount of

[118] Respondent's BIOLOX forte and BIOLOX delta ceramic cups and inserts (October 1, 2008), PNOR3, Exh. 3, 43 TTABVUE 60-107 at 62-63, 86.

> **chromium** is the reason for the **pink** color of the material. . . . (2012).[119]
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> * * *
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> BIOLOX delta Alumina Ceramic is an alumina based composite ceramic that was created based on the proven attributes of the BIOLOX forte Alumina Ceramic. The goal of the development of the BIOLOX delta material was to preserve the desirable properties of the BIOLOX forte - as an excellent bioceramic with more than 30 years clinical experience - while increasing the strength and toughness. . . . This goal was accomplished by integrating reinforcing components (tetragonal zirconia particles and platelet shaped crystals of the composition strontium aluminate) and by adding stabilizing elements (Yttrium and **Chromium**) into the BIOLOX delta material. . . . **Chromium oxide** is added as a solid solution to increase **hardness** and compensate for the decrease in **hardness** caused by the addition of the lower hardness zirconia particles in the microstructure. The minor amount of **Cr** is the reason for the **pink** color of the

[119] Respondent's Master File 197, Amendment 11, BIOLOX forte, [a]nd BIOLOX delta ceramic ball heads (October 11, 2012), PNOR3, Exh. 4, 43 TTABVUE 197-172 at 109, 134.

> composite. . . . The resulting BIOLOX delta material further develops nearly the **hardness** of Alumina while offering a major improvement in **strength** and **toughness**. (2013).[120]
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> * * *
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> BIOLOX delta is the tradename of a Composite Material based on high purity alumina matrix with zirconia reinforcement (ZTA). . . . BIOLOX delta Alumina Ceramic is an alumina based composite ceramic that was created based on the proven attributes of the BIOLOX forte Alumina Ceramic. The goal of the development of the BIOLOX delta material was to preserve the desirable properties of the BIOLOX forte - as an excellent bioceramic with more than 30 years clinical experience - while increasing the **strength** and **toughness**. . . . This goal was accomplished by integrating **reinforcing components** (tetragonal zirconia particles and platelet shaped crystals of the composition strontium aluminate) and by adding stabilizing elements (Yttrium and **Chromium**) into the BIOLOX *delta* material.

[120] Respondent's Master File 746, Amendment 20, BIOLOX delta ceramic liners (June 25, 2013), PNOR12, Exh. 6, 61 TTABVUE 343-428 at 377, 379.

> . . .**Chromium oxide** is added as a solid solution to increase **hardness** and compensate for the decrease in **hardness** caused by the addition of the lower hardness zirconia particles in the microstructure. The minor amount of **Cr** is the reason for the **pink** color of the composite. . . . The resulting BIOLOX delta material further develops nearly the **hardness** of Alumina while offering a major improvement in **strength** and **toughness**. (2015).[121]

Respondent did not retract the statements made in its master files regarding the contributions of chromia to the desired mechanical properties of the BIOLOX delta composition until 2015 and 2016 in correspondence and enclosures filed with the FDA. This was after Petitioner filed its district court action and these cancellation proceedings against Respondent.

Specifically, in its letters to the FDA dated August 26, 2015 and April 25, 2016,[122] Respondent cited to an October 22, 2014 article written by Dr. Meinhard Kuntz entitled "The Effect of Chromia Content on

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[121] Respondent's Master File 746, BIOLOX delta ceramic liners (Update March 15, 2015), PNOR4, Exh. 5, 44 TTABVUE 50-156 at 77-78, 80.

[122] Petkow Decl., 114 TTABVUE 12, ¶ 41 and 120 TTABVUE 15-20, Exh. 19; Stroetgen Colorado litigation trial testimony ("Stroetgen Lit. Testim."), PNOR28, 128 TTABVUE 41-46.

Hardness of Zirconia Platelet Toughened Alumina Composites" (the so-called "White Paper" discussed in detail below). In its correspondence, Respondent reported Dr. Kuntz's conclusions to the FDA that the chromia in the BIOLOX delta ceramic material did not contribute to the hardness of the material. Respondent's correspondence sought to amend historical statements previously made in its Device Master Files, quoted above, that chromium increases hardness in the BIOLOX delta ceramic material, which Respondent said were at odds with its most recent research to be found in the Kuntz article.

XIV. Product Advertising by Respondent and its OEM Customers Regarding the Benefits of the BIOLOX delta chemical composition used in Hip Implant Components

Respondent and its customers (OEM medical device manufacturers) have for many years engaged in product advertising, extolling the benefits of chromia within the BIOLOX delta ZTA ceramic composite:

> BIOLOX delta is a new alumina matrix composite, which makes use of the following principles: [1] Transformation toughening resulting from the addition of small homogeneously dispersed oxide particles in the alumina matrix, [2] Platelet reinforcement resulting from the formation of larger oxide crystals. [3] Composite **hardening** resulting from the addition of **chromium oxide**. BIOLOX delta is composed of aluminum oxide

(approximately 75%), zirconium oxide, **chromium oxide** and other oxides. [BIOLOX delta, A new ceramic in Orthopaedics, CeramTec (undated), PNOR5, Exh. 1, 45 TTABVUE 5-13 at 8].

BIOLOX delta is an aluminum oxide matrix composite ceramic consisting of approx. 82% alumina (Al203), 17% zirconia (ZrO_2) and other trace elements (percent by volume). The **pink color** is due to the **chromium oxide (Cr_2O_3)**. . . . Alumina provides the material's hardness and wear resistance, while zirconia, together with **other additives**, provides **improved mechanical properties**. These properties are achieved, among other things, by means of the high strength, the high density of the material and the very small grain size of the alumina matrix. [Ceramic-on-Ceramic – Scientific Information, BIOLOX delta Ceramic, Zimmer website (undated), PNOR8, Exh. 10, 50 TTABVUE 301-03 at 302].

The alumina material provides BIOLOX delta with high **hardness**, excellent biocompatibility and hydrothermal stability. Yttria-stabilized zirconia particles (Y-TZP) are finely dispersed throughout the alumina matrix, increasing mechanical strength and fracture toughness over pure alumina. In zirconia-toughened alumina (ZTA) materials, some of the original hardness of the alumina material is lost. The addition of **chromium oxide** restores the desired material **hardness** to the matrix.

[BIOLOX delta ceramic femoral heads material rationale, DePuy Synthes (2003), RNOR5, Exh. 7, 45 TTABVUE 153-65 at 157].

BIOLOX delta is an aluminum oxide matrix composite ceramic consisting of approx. 75% alumina (Al_2O_3), 24% zirconia (ZrO_2) and other trace elements. The **pink** color is due to the **chromium oxide (Cr_2O_3)** that improves the **hardness** of the composite material. [BIOLOX delta ceramic femoral head data sheet, Zimmer (2008), PNOR4, Exh. 8, 44 TTABVUE 180-84 at 182].

Alumina Matrix Ceramic Composite, **chromium oxide** compensates the **hardness** difference. [Ceramic Market and Main Trends Worldwide: Technical Evolution of Ceramics in Orthopaedics, CeramTec (2008), PNOR5, Exh. 9, 45 TTABVUE 201-228 at 208].

Vadin Implants uses the newest ceramic material which is an alumina matrix composite, labeled BIOLOX Delta. BIOLOX delta is a zirconia-toughened, platelet-reinforced alumina ceramic (ZPTA), designed to incorporate the wear properties and stability of alumina with vastly improved material strength and toughness. BIOLOX delta contains approximately 74% alumina and 25% zirconia. Additives of **chromium dioxide** and strontium oxide **enhance the performance** of the material. [Vadin Implants (website) (©

2008-2020), PNOR8, Exh. 9, 50 TTABVUE 298-300 at 299-300].

Biolox delta is an alumina composite matrix comprised of 74% alumina, 25% zirconia and 1 % additives such as strontium and **chromium** to **enhance the performance** of the material. As we will see later, this matrix improves wear characteristics and fracture toughness which are critical factors for hard bearings. . . . BIOLOX delta is a nanocomposite, of 82% Alumina and 17% Zirconia nanoparticles with traces of Strontium Aluminate platelet crystals for crack shielding and **Chromium Oxide** for **stabilization**. . . . The last components of the Biolox delta matrix are mixed oxides . . . . The mixed oxides consist of **chromium oxide** which helps to achieve the desired **hardness**. Strontium oxide prevents micro cracks in the material from advancing by dissipating crack energy. These two oxides further increase the materials **strength** and fracture **toughness**. 453 [BIOLOX delta Education Guide (DePuy) (September 2009), PNOR12, Exh. 11, 61 TTABVUE 438-67 at 446-47, 453]

BIOLOX delta: Alumina Matrix Composite, **Chromium Oxide, Phase Stabilization, Hardness**; Questions before my presentation or during the coffee breaks: Why Biolox delta has a **pink** color? Answer: **Cr^{3+}** [Advanced metrology of bioceramics: an independent overview on BIOLOX delta, Sponsored by

CeramTec (December 2011), PNOR1, Exh. 1, 41 TTABVUE 5-36 at 14]

Biolox delta: 82 Vol.% aluminum oxide, 17 Vol.% zirconium oxide (zirconia oxide) and less than 1 Vol.% strontium aluminate platelets and **chromium oxide** [for] **hardness**. . . . Why is Biolox delta pink colored? A: The added **chromium oxide** gives the **pink** color after sintering. **Chromium oxide** is added to increase the **hardness** of Biolox delta. [CeramTec Sales Questionnaire and FAQs (March 2, 2012), PNOR5, Exh. 5, 45 TTABVUE 91-144 at 99, 101].

BIOLOX delta composition (AMC) Alumina Matrix Composite: **Chromium oxide (Cr_2O_3)** [added] to balance **hardness** reduction introduced by the Y-TZP [Yttria Stabilized Zirconia]; CeramTec/DePuy Sales Training (August 2013), PNOR12, Exh. 1, 61 TTABVUE 6-105 at 31].

BIOLOX delta (AMC) Chemical Composition: Chromium Oxide (0.5 vol %), phase stabilization, hardness; Chromium makes it pink. It is from ruby [CeramTec/Biomet Training (March 2013), PNOR12, Exh. 2, 61 TTABVUE 106-84 at 123].

BIOLOX Delta [i]s composed of approximately 75% aluminum oxide, which provides the basic hardness and wear resistance. and approximately 25% zirconia. which together with other additives (mixed oxide platelets like

> **chromium oxide**) provide the **improved mechanical properties**. Compared with pure aluminum oxide, ceramic BIOLOX Delta offers higher mechanical properties including **higher fracture toughness**. R3° acetabular system, design rationale, Smith & Nephew (2013), PNOR8, 50 TTABVUE 317-37 at 324].

Respondent readily concedes that "in certain older advertising and marketing for BIOLOX delta," it "stated that the product was pink because of the presence of chromium in the BIOLOX delta material and in some instances also stated that the chromium increased the hardness of the product," and "included this statement originally in some of [its] . . . materials in order to provide . . . customers with the full information about the BIOLOX delta material and to explain why the components were pink."[123] Prior to late 2014 (as noted in the numerous examples above), the statement that chromium increased the hardness of the BIOLOX delta compound appeared in Respondent's marketing materials, such as presentations to OEM customers, Respondent's website, brochures, as well as on Respondent's customers' websites and materials — going (by Respondent's own account) as far back as 2001.[124] Since at least as early as 2012, Respondent in fact was actively giving presentations and telling customers

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[123] Petkow Decl., 114 TTABVUE 8-9, ¶¶ 26, 31.

[124] Petkow Decl., 114 TTABVUE 9, ¶ 30; *see also* Exh. 14, 115 TTABVUE 225-38 at 228, 231.

that chromium oxide contributed to hardness,[125] and as late as 2019 Respondent was still sending articles to its customers referencing the fact that chromium oxide increases the hardness of the BIOLOX delta ceramic.[126]

All of the above statements made by Respondent or its OEM customers in scientific literature, filings with the FDA, and advertising and marketing activities, regarding the contribution of chromia to the mechanical properties of the BIOLOX delta composition, render suspect Respondent's current assertions that (1) "it was not [Respondent]'s understanding that this increase to the hardness of the material [from chromia, when added to alumina] was of significant importance to the performance of the material" and that (2) Respondent "did not believe chromia materially impacted the quality of BIOLOX [d]elta or was essential to the use or purpose of BIOLOX [d]elta."[127]

As an attempted counter-balance to the above-quoted advertising literature and above-noted marketing activities, Respondent states it was the first to offer pink ceramic hip implant components, and points to its advertising and marketing efforts

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[125] Echols Discov. Depo., PNOR13, 154 TTABVUE 13, 23-25, Exh. 1.

[126] Echols Colorado litigation trial testimony ("Echols Lit. Testim."), PNOR2, 42 TTABVUE 167-69; Echols Discov. Depo., PNOR13, 154 TTABVUE 31-41, 52-117, Exhs. 1, 3-6.

[127] Kuntz Decl., 101 TTABVUE 10, ¶ 30.

around the color pink, from 2009 through 2021, evincing its evolving strategy to build an entire brand around the color pink.[128] Respondent also states that, once one of its scientists (Dr. Meinhard Kuntz) in late 2014 (after the petitions for cancellation were filed) investigated and reported that chromia did not contribute to the hardness of the BIOLOX delta ceramic, Respondent formulated a plan to contact all customers and inform them of this new information and ask them to correct their websites and marketing materials accordingly.[129]

XV. Reported Experimental Data

The parties submitted a wealth of experimental data and reports, and suggested implications to be drawn from them, regarding whether the addition of chromia to the ZTA compound (resulting in the pink color of the ceramic) contributes to the mechanical performance of the compound. Unsurprisingly, for each set of experimental data and report submitted by the proponent (by way of experts or employees), its adversary criticizes the experimental methodology, data collection procedures or stated conclusions.

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[128] Petkow Decl., 114 TTABVUE 6-8, ¶¶ 14-15, 17, 19-22, 24 and 115 TTABVUE 138-74, Exh. 8.

[129] Petkow Decl., 114 TTABVUE 9-11, ¶¶ 29, 33-39 and 115 TTABVUE 175-79, 206-250, 116 TTABVUE 2-46, 117 TTABVUE 2-30, 118 TTABVUE 2-59, 119 TTABVUE 2-51, 120 TTABVUE 2-13, Exhs. 9, 12-17, 113 TTABVUE 23-47, Exh. 18.

A. The Kuntz White Paper (2014)

Dr. Meinhard Kuntz joined Respondent's Oxide Ceramics Department in 2005, which he later managed until his departure from the company in 2017. [130] Based on other experimental activities conducted by his work colleagues in 2006, 2008 and 2009, Dr. Kuntz began to suspect that chromium possibly may not be contributing to the desirable mechanical properties of BIOLOX delta notwithstanding Respondent's ongoing marketing statements that it did so.[131]

In order to confirm his suspicions, Dr. Kuntz conducted an experiment testing the effect of chromium on the material properties of BIOLOX delta. Dr. Kuntz published the results of his findings in a so-called "White Paper" in October 2014.[132] In his White Paper, Dr. Kuntz concluded:

> The acceptable range of chromia content for BIOLOX delta is between 0.31 – 0.37% [by weight]. . . . [My test] results demonstrate that the existence or non-existence of chromia in a ZTA material that is otherwise identical to BIOLOX delta has no influence on the hardness of

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[130] Kuntz Decl., 101 TTABVUE 4, ¶¶ 8-9; Kuntz Lit. Testim., RNOR1, 70 TTABVUE 373-74.

[131] Kuntz Decl., 102 TTABVUE 14-17; ¶¶ 42-50; Kuntz Lit. Testim., RNOR1, 70 TTABVUE 413-429.

[132] Kuntz Decl., 101 TTABVUE 20-21; ¶¶ 56-57; Kuntz Lit. Testim., RNOR1, 70 TTABVUE 450-57.

> the material, at least in the range of the amount of chromia investigated here ([0.0%, 0.14%, 0.32% and] 0.5% by weight). . . . [T]he statistically substantiated test results discussed herein demonstrate that the chromia content of BIOLOX delta does not measurably influence the hardness.[133]

At the trial in the Colorado Litigation, Petitioner's materials expert, Dr. Fischman, criticized the experiment and results of Dr. Kuntz's white paper in several respects: (1) Dr. Kuntz's experiment was not reproducible because the oxide information was not provided, (2) the alumina levels were not held constant in the different vats of materials Dr. Kuntz compared, and (3) Dr. Kuntz's study lacked a control.[134] Even Respondent's materials expert at the Colorado Trial, Dr. Mecholsky, had his own criticisms of Dr. Kuntz's white paper: (1) it wasn't peer-reviewed, and (2) it contained insufficient references to and consideration of prior experimental literature in this area.[135] Dr. Kuntz himself recognized some of the shortcomings of the White paper when he testified at the Colorado trial that (1) it was not peer-reviewed

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[133] Kuntz White Paper, Kuntz Decl., Exh. 7, 101 TTABVUE 77-81 at 78, 81.

[134] Dr. Gary Fischman Colorado litigation trial testimony ("Fischman Lit. Testim."), DNOR1, 70 TTABVUE 284-86, 291-92.

[135] Dr. John Mecholsky Colorado litigation trial testimony ("Mecholsky Lit. Testim."), PNOR2, 42 TTABVUE 230-31.

by persons outside of Respondent, (2) it was important to Respondent that the White Paper be sent out as quickly as possible, so the paper was not scientific journal quality, and (3) Dr. Kuntz did not show in the White Paper the complete experimental techniques he employed.[136]

In his initial report for these proceedings, Petitioner's materials expert, Dr. William Carty, discusses his similar criticisms of Dr. Kuntz's White Paper, and included others, namely: (1) lack of peer review, (2) the samples Dr. Kuntz used for the White Paper were processed differently than the equivalent medical grade product intended for implantation, (3) the paper does not fully disclose the chemistries of the samples tested, making the study as published impossible to reproduce, (4) the underlying worksheet memorializing the data from Dr. Kuntz's study contains numerous errors, again making a reproduction of the study underlying the White Paper impossible, (5) Dr. Kuntz's study does not attempt to optimize the mechanical properties of the material for purposes of implantation in the body, (6) the White Paper does not evaluate any mechanical properties of the samples other than hardness, and (7) the White Paper does not disclose the sintering conditions of the samples tested, which can have significant impact on the properties of the composite.[137] In his rebuttal report for these proceedings, Dr. Mecholsky dismisses Dr. Carty's criticisms at every turn, either as

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[136] Kuntz Lit. Testim., PNOR1, 41 TTABVUE 221-25.

[137] Carty Rpt., 60 TTABVUE 74-76, ¶ 159.

irrelevant or because of additional factors outside of the White Paper's scope (that is, the mechanical properties other than hardness).[138]

B. The Kuntz and Krüger Paper (2018)

As we noted earlier, the trial in the Colorado Litigation ended in late 2016, the district court's decision issued in 2017, and the Tenth Circuit's decision reversing the district court on jurisdictional grounds issued in 2019. In between these events, Dr. Kuntz and his colleague, Dr. Reinhard Krüger, performed experiments on different material properties of the same samples Dr. Kuntz used for his 2014 White Paper.[139] In 2018, Drs. Kuntz and Krüger published their paper in a scientific journal (which was anonymously peer-reviewed) discussing the results of their findings.[140] In their paper, Drs. Kuntz and Krüger concluded:

> [U]p to an amount of 0.5 wt% [the amounts tested here were 0.00, 0.14, 0.32 (prepared with a compound YCr03 oxide), 0.33 (prepared with separate Y203 and oxides) and 0.5 wt%], there is

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[138] Mecholsky TTAB Rebuttal Rpt., 105 TTABVUE 437-440, ¶¶ 94-97, 99-101.

[139] Kuntz Decl., 101 TTABVUE 22, ¶ 59.

[140] Kuntz Decl., 101 TTABVUE 22, 134-44, ¶ 60, Exh. 9. Respondent also made the Kuntz/Krüger article of record at RNOR24, Exh. 1, 95 TTABVUE 5-15. We cite herein to the version of the article submitted under Respondent's Twenty-Fourth Notice of Reliance.

> no effect of chromia to the mechanical performance (hardness, toughness, stiffness, scratch performance) or manufacturing process [of ZTA compositions and alumina similar or equivalent to the commercial materials BIOLOX delta and BIOLOX forte]. It was further investigated how variation of grain size and final density influence the material properties of ZTA and alumina. There is a measurable effect on hardness but a negligible effect on fracture toughness. The scratch performance seems to be closely linked to the toughness as can be seen from the comparison of ZTA and alumina. There is a certain probability that formerly misleading results about the correlation of hardness and chromia content arise from secondary effects (grain size, density) and measurement uncertainty of inappropriately chosen [hardness testing] load levels.[141]

As he did with Dr. Kuntz's 2014 White Paper, Dr. Carty had a number of criticisms of the 2018 Kuntz/Krüger paper: (1) the actual chemistry of the test specimens was not provided, so it is impossible to duplicate or reproduce the test results, (2) the specific sintering conditions for the samples in order to isolate

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[141] Kuntz/Krüger article, RNOR24, Exh. 1, 95 TTABVUE 5-15 at 14.

potential effects of grain growth on mechanical properties are not disclosed, (3) the levels of raw materials and the densities of chromium used to prepare the samples for testing were not given, i.e., the batch information, or recipe, used to create the test specimens were not provided, (4) the Kuntz/Krüger paper does not consider the impact of the variation of chromium on a ceramic hip implant component system that is optimized for performance in vivo, (5) in their paper, Dr. Kuntz and Dr. Krüger claim their research and conclusions are consistent with the Bradt (1966) article, [142] when Dr. Carty believes they are not, and (6) the data in Dr. Kuntz and Dr. Krüger 2018 paper is also insufficient to rebut the well-established literature[143] that chromium has an impact on hardness.[144] Once again in his rebuttal report, Dr. Mecholsky dismisses Dr. Carty's criticisms point-by-point, either as immaterial to the results Dr. Kuntz and Dr. Krüger obtained or because Dr. Carty did not conduct these experiments himself using Dr. Carty's desired methodology. [145] However, when pressed on cross-examination, Dr. Mecholsky did admit to many of the above-noted shortcomings of the

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[142] See discussion of the Bradt (1966) article in Section X above.

[143] See discussion and summary of the technical literature in Section X above.

[144] Carty Rpt., 60 TTABVUE 75-77, ¶¶ 161-67.

[145] Mecholsky TTAB Rebuttal Rpt., 105 TTABVUE 440-442, ¶¶ 102-107.

Kuntz/Krüger paper[146] - although on re-direct he suggested methods to address those shortcomings[147] - and that the data used for the Kuntz White Paper and Kuntz/Krüger paper indeed were the same.[148]

Of particular import in adjudicating witness credibility, Dr. Mecholsky was chosen as an anonymous, independent peer reviewer for the Kuntz/Krüger paper,[149] yet he did not reveal to the publication in which the article appeared that he was a testifying expert on Respondent's behalf. This presented Dr. Mecholsky with a clear conflict of interest, on which he remained silent despite the publication's policies he should disclose his interest in the matter.[150] When asked about his apparent conflict of interest during cross-examination, Dr. Mecholsky conceded that he did not bring the pertinent facts to the publication's attention, because he thought the parties' litigation was over and that his participation in the litigation was not relevant.[151] Dr. Mecholsky also noted there was another designated anonymous reviewer for the Kuntz/Krüger paper, Jerome

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[146] Mecholsky CX Testim. Depo., 155 TTABVUE 17-22, 40-44.

[147] Mecholsky CX Testim. Depo., 155 TTABVUE 31-36.

[148] Mecholsky CX Testim. Depo., 155 TTABVUE 16.

[149] Mecholsky TTAB Rpt., 105 TTABVUE 201 at n.3.

[150] Carty Rebuttal Rpt., 153 TTABVUE 18-22, ¶¶ 39-44, 48.

[151] Mecholsky CX Testim. Depo., 155 TTABVUE 28-30, 37-38.

Chevalier, but later when pressed, Dr. Mecholsky could not say for sure whether Dr. Chevalier was actually another reviewer of the paper.[152]

C. Dr. Mecholsky's Testing and Analysis (2016)

Part of Dr. Mecholsky's report in the Colorado Litigation included his own analysis of ceramic test samples he requested and received from Respondent.[153] Unfortunately, a very sizeable portion of this part of Dr. Mecholsky's report has been filed under seal in these proceedings. We therefore can only discuss Dr. Mecholsky's analysis and conclusions in general terms.

Similar to the experiments supporting the Kuntz White Paper and the Kuntz/ Krüger paper, Dr. Mecholsky conducted hardness testing on ZTA ceramic compounds containing < 0.01, 0.15, 0.33 and 0.5 %-vol. chromium oxide, discussing the make-up of the samples and his testing procedures in detail.[154] Based upon this data, as confirmed with Respondent's statistics expert Dr. Kadane, Dr. Mecholsky concludes that "the hardness values are the same for all compositions" and "that chromium did not impact the

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[152] Mecholsky CX Testim. Depo., 155 TTABVUE 38-39, 45-47.

[153] Mecholsky Lit. Rpt. 105 TTABVUE 89-102, ¶¶ 144-65 (public/redacted); 106 TTABVUE 89-102, ¶¶ 144-65.

[154] Mecholsky Lit. Rpt. 106 TTABVUE 89-102, ¶¶ 145-160, 162-65. All of this discussion has been redacted from the public version of the Mecholsky Lit. Rpt.

hardness of these ZTA samples."[155] Except in a passing footnote,[156] Dr. Carty appears not to have critiqued Dr. Mecholsky's testing and analysis of the ceramic samples he obtained from Respondent.

D. Testing and Analysis Conducted in Connection with German Litigation between the Parties (2018)

In addition to the Colorado Litigation and these proceedings, Petitioner and Respondent were engaged in trademark litigation in Germany (the "German Litigation"). Respondent also was engaged in trademark litigation in Germany with Metoxit, another supplier of ZTA ceramic hip implant components based in Switzerland. As a part of those litigations, the Stuttgart Regional Court directed the Federal German Institute for Materials Research and Testing (Bundesanstalt Für Materialforschung und-prüfung, hereinafter the "German Federal Institute" or "BAM") to examine whether chromium had any effect, other than color, on the material properties of certain ceramic hip implant components. The German Federal Institute is a senior scientific and technical federal institute with responsibility to the German Federal Ministry for Economic Affairs and Energy. In the German Litigation, BAM was commissioned as an independent, scientific fact-finder. Dr. Torsten Rabe, the leader of the German Federal Institute's

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[155] Mecholsky Lit. Rpt. 105 TTABVUE 96, ¶ 161; 106 TTABVUE 96, ¶ 161.

[156] Carty Rpt., 60 TTABVUE 83 at n.123.

department of Technical Ceramics, conducted BAM's testing and drafted these reports.[157] As the only BAM report for the German Litigation (translated into English) made of record in these proceedings was the one for the litigation between Petitioner and Respondent (and not between Respondent and Metoxit), that is the only report we discuss here. Since the BAM report in its entirety was filed as confidential, we discuss it only in general terms.

In the German Litigation, Dr. Rabe obtained ceramic specimens from both Petitioner and Respondent containing 0, 0.1, 0.3 and 0.5 % chromium oxide content by weight percent.[158] Otherwise, the material variations of the specimens provided by both companies were produced with identical production parameters, with BAM requiring that these parameters for the test specimens correspond to the respective standard manufacturing conditions for ZTA materials at both companies as much as possible.[159] The BAM report notes there were no significant differences in the Al_2O_3 (alumina), ZrO_2 (zirconia), HfO2 (hafnia), Y_2O_3 (yttria) and SrO (strontia) content between the specimens provided by the parties, except the strontia content of the samples

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[157] Mecholsky TTAB Rpt., 105 TTABVUE 210, ¶ 44.

[158] BAM Report, Haftel CX Testim. Depo., Exh. 11, 147 TTABVUE 4 at 13-14.

[159] BAM Report, Haftel CX Testim. Depo., Exh. 11, 147 TTABVUE 4 at 15.

free from chromium oxide was somewhat higher in the samples provided by Petitioner.[160]

BAM tested the parties' specimens for color, hardness and wear resistance. The German Federal Institute concluded that, with the addition of chromium oxide to a ZTA ceramic in quantities up to 0.5 Ma.-% wt., the pink color intensity increases as the chromium oxide content increases, but there was no increase in the hardness or wear resistance of either company's ZTA ceramic test specimens.[161]

Petitioner's materials expert, Dr. Carty, criticizes BAM's testing methodology and conclusions as follows: (1) the hardness levels start high and remain high with the addition of chromium oxide throughout Respondent's samples in the BAM study, and this high baseline hardness serves to mask any contribution of chromium oxide; (2) the BAM report does not state that the tested samples were subject to autoclaving before testing; (3) the BAM report does not provide the precise sintering conditions of the samples; (4) the BAM report does not seek to determine the role of chromium in a ZTA system optimized for performance in the body over long periods of time; (5) contrary to the conclusions of the BAM report, the wear data of Petitioner's tested samples shows a significant improvement in wear resistance with the addition of chromium; and (6)

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[160] BAM Report, Haftel CX Testim. Depo., Exh. 11, 147 TTABVUE 4 at 24-25.

[161] BAM Report, Haftel CX Testim. Depo., Exh. 11, 147 TTABVUE 4 at 7-8, 48, 56, 63.

BAM's experimental procedure does not mirror the environmental conditions under which it has been demonstrated that chromium improves the in vivo wear performance of ZTAs.[162]

Dr. Mecholsky's replies to Dr. Carty's criticisms of the BAM report were all filed as confidential, so here we only discuss them in general terms. Dr. Mecholsky's rebuttals to Dr. Carty may be summarized as follows: (1) as noted by Dr. Carty, chromia's contribution, if any, to the tested ZTA specimens is undetectable through measurement techniques, and thus could not result in a sufficient difference in material properties to represent a functional difference in the material; (2) Dr. Carty does not explain what he means by "an optimized system" or how such discussion is relevant to the question presented (whether chromium affects any property of a ZTA ceramic material); (3) Dr. Carty cites to no experimental data on the relevant materials to establish that chromia at a level within the range tested, and not any other factor, contributes to any material property of a ZTA ceramic; (4) Dr. Mecholsky questions Dr. Carty's conclusion regarding the improvement in wear resistance with the addition of chromia to Petitioner's samples, because Dr. Carty does not appear to have conducted any statistical analysis of the BAM data; and (5) Dr. Carty's criticisms that BAM did not perform its examinations using in vivo testing or autoclaving is not supported

[162] Carty Rpt., 60 TTABVUE 89-90, ¶¶ 184-185, 187.

by any such testing Dr. Carty performed himself, and no such testing appears to exist anywhere else.[163]

E. Research Conducted by Dr. Porporati

As noted above in our review of the technical literature, Dr. Alessandro Alan Porporati was co-author of a paper with Dr. Giuseppe Pezzotti suggesting a role of Cr_2O_3 (chromium oxide) dopant on thermal stability and, thus, the possibility of tailoring environmental performance through a suitable doping not only of the ZrO_2 (zirconia) phase but also of the Al_2O_3 (alumina) matrix phase.[164] At trial in the Colorado Litigation, Dr. Porporati testified about his theories that chromium might be impacting phase stabilization of the ZTA material, which in turn would mean it had an effect on fracture toughness or aging resistance of the material.[165] Dr. Porporati's experiments first indicated to him that chromium oxide might improve phase stabilization, then that it might negatively affect phase stabilization, then that chromium oxide had no effect on phase stabilization at all.[166]

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[163] Mecholsky TTAB Rebuttal Rpt., 112 TTABVUE 820-23, ¶¶ 114-21.

[164] Pezzotti, Porporati, et al. (2010), PNOR6, Exh. 1, 46 TTABVUE 5-13 at 6, 12.

[165] Porporati Colorado Litigation trial testimony ("Porporati Lit. Testim."), RNOR1, 70 TTABVUE 496-97.

[166] Porporati Lit. Testim., RNOR1, 70 TTABVUE 498-500, 519.

Dr. Porporati also testified at the Colorado trial regarding his hardness testing on Respondent's materials with and without chromium oxide. When reporting his inconclusive results to Respondent (some results indicating that chromia was contributing to hardness, others not), Respondent pointed to a number of possible mistakes in Dr. Porporati's measurements.[167] Another topic of Dr. Porporati's trial testimony concerned his experiments on the effect of yttria on zirconia stabilization, and in turn its positive effect on fracture toughness and aging resistance in Respondent's ZTA material.[168]

Dr. Porporati also submitted a testimony declaration in these proceedings.[169] In his declaration, Dr. Porporati seeks to distance himself from the paper he co-wrote with Dr. Pezzotti, stating "Prof. Pezzotti's observations when comparing chromia and chromia-free material were due to the fact that the yttria contents in the chromia and chromia-free material varied, and were not due to the chromia content in the material."[170] Dr. Porporati's present position is that "small changes in yttria content have a significant effect on the toughness, zirconia phase stabilization, and potentially the wear performance of a ZTA

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[167] Porporati Lit. Testim., RNOR1, 70 TTABVUE 520-27, 530-51.

[168] Porporati Lit. Testim., RNOR1, 70 TTABVUE 506-10.

[169] Porporati Decl., 98 (confidential)/99 (public, redacted) TTABVUE.

[170] Porporati Decl., 99 TTABVUE 3, ¶ 3.

ceramic material . . . . By contrast, my research does not establish that changes in chromia content between 0 and 0.33 wt % have any impact on the material properties or wear performance of a ZTA ceramic . . . ."[171]

We reviewed Dr. Porporati's internal research report submitted to Respondent, [172] his current employer. [173] What Dr. Porporati reports in his declaration as "changes in yttria content" having an "effect on . . . toughness, zirconia phase stabilization, and potentially . . . wear performance" of the ZTA material is in fact the addition of yttrium chromite ($YCrO_3$), a chemical combination of yttrium and chromia, not the addition of yttrium by itself, albeit increasing the overall yttria content while keeping chromia content relatively constant.[174] In addition to this observation from our own reading of the evidence, Petitioner responds that "[e]ven assuming . . . Dr. Porporati's experiments demonstrate that yttria can have an impact on zirconia phase stability in ZTA ceramic materials, this does not establish that chromium oxide does not **also** impact zirconia phase stability." (emphasis original).[175]

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[171] Porporati Decl., 99 TTABVUE 4, ¶ 8.

[172] Porporati Decl., 99 TTABVUE 10, 56-76, ¶ 28, Exh. 3.

[173] Porporati Decl., 99 TTABVUE 4, ¶ 7.

[174] Porporati Decl., Exh. 3, 99 TTABVUE 56-76 at 56-58.

[175] Haftel Rebuttal Decl., 138 TTABVUE 3, ¶ 6.

F. Analysis of Certain Mechanical Properties of Petitioner's Ceramic Materials at Certain Intervals and over the Passage of Time

In 2020, Jonathan Haftel, Petitioner's Plant Manager,[176] analyzed data from internal hardness testing Petitioner conducted on its CeraSurf-p and CeraSurf-w materials between 2010 and 2020. Petitioner's tests show that CeraSurf-w — which does not contain chromium oxide — is not as hard as CeraSurf-p — which does contain chromium oxide (0.33 wt%).[177] Also in 2020, Petitioner conducted and analyzed strength testing on its CeraSurf-p and CeraSurf-w materials in addition to hardness. Petitioner's test data showed significantly higher flexural strength values for CeraSurf-p than for CeraSurf-w.[178] In 2021, Petitioner conducted further testing and analysis, again to demonstrate that its CeraSurf-p material has greater hardness and greater flexural strength than its CeraSurf-w material from that year.[179]

Dr. Mecholsky's critique of Petitioner's analysis of and conclusions from its CeraSurf-p and CeraSurf-w

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[176] Haftel Decl., 59 TTABVUE 2, ¶ 4.

[177] Haftel Decl., 59 TTABVUE 7-9, ¶¶ 18-23; and Exhs. 2-4, 58 TTABVUE 35-64 (confidential).

[178] Haftel Decl., 59 TTABVUE 9-10, ¶¶ 26-26; and Exh. 5, 58 TTABVUE 65-67.

[179] Haftel Rebuttal Decl. 138 TTABVUE 2-3, ¶¶ 4-5; and Exhs. 1-2, 137 TTABVUE 5-48 (confidential).

testing data was filed in this proceeding as entirely confidential.[180] We therefore discuss Dr. Mecholsky's numerous criticisms in general terms. In the Colorado Litigation, Dr. Mecholsky investigated the hardness testing performed by Petitioner and concluded that Petitioner's hardness testing failed to show that

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[180] The critique from Dr. Joseph Kadane (Respondent's statistics expert) of Petitioner's CeraSurf-p and CeraSurf-w testing data mirrors that of Dr. Mecholsky, except from a statistical analysis point of view. Kaden Rpt. 103 TTABVUE 21-31, ¶¶ 26-43. Dr. Kadane's critique too was filed in this proceeding as entirely confidential. Like Dr. Mecholsky, Dr. Kadane opines that, over time, the hardness of Petitioner's pink samples increased. This increase, Dr. Kadane says, was not related to chromium oxide concentration because, over time, all of the pink samples had the same amount of chromium oxide by percentage of weight. To determine whether the inclusion of chromium oxide increases the hardness of a sample, says Dr. Kadane, it is necessary to compare samples from the identical time periods. According to Dr. Kadane, Petitioner's data from 2013-2016 was unreliable for the reasons explained by Dr. Mecholsky. Thus, the only reliable test data Petitioner provided, from 2010, shows at best weak evidence that the 2010 pink samples were harder than the 2010 white samples. Petitioner's statistics expert, Dr. Arnold Barnett, opines that Dr. Kadane's remedy of excluding the vast majority of Petitioner's pink measurements between 2010 and 2020 is far more extreme than warranted. Dr. Barnett's analyses that compare pink measurements with a far larger data set from the disputed time periods generates statistically-significant evidence that chromium oxide increases the hardness of Petitioner's ZTA samples. Kadane Rpt., 56 TTABVUE 15-24, ¶¶ 23-38.

chromium oxide had any impact on the hardness of Petitioner's material.[181] Among other things, Dr. Mecholsky concluded that:

> Even assuming that there is some hardness difference between Petitioner's Cerasurf-w and Cerasurf-p materials, it is an inconsequential difference that would not have any impact on the performance of Petitioner's white and pink ZTA materials when used in hip implant components.[182]
>
> The hardness of Petitioner's pink material increased over time. If Petitioner's pink material went from the same hardness as its white material to slightly harder over a number of years, without any change in chromium content, then chromium must not be responsible for any hardness improvement in the pink material. If chromium was causing the pink material to be harder, it would have been harder in 2010, and would not have gotten harder between 2010 and 2016, without any chromium increase. Thus, something else must be responsible for the hardness increase. The potential causes of this apparent change in hardness include one or more of: measurement inconsistencies; differences in processing over time; improvements in the hardness

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[181] Mecholsky TTAB Rpt., 112 TTABVUE 59, ¶ 98.

[182] Mecholsky Lit. Rpt., 106 TTABVUE 128, 137, 151-52, ¶¶ 204, 225, 227, 246 and 249.

> measurement technique and procedure; differences in the number of samples tested (far more pink than white); and improper, and/or inconsistent, measurement techniques.[183]
>
> In 2011, Petitioner opened a new facility, and powder production was performed at this new facility sometime after that date. This new facility helped solve contamination and processing issues that Petitioner was experiencing with its material. Thus, the processing and manufacture of Petitioner's ZTA materials went through significant change between 2010 and 2012.[184]
>
> Dr. Mecholsky noted several irregularities calling into question the hardness measurements and the ultimate conclusions reached by Petitioner. Any hardness differences Petitioner found was due to one or more of the following deficiencies or discrepancies: differences in the number of samples tested (far more pink than white), differences in the timing and testing and powder preparation from which the samples

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[183] Mecholsky Lit. Rpt., 106 TTABVUE 128, 133-34, 136, 137-150, ¶¶ 205, 216, 223, 226, 228-241 and 243.

[184] Mecholsky Lit. Rpt., 106 TTABVUE 129, 135, 150, ¶¶ 207, 219, 221 and 245; *See also* Steven Hughes Colorado Litigation trial testimony ("Hughes Lit. Testim."), RNOR1, 70 TTABVUE 71-74 and Frank Anderson Colorado Litigation trial testimony ("Anderson Lit. Testim."), RNOR1, 70 TTABVUE 246-248.

were made, differences in testing methods over time, differences in material processing.[185]

Mr. Haftel appears to agree with Dr. Mecholsky's conclusion that Petitioner has gotten better at making ceramic samples over time including "getting better repeatability out of the preparation process." Mr. Haftel also notes that Petitioner has seen improvements to both its pink and white material over time, but that "there [are] not a lot of data points" with regard to any potential improvement in the white material. Mr. Haftel notes that Petitioner produces pink material on a regular basis, but, with the exception of two batches made in 2020, does not regularly produce white material.[186]

As Dr. Mecholsky noted during the Colorado Litigation, Petitioner's hardness testing was performed at different times, on samples created during different time periods, and using different techniques. An analysis of Petitioner's pre-2016 hardness testing showed that four different testing methods were used.[187] The measurement variance in Petitioner's testing of its white samples alone appears to be atypically high, having a wide range of potential

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[185] Mecholsky Lit. Rpt., 106 TTABVUE 130-135, ¶¶ 210-215 and 218.

[186] Mecholsky TTAB Rpt., 112 TTABVUE 60, ¶ 99; Haftel Discov. Depo., RNOR13, 129 TTABVUE 75-77; Haftel CX Testim. Depo., 146 TTABVUE 42-44.

[187] Mecholsky TTAB Rpt., 112 TTABVUE 60, ¶ 101; Mecholsky Lit. Rpt., 106 TTABVUE 131, ¶ 213; Haftel CX Testim. Depo., 146 TTABVUE 42-44.

testing values, making it less likely to accurately represent the properties of the material.[188]

According to Dr. Mecholsky, there are many potential explanations for measurement variance that have nothing to do with chromium content in a material, including differences in: testing machinery, testing methodology, testing machine calibration, electronic measuring equipment calibration, the skill of the technicians performing the tests and taking the measurements, the performance of visual versus automatic measurements; material variability, such as surface finish, and processing methods.[189]

Even if Petitioner's pink material is, on average, harder than its white material, as Petitioner's average of hardness measurements suggests, Dr. Mecholsky opines such difference is slight, having no functional effect on the quality of the ceramic material produced. The ceramics used to make hip implant components are very hard, and small changes in hardness (on the order of the changes that Petitioner is arguing exist in these proceedings) do not impact the performance or function of the material used to produce the hip implant components.[190]

Dr. Mecholsky also says his criticisms discussed above of Petitioner's hardness testing apply to its

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[188] Mecholsky TTAB Rpt., 112 TTABVUE 60-61, ¶ 102.

[189] Mecholsky TTAB Rpt., 112 TTABVUE 61, ¶ 103; Mecholsky Lit. Rpt., 106 TTABVUE 133-34, ¶ 215.

[190] Mecholsky TTAB Rpt., 112 TTABVUE 61-62, ¶ 104; Mecholsky Lit. Rpt., 106 TTABVUE 151, ¶¶ 246-47.

fracture toughness testing measurements of its pink and white materials as well. Dr. Mecholsky notes Mr. Haftel's belief that a further "scientific endeavor" would be required to draw any conclusion that Petitioner's pink material is tougher than its white material.[191]

Dr. Carty reviewed Petitioner's comparative hardness and flexural strength test results of Petitioner's pink CeraSurf-p product and its white CeraSurf-w product. In Dr. Carty's opinion, Petitioner's data confirms that chromium oxide affects the material's hardness. Specifically, Petitioner's hardness testing data shows significantly higher values in hardness for CeraSurf-p over CeraSurf-w. Additionally Petitioner's flexural strength test data shows significantly higher values in flexural strength in CeraSurf-p as compared to CeraSurf-w.[192]

Responding to Dr. Mecholsky's criticisms of Petitioner's testing data, Dr. Carty says that even though there is scatter (outliers in the measurement observations) in the data, hardness measurably increases with the addition of chromium oxide, even at the low levels observed in Petitioner's chromium-doped ZTA.[193] Dr. Carty was not surprised that the

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[191] Mecholsky TTAB Rpt., 112 TTABVUE 62, ¶ 105; Haftel CX Testim. Depo., 146 TTABVUE 50-52.

[192] Carty Rpt. 48 TTABVUE 61-64, ¶¶ 134-39 (confidential); 60 TTABVUE 62-65, ¶¶ 134-39 (charts redacted).

[193] Carty Rebuttal Rpt., 153 TTABVUE 26, ¶ 65.

hardness properties of Petitioner's pink ZTA material changed over time, because this was also true with respect to Respondent's pink ZTA material based on Respondent's data Dr. Carty analyzed.[194] Finally, Dr. Carty points out that the documents on which Dr. Mecholsky relied in criticizing Petitioner's fracture toughness data were actually measurements of flexural strength.[195]

As to the additional testing data that Petitioner provided for its ZTA ceramic products for 2021, it appears that the backup documentation on Mr. Haftel's summary chart (in his rebuttal declaration) was not provided for Petitioner's white, CeraSurf-w product; only for Petitioner's pink, CeraSurf-p product.[196] This renders Mr. Haftel's summary chart suspect as it purports to include testing data for both products.

Respondent's experts, Drs. Mecholsky and Kadane, as well as the cross-examination of Jonathan Haftel, raised sufficient concerns about Petitioner's processing and testing methods, data collection, reporting and conclusions reached over the relevant time period to cast doubt on the probative value of this evidence. We further find wanting the efforts of Petitioner's experts, Drs. Carty and Barnett, to

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[194] Carty Rebuttal Rpt., 141 TTABVUE 27, ¶ 66 (confidential).

[195] Carty Rebuttal Rpt., 153 TTABVUE 228-29, ¶ 67.

[196] Haftel CX Testim. Depo., 146 TTABVUE 77-81, 554-556 Exh. 6 at ¶¶ 4-5.

explain away Respondent's critique of Petitioner's testing data.

G. Petitioner's Survey Evidence

Petitioner's expert, Dr. Sara Parikh, prepared and conducted a survey of orthopaedic surgeons to establish that the primary significance of the color pink used in the context of hip implant components is to tell orthopaedic surgeons from what type of material the hip implant component is made. Ninety percent of respondents in Dr. Parkih's survey considered the color pink used in the context of hip implant components to be an indicator of the material composition of the component, and 85% consider it to indicate that the material is ceramic.[197] Dr. Parikh's test stimulus was a BIOLOX delta (pink) hip joint ball or head; the control stimulus was a BIOLOX forte (ivory) hip joint ball or head. [198] Dr. Parikh's understanding of "primary significance" refers to the general meaning of something, for example when someone encounters something what it tells them, brings to mind or connotes.[199]

Respondent's survey expert, Robert Klein, opines that neither the methodology nor the primary question employed by Dr. Parikh tests for or measures functionality. Dr. Parikh conceded during her cross-examination that her survey did not test for

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[197] Parikh Decl., 47 TTABVUE 2, ¶ 3; Parikh Rpt., 47 TTABVUE 4-40 at 19-20.

[198] Parikh Rpt., 47 TTABVUE at 32-33.

[199] Parikh CX Testim., 152 TTABVUE 24-25.

functionality.[200] Instead, Dr. Parikh's survey purports to measure the "primary significance" of the color pink for a femoral ball hip implant component. The "primary significance" of a trademark, however (says Mr. Klein), commonly relates to the issue of whether a mark is generic; it is not the proper methodological inquiry for measuring any alleged functionality of a mark.[201] That is, the key question of Dr. Parikh's survey: "What, if anything, does the color tell you about the hip implant component in the photograph? Please be specific," in no way inquires as to whether the color pink is essential to the use or purpose of a hip implant component (the considerations used to determine whether trade dress is functional based on utilitarian concerns).[202] Mr. Klein's other criticisms of Dr. Parikh's survey include:

> The question presented to the respondents was leading;[203] and
>
> The near identical answers and their virtually identical distribution in Dr. Parikh's test and control cells when comparing material

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[200] Parikh CX Testim., 152 TTABVUE 18-22. In fact, Dr. Parikh conceded that she had never worked on a functionality survey before. 152 TTABVUE 22-24.

[201] Klein Decl., 84 TTABVUE 6, ¶ 16.

[202] Klein Decl., 84 TTABVUE 6-7, ¶ 17.

[203] Klein Decl., 84 TTABVUE 7, ¶ 19. Dr. Parikh agreed on cross-examination that questions which are suggestive or leading in nature are an inappropriate Parikh CX Testim., 152 TTABVUE 31-34).

> responses contradicts Dr. Parikh's conclusion that the primary significance of the color pink, used in this context, is to tell orthopedic surgeons from what type of material the hip implant component is made.[204]

Other problems with Dr. Parikh's survey methodology were elicited from her during cross-examination, namely:

> The survey universe was too broad, in that it included both users and prospective users of metal and ceramic hip implant components. That is, they could use any type of material as implant components in the surgeries that they perform, and they would still qualify for Dr. Parikh's survey. Even an orthopedic surgeon who had never used a ceramic hip implant component before, or an orthopedic surgeon who would never consider using a ceramic hip implant component were considered part of the survey universe.[205]
>
> Dr. Parikh did not screen for respondents who were familiar with ceramic hip implant components in particular. Dr. Parikh did not know whether it was possible that respondents in her survey may never have used ceramic hip implant components before in their surgeries.[206]

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[204] Klein Decl., 84 TTABVUE 8, ¶¶ 20-21.

[205] Parikh CX Testim., 152 TTABVUE 37-40.

[206] Parikh CX Testim., 152 TTABVUE 43-46.

> In reporting her results, Dr. Parikh did not "net out" (subtract) the ivory (control) survey results from the pink (test) survey results. This is important, because one of the conclusions Parikh drew when she looked at the results in the test group and in the control group was that the results were similar in several respects; if not virtually identical.[207]

Respondent's critique raised significant concerns—with which we agree—regarding Dr. Parikh's survey methodology (namely, a leading question, insufficient accounting for control group results, an overly broad survey universe and insufficient screening of survey respondents). These concerns alone cast significant doubt on the probative value of Petitioner's survey evidence.

Our greater problem with Petitioner's survey is that it asked the wrong question. Inquiring about the primary significance to orthopaedic surgeons of the color pink in connection with a hip implant component in no way seeks to resolve the issue involved in this case: whether pink as applied to a ceramic implant component is functional from a utilitarian perspective. On cross-examination, Dr. Parikh testified that her survey did not test for functionality. For this reason alone, we give Petitioner's survey evidence no probative weight.

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[207] Parikh CX Testim., 152 TTABVUE 53-56.

XVI. Entitlement to a Statutory Cause of Action

A plaintiff's entitlement to invoke a statutory cause of action for opposition or cancellation is a necessary element in every inter partes case. *Corcamore, LLC v. SFM, LLC*, 978 F.3d 1298, 2020 USPQ2d 11277, at *6-7 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 2671 (2021). To establish entitlement to a statutory cause of action under Trademark Act Section 14, 15 U.S.C., § 1064, a plaintiff must demonstrate "an interest falling within the zone of interests protected by the statute and . . . proximate causation." *Corcamore,* 2020 USPQ2d 11277, at *4 (citing *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 109 USPQ2d 2061, 2067-70 (2014)).[208] Stated another way, a plaintiff is entitled to bring a statutory cause of action by demonstrating a real interest in the proceeding and a reasonable belief of damage from the registration. *Australian Therapeutic Supplies Pty. Ltd. v. Naked TM, LLC*, 965 F.3d 1370, 2020 USPQ2d 10837, at *3 (Fed. Cir. 2020), *cert. denied*, 142 S. Ct. 82 (2021); *see also Empresa Cubana Del Tabaco v. Gen. Cigar Co.,*

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[208] Our decisions have previously analyzed the requirements of Trademark Act Sections 13 and 14, 15 U.S.C. §§ 1063-64, under the rubric of "standing." We now refer to this inquiry as entitlement to a statutory cause of action. Despite the change in nomenclature, our prior decisions and those of the Federal Circuit interpreting Trademark Act Sections 13 and 14 remain applicable. *Spanishtown Enters., Inc. v. Transcend Res., Inc.*, 2020 USPQ2d 11388, at *2 (TTAB 2020).

753 F.3d 1270, 111 USPQ2d 1058, 1062 (Fed. Cir. 2014).

There is "no meaningful, substantive difference between the analytical frameworks expressed in *Lexmark* and *Empresa Cubana*." *Corcamore*, 2020 USPQ2d 11277 at *4. Thus, "a party that demonstrates a real interest in canceling a trademark under [Trademark Act Section 14, 15 U.S.C.] § 1064 has demonstrated an interest falling within the zone of interests protected by § 1064. Similarly, a party that demonstrates a reasonable belief of damage by the registration of a trademark demonstrates proximate causation within the context of § 1064." *See Corcamore*, 2020 USPQ2d 11277 at *7.

When Petitioner first sought to enter the ceramic hip replacement component market as a competitor to Respondent, Petitioner was aware of Respondent's then-extant patent rights covering ceramics containing chromium oxide. In developing its first ceramic component products, Petitioner waited to introduce its products until Respondent's '816 patent had expired in 2013. [209] Upon introduction of Petitioner's pink ceramic component products, Respondent caused them to be seized at a Paris trade show. This event was the first time Petitioner became aware that Respondent claimed trademark rights in the color pink for the compound used to make ceramic

[209] Jonathan Haftel Colorado Litigation trial testimony ("Haftel Lit. Testim."), PNOR2, 42 TTABVUE 103-104; Haftel Decl., 59 TTABVUE 4-5, ¶¶ 9-11.

hip implant components.[210] Following the seizure, Respondent sent Petitioner a cease-and-desist letter, dated November 20, 2013, reading in part as follows:

> At [a trade show] . . . that took place in Paris [in] . . . November 2013, [Respondent] . . . learn[ed] about [Petitioner's] pink coloured hip joint balls. As you know, [Respondent] . . . immediately requested . . . an authorization to have an infringement seizure conducted by a court bailiff during the [trade show] . . . which was granted . . . . We initiated these measures because [Respondent] considers this use of the colour pink in connection with hip joint balls as an infringement of its trademark rights and . . . unfair competition.
>
> As you know as being a direct competitor, [Respondent] . . . is [a] . . manufacturer of technical ceramics, specializing in the development, manufacture and distribution of . . . products made of ceramics . . . . [Respondent] . . . has been producing ceramic components for the manufacturer of hip implants for more than 30 years.

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[210] Hughes Lit. Testim., PNOR2, 42 TTABVUE 85-88.

In 2004, [Respondent] . . . launched a new product line of hip joint balls and hip shells as well as other hip and knee joint components named BIOLOX-delta[,] . . . distinguished by the unusual and unique colouring in pink . . . .

* * *

[Respondent] has applied for various trademarks worldwide illustrating its pink coloured hip joint balls. Several registration proceedings are already completed . . . . In other countries, the applications are at least already published . . . .

* * *

The . . . colouring of [Petitioner's] . . . implant components . . . infringes [Respondent's] . . . trademark rights and violates unfair competition law.

[Petitioner's pink] colour [on its products] . . .constitutes a likelihood of confusion. The relevant public of implant manufacturers, orthopaedists and surgeons will . . . assume that [Respondent] . . . is the manufacturer or cooperates with [Petitioner].

* * *

[Respondent] will not tolerate this infringement of its rights and is **willing to commence legal action in each**

> **and every country in which it is necessary to stop the use of the colour pink.**[211] (emphasis added).

As discussed earlier, nearly simultaneous with its filing of these cancellation proceedings, Petitioner filed an action for a declaratory judgment of non-infringement and for cancellation of Respondent's trademark registrations in Colorado federal court. Respondent counterclaimed for infringement and unfair competition with respect to its asserted trademark rights in the color pink.

Based on the foregoing, Petitioner has demonstrated that its interest in cancellation of Respondent's registrations falls within the zone of interests protected by the statute, and Petitioner has a reasonable belief that damage is proximately caused by continued registration of Respondent's asserted marks. *See Tanners' Council of Am., Inc. v. Gary Indus., Inc.*, 440 F.2d 1404, 169 USPQ 608, 609 (CCPA 1971) ("It seems clear enough that registration of the mark as applied for could weaken the sales positions of appellants' members and hence reduce the income of appellant. We think this last factor is alone sufficient to bring appellant within the category of ¨any person who believes he would be damaged' by the registration."); *McGowen Precision Barrels, LLC v. Proof Research, Inc.*, 2021 USPQ2d 559, at *17-17 (TTAB 2021) (entitlement to a statutory cause of action found where Respondent filed complaint in

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[211] Respondent's cease-and-desist letter, PNOR5, Exh. 12, 45 TTABVUE 272-93.

federal court against Petitioner as the defendant, alleging that gun barrels being manufactured and sold by Petitioner's sister company infringed Respondent's registered trademark rights); *Ipco Corp. v. Blessings Corp.*, 5 USPQ2d 1974, 1977 (TTAB 1988) (Opposer's "use of the word [CONFIDENCE] on its brochures, its right to continue such use, and the cease and desist letter sent by applicant, evidence a sufficient interest by opposer to demonstrate its [entitlement to a cause of action]."). Petitioner has thus established its entitlement to petition for cancellation of Respondent's registrations.

XVII. Functionality: Applicable Law and Analysis

Generally, for matter claimed as trade dress to be capable of protection as a "mark," it must be distinctive and not functional. *Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 23 USPQ2d 1081, 1084 (1992). These also are requisites when the claimed "mark" is a particular color applied to the entirety of a product. *Qualitex Co. v. Jacobson Prods. Co.*, 514 U.S. 159, 34 USPQ2d 1161, 1163-64 (1995) (green-gold as applied to dry cleaning press pads); *Brunswick Corp. v. British Seagull Ltd.*, 35 F.2d 1527, 32 USPQ2d 1120, 1121-22 and 1125 (Fed. Cir. 1994), *cert. denied*, 514 U.S. 1050 (1995) (black as applied to outboard boat motors). Petitioner has not pled that the color pink as applied to Respondent's hip implant components lacks distinctiveness, and the parties have not argued that question in their briefs. The sole issue to be decided in these proceedings pertaining to Respondent's trademark rights is functionality.

The Trademark Act does not exist to reward manufacturers for their innovations. "It is the province of patent law, not trademark law, to encourage invention by granting inventors a monopoly over new product designs or functions for a limited time . . ., after which competitors are free to use the innovation." *Qualitex*, 34 USPQ2d at 1163. "[T]rademark . . . law can[not] properly make an 'end run' around the strict requirements of utility patent law by giving equivalent rights to exclude." J. Thomas McCarthy, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 7:64 (5th ed., Sept. 2022 update). Thus, a product feature that is functional "is incapable of registration on either the Principal or Supplemental Register." *AS Holdings, Inc. v. H & C Milcor, Inc.*, 107 U.S.P.Q.2d 1829, 1837 (TTAB 2013). Accordingly, Trademark Act Section 2(e)(5), 15 U.S.C. § 1052(e)(5), prohibits registration of "a mark which . . . comprises any matter that, as a whole, is functional."

There are two types of functionality recognized by controlling case law. One formulation states that "a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 214 USPQ 1, 4 n.10 (1982). This we refer to as "utilitarian functionality." The other theory of functionality posits "that, if a design's 'aesthetic value' lies in its ability to 'confe[r] a significant benefit that cannot practically be duplicated by the use of alternative designs,' then the design is 'functional.' . . . The 'ultimate test of aesthetic functionality,' . . .

[under this theory], 'is whether the recognition of trademark rights would significantly hinder competition.' " *Qualitex*, 34 USPQ2d at 1165 (citing RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 17, Comment c, pp. 175-176 (1993)). This we refer to as "aesthetic functionality." It is clear from our reading of the pleadings, evidence and briefing in this case that Petitioner's functionality claim under Trademark Act Section 2(e)(5) is based on functionality based on utilitarian considerations and not aesthetic functionality. Neither Petitioner nor Respondent argue otherwise.

The Court of Customs and Patent Appeals, in *In re Morton-Norwich Prods., Inc.*, 671 F.2d 1332, 213 USPQ 9, 15-16 (CCPA 1982), suggested four factors to consider when evaluating utilitarian functionality:

> (1) the existence of a utility patent that discloses the utilitarian advantages of the registered subject matter;
>
> (2) advertising by the registrant that touts the utilitarian advantages of the subject matter;
>
> (3) facts pertaining to the availability of alternative designs; and
>
> (4) facts pertaining to whether the subject matter results from a comparatively simple or inexpensive method of manufacture.

See also, In re Change Wind Corp., 123 USPQ2d 1453, 1456 (TTAB 2017) ("*Morton-Norwich* identifies four nonexclusive categories of evidence which may be

helpful in determining whether a particular design is functional[.1").

However, the U.S. Supreme Court has stated that if functionality is established under the *Inwood* test (essential to the use or purpose of the article or affecting the cost or quality of the article), a full analysis of all types of *Morton-Norwich* evidence is not necessary. *TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 58 USPQ2d 1001, 1006-07 (2001) ("Where the design is functional under the *Inwood* formulation there is no need to proceed further to consider if there is a competitive necessity for the feature. . . . There [also] is no need, furthermore, to engage . . . in speculation about other design possibilities, . . . which might serve the same purpose. . . . Other designs need not be attempted.").

The U.S. Court of Appeals for the Federal Circuit later had occasion to comment on the Supreme Court's observations in *TrafFix*:

> We do not understand the Supreme Court's decision in *TrafFix* to have altered the *Morton-Norwich* analysis. . . . [T]he *Morton-Norwich* factors aid in the determination of whether a particular feature is functional, . . . [one] factor focus[ing] on the availability of "other alternatives." (citation omitted). . . . Nothing in *TrafFix* suggests that consideration of alternative designs is not properly part of the overall mix, and we do not read the Court's observations

> in *TrafFix* as rendering the availability of alternative designs irrelevant. Rather . . ., once a product feature is found functional based on other considerations [such as if it "affects the cost or quality of the device,"] there is no need to consider the availability of alternative designs, because the feature cannot be given trade dress protection merely because there are alternative designs available. But that does not mean that the availability of alternative designs cannot be a legitimate source of evidence to determine whether a feature is functional in the first place.

Valu Eng'g, Inc. v. Rexnord Corp., 278 F.3d 1268, 61 USPQ2d 1422, 1427 (Fed. Cir. 2002).

Functionality is a question of fact and depends on the totality of the evidence in each particular case. *Valu Eng'g*, 61 USPQ2d at 1424. Petitioner bases its functionality claim on an application of the *Morton-Norwich* factors, and Respondent equally argues the non-application of those factors to its trademark rights.[212] We consider the *Morton-Norwich* factors to the extent raised in the arguments and based on the evidence made of record. All four *Morton-Norwich* factors need not be considered or proven in every case, nor do all four factors have to weigh in favor of functionality to support a functionality refusal. *Poly-*

[212] Petitioner's Brief, 158 TTABVUE 41-51; Respondent's Brief, 160 TTABVUE 40-49.

America, 124 USPQ2d at 1514. However, for the sake of completeness, we will address each *Morton-Norwich* factor below.

A. Respondent's Utility Patents and Patent Application

As the Supreme Court said long ago, "there passe[s] to the public upon the expiration of [a] patent . . . the right to make the article as it was made during the patent period . . . ." *Kellogg Co. v. Nat'l Biscuit Co.*, 305 U.S. 111, 39 USPQ 296, 299 (1938). That is because "[s]haring in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all – and in the free exercise of which the consuming public is deeply interested." *Id.* at 301. The public policy as stated in *Kellogg* has been brought into the modern age by the Supreme Court's functionality case law; particularly when expired patent rights are involved.

Whether one can assert trademark rights following the expiration of its utility patent is not newly trodden ground in trademark law. For example, in *TrafFix*, the plaintiff, Marketing Displays, Inc. ("MDI") was the holder of two utility patents for a two-spring mechanism (the "dual-spring design") to keep outdoor signs upright despite adverse wind conditions. After the patents expired, a competitor, TrafFix Devices, Inc. ("TrafFix"), sold sign stands with a visible spring mechanism that looked like MDI's. MDI brought suit against TrafFix for, inter alia, trade dress infringement based on the copied dual-spring design. *TrafFix*, 58 USPQ2d at 1003-04. The district

court granted summary judgment to TrafFix, in part on the basis that MDI's asserted dual-spring design was functional. *Id.* at 1004. The court of appeals reversed, suggesting that the district court committed legal error in its functionality ruling on the dual-spring design. *Id.*

Considering the legal significance of an expired utility patent on a trade dress claim, the Supreme Court stated:

> A prior patent, we conclude, has vital significance in resolving the trade dress claim. **A utility patent is strong evidence that the features therein claimed are functional**. If trade dress protection is sought for those features the strong evidence of functionality based on **the previous patent adds great weight to the statutory presumption that features are deemed functional until proved otherwise by the party seeking trade dress protection**. Where the expired patent claimed the features in question, one who seeks to establish trade dress protection must **carry the heavy burden of showing that the feature is not functional**, for instance by showing that it is merely an ornamental, incidental, or arbitrary aspect of the device. . . . Th[is] rule . . . bars [a] . . . trade dress claim [when the plaintiff] . . . cannot[] carry the burden of

> overcoming the strong evidentiary inference of functionality based on the disclosure of the [invention] . . . in the claims of the expired patents.

Id. at 1005 (emphasis added).

Our inquiry whether a utility patent renders asserted trade dress functional is not limited to our examination of the patent's claims:

> The inquiry into whether such features, asserted to be trade dress, are functional by reason of their inclusion in the claims of an expired utility patent could be aided by **going beyond the claims and examining the patent and its prosecution history to see if the feature in question is shown as a useful part of the invention**.

Id. at 1005 (emphasis added); *see also*, *Kohler Co. v. Honda Giken Kogyo K.K.*, 125 USPQ2d 1468, 1478 (TTAB 2017) (Our "analysis requires us to do what we must do in considering Applicant's issued United States patents to determine whether the claims and disclosures in the patent show the utilitarian advantages of the design sought to be registered as a trademark.") (citing *In re Becton, Dickinson and Co.*, 675 F.3d 1368, 102 USPQ2d 1372, 1377 (Fed. Cir. 2012)). The Supreme Court, in fact, did just that in *TrafFix* by looking not only at the claims of MDI's expired patents but also their specifications and "statements made in the patent applications and in the course of procuring the patents demonstrat[ing]

the functionality of the design." *TrafFix*, 58 USPQ2d at 1006.

The exception to the general rule expressed in *TrafFix* is stated as follows:

> In a case where a manufacturer seeks to **protect arbitrary, incidental, or ornamental aspects of features** of a product found in the patent claims, such as arbitrary curves in the legs or an ornamental pattern painted on the springs, **a different result might obtain**. There the manufacturer could perhaps prove that those aspects do not serve a purpose within the terms of the utility patent.

Id. at 1007 (emphasis added).

We start with the parties' agreement that the addition of chromia to a ZTA ceramic causes the material to become pink. In further support of its argument that practicing the '816 patent renders Respondent's pink trade dress functional, Petitioner directs us to (1) Respondent's admitted practicing of the claimed invention in its BIOLOX delta product, with each patent claim including the presence of chromium oxide, (2) statements made in the patent's specification regarding the benefits of chromia to the mechanical properties of the material, and (3) assertions made by Respondent's patent counsel during prosecution regarding the addition of chromia in a specified ratio to the other chemical additives (alumina and zirconia) in order to overcome prior

art;[213] all of which we set out in detail above. Looking at this evidence collectively, the claims, specification and prosecution history of the '816 patent disclose the functional benefits of chromia with respect to the toughness, hardness, stability and suppression of brittleness of the ZTA ceramic.

Petitioner also directs us to Respondent's '955 and '970 patents, the disclosures of which discuss the benefits of chromia to toughness and hardness; as well as Respondent's '237 application that discusses the benefits of Cr-doping to make the material particularly suitable for medical applications.[214]

Respondent asserts that the expired '816 patent does not, by the evidentiary presumptions outlined in *TrafFix*, render its trade dress functional because pink is not claimed in the patent. [215] However, Respondent readily concedes that a pink ceramic results from the implementation of the patent. [216] Nonetheless, Respondent argues that the patent claims a range of chromium that could naturally

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[213] Petitioner's Brief, 158 TTABVUE 16-17.

[214] Petitioner's Brief, 158 TTABVUE 17.

[215] Respondent's Brief, 160 TTABVUE 41. Respondent's corollaries to this argument are that "[o]ne can practice the patent's claims without yielding a pink product, and . . . one can produce a pink-colored hip implant component without practicing the patent." Respondent's Brief, 160 TTABVUE 41. These arguments at best are the product of circular reasoning; at worst a red herring.

[216] Respondent's Brief, 160 TTABVUE 43.

produce a broader range of pinkish hues ("almost white, red, or purple").[217] However, "[t]he fact that the patent[] may encompass a wide variety of [design variations] means only that the patent[] [is] broad in scope, not that [Respondent's] particular [registered] design is not functional." *McGowen Precision Barrels,* 2021 USPQ2d 559, at *75. Respondent's further statement that "the color pink is not a natural byproduct of practicing [its] . . . patent"[218] is thus a non sequitur. In any event, we need not, and do not, constrict our inquiry to the '816 patent claims. As noted above, the patent's specification and prosecution history provide additional evidence regarding the contribution of chromia to the inventions claimed therein.

Respondent further contends that the so-called "central advance" of the '816 patent is not directed to the improvement of the composition for hip implant components, but rather for cutting tools.[219] This argument fails for two reasons. First, Respondent derives its "not the central advance" theory from a passing comment in *TrafFix*, 58 USPQ2d at 1005 ("the central advance claimed in the expired utility patents . . . is the dual-spring design"). This passing comment comprises neither a holding of nor arguably even dicta from *TrafFix*. Second, as noted numerous times in the record, even though the ZTA chemical combination

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[217] Respondent's Brief, 160 TTABVUE 42.

[218] Respondent's Brief, 160 TTABVUE 42.

[219] Respondent's Brief, 160 TTABVUE 43-44.

developed, produced and now sold under the name BIOLOX delta originally was conceived for cutting tools, it has since been optimized for medical use - specifically for prosthetic hip joint components - with ZTA formulations including chromium oxide as contributing to the desired mechanical properties of hardness, toughness and strength.

We thus find that the expired '816 patent, as supported by the statements made in the '955 and '970 patents and the '237 application combined with Respondent's admissions that the addition of chromia renders the ZTA ceramic pink, is strong evidence that the color pink for ceramic hip implant components is functional. We further find that the color pink is not merely an ornamental, incidental, or arbitrary aspect of what is disclosed in the patent, but rather the natural byproduct of practicing the patent. *See McGowen Precision Barrels,* 2021 USPQ2d 559, at *81 ("[T]he appearance of the barrel [resulting from practicing expired patent] is dictated by its function").

B. Respondent's Advertising and Other Public Statements Touting Utilitarian Advantages

"If a seller advertises the utilitarian advantages of a particular feature of its product, this constitutes strong evidence of functionality." *Kohler*, 125 USPQ2d 1468, 1502 (TTAB 2017) (quoting *Kistner Concrete Prods., Inc. v. Contech Arch Techs., Inc.*, 97 USPQ2d 1912, 1924 (TTAB 2011)). In the context of the evidence made of record, we examine the promotional literature and other public statements made by

Respondent, as well as statements made on Respondent's behalf (or with its apparent permission and consent).

As noted, Respondent's hip implant components comprised of its BIOLOX delta pink ceramic material were introduced in 2003. Since at least that time until 2013, the record discloses that Respondent and its OEM customers made promotional literature available to the public extolling the benefits of chromia to the mechanical properties and performance of its compound used to make ceramic hip implant components; particularly hardness but other mechanical properties as well. Some of this literature also mentions that chromia is responsible for the pink color of the material. As late as 2019, Respondent was still sending articles to its customers referencing the fact that chromium oxide increases the hardness of the BIOLOX delta ceramic compound.

The record also includes technical literature dated from 1966 to 2020, expressing the benefits of chromia to the mechanical properties of compound ceramics comprising or including alumina; particularly hardness, strength and wear resistance. A good number of these articles excerpted above were written or co-written by Respondent's current or former employees — such as Drs. Burger, Kuntz and Porporati. Some of these articles also mention that chromia is responsible for the pink color of the material.

The evidence further contains references to Respondent's master files submitted to the FDA in

2004, 2008, 2012 and 2013, stating that chromia contributes to the hardness of its ceramic hip components, once again mentioning that chromia is responsible for the pink color of the material. Respondent did not alter or revise these statements made in its FDA filings until 2015.

Collectively, the above statements regarding the contribution of chromia to the mechanical properties of BIOLOX delta made by Respondent or its OEM customers in scientific literature, filings with the FDA, and advertising and marketing activities, served to educate the relevant market for an extended period of time that hip replacement components made from ceramic compositions including chromia (thus turning the compound pink) were superior in mechanical performance.

In the context of Respondent's current litigation position that chromia does not contribute to the mechanical properties or performance of ceramic hip implant components, contrary to what Respondent has publicly stated over an extended period of time, Respondent's internal correspondence made of record in these proceedings is probative:

> **Challenges - new Branding + Advertising Campaign**: In former times were [sic] our market share was low a higher price of our technology was not a big problem. . . . This have [sic] changed dramatically - WW increasing demands for Ceramics . . . BIOLOX is going in the direction of "Commodity " . . . Increasing price pressure for our customers in their

> hospital price negotiations . . . BIOLOX Patents expired . . . Risk that cheaper Generika [sic] Ceramic from our competition will enter the market . . . Establishment of the color pink in conjunction with the branding BIOLOX inside [2012-2013].[220]
>
> **Strategy Project: Pink Trademark Protection:** Our pink color is closely connected with our Biolox Delta product in the market and thus greatly helps with Biolox Delta branding. . . . Now we have verifiable information that our competitors are preparing to enter the market with a ceramic in the color pink. For this reason, we are currently engaged in activities designed to obtain trademark protection for the color pink in connection with orthopedic implants [2013].[221]
>
> The Coorstec [sic] guys are not just "ceramic bloody starters", in my eyes their current strategy will become very very dangerous for us and this very very soon. . . . This is conjunction with our pricing strategy were we [sic] blaming all of our customers and destroying long term relationships - this is poison for us. . . . The feedback we got so far from customers is

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[220] Review 2012 and BIOLOX Brand: New Slogan, New advertising Campaign Message 2013, PNOR1, Exh. 9, 41 TTABVUE 201-274 at 233.

[221] Internal memorandum from Dieter Burkhardt, October 17, 2013, PNOR1, Exh. 8, 41 TTABVUE 197-200 at 199 (English translation).

> absolut[e]ly negativ[e]- all of them are looking for alternatives. Nobody is understanding and also not accepting our current approach. It's coming at the wrong time [2014].[222]

The impression we are left with is that Respondent sought trademark protection to stave off competition after the expiration of its patent protection. We find Respondent's extended and continual advertising and other public statements (made at least until the institution of these proceedings), highlighting the utilitarian advantages of chromia in its ceramic product mix and that adding chromia turns the product pink, constitute strong evidence of functionality.

C. Facts Pertaining to the Availability of Alternative Designs

Although above we found that pink is a natural byproduct of the manufacturing process for Respondent's BIOLOX delta chemical composition, we examine the *Morton-Norwich* "alternative designs (or colors) factor" to determine if it weighs against a finding of functionality. To consider this question, we begin with the understanding that there are only a few companies that make these ceramic hip implant components because of the technical challenges involved; there are only a few companies that have the proper technology.[223]

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[222] Email from Dieter Burkhardt, November 27, 2014, PNOR1, Exh. 6, 41 TTABVUE 145-151 at 147.

[223] Haftel Lit. Testim., RNOR1, 70 TTABVUE 147-48.

Respondent provided evidence that, in addition to Respondent's components, OEM customers purchase other manufacturers' ceramic components — produced and sold in different colors — and integrate them into their own total hip replacement systems, which are then sold to hospitals or buying associations. Respondent cites the following examples: a Swiss company called Metoxit AG offers blue and peach-colored ceramic hip implant components; a Japanese company called Kyocera offers a blue ceramic hip implant component; a Swiss company called Mathys AG manufactures and sells a white ceramic hip implant component; and Smith & Nephew offers a black ceramic-coated hip implant component.[224]

A problem we have with these examples is that, except for Kyocera,[225] Respondent has not provided evidence that the competitors' products are equivalent in desired ceramic mechanical properties to those of Respondent. *See Valu Eng'g*, 61 USPQ2d at 1427 (discussing that the law of functionality considers in part "[t]he existence of **actual or potential alternative designs that work equally well**

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[224] Petkow Decl., 114 TTABVUE 5, ¶ 13, 115 TTABVUE 104-131, Exhs. 2-5.

[225] As to the competitive equivalence of Kyocera's product, *see, e.g.,* Dieter Burkhardt Colorado Litigation Testimony ("Burkhardt Lit. Testim."), PNOR2, 42 TTABVUE 9-14; Kuntz Lit. Testim., PNOR2, 42 TTABVUE 198-99 and DNOR1, 70 TTABVUE 423; Haftel Lit. Testim., DNOR1, 70 TTABVUE 146-47; Kuntz Decl., 101 TTABVUE 17, ¶ 47.

[which] strongly suggests that the particular design used by plaintiff is not needed by competitors to effectively compete on the merits." (emphasis added)) (citing J. Thomas McCarthy, 1 MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION, § 7:75, 7-180-1 (4th ed. 2001)).

In view of the dearth of probative evidence, we find the presence or absence of alternative "designs" (colors) to be a neutral factor regarding our ultimate determination whether the color pink for the products of interest is functional.

D. Whether the Subject Matter Results from a Comparatively Simple or Inexpensive Method of Manufacture

Petitioner is not aware of any difference in the overall cost for manufacturing its pink and white products, whether in manufacturing or raw material. They are pretty similar to make and manufacture.[226] Respondent, on the other hand, believes that because the raw material yttrium chromite is much more expensive than if Respondent were to use yttrium oxide, chromia does impact the cost of its product. That is, using chromia makes Respondent's product more expensive to produce.[227] In either event, in view of this testimony, we find that adding chromia to a ZTA ceramic does not make the product simpler or less expensive to make. We therefore find this *Morton-Norwich* factor to be neutral.

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[226] Hughes Lit. Testim., RNOR1, 70 TTABVUE 113.

[227] Kuntz Lit. Testim. RNOR1, 70 TTABVUE 475-77.

E. Other Considerations

1. Respondent's Testing Data

Respondent spent a great deal of time and effort to support its argument that "recent" reported experimental data should convince us that chromia has little to no impact on the desired mechanical properties of a ZTA ceramic. The experimental data to which we refer comprises the Kuntz 2014 White Paper, the Mecholsky 2016 litigation findings, the Kuntz/Krüger 2018 paper and the BAM 2018 findings from the German Litigation. As detailed above, Dr. Carty extensively criticized this research, and we find his criticisms persuasive.[228] Our additional concerns with this research over and above what Dr. Carty testified to are of a different ilk.

Specifically, the theme running through most of the experimental research offered in Respondent's favor is that the addition of chromia to a ZTA ceramic **up to 0.5% by weight** has no influence on the hardness, toughness, stiffness or mechanical performance of the composite material. Kuntz and Krüger suggest other reasons for improvements in the material, such as grain size and final density. Dr.

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[228] We are additionally troubled that the Kuntz 2014 White Paper and the Kuntz/Krüger 2018 paper appear to have been written to justify Respondent's litigation positions that are contrary to its public statements regarding chromia made for over a decade prior. We also noted above our concern that the Kuntz/Krüger 2018 paper was peer reviewed by Respondent's litigation expert, Dr. Mecholsky, who failed to disclose his conflict of interest to the publisher.

Porporati's research suggests that changes in yttria content have an effect on toughness, zirconia phase stabilization, and potentially wear performance of the ZTA material (although the product actually tested was yttrium chromite ($YCrO_3$), a chemical combination of yttrium and chromia, not the addition of yttrium by itself, albeit increasing the overall yttria content while keeping chromia content relatively constant).

The problem with Respondent's research is that it goes only so far, and not far enough in its scope — to address the full range of chromia content encompassed by the '816 patent. For one, suggesting other reasons for improvements in the material does not perforce exclude the contributions of chromia as well based upon the technical literature made of record. Further, we recall here the disclosures in the '816 patent that the addition of **chromium oxide in a weight ratio of 0.004 to 6.57% by weight** contributes to hardness and toughness, and can serve to counteract the embrittlement of the material. When the '816 patent expired, its claimed and disclosed inventions were dedicated to the public. *Kellogg*, 39 USPQ at 299.

In 2008, Respondent produced hundreds of specimens of varied material properties as part of an internal research project. The picture below shows Respondent's so-called "color board," containing some

of the samples Respondent created along with composition information for the samples:[229]

As can be observed, the materials vary in color. The first three materials on the top left comprise a combination of alumina and chromia with no zirconia. At much higher chromia concentrations than the 0.33 wt % of BIOLOX delta, the material becomes dark red. In between the lightest shades (practically white) and the dark red are multiple gradations of pink, growing progressively darker. The materials colored blue and green were simply test samples as a proof of concept that Respondent could develop material in several different colors.[230]

What this evidence shows is that chromia can be added to the ceramic composite **in greater**

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[229] Kuntz Decl., 101 TTABVUE 16, ¶ 46.

[230] Kuntz Decl., 101 TTABVUE 17, ¶ 47.

concentrations by weight percent than the 0%-0.5% wt. levels tested. It is certainly possible that, based on the historical literature made of record and reviewed by both parties' materials experts, [231]

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[231] Summarizing his prior testimony and reports, Respondent's materials expert, Dr. Mecholsky, suggests that we should dispense with this body of experimental research (the "older" literature from 1967 to 2013) as being of limited (if any) use in these proceedings because: (i) the compositions of ceramics addressed by the literature are either not reported or are different than the products at issue in these proceedings; (ii) the concentrations of chromium are different than the range of concentrations relevant to these proceedings; and (iii) other variables that affect material properties, such as grain size and density of the tested ceramic, are not reported. Mecholsky TTAB Rebuttal Rpt., 105 TTABVUE 393-94, ¶ 8. Petitioner's materials expert, Dr. Carty, notes that even the composition of BIOLOX delta did not remain constant during its development. However, with the exception of two testing samples, all of Respondent's samples contained chromia. Once an optimal chromia level was established, that level was kept constant. In any event, Respondent's developmental timeline for the BIOLOX delta composition showed that hardness clearly increased linearly with chromium content. Accordingly, different compositions (including those in the so-called "older" literature) are relevant to the ultimate issue of whether chromia contributes to the hardness of a ZTA ceramic compound. Accordingly, Dr. Mecholsky's suggestion that measured properties in prior literature should not be considered, because they are not the same composition as BIOLOX delta, is unsupportable given the developmental timeline for the development of the BIOLOX delta compound. Carty Rebuttal Rpt. (confidential), 141 TTABVUE 11-13 ¶¶ 15-18.

greater concentrations of chromia by weight than those Respondent tested do contribute to the desired mechanical properties of the ceramic material and still come within the coverage of the now-expired '816 patent. However, we do not know this because the research was not done and brought to our attention.

Thus, due to a lack of proof, we do not know whether adding levels of chromia in excess of 0.5% (by %-wt.) to the ZTA ceramic would contribute to the mechanical properties of the material, yet the material would still turn out pink — as shown in Respondent's trademark registrations.

2. Petitioner's Testing Data and Survey Evidence

Petitioner also spent a great deal of time and effort to support its argument that, over time, its pink ZTA ceramic containing chromia, CeraSurf-p, exhibited greater hardness and strength than its white ZTA ceramic not containing chromia, CeraSurf-w. As we extensively discussed above, Respondent's experts, Drs. Mecholsky and Kadane, as well as the cross-examination of Jonathan Haftel, raised sufficient doubts about Petitioner's processing and testing methods, data collection, reporting and conclusions reached over the relevant time period to cast doubt on the probative value of this evidence. We further find wanting the efforts of Petitioner's experts, Drs. Carty

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We decline Dr. Mecholsky's invitation to cast aside the findings made and conclusions from the historical experimental research, published over an extended period of time in peer-reviewed articles by experts in the field.

and Barnett, to explain away Respondent's critique of Petitioner's testing data.

Petitioner's survey conducted by Dr. Parikh, to establish that the primary significance of the color pink used in the context of hip implant components, was heavily criticized by Respondent's survey expert. Further problems with Dr. Parikh's survey were uncovered during her cross-examination. As we discussed above, these survey methodology defects alone cast significant doubt on the probative value of Petitioner's survey evidence.

As we also noted above, our greater problem with Petitioner's survey is that it asked the wrong question. Petitioner's survey in no way sought to determine whether pink as applied to the compound of a ceramic implant component is functional based on utilitarian considerations. We thus give Petitioner's survey evidence no probative weight.

XVIII. Conclusion: Functionality

Respondent's expired '816 patent, as well the other patent properties in Respondent's portfolio discussed above, disclose the utilitarian advantages of Cr^{3+}-doped ZTA ceramic hip replacement component materials, which as a natural byproduct turns the chemical compound pink — and that is the color shown in Respondent's Trademark Registration Nos. 4319095 and 4319096. The advertising and public statements made by Respondent and OEM customers on Respondent's behalf — for an extended period of time — touted the utilitarian advantages of chromia to Respondent's ZTA ceramic compounds; some

statements made in conjunction with the comment that the addition of chromia turns the material pink. Respondent did not withdraw these noted advertising and other public statements until the parties were in litigation and its registrations were being challenged.

Facts pertaining to the availability of alternative "designs" (colors) comprise a neutral factor here, due to the dearth of relevant evidence. In view of the parties' testimony that the use of chromia either does not affect the cost of a ZTA ceramic or makes the product more expensive, whether the addition of chromia (turning the product pink) results from a comparatively simple or inexpensive method of manufacture is also a neutral factor.

The parties' product testing data, and the survey evidence offered by Petitioner, does not change our findings with respect to the *Morton-Norwich* factors. In sum, we find that the color pink (caused by the addition of chromia) of the compound used to make ceramic hip implant components, as shown in Respondent's trademark registrations, is functional based on utilitarian considerations.

XIX. Respondent's Unclean Hands Defense

In its Answers to both Petitions for Cancellation, Respondent alleges that "Petitioner is precluded from petitioning to cancel [Respondent's] . . . U.S. Registration Number[s] 4,319,095 [and] 4,319,096 by

the affirmative defense of unclean hands." [232] Generally, unclean hands is an available defense in cancellation proceedings before the Board. Trademark Act Section 19, 15 U.S.C. § 1069 ("In all inter partes proceedings equitable principles . . . where applicable, may be considered and applied."); Trademark Rule 2.114(b)(2), 37 C.F.R. § 2.114(b)(2) ("An answer may contain any defense, including the affirmative defense[] of unclean hands, . . ., or any other matter constituting an avoidance or affirmative defense.").

However, we may properly exercise our discretion, when there is a strong public policy interest in removing a category of marks from the Register, to find the defense unavailable against certain claims for cancellation. *See Loglan Inst., Inc. v. Logical Language Grp., Inc.*, 962 F.2d 1038, 22 USPQ2d 1531, 1534 (Fed. Cir. 1992) ("The Board did not err in declining to apply the [unclean hands] defense[], as the public interest in a cancellation proceeding to rid the register of a generic mark transcends [this defense]."); *Maids to Order of Ohio, Inc. v. Maid-to-Order, Inc.*, 78 USPQ2d 1899, 1904 (TTAB 2006) ("[S]ince . . . the affirmative defense of unclean hands . . . is . . . unavailable against a claim of fraud . . ., we have given it no consideration."); *Am. Vitamin Prods. Inc. v. DowBrands Inc.*, 22 USPQ2d 1313, 1314 (TTAB 1992) ("Where the ground for cancellation is abandonment, equitable defenses such as . . . unclean

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[232] Answer in in Cancellation No. 92058781, 28 TTABVUE 8-12, ¶¶ 37-52; Answer in Cancellation No. 92058796, 22 TTABVUE 8-12, ¶¶ 37-52.

hands, are not available in light of the overriding public interest in removing abandoned registrations from the register.").

We exercise our discretion now, and thus hold that the unclean hands defense is unavailable in Board functionality proceedings in view of the prevailing public interest in removing registrations of functional marks from the register. *See ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 97 USQP2d 1048, 1057 (Fed. Cir. 2010) ("the 'functionality doctrine stems from the public interest in enhancing competition' and avoiding improper hindrance of competition in the marketplace") (citation omitted).

XX. Culmination of Findings and Rulings

In sum, we find that the color pink for the identified goods in Respondent's Trademark Registration Nos. 4319095 and 4319096 is functional and therefore unregistrable. In view of our determination of Petitioner's functionality claim, we do not reach Petitioner's alternative claim that Respondent's Registration Nos. 4319095 and 4319096 were procured through fraud. We further find Respondent's unclean hands defense inapplicable to these proceedings (including as against Petitioner's fraud claim that we did not reach). Finally, we deny as moot Respondent's motion filed in Cancellation No. 92058796 to amend the date of first use claimed in Registration No. 4319096.

Decision:

The Petitions to Cancel Trademark Registration Nos. 4319095 and 4319096 are granted. The registrations will be canceled in due course.

APPENDIX C

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERAMTEC GMBH,
Appellant

v.

COORSTEK BIOCERAMICS LLC, FKA C5 MEDICAL WERKS, LLC,
Appellee

2023-1502

Appeal from the United States Patent and Trademark Office, Trademark Trial and Appeal Board in Nos. 92058781, 92058796.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MOORE, *Chief Judge*, LOURIE, DYK, PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL, CUNNINGHAM, and STARK, *Circuit Judges*.[1]

[1] Circuit Judge Newman did not participate.

PER CURIAM.

ORDER

CeramTec GmbH filed a combined petition for panel rehearing and rehearing en banc. The petition was referred to the panel that heard the appeal, and thereafter the petition was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

FOR THE COURT

Jarrett B. Perlow
Clerk of Court

April 22, 2025
Date