

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge R. Brooke Jackson

Civil Action No 14-cv-00643-RBJ

C5 MEDICAL WERKS, LLC and
COORSTEK MEDICAL, LLC,

Plaintiffs and Counter-Defendants,

v.

CERAMTEC GMBH,

Defendant and Counter-Plaintiff.

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER OF JUDGMENT

This case was tried to the Court from August 29, 2016 to September 8, 2016 and from October 3, 2016 to October 5, 2016.

I. FINDINGS OF FACT

A. The Parties.

1. Defendant/counter-plaintiff CeramTec GmbH (“CeramTec”) is a company that produces pink-colored ceramic hip implant components sold under the name BIOLOX Delta. *See* Trial Tr. 619:1–10; DX-399. CeramTec sells these products to Original Equipment Manufacturers (“OEMs”). DX-1095. OEMs incorporate BIOLOX Delta products into hip implant systems that the OEMs in turn sell to hospitals for use by surgeons in orthopedic surgeries. *Id.*; Tr. 1618:19–1619:3. CeramTec currently controls roughly 95% of the ceramic hip implant market in the United States. Tr. 1617:21–25.

2. Plaintiff/counter-defendant C5 Medical Werks, LLC (“C5”), which later became CoorsTek Medical, LLC (“CoorsTek”), was founded in 2005 to produce ceramic products,

including ceramic hip implant components, for sale in the orthopedic market.¹ Tr.149:19–151:25, 153:3–17, 213:9–15.

B. Timeline of Events.

3. On July 2, 1996 CeramTec applied for a utility patent on a ceramic cutting tool. DX-423 at 1. This application asserted that CeramTec had solved a pre-existing problem with certain ceramic composites known as zirconia-toughened alumina or “ZTA” ceramics whereby the introduction of zirconium used to toughen the material caused a drop in the material’s hardness. *See* Tr. 657:16–658:5; PX-190 (Applicant’s April 15, 1997 Response to Patent Office). CeramTec claimed that through the introduction of chromium in a specific molar ratio with other components of ZTA ceramics, namely zirconium dioxide, Tr. 657:19–25; *see also* PX 190 at 216, it could achieve hardness scores for ZTA ceramics that had never been achieved with corresponding zirconium dioxide contents, Tr: 657:19–658:8; PX-190 at 216. Hardness is an important characteristic of ceramic materials because it affects the ceramic’s wear properties, which influence performance.² Tr. 219:12–16, 643:25–644:13.

4. Although an existing patent already taught the use of chromium in ZTA ceramics, *see* Tr. 656:20–657:7 (describing the “Ekstrom” patent), the Patent Office issued CeramTec a patent on November 3, 1998 (the ‘816 patent). DX-423 (the ‘816 patent). CeramTec overcame a contrary office action based in part on the company’s insistence that it had discovered that a small and specific ratio of chromium improved ZTA ceramic hardness values dramatically. Tr. 656:20–659:10; DX-423; PX-190.

¹ For ease of use, the Court will collectively refer to plaintiffs C5 and CoorsTek simply as “C5” or “plaintiffs” throughout this Order.

² In addition to increasing the hardness of ceramic materials, chromium is touted for its numerous other useful benefits, including increasing toughness and phase stabilization. *See, e.g.*, Tr. 691:11–17.

5. Around the same time that it obtained the '816 patent, CeramTec developed BIOLOX Delta. *See* DDX-1017; Tr. 1016:20–1017:15; 1018:20–23. In producing BIOLOX Delta, which is a ZTA ceramic product, CeramTec practices at least claim 3 of the '816 patent. ECF No. 247 at 2, ¶4 (joint pretrial stipulations). The chromium added to BIOLOX Delta gives it a light pink color. DX-228; DX-281.

6. In the early 2000s, CeramTec began to market BIOLOX products commercially. DDX-1017.

7. In September of 2002 CeramTec obtained another patent for ZTA ceramics (the '957 patent). PX-142. Like the '816 patent, the '957 patent claimed the use of chromium in ZTA ceramics. PX-142 (the '957 patent), claims 1-4 and at 4:37–56, 5:12–51, 7:14–27. Echoing the '816 patent, the '957 patent also explained that the introduction of chromium in a specific ratio with zirconium counteracted a drop in hardness. PX-142 at 5:41–44 (“[T]he chromium addition counteracts any drop in the hardness values when the proportion of zirconium dioxide rises.”). CeramTec does not specifically practice the '957 patent in producing BIOLOX Delta products. Tr. 394:4–10. This patent is still in force today.

8. CeramTec owns an additional patent on ZTA ceramics (the '970 patent) and a pending patent application (U.S. Patent Publ. No. 2012/0142237 or the '554 Appl.) that similarly teach the use of chromium to improve the properties of ceramic materials. PX-550 (the '970 patent), claims 1 and 20; PX-551 (the '554 Appl.), claim 8; Tr. 1136:16–24.

9. In April of 2004 CeramTec made two submissions to the Food & Drug Administration (“FDA”) in which the company represented that the addition of chromium in its composite material counteracts a drop in hardness caused by an increasing amount of zirconia. *See* PX-79 at 6; PX-86 at 6.

10. In 2006 CeramTec produced research that suggested that chromium did *not* increase hardness. Tr. 1100:18–1101:4. CeramTec refers to this as its first “data point” that chromium might actually be a non-functional component of BIOLOX Delta. *See id.*

11. However, despite that research and a few additional studies in the late 2000s that reached similar results, see PX-554, the company did not change its public stance that chromium increased hardness. On the contrary, it maintained its position that chromium increased hardness in additional submissions to the FDA in September 2008, October 2008, February 2012, October 2012, and June of 2013. PX-79; PX-86; PX-87 at 26–27; PX-22 at 6; PX-82; PX-88; PX-84 at 26; PX-166 at 34. CeramTec also reiterated this stance, as well as the fact that chromium turned the product pink, in numerous training materials for its customers, research articles, and marketing campaigns spanning this same time period. *See, e.g.*, Tr. 1151:4–14, 2029:1–9 (referencing an e-mail chain involving the marketing “story” of chromium increasing hardness that CeramTec adopted); DX-215 (e-mail chain); Tr. 223:4–231:1; PX-429 (Summary of CeramTec presentations); PX-40 (Training Guide); PX-129 (Research).

12. In 2009 C5 entered the ceramic hip component market and began to compete with CeramTec with two products of its own: (1) Cerasurf-p, a ceramic product that like BIOLOX Delta contains chromium and is pink; and (2) Cerasurf-w, a white ceramic product that does not contain chromium. DX-517; DX-090 at 91; DX-90 at 118; DX-517; Tr. 297:4-12; DX-519 at 9; DX-065. Initially, C5’s internal testing revealed no difference in hardness or strength between Cerasurf-p, which contains chromium, and Cerasurf-w, which does not. *See DX-527.* Nevertheless, additional testing C5 conducted eventually showed statistically significant evidence that its pink material was harder than its white material. *See, e.g.*, Tr. 1307:11–12, 1941:3–20. While the Cerasurf-p product looks identical to CeramTec’s BIOLOX Delta product

aside from the companies' logos engraved on these products, C5 claims that it carefully designed its product so that it did not infringe on CeramTec's '816 patent. Tr. 923:1–13; Tr. 239:3–13.

13. Although BIOLOX Delta controlled the vast majority of the ceramic hip implant market at this time, CeramTec soon grew concerned when C5 entered the market. *See* PX-44 at 62; PX-68 at 2. The company subsequently took three actions to preserve its market share. First, on April 9, 2013 CeramTec filed an application with the United States Patent and Trademark Office (“USPTO”) seeking trade dress protection on the pink color of chromium in BIOLOX Delta on the principal register. DX-156; DX-157. In response to questions, CeramTec asserted that the color pink was *not* a functional component of BIOLOX Delta. *See* DX-156 at 56-57, 65-66; DX-157 at 53–54, 61–62. It informed the USPTO that “[t]he color pink is not a natural by-product of the manufacture of implants *generally*, supported by the fact that none of Applicant’s competitors create pink implants.” DX-156 at 56 (¶II.7), DX-157-53 (¶II.7) (emphasis added). It added that the color pink is a result of CeramTec’s proprietary manufacturing process. *Id.* Significantly, however, the response did not explain that the color pink was a natural byproduct of the chromium in CeramTec’s implants or that CeramTec had for many years claimed that the chromium was a functional component of its BIOLOX Delta products. *Id.* The USPTO nevertheless rejected CeramTec’s application because it found that CeramTec had not acquired secondary meaning or distinctiveness, which is necessary in order to register a color as trade dress. DX-156 at 29–30; DX-157 at 29–30.

14. Second, having been rejected by the USPTO, CeramTec obtained U.S. Supplemental Trademark Registration Nos. 4,319,095 and 4,319,096 (the ‘095 and ‘096 registrations) for the pink color of chromium in hip implants. DX157 at 6; DX156 at 7.

15. Third, on November 20, 2013 CeramTec sent a cease and desist letter to C5 asserting that Cerasurf-p infringed on the '816 patent. PX-558 at 24–44. This became moot when the '816 patent expired that same year.

16. On March 3, 2014 C5 took the offensive, initiating this lawsuit against CeramTec. ECF No. 1 (Complaint).³ In its initial Complaint, C5 sought to cancel CeramTec's '095 and '096 registrations and to obtain several other rulings regarding C5's rights to manufacture and market Cerasurf-p. *Id.* at ¶¶78–106.

17. CeramTec answered C5's Complaint on September 25, 2014 with numerous affirmative defenses and counterclaims of its own, asserting among other things that Cerasurf-p infringed on CeramTec's trademark registrations on the color pink. ECF 41; ECF No. 191.

18. As C5's initial Complaint made clear, the threshold issue in this lawsuit was the functionality of chromium in BIOLOX Delta. *See generally* ECF No. 1.

19. Roughly eight months after C5 filed suit and one month after CeramTec answered C5's initial Complaint, Dr. Meinhard Kuntz, the manager of oxide development at CeramTec, Tr. 988:18–20, published a White Paper experiment that concluded that the introduction of chromium in BIOLOX Delta did *not* increase hardness, DX-228 (published on October 22, 2014).

20. The authority of Dr. Kuntz's paper, however, was undermined at trial because it was not the product of a controlled experiment regarding chromium, it was not peer reviewed, and because it contradicted decades of past research into the benefits of chromium, aside from a few "data points" of contrary evidence referenced above. *See* Tr. 664:6–21, 1100:18–1110:23,

³ The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338 and 2201 and 15 U.S.C. §§ 1119 and 1121(a). The Court denied CeramTec's motion to dismiss for lack of personal jurisdiction on September 8, 2014. ECF No. 35.

1265:2–11. The timing of the White Paper likewise did not bolster its credibility, nor, frankly, did Dr. Kuntz’s trial testimony.

II. CONCLUSIONS OF LAW

The late Arnold Palmer once said that golf is a game that is deceptively simple but endlessly complicated. Here, I find the opposite is true: while deceptively complicated, in the end this case is relatively simple. From the ‘816 patent alone, but also from the abundance of additional evidence in this case that chromium increases hardness, I find that chromium is a functional component of BIOLOX Delta. *See TrafFix Devices, Inc. v. Mktg. Displays, Inc.*, 532 U.S. 23, 28–30 (2001). As such, CeramTec cannot claim trade dress (or trade mark) protection on the pink color that is a natural byproduct of the chromium used in that product.⁴ *See id.* Accordingly, judgment will enter in C5’s favor on Counts I and III of its First Amended Complaint, ECF No. 124, and also in favor of C5 on CeramTec’s counterclaims, see ECF No. 191. In light of this holding, I do not reach or decide the merits of Count II of C5’s First

⁴ C5 has additionally argued that, regardless of whether chromium is functional, CeramTec is absolutely precluded from claiming trade dress protection under the Tenth Circuit’s decision in *Vornado Air Circulation Systems, Inc. v. Duracraft Corp.*, 58 F.3d 1498, 1500 (10th Cir. 1995) because chromium was a “described, significant inventive component” of the hip implant components covered by the ‘816 patent. *See* Tr. 19:18–22 (opening statement for plaintiff). Under that test, C5 easily prevails in this case. But CeramTec counters that *Vornado* is no longer good law after *TrafFix*, noting that *Vornado* created the “circuit split” leading to that case. 532 U.S. at 29. As C5 rightly points out, *TrafFix* never confronted the Tenth Circuit’s alternative “described, significant inventive component” standard head on, nor did it explicitly state that it was overruling that decision. Nevertheless, I assume for purposes of this order that *TrafFix* did overrule *Vornado*. For one thing, the Court in *TrafFix* framed the issue on appeal as “whether the existence of an expired utility patent *forecloses* the possibility of the patentee’s claiming trade dress protection in the product’s design.” *Id.* at 28 (emphasis added). The Court’s answer was “no.” *See id.* at 29–30. Thus, the Court seemingly resolved the circuit split *against* the Tenth Circuit’s position. *See id.* at 28 (noting in a parenthetical that *Vornado* held the opposite). I also note that, so far as I can determine, only one court has quoted *Vornado*’s “significant inventive component” standard post-*TrafFix*, and it did so in explaining the circuit split *TrafFix* resolved. *Logan Graphics Prod., Inc. v. Textus USA, Inc.*, No. 02 C 1823, 2002 WL 31870549, at *4 (N.D. Ill. Dec. 23, 2002), *report and recommendation adopted sub nom. Logan Graphic Prod., Inc. v. Textus USA, Inc.*, No. 02 C 1823, 2003 WL 21011746 (N.D. Ill. May 5, 2003).

Amended Complaint. *See* ECF No. 124 at ¶¶97–110. Counts IV and V were previously dismissed. ECF No. 182.

A. Background: Trade Dress Functionality Analysis.

In order to claim trade dress protection, the proponent of the trade dress must prove that the feature on which it seeks protection is “non-functional.” *Id.*; *see* 15 U.S.C. § 1125(a)(3) (“In a civil action for trade dress infringement under this chapter for trade dress not registered on the principal register, the person who asserts trade dress protection has the burden of proving that the matter sought to be protected is not functional.”); *see also* 15 U.S.C. § 1125(c)(4)(A) (similar burden in actions for trade dress dilution). This is no easy task. Not only are features statutorily presumed to be “functional,” but the Supreme Court has also laid out alternative tests for determining whether a product feature is “functional” and preclusive of trade dress protection. *See TrafFix*, 532 U.S. at 31–33.

One approach is competition-focused. *See id.* at 32. A product’s feature is “functional” if the “exclusive use of [the feature] would put competitors at a significant non-reputation-related disadvantage.” *TrafFix*, 532 U.S. at 32. For example, in *John Deere & Co. v. Farmhand, Inc.*, 560 F. Supp. 85, 98 (S.D. Iowa 1982), *aff’d*, 721 F.2d 253 (8th Cir. 1983), this definition of functionality was applied to prevent John Deere from asserting trade dress protection on the “green” color of its farm machinery. The court reasoned that because customers wanted their farm machinery to match, precluding other companies from using “John Deere green” would put them at a significant, non-reputation-related disadvantage in the market. *See also Qualitex Co. v. Jacobson Products Co., Inc.*, 514 U.S. 159, 165–66 (1995) (explaining the competition-focused definition of functionality and holding that the green gold shade of a dry cleaning pad was non-

functional as it served no non-trademark function). This definition of functionality is not at issue in this case.

Alternatively, a feature is functional if “it is essential to the use or purpose of the device or when it affects the cost or quality of the device.” *TrafFix*, 532 U.S. at 33 (emphasis added); accord *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 850, n.10 (1982). Framed in the disjunctive, this second definition of functionality is multifaceted. The “essential to the use or purpose” prong is a primary focus in the present case. Although addressing the issue in a design patent context, my colleague Judge Brimmer captured the concept well: “[T]he crucial determination is not the availability of alternative designs, but whether the design at issue is ‘the reason the device works.’” *OraLabs, Inc. v. Kind Grp. LLC*, No. 13-CV-00170-PAB-KLM, 2015 WL 4538444, at *12 (D. Colo. July 28, 2015) (quoting *TrafFix*, 532 U.S. at 34). Thus, in *TrafFix*, discussed in greater detail *infra*, the Supreme Court held that a dual-spring feature of a road sign stand was “functional” despite the existence of equally effective three- or four-spring designs because the two-spring feature on which trade dress protection was claimed was the very aspect of the product that enabled it to achieve its intended purpose: withstanding strong gusts of wind. *TrafFix*, 432 U.S. 23 at 34.

Under the alternative “affects the cost or quality” prong, courts have followed several different paths in assessing functionality. For instance, when deciding whether a feature affects “cost” (which like the competition-focused approach to determining functionality is not at issue here) one can examine whether the feature at issue is “essential to achieving cost savings” in the manufacturing process of the underlying product. See *OraLabs, Inc.*, 2015 WL 4538444, at *13 (reasoning, in part, that because the spherical shape of the lip balm dispenser at issue in the case did not lower the product’s cost, the unique design of the product on which trade dress protection

was sought was non-functional). By contrast, in deciding whether the feature in question affects “quality,” which is a definition of functionality that is pertinent here, the Federal Circuit has examined whether or not the feature on which trade dress protection is sought has a purposeful relationship with the underlying material of the product. *See In re Owens-Corning Fiberglas Corp.*, 774 F.2d 1116, 1123–24 (Fed. Cir. 1985) (holding that the “pink” color of insulation was non-functional because it did not affect the quality of insulation in that the color used had no effect on the product’s ability to regulate a building’s temperature).

B. *TrafFix* and a Prior Patent’s Application in Functionality Analysis.

Although courts for decades routinely assessed trade dress claims by deciding whether or not the feature on which protection was claimed was “functional,” the Court in *TrafFix Devices, Inc. v. Marketing Displays, Inc.* confronted a potentially disrupting circuit split: does “the existence of an expired utility patent foreclose[] the possibility of the patentee’s claiming trade dress protection in the product’s design[?]” *TrafFix*, 532 U.S. at 28 (citing *Marketing Displays, Inc. v. TrafFix Devices, Inc.*, 200 F.3d 929, 939 (6th Cir. 1999); *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999); *Thomas & Betts Corp. v. Panduit Corp.*, 138 F.3d 277 (7th Cir. 1998); *Sunbeam Products, Inc. v. West Bend Co.*, 123 F.3d 246 (5th Cir. 1997); and *Vornado Air Circulation Systems, Inc. v. Duracraft Corp.*, 58 F.3d 1498, 1500 (10th Cir. 1995)).

As the Court recognized, this issue not only had the potential to short-circuit the traditional functionality tests by which courts assessed trade dress protection, but it also raised complex policy considerations concerning how patent law and trade dress law—two bodies of law seemingly at odds with one another—should interact. *Id.* at 29 (“Trade dress protection must subsist with the recognition that in many instances there is no prohibition against copying

goods and products. In general, unless an intellectual property right such as a patent or copyright protects an item, it will be subject to copying.”).

Striking a compromise of sorts, the Court held that while prior patents on a product’s design do not *foreclose* the possibility of obtaining trade dress protection, patents nevertheless have “vital significance” in trade dress functionality analysis. *Id.* “A utility patent is *strong evidence* that the features therein claimed are functional.” *Id.* (emphasis added). Prior patents therefore add “great weight to the statutory presumption that features [of the product] are deemed functional until proved otherwise by the party seeking trade dress protection.” *Id.* at 30.

Given the substantial weight attached to prior patents, the Court warned that “one who seeks to establish trade dress protection” on a feature claimed within a prior patent “must carry the *heavy burden* of showing that a feature is not functional[.]” *Id.* at 30 (emphasis added). This is not an impossible task. For instance, a party could carry this burden by proving that the feature was “merely an ornamental, incidental, or arbitrary aspect of the device” (e.g., “arbitrary curves in the legs” of the sign or “an ornamental pattern painted on the springs” of the device). *Id.* But it is a quite difficult task.

The Court then turned to the feature on which trade dress protection was actually sought: the road sign stand’s dual-spring mechanism. Recognizing that Marketing Displays, Inc. (“MDI”), the party seeking trade dress protection, had not “pointed to [anything] arbitrary about the components of its device or the way they are assembled[,]” the Court examined the claims of MDI’s expired utility patents covering the device, the utility patents themselves, and the statements MDI had made “in the course of procuring the patents” to assess the feature’s functionality. *Id.* It found that not only had the prior patents claimed the use of the dual-spring feature, but that this evidence collectively demonstrated that the dual-spring design was

“essential” to the purpose of the device because it was “a unique and useful mechanism to resist the force of the wind.” *Id.* at 33. In other words, the Court concluded, the dual-spring design was “the reason the device works.” *Id.* at 33–34. Accordingly, the Court held that this feature was “functional,” and that MDI was prevented from asserting trade dress protection on it. *Id.* at 33.

C. The Pink Color of Chromium in BIOLOX Delta is “Functional.”

Here, I conclude that CeramTec has failed to carry its heavy burden of proving that chromium’s pink color in BIOLOX Delta is “non-functional.” *See id.* at 31–33. I reach this conclusion after finding from the ‘816 patent covering BIOLOX Delta that chromium is an “essential” component of that product. I also find, from the copious amount of additional evidence presented at trial, that chromium, which gives BIOLOX Delta its pink color, see, e.g., Tr. 1127:3–4, is functional because it affects the “quality” of BIOLOX Delta.⁵ I begin, as the Court did in *TrafFix*, with the patent.

1. The ‘816 Patent.

In claims 1 and 3 of the ‘816 patent, the latter of which CeramTec admits it practices in producing BIOLOX Delta, CeramTec disclosed the use of a specific molar ratio of chromium to produce harder ZTA ceramics. *See* DX-423 at 12 (the ‘816 patent); PX-17; Tr. 652:13–653:10 (“Here, you see claim 3 . . . you must have chromium oxide in order to create those claims. Without those claims, without chromium oxide, those claims don’t exist. So claims 1 and claim 3 can’t exist without chromium oxide.”). These claims about chromium are, at the very least, “strong evidence” of chromium’s functionality. *See TrafFix*, 522 U.S. at 29 (“A utility patent is strong evidence that the features therein *claimed* are functional.”) (Emphasis added).

⁵ Concluding that the chromium in BIOLOX Delta is “functional” because it increases hardness, I reiterate that this is a *legal* conclusion, not necessarily a scientific one, based on the evidence presented at trial.

But like the expired patents at issue in *TrafFix*, the ‘816 patent goes further. In addition to claiming the use of chromium in ZTA ceramics, the ‘816 patent and statements CeramTec “made . . . in the course of procuring” that patent explain that the addition of chromium in ZTA ceramics solved an existing problem of a drop in hardness due to zirconium dioxide used to toughen ceramic composites. DX-423 at 9, col. 3:39–42, col 3:51–66; PX-190 at 216. *See* Tr. 648:9–649:17. That is, through the use of chromium in a specific molar ratio with other components, CeramTec made “it possible for the *first time* to achieve hardness values such as *have not previously been achieved* at such zirconium dioxide contents[.]” DX-423 at 9, col. 3:61–64 (emphasis added).

By this language, chromium was not some minor or useless aspect of the ‘816 patent, nor some minor component of BIOLOX Delta. Rather, just as the expired patents and MDI’s statements in procuring them revealed to the Supreme Court that the dual-spring feature at issue in *TrafFix* was the “central advance” therein claimed, the ‘816 patent and CeramTec’s prosecution history similarly illustrate that chromium in the ‘816 patent, and therefore the chromium in BIOLOX Delta, “is the reason the device works.” *TrafFix*, 532 U.S. at 30. As such, the ‘816 patent establishes that chromium in BIOLOX Delta is “functional” because it is an essential component of that product. *See id.* (“In the case before us, the central advance claimed in the expired utility patents . . . is the dual-spring design; and the dual-spring design is the essential feature of the trade dress MDI now seeks to establish and to protect. The rule we have explained bars the trade dress claim, for MDI did not, and cannot, carry the burden of overcoming the strong evidentiary inference of functionality based on the disclosure of the dual-spring design in the claims of the expired patents.”). For this reason alone, CeramTec cannot obtain trade dress protection on chromium’s pink color in BIOLOX Delta. *See id.*

2. Additional Evidence of Chromium's Functionality.

But, as I have indicated, there is more. Roughly four years after it obtained the '816 patent, CeramTec applied for and obtained another patent on ceramic materials: the '957 patent. *See* PX-142. Like the '816 patent, the '957 patent similarly claimed the use of chromium in ceramic composites. *See id* at 6, col. 9:31–46; Tr. 467:14–468:8. It too explained the essential role chromium plays in ZTA ceramics, echoing the '816 patent in stating that the addition of chromium in ZTA ceramics “counteracts any drop in the hardness values when the proportion of zirconium dioxide rises.” PX-142 at 4, col. 5:41–44. Furthermore, years later, CeramTec obtained yet another patent (the '970 patent) and applied for one more that both similarly teach the use of chromium in producing ZTA ceramics. *See* PX-550 (the '970 patent), claims 1, 20; PX-551 (U.S. Patent Publ. No. 2012/0142237), claim 8.

While CeramTec does not practice either of these latter two issued patents in producing BIOLOX Delta, they are nonetheless telling. They reveal that up until this litigation commenced, or at least up until CeramTec decided to claim trade dress protection on chromium's pink color one year earlier, the company's stated position was that chromium affected the quality of ZTA ceramics by increasing their hardness and that chromium was therefore a functional component of these products.

Indeed, CeramTec's own paper trail bears this out. Over the span of roughly two decades, during which time the company now tells us that it discovered “data points” that chromium might *not* be functional, CeramTec made no less than six FDA filings, published additional research, and distributed training and marketing materials that all maintained that chromium “affects the quality” of BIOLOX Delta by making it harder. *See, e.g.*, PX-79 at 6; PX-86 at 6; PX-87 at 26–27; PX-22 at 6; PX-82; PX-88; PX-84 at 26; PX-166 at 34; Tr. 1151:4–

14; 2029:1–9; Tr. 223:4–231:1; PX-429; PX-129. For this additional, but related, reason, I find that chromium is a functional component of BIOLOX Delta.

CeramTec nevertheless makes two principal counter-arguments why the pink color of chromium is actually a non-functional component of BIOLOX Delta. I discuss both in turn.

3. **Counter-Argument #1: Even if Chromium is Functional, its Pink Color is Not.**

CeramTec’s first argument attempts to thread the needle. It distinguishes between chromium and chromium’s pink color, arguing that while the former may be a functional feature of BIOLOX Delta, the latter is not because it is merely ornamental, incidental, or arbitrary.⁶ In that vein, CeramTec argues that the “pink” color of BIOLOX Delta should be considered similar to other non-functional colors of products—for instance, the “pink” color of insulation that the Federal Circuit deemed non-functional in *In re Owens-Corning Fiberglas Corporation*. See 774 F.2d at 1123–24. This argument, however, is unconvincing for two reasons.

First, the comparison is faulty. As the Federal Circuit noted in *In re Owens-Corning Fiberglas Corporation*, the pink color of the company’s insulation was non-functional because it bore “no relationship to production of fibrous glass insulation.” *Id.* at 1123 (emphasis added). Rather, it was a color that the company “uniformly applied” to the insulation during production simply for trademark purposes. *Id.*; see also, e.g., *Ideal Toy Corp. v. Plawner Toy Mfg. Corp.*, 685 F.2d 78, 81 (3d Cir. 1982) (finding the district court did not err when it determined that the colors of the panels on a Rubik’s Cube were “non-functional” as the colors themselves bear no relationship to the underlying puzzle because the point of the game was to “end where one has begun,” meaning the colors used were arbitrary).

⁶ CeramTec points out that while chromium was claimed in the ‘816 patent, its pink color was not. As discussed *infra*, however, that is a distinction without a difference.

By contrast, chromium's pink color is the natural byproduct of the chromium that is used in the production of BIOLOX Delta. Dr. Kuntz, CeramTec's manager of oxide development, admitted this fact at trial. Tr. 1127:3–4 (“Q: BIOLOX Delta is pink because it has chromium, correct? A: Yes, it is correct.”). Thus, one cannot logically separate the chromium, which is a functional component, from the color that it produces. Moreover, unlike in *In re Owens-Corning Fiberglas Corporation*, I find that there is no credible evidence that CeramTec initially decided to make its product “pink” purely because it wanted to attempt to use that color later on for trademark or trade dress purposes. Rather, CeramTec chose to introduce chromium in this ZTA ceramic product because the research, much of which the company conducted, showed that chromium counteracted a drop in hardness caused by increasing concentrations of zirconium, and because that was ultimately its means of obtaining the patent. Thus, chromium's “pink” color in BIOLOX Delta is not some arbitrary design flourish. Rather, it is a feature fundamentally related to the underlying product it adorns.

But CeramTec's attempt to distinguish chromium's pink color is also unpersuasive for an additional reason: it turns trade dress protection on its head. *See, e.g., Leatherman Tool Grp., Inc. v. Cooper Indus., Inc.*, 199 F.3d 1009, 1013 (9th Cir. 1999). The Ninth Circuit explained it well. Dealing with an argument that the overall design of a multi-function pocket tool could be distinguished from the functional components (i.e. the tools) comprising it, the court noted that “it is semantic trickery to say that there is still some sort of separate ‘overall appearance’ [of the product] which is non-functional.” *Id.* It reasoned that “[i]f it is permissible to draw a distinction between . . . [a functional] object and its ‘general appearance,’ then virtually nothing is utilitarian, and virtually the only product designs which could be copied faithfully are those

which are widely used and therefore in the public domain.” *Id.* The Ninth Circuit considered this to be an untenable outcome. *See id.* I agree.

Consider the implications. If CeramTec is correct that the general appearance of a functional feature can be distinguished from the underlying functional object, then the “orange” color of orange juice can be distinguished from the orange fruit used to make it. By that logic, Tropicana, Minute Maid, or any other orange juice company could obtain trade dress protection on an “orange-colored” fruit juice made from oranges, asserting that while the orange fruits used to make the juice are functional, their attendant “orange color” is merely incidental. As a result, one orange juice company could prevent all others from producing “orange-colored” orange juice.

4. **Counter-Argument #2: Chromium does not Actually Increase Hardness.**

CeramTec’s second main contention is that despite the large amount of evidence of chromium’s functionality, much of which CeramTec produced, the science now suggests that chromium does *not* increase hardness and therefore that chromium is actually a non-functional component of BIOLOX Delta.⁷ In making this argument, CeramTec highlights the “data points”

⁷ Within its second argument CeramTec makes another attempt at threading the needle, contending that while chromium may be functional when present in certain quantities, the small amount of Chromium used in BIOLOX Delta (0.33%) is non-functional. Tr.1022:23–1023:7 (“[T]here is a level of chromium content which gives an impact [on hardness]. We understand so far, from our own experiments, that this level is at least at the range of 0.5 percent[.]”). However, as explained *infra*, I find that CeramTec cannot overcome the bulk of evidence in this case, especially the prior patents that reveal that chromium, even when present in the small quantity that exists in BIOLOX Delta, is functional. *See, e.g.*, PX-550 at 3, col. 3:15, col. 4:27–29.

Similarly, I find unconvincing CeramTec’s assertion that chromium is “non-functional” because a “drop” in hardness caused by zirconium, which chromium corrects, “does not constitute a disturbing effect” in some materials. *See* PX-142 at 7:14–18. First, as this language from the ‘957 patent reveals, whether or not a drop in hardness is “disturbing” is very context-specific. Here, in the context of ceramic hip implants, the evidence shows that it actually can be. *See, e.g.*, Tr. 454:20–3 (noting that suffering a drop in hardness was a “disturbing effect” for ceramic hip ball implants). Furthermore, CeramTec’s argument on this point is unpersuasive because even an answer to a “non-disturbing” problem can still constitute a functional solution to that issue. That is, as the Supreme Court’s alternative definitions of functionality

of contrary research from the 2000s, but it leans most heavily on the White Paper published in 2014 by CeramTec’s own Dr. Meinhard Kuntz, in which Dr. Kuntz concludes that the level of chromium present in BIOLOX Delta does not have an impact on the hardness of that product. *See* DX-228. However, for two reasons I find this attempt to put the toothpaste back in the tube unavailing.

First, CeramTec’s argument is of questionable foundation. As mentioned above, it relies strongly on Dr. Kuntz’s 2014 White Paper. The authority of that research, however, was significantly undermined at trial by numerous witnesses whom picked apart the experiment’s methodology and conclusions.⁸ *See, e.g.*, Tr. 680:24–681:2 (“[I]t’s not really a believable article to take away all of the years of research that suggest [chromium increases hardness].”). Furthermore, as already described above, CeramTec’s newfound position on chromium clashes with the vast majority of evidence in this case, including the ‘816 patent and CeramTec’s own decades-long paper trail. *See supra* Parts II.C.1–2. As I said, I did not find CeramTec’s position (or Dr. Kuntz’s testimony) to be credible, as it was plainly slanted to achieve a litigation objective. Accordingly, I find that CeramTec simply fails to carry its resulting “heavy burden” of proving chromium’s non-functionality. *See TrafFix*, 532 U.S. at 30.

D. Estoppel.

Finally, even if science conclusively proved that the chromium in BIOLOX Delta does not in fact achieve any increase in hardness (which was not conclusively proved in this case), I conclude that CeramTec is estopped from denying that chromium is functional based on the

reveal, a component of a product can still be functional even if it is not *essential* to a product so long as it affects its “cost” or “quality.” *See supra* Part II.A.

⁸ CeramTec also contends that C5 has used chromium in Cerasurf-p *solely* as a means of mimicking BIOLOX Delta’s pink color, which suggests that chromium is nonfunctional because C5 believes chromium does not have any purported effect on ceramic hardness. Assuming for the sake of argument that this allegation is indeed true, it simply fails to tip the balance of the analysis in CeramTec’s favor.

contrary language of the various patents, the representations it made to the Patent Office to obtain the patents, and its representations to the FDA, its representations to its customers and potential customers, and its representations in scientific papers, all made during the period that CeramTec was enjoying the monopoly created by the '816 patent. *Cf. Disc Golf Ass'n, Inc. v. Champion Discs, Inc.*, 158 F.3d 1002, 1008 (9th Cir. 1998) (“A trademark proponent cannot create an issue of material fact regarding . . . [a feature’s] functionality, and thus survive summary judgment, by contradicting an earlier assertion contained in an expired utility patent that the [feature] is functional. ‘A kind of estoppel arises. That is, one cannot argue that a shape is functionally advantageous in order to obtain a utility patent and later assert that the same shape is non-functional in order to obtain trademark protection.’”) (quoting McCarthy, § 7:89.30); *see also Eco Mfg. LLC v. Honeywell Int’l, Inc.*, 295 F. Supp. 2d 854, 872 (S.D. Ind. 2003), *aff’d sub nom. Eco Mfg. LLC v. Honeywell Int’l, Inc.*, 357 F.3d 649 (7th Cir. 2003) (finding the round design of Honeywell International, Inc.’s thermostat was functional on estoppel grounds based on “sworn claims of the round shape’s utility that Honeywell made to secure issuance of” a claim in its prior patent on the product).

ORDER

The undisputed evidence established that BIOLOX Delta hip implant components produced by CeramTec are excellent products. The evidence also established that CeramTec spent many years developing a reputation for quality with OEMs, hospitals and surgeons, and that today many surgeons associate the color pink with CeramTec’s products. But for the reasons discussed above, this is an instance where copying is not foreclosed by what otherwise would be protection of trade dress. Accordingly, the Court enters the following orders:

1. The Court directs that judgment enter in favor of C5 and against CeramTec on Counts I and III of C5's First Amended Complaint. ECF No. 124. Because the Court has found that the use of chromium oxide in BIOLOX Delta is functional, and alternatively because the Court has found that CeramTec is estopped from denying its functionality, and because the color pink is the natural byproduct of the use of chromium oxide, the Court declares that CeramTec cannot and therefore does not own any trademark or trade dress rights in the color pink. The Court further declares that plaintiffs are not infringing upon any purported rights in the color pink, and that plaintiffs are not competing unfairly by marketing ceramic hip implant components that have the same or similar pink color as CeramTec hip implant components. I assume that, based on these findings and conclusions, United States Supplemental Registration Nos. 4,319,095 and 4,319,096 will be cancelled, although I do not directly so order because the United States Patent & Trademark Office is not a party to this case. CeramTec is enjoined from seizing C5's products or otherwise interfering with plaintiffs' efforts to market pink orthopedic products based upon any claim of trademark or trade dress protection for the color pink. Count II of the First Amended Complaint is deemed moot in light of the Court's resolution of Counts I and III.

2. Judgment will also enter in favor of C5 and against CeramTec on its counterclaims against C5 (asserting federal trademark infringement, federal unfair competition, common law trademark infringement under Colorado law, common law unfair competition under Colorado law, and deceptive business practices under Colorado law as set forth at ECF No. 191). Those claims are dismissed with prejudice.

3. The Court finds that the C5 is the prevailing party for purposes of Fed. R. Civ. P. 54(d)(1). It may apply for an award of costs to be taxed by the Clerk of Court as provided in D.C.COLO.LCivR (local rule) 54.1.

DATED this 5th day of January, 2017.

BY THE COURT:

A handwritten signature in black ink, appearing to read "R. Brooke Jackson". The signature is written in a cursive style with a long, sweeping tail that extends to the right.

R. Brooke Jackson
United States District Judge