

**UNITED STATES DISTRICT COURT  
 FOR THE NORTHERN DISTRICT OF ALABAMA  
 SOUTHERN DIVISION**

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| <b>D. BLAINE LEEDS DDS, et al.,</b>                      | } |                                    |
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| <b>Plaintiffs,</b>                                       | } |                                    |
|  | } |                                    |
| <b>v.</b>  | } | <b>Case No.: 2:18-cv-01679-RDP</b> |
|  | } |                                    |
| <b>BOARD OF DENTAL EXAMINERS OF<br/>ALABAMA, et al.,</b> | } |                                    |
|  | } |                                    |
| <b>Defendants.</b>                                       | } |                                    |

**MEMORANDUM OPINION**

In September 2018, the Board of Dental Examiners of Alabama (“Board” or “Dental Board”) sent a cease-and-desist letter to SmileDirectClub, LLC (“SmileDirect”). The letter and subsequent communications from the Board informed SmileDirect that certain services it performs for customers at its Alabama shop can only be performed at facilities where a licensed dentist is physically present. Because SmileDirect does not have a licensed dentist physically present at its facility, the Board considers SmileDirect’s nondentist personnel to be engaged in the unauthorized practice of dentistry. It therefore ordered SmileDirect to immediately cease performing those services without a supervising dentist present at the facility.

SmileDirect and one of its affiliated dentists, Dr. Blaine Leeds, claim that the Board’s actions violate federal and state law. They filed this action against the Board and its members (in their official and individual capacities). SmileDirect and Dr. Leeds (“Plaintiffs”) seek (1) an injunction forbidding the Board and its members (“Defendants”) from requiring SmileDirect to have a dentist physically present at its facility and (2) a declaration that Defendants’ conduct is unlawful. (Doc. # 29 at 46). Defendants have moved to dismiss Plaintiffs’ claims for lack of

subject matter jurisdiction and failure to state a claim. (Doc. # 32); *see* Fed. R. Civ. P. 12(b)(1), 12(b)(6). After careful consideration, and for the reasons explained below, the court concludes that the motion (Doc. # 32) is due to be granted in part and denied in part.

## I. Background<sup>1</sup>

SmileDirect operates a web-based teledentistry platform that connects patients seeking clear aligner therapy with licensed dentists. (Doc. # 29 at ¶ 23). Dentists like Dr. Leeds contract with SmileDirect to provide certain support services that enable them to treat patients remotely, often across state lines. (*Id.*). The platform enables Dr. Leeds, who has an Alabama dental license but resides in Nashville, Tennessee, to provide corrective teeth realignment for patients in Alabama who have mild to moderate malocclusion (*i.e.*, improperly positioned teeth when the jaws are closed). (*Id.*).

SmileDirect's business model operates as follows. A prospective patient considering clear aligner therapy first visits one of SmileDirect's physical locations, known as "SmileShops." (*Id.* at ¶ 29). There, SmileDirect employees use an iTero device -- described by Plaintiffs as "essentially a wand with a camera" -- to rapidly take thousands of digital photographs of the patient's teeth and gums. (*Id.* at ¶ 30). The iTero is inserted into the patient's mouth "at varying angles to photograph the teeth and tissue." (*Id.* at ¶ 92).<sup>2</sup> The iTero does not use ionizing radiation, x-rays, or gamma rays; instead, it simply takes digital photographs. (*Id.* at ¶¶ 29-30). After each use of the iTero, SmileDirect employees remove and discard the disposable cover on

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<sup>1</sup> For purposes of ruling on Defendants' motion to dismiss, the court treats the factual allegations of the Amended Complaint (Doc. # 29) as true, but not its legal conclusions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009).

<sup>2</sup> Though the Amended Complaint does not expressly state that the iTero is inserted into the patient's mouth, Plaintiffs filed an affidavit in support of their motion for a temporary restraining order representing to the court that it is. (Doc. # 3-4 at 5, ¶¶ 8-9). Additionally, other statements in the Amended Complaint strongly imply that the iTero is inserted into the patient's mouth. (Doc. # 29 at ¶ 95) ("The iTero is also easy to clean between uses and thus presents no meaningful risk of cross-contamination as long as the person performing the photography removes and discards the disposable cover and wipes the wand with a disinfecting wipe after each use.").

the device and clean the wand with a disinfecting wipe. (*Id.* at ¶¶ 95-96). SmileDirect employees also take standard digital photographs of the patient's teeth and gums using a regular digital camera. (*Id.* at ¶ 31).

The iTero images are then sent to a dental lab, which creates a three-dimensional model of the prospective patient's teeth, bite, gums, and palate. (*Id.* at ¶¶ 32, 87). Dr. Leeds or another Alabama-licensed dentist then reviews the three-dimensional model -- along with the standard digital photographs, the patient's health and dental histories, and other pertinent information -- to decide whether clear aligner therapy may be appropriate. (*Id.* at ¶¶ 32-36). The dentist reviews these materials to identify any periodontal disease, cavities, or other conditions that would require further clearance or prevent the patient from receiving clear aligner therapy through SmileDirect. (*Id.* at ¶ 31). If the dentist determines clear aligner therapy is appropriate and the patient agrees, the dentist writes a prescription to a lab to have the clear aligners fabricated and shipped. (*Id.* at 2). The patient then receives a series of custom-made removable plastic retainers that are placed on the patient's teeth to move them in small increments until the desired positioning is achieved. (*Id.* at ¶ 23).

On September 20, 2018, the Board sent SmileDirect a cease-and-desist letter stating that SmileDirect was engaged in the unauthorized practice of dentistry. (*Id.* at ¶ 59). Plaintiffs allege the letter was sent in response to a complaint the Board received from a competing Alabama-licensed dentist about SmileDirect's operations. (*Id.* at ¶ 58). On October 3, 2018, representatives from SmileDirect met with the Board to explain the function of the iTero and their belief that its use does not constitute a dental procedure that would require the presence of a licensed dentist on site. (*Id.* at ¶ 61). Six days later, the Board emailed the following message to counsel for SmileDirect: "Thank you for coming by the Board office last week to discuss Smile Direct Club.

I reviewed the situation with the Board last Friday in detail. I was directed to inform you that your client immediately must cease and desist performing the services that are considered the practice of dentistry (i.e. digital imaging) without a supervising dentist present.” (*Id.* at ¶ 62). SmileDirect and Dr. Leeds responded by filing this lawsuit. (Doc. # 1).

The Board’s cease-and-desist letter and subsequent communications were based on certain provisions of the Alabama Dental Practice Act, Ala. Code § 34-9-1 *et seq.*, and a regulation promulgated by the Board pursuant to its authority to “[a]dopt rules and regulations to implement” the Act, *id.*, § 34-9-43(a)(10). The Act defines what constitutes the practice of dentistry in Alabama, stating in relevant part:

Any person shall be deemed to be practicing dentistry who does any of the following:

...

(7) Uses a roentgen, radiograph, or digital imaging machine for the purpose of making dental roentgenograms, radiographs, or digital images . . . .

*Id.*, § 34-9-6. However, the Act goes on to exempt certain practices that would otherwise fall within this definition from being considered the practice of dentistry:

Nothing in this chapter shall apply to the following practices, acts, and operations:

...

(5) The use of roentgen machines or other means for making radiographs, digital images, or similar records, of dental or oral tissues under the supervision of a licensed dentist or physician . . . .

*Id.*, § 34-9-7(a).

The Board contends the iTero is a “digital imaging machine” and that the images it produces are “digital images” within the meaning of Alabama Code § 34-9-6. (Doc. # 29 at ¶¶ 2,

62-68). It therefore understands persons who use the iTero to be practicing dentistry—unless they do so “under the supervision of a licensed dentist or physician.” Ala. Code § 34-9-7(a)(5).

The Board also claims SmileDirect’s use of an iTero violates one of the Board’s regulations. (Doc. # 29 at ¶¶ 2, 62-68). The regulation defines dental hygienists, dental assistants, and dental laboratory technicians as “[a]llied dental personnel” and identifies certain dentistry-related duties they are permitted to perform. Ala. Admin. Code 270-X-3-.10. Under the regulation, dental assistants and dental hygienists may “[m]ake dental radiographs or digital images.” *Id.* Importantly, however, all of the duties listed—including making digital images—are “[s]ubject to the prohibition that no intra-oral procedure can be performed unless under the direct supervision of a duly licensed dentist as defined by Board rule.” *Id.* “Direct supervision” is defined by another Board regulation as “supervision by a dentist who authorizes the intraoral procedure to be performed, is physically present in the dental facility and available during performance of the procedure, examines the patient during the procedure and takes full professional responsibility for the completed procedure.” Ala. Admin. Code 270-X-3-.06. Because SmileDirect employees make intraoral digital images using an iTero at a facility where no licensed dentist is physically present, the Board understands them to be engaged in the unauthorized practice of dentistry, in violation of Alabama Administrative Code 270-X-3-.10.

Plaintiffs contend that the Board’s actions against SmileDirect are not motivated by a desire to protect the public from the unauthorized practice of dentistry. Instead, Plaintiffs argue the Board -- which by statute consists of six dentists and one dental hygienist who are all selected by other members of the dental profession, Ala. Code § 34-9-40 -- seeks to protect Alabama dentists from competition by innovators like SmileDirect and Dr. Leeds, who provide clear aligner therapy at lower prices than traditional dentists. They claim that use of the iTero

poses no health or safety risks and that the Board's requirement that SmileDirect have a licensed dentist physically present at its SmileShops cannot be justified by anything besides economic protectionism. Plaintiffs therefore filed this lawsuit against the Board and each of its members (in their individual and official capacities), asserting claims under the Sherman Antitrust Act, U.S. Constitution, and Alabama Constitution. (Doc. # 29 at ¶¶ 107-185).

The Board and its members, for their part, claim that the physical-presence requirement serves important public health and safety purposes and that all of Plaintiffs' claims are due to be dismissed.

## **II. Legal Standard**

The Federal Rules of Civil Procedure require that a complaint provide "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The complaint must include enough facts "to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Pleadings that contain nothing more than "a formulaic recitation of the elements of a cause of action" do not satisfy Rule 8, and neither do pleadings that are based merely upon "labels and conclusions" or "naked assertion[s]" without supporting factual allegations. *Id.* at 555, 557. In deciding a Rule 12(b)(6) motion to dismiss, courts view the allegations in the complaint in the light most favorable to the nonmoving party. *Watts v. Fla. International Univ.*, 495 F.3d 1289, 1295 (11th Cir. 2007).

In considering a motion to dismiss, a court should "1) eliminate any allegations in the complaint that are merely legal conclusions; and 2) where there are well-pleaded factual allegations, 'assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.'" *Kivisto v. Miller, Canfield, Paddock & Stone, PLC*, 413 F. App'x 136, 138 (11th Cir. 2011) (quoting *Am. Dental Assn. v. Cigna Corp.*, 605 F.3d 1283, 1290 (11th Cir.

2010)). That task is context specific, and to survive the motion, the allegations must permit the court, based on its “judicial experience and common sense . . . to infer more than the mere possibility of misconduct.” *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). If the court determines that well-pleaded facts, accepted as true, do not state a claim that is plausible, the claims must be dismissed. *Twombly*, 550 U.S. at 570.

### **III. Analysis**

Plaintiffs assert claims under (1) the Sherman Antitrust Act, (2) the U.S. Constitution’s Dormant Commerce, Equal Protection, and Due Process Clauses, and (3) the Alabama constitutional provisions guaranteeing due process of law. They also request a declaratory judgment that the Board’s challenged conduct exceeded its authority under the Alabama Dental Practice Act. For the reasons explained below, the court concludes that Plaintiffs may proceed with their Sherman Act and Dormant Commerce Clause claims against the Board members in their official capacities. Before addressing Plaintiffs’ various claims, the court first deals with several threshold issues concerning sovereign immunity.

#### **A. The Board of Dental Examiners is Entitled to Sovereign Immunity**

As a threshold matter, the Board argues it is entitled to sovereign immunity under the Eleventh Circuit’s decision in *Versiglio v. Bd. of Dental Examiners of Alabama*, 686 F.3d 1290 (11th Cir. 2012). The court agrees. Plaintiffs’ claims against the Board itself are barred by sovereign immunity and must therefore be dismissed.

In *Versiglio*, the Eleventh Circuit held that the Board of Dental Examiners was an arm of the State of Alabama and therefore entitled to Eleventh Amendment immunity from a claim asserted under the Fair Labor Standards Act. 686 F.3d at 1291-93. The Eleventh Circuit based its decision on a ruling by the Alabama Supreme Court that the Board was an arm of the state

entitled to immunity from a breach-of-contract claim under Alabama's constitution. *See Ex parte Bd. of Dental Examiners of Alabama*, 102 So. 3d 368, 370, 386 (Ala. 2012). Though “[w]hether an agency qualifies as an arm of the state is a federal question with a federal standard,” the Eleventh Circuit observed that “whether that standard is met [is] determined by carefully reviewing how the agency is defined by state law.” *Versiglio*, 686 F.3d at 1291. Because the Alabama Supreme Court had defined the Board as an arm of the state for purposes of immunity under the Alabama constitution, and because federal courts give “great deference to how state courts characterize the entity in question,” the Eleventh Circuit held the Board immune from suit on a federal claim in federal court. *Id.* at 1292-93.

Plaintiffs argue that *Versiglio* does not bar their claims against the Board because the Board's challenged conduct in this case (enforcing a state statute and regulation) differs from its challenged conduct in *Versiglio* (incorrectly paying Board employees and miscalculating overtime wages). Plaintiffs are correct that under Eleventh Circuit precedent, “[w]hether an entity is an ‘arm of the state’ must be assessed in light of the particular function in which the entity was engaged when taking the actions out of which liability is asserted to arise.” *Walker v. Jefferson Cty. Bd. of Educ.*, 771 F.3d 748, 757 (11th Cir. 2014) (quoting *Manders v. Lee*, 338 F.3d 1304, 1308 (11th Cir. 2003) (en banc)) (internal quotation marks and brackets omitted). In *Walker*, for example, the Eleventh Circuit held that local school boards in Alabama were not arms of the state with respect to employment-related decisions like hiring, assignment, and compensation. *Id.* Thus, they were “not immune under the Eleventh Amendment from suits challenging those decisions under federal law.” *Id.* But the function-specific nature of Eleventh Amendment immunity does not help Plaintiffs in this case.

The Eleventh Circuit “uses four factors to determine whether an entity is an ‘arm of the State’ in carrying out a particular function: (1) how state law defines the entity; (2) what degree of control the State maintains over the entity; (3) where the entity derives its funds; and (4) who is responsible for judgments against the entity.” *Manders*, 338 F.3d at 1309. Though it did not expressly apply this four-factor test, the Eleventh Circuit in *Versiglio* squarely held that the Dental Board is immune from suits challenging the Board’s payment of overtime wages to its employees. *See Versiglio*, 686 F.3d at 1291-93; *see also Versiglio v. Bd. of Dental Examiners of Alabama*, 2010 WL 11520474, at \*1 (N.D. Ala. Aug. 27, 2010) (district court opinion describing *Versiglio*’s claim as one “for alleged unpaid overtime” under the FLSA). Thus, the only question even arguably presented here is whether the four-factor test calls for a different result with respect to the Board’s function of enforcing state statutes and regulations, which is the conduct Plaintiffs challenge in this lawsuit.

It is difficult to see how the first, third, and fourth factors could call for a different result when applied to the Board’s function of enforcing statutes and regulations instead of paying its employees. Plaintiffs have not suggested that state law defines the Board differently with respect to its regulatory and enforcement functions than it does with respect to its employee-payment functions. Nor have they argued that the source of the Board’s funds or the party responsible for judgments against it differ when the challenged conduct is the Board’s enforcement of statutes and regulations rather than its payment of employees. Instead, Plaintiffs argue the degree-of-control factor makes all the difference and “weighs decisively against a finding that the Dental Board is an arm of the state” when engaged in the conduct challenged in this lawsuit. (Doc. # 44 at 3). The court is unpersuaded.

Plaintiffs marshal a variety of arguments to show that the State of Alabama exercises little to no control over the Board with respect to the challenged activities in this lawsuit, namely, promulgating regulations and issuing cease-and-desist letters to enforce statutes and regulations. (*Id.* at 3-5). But given the Eleventh Circuit’s holding in *Versiglio*, the critical issue is not the absolute degree of control the state exercises over the Board’s challenged activities, considered in the abstract. The decisive question is whether the state exercises any *less* control over the Board’s rulemaking and enforcement functions than it does over the Board’s payment of its employees. After all, *Versiglio* necessarily held that whatever degree of control the state exercises over the Board with respect to its wage payments to employees is sufficient to render the Board an arm of the state as to that function.

Plaintiffs have offered no reason to think that the state exercises any less control over the Board’s rulemaking and enforcement functions than it does over the Board’s payment of employees, such that *Versiglio* can be persuasively distinguished—and the court is unable to think of one. Indeed, if anything, it seems likely that the state exercises *more* control over the Board’s rulemaking and enforcement decisions than it does over its wage payments to employees. For example, the Board’s rulemaking and enforcement authority is constrained by legislative guidelines. *See* Ala. Code § 34-9-43(a) (granting the Board authority to adopt rules and regulations “subject to” the provisions of Chapter 9 of the Alabama Code). The Alabama Legislature has defined what constitutes the practice of dentistry, *id.*, §§ 34-9-6 and 34-9-7, and Board regulations defining and regulating the practice of dentistry must “not conflict with any statute which defines the practice of dentistry,” *id.*, § 34-9-43.2(c). The Legislature has also limited the fine that may be imposed for violating a Board regulation to “not more than five thousand dollars . . . for each offense.” *Id.*, § 34-9-5. Finally, the Legislature has directed the

Legislative Services Agency to engage in some form of review of the Board's regulations, though the parties dispute the nature and extent of that review. *See id.*, § 41-22-22.1; (Docs. # 29 at ¶ 56; 33 at 6-9). In short, the state has established a number of mechanisms by which it exercises a degree of control over the Board's rulemaking and enforcement functions.

The Eleventh Circuit has found similar considerations relevant in concluding that a state exercised sufficient control over an entity to render it an arm of the state for sovereign immunity purposes. *See Miccosukee Tribe of Indians v. Fla. State Athletic Comm'n*, 226 F.3d 1226, 1232 (11th Cir. 2000) (“[Florida] has provided [legislative] guidelines to limit the Commission’s ability to make regulations and, consequently, has some control over the Commission’s rule making powers.”). But again, the question is not whether the measures described above would give Alabama sufficient control over the Board to render it an arm of the state as a matter of first principles. The question is how Alabama’s control over the Board’s rulemaking and enforcement functions compares to its control over the Board’s payment of employees, a function for which the Eleventh Circuit has already held that the Board is entitled to sovereign immunity. *See Versiglio*, 686 F.3d at 1291-93. A review of the Alabama Code reveals that the state has provided scant guidance to the Board on the subject of how it should pay its employees. Indeed, the only direction the Legislature has apparently given is that Board members “shall receive as compensation a sum to be fixed by the board”; that the secretary and secretary-treasurer shall each “receive such compensation as may be fixed by the board”; and that “[t]he board is authorized to expend such funds as shall be necessary . . . to pay salaries.” Ala. Code § 34-9-41. Thus, there can be no doubt that the control Alabama maintains over the Board’s rulemaking and enforcement functions is at least as great as (probably greater than) the control it exercises over the Board’s payment of its employees. *Versiglio* therefore controls this case.

Because *Versiglio* held the Board immune from a claim based on its payment of employees, that decision compels the conclusion that the Board is also immune from claims based on its rulemaking and enforcement decisions. The four-factor Eleventh Amendment immunity test does not yield a different result. If anything, the Board has a stronger claim to Eleventh Amendment immunity in this case than it did in *Versiglio*. Accordingly, all of Plaintiffs' claims against the Board itself are due to be dismissed under Rule 12(b)(1) for lack of subject matter jurisdiction. See *Edelman v. Jordan*, 415 U.S. 651, 678 (1974) (“[T]he Eleventh Amendment defense . . . partakes of the nature of a jurisdictional bar . . . .”); *Silver v. Baggiano*, 804 F.2d 1211, 1213 (11th Cir. 1986) (describing Eleventh Amendment immunity as “a jurisdictional issue”). As discussed below, however, some of Plaintiffs' claims may proceed against the Board members in their official capacities.

**B. Plaintiffs' Federal Claims Against the Board Members in Their Official Capacities Are Not Barred by Sovereign Immunity**

In addition to barring suits against the state itself, the Eleventh Amendment also bars suits against state officials “when the state is the real, substantial party in interest.” *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101 (1984) (internal quotation marks omitted). The state is the real party in interest “if the effect of the judgment would be to restrain the Government from acting.” *Id.* at 101 n.11 (internal quotation marks omitted). That is exactly what this lawsuit seeks to do. Plaintiffs seek an injunction forbidding the enforcement of state law against them and a declaration that the Board members' official conduct in this case is unlawful. (Doc. # 29 at 46). Thus, though Plaintiffs have nominally asserted their claims against the Board members, the real party in interest in this lawsuit is the State of Alabama. The Eleventh Amendment would ordinarily bar such a suit. *Pennhurst*, 465 U.S. at 100-102. But not here.

The Supreme Court has recognized an important exception to Eleventh Amendment immunity that applies here. Under the doctrine of *Ex parte Young*, 209 U.S. 123 (1908), the Eleventh Amendment does not bar suits seeking prospective relief against state officials to prevent them from violating federal law. *Id.* at 102. Here, even though the Eleventh Amendment bars Plaintiffs’ claims against the Board itself, Plaintiffs’ federal claims may proceed against the individual Board members in their official capacities pursuant to the doctrine of *Ex parte Young*.

“In determining whether the doctrine of *Ex parte Young* avoids an Eleventh Amendment bar to suit, a court need only conduct a straightforward inquiry into whether the complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective.” *Verizon Maryland, Inc. v. Pub. Serv. Comm’n of Maryland*, 535 U.S. 635, 645 (2002) (internal quotation marks and brackets omitted). Plaintiffs’ Amended Complaint (Doc. # 29) readily satisfies that standard. It seeks an injunction restraining the Board members from enforcing a state statute and regulation in contravention of controlling federal law—specifically, various provisions of the U.S. Constitution and the Sherman Antitrust Act. (Doc. # 29 at 46). It is well settled that a plaintiff may properly assert such claims for prospective injunctive and declaratory relief against state officials alleged to be violating federal law. *Verizon Maryland*, 535 U.S. 645-46. Moreover, prospective relief is equally available whether the law that state officials are allegedly violating is a federal statute (like the Sherman Act) or the Constitution. *See id.* (permitting suit for prospective relief against state officials alleged to be violating a federal statute and administrative order); *Doe 1-13 By & Through Doe, Sr. 1-13 v. Chiles*, 136 F.3d 709, 720-21 (11th Cir. 1998) (affirming prospective injunctive relief forbidding state officials from continuing to violate a federal statute); *Edelman v. Jordan*, 415 U.S. 651, 664 (1974) (explaining that *Ex parte Young* permits suits to enjoin state officials from prospectively violating the

Constitution). Plaintiffs' federal claims against the individual Board members fall squarely within the *Ex parte Young* exception to Eleventh Amendment immunity, and may therefore proceed.

Though *Ex parte Young* permits Plaintiffs' federal claims to proceed, it does not avoid an Eleventh Amendment bar to Plaintiffs' state-law claims. In *Pennhurst*, the Supreme Court held that *Ex parte Young* was "inapplicable in a suit against state officials on the basis of state law." 465 U.S. at 106. The Court therefore concluded "that a claim that state officials violated state law in carrying out their official responsibilities is a claim against the State that is [barred] by the Eleventh Amendment." *Id.* at 121. As a result, though official-capacity suits seeking prospective relief are permissible under *Ex parte Young* for violations of *federal* law, they are impermissible under the Eleventh Amendment for violations of *state* law. *Id.* at 103-06. The *Pennhurst* Court further held that even supplemental state-law claims against state officials brought alongside federal claims are likewise barred by the Eleventh Amendment. *Id.* at 117-21.

Here, *Pennhurst* bars Plaintiffs' state-law claims against the Board members. In Count Nine of the Amended Complaint, Plaintiffs seek a declaratory judgment that the Board members' enforcement of state law to require nondentists who use an iTero to be directly supervised by an on-site dentist violates Plaintiffs' right to due process under the Alabama Constitution. (Doc. # 29 at ¶ 185). In Count Ten, Plaintiffs seek a declaratory judgment that the Board members exceeded their authority under the Alabama Dental Practice Act by requiring nondentists who use an iTero to be directly supervised by an on-site dentist. (*Id.* at ¶ 192). The only difference between the relief sought here and the relief sought in *Pennhurst* is that Plaintiffs seek a declaratory judgment against the Board members for violations of state law, rather than an

injunction. But that slim difference in the relief sought does not take Plaintiffs' state-law claims against the Board members outside of the *Pennhurst* rule.

In *Pennhurst*, the Court reasoned that the Eleventh Amendment generally bars officer suits where the state is the real party in interest, regardless of the relief sought. 465 U.S. at 102 (“[A] suit against state officials that is in fact a suit against a State is barred regardless of whether it seeks damages or injunctive relief.”). Absent state consent to suit or congressional abrogation of immunity, the only route around this general bar to suit is the doctrine of *Ex parte Young*, which permits federal courts to order prospective relief against state officials for ongoing violations of federal law. *Id.* But *Pennhurst* held that *Ex parte Young* was “inapplicable in a suit against state officials on the basis of state law.” *Id.* Without *Ex parte Young*, then, any “claim that state officials violated state law in carrying out their official responsibilities is a claim against the State that is [barred] by the Eleventh Amendment.” *Id.* at 121. That includes claims for declaratory relief no less than claims for injunctive relief.

Though the relief sought in *Pennhurst* was an injunction ordering state officials to conform their conduct to state law, *Pennhurst*'s rule applies equally to a suit seeking a declaration that the conduct of state officials violates state law. *Pennhurst*'s rule was based on the idea that “it is difficult to think of a greater intrusion on state sovereignty than when a federal court instructs state officials on how to conform their conduct to state law.” *Id.* at 106. A judgment declaring that the conduct of state officials violates state law does just that. It is no less an intrusion on state sovereignty than an injunction forbidding the state officials' conduct. Under *Pennhurst*, the Eleventh Amendment bars declaratory relief based on alleged state-law violations no less than it does injunctive relief.

This conclusion follows inexorably from *Pennhurst*'s reasoning and is confirmed by Eleventh Circuit precedent. The Eleventh Circuit's decision in *Silver v. Baggiano*, 804 F.2d 1211 (11th Cir. 1986) is particularly instructive. *Silver* was a suit against a state official seeking both declaratory and injunctive relief for violations of state law. *Id.* at 1213. The Eleventh Circuit held that all of the claims based on state law were barred by the Eleventh Amendment. *Id.* at 1215. The court did not distinguish between the plaintiff's claims for injunctive relief and his claims for declaratory relief. *Id.* at 1214. Instead, it explained that either form of relief would run against the state and was therefore barred by the Eleventh Amendment. *Id.* ("A declaratory judgment *or* injunction against [the state official] would clearly compel the government of Alabama to act . . .") (emphasis added).<sup>3</sup>

As in *Silver*, a judgment declaring that the Board members' actions violate the Alabama Constitution or an Alabama statute would run against the State of Alabama. The "effect of the judgment would be to restrain the Government from acting," by preventing the enforcement of state laws against SmileDirect. *Pennhurst*, 465 U.S. at 101 n.11 (internal quotation marks omitted). That is precisely the type of relief the Eleventh Amendment forbids. *Id.* Accordingly, Plaintiffs' claims against the Board members in their official capacities for violating the Alabama Constitution and for exceeding their authority under the Alabama Dental Practice Act (Counts Nine and Ten) must be dismissed for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1).

Finally, Plaintiffs' individual-capacity claims against the Board members are also due to be dismissed. "In an official-capacity claim, the relief sought is only nominally against the official and in fact is against the official's office and thus the sovereign itself." *Lewis v. Clarke*,

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<sup>3</sup> *Silver* also held that removal of an action from state to federal court by state officials did not waive the officials' Eleventh Amendment immunity. 804 F.2d at 1214-15. That holding was later abrogated by *Lapides v. Bd. of Regents of Univ. Sys. of Georgia*, 535 U.S. 613 (2002). But *Silver* otherwise remains good law.

137 S. Ct. 1285, 1291 (2017). Individual-capacity claims, “on the other hand, seek to impose *individual* liability upon a government officer for actions taken under color of state law.” *Id.* (internal quotation marks omitted). In an individual-capacity claim, “the real party in interest is the individual, not the sovereign.” *Id.*

Here, Plaintiffs’ claims against the Board members are clearly of the official-capacity variety. Plaintiffs do not seek to impose personal liability upon the Board members by, for example, seeking an award of damages against the individual officers for their allegedly unlawful conduct. *Cf. Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388, 389-90 (1971). Nor do they seek to enjoin the Board members with respect to conduct “undertaken by individuals acting independently of their offices.” *United States v. Alabama*, 791 F.2d 1450, 1457 (11th Cir. 1986). Instead, Plaintiffs seek injunctive and declaratory relief that would forbid the Board members (or any of their successors, for that matter) from acting in their official capacities to enforce state law in a manner that requires SmileDirect to keep a licensed dentist on site when its employees use an iTero. (Doc. # 29 at 46). As discussed above, Plaintiffs’ requested relief would run against the state itself, not merely against the individual Board members. Accordingly, Plaintiffs’ individual-capacity claims against the Board members “fail[ ] to state a claim upon which relief may be granted” and must therefore be dismissed under Rule 12(b)(6). *Feit v. Ward*, 886 F.2d 848, 858 (7th Cir. 1989).<sup>4</sup>

Plaintiffs argue that their individual-capacity antitrust claims against the Board members are valid and should not be dismissed because the Board members are active market participants

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<sup>4</sup> Plaintiffs concede as much with respect to their federal and state constitutional claims against the Board members. In their motion to dismiss, the Board members asked the court to dismiss *all* of Plaintiffs’ individual-capacity claims. (Doc. # 33 at 29). In response to that motion, Plaintiffs argued only that their individual-capacity *antitrust* claims should go forward. (Doc. # 41 at 25). They did not dispute that their individual-capacity constitutional claims should be dismissed. (*Id.*). Thus, Plaintiffs have abandoned their non-antitrust individual-capacity claims by failing to address the Board members’ arguments that they should be dismissed. *See Chambers v. Cherokee Cty.*, 743 F. App’x 960, 962 (11th Cir. 2018).

with an incentive to pursue their own self-interests under the guise of implementing state policies. (Doc. # 41 at 25). Plaintiffs contend the Board members can therefore “be held individually accountable” for violating the antitrust laws. (*Id.*).

That might well be true. In *North Carolina State Board of Dental Examiners v. F.T.C.*, the Supreme Court left open “the question whether agency officials, including board members, may, under some circumstances, enjoy immunity from [antitrust] *damages* liability.” 135 S. Ct. 1101, 1115 (2015) (emphasis added). Thus, it is at least possible that the Board members could be held personally liable in damages for using their office to violate the antitrust laws. (To be clear, the court takes no position on that question at this time). But the fact remains that, in this case, Plaintiffs have not *sought* relief against the Board members in their individual capacities. Instead, all of Plaintiffs’ requested relief (an injunction forbidding the Board members from enforcing state law and a judgment declaring the Board members’ official conduct unlawful) would run against the state, not against the individual Board members. Accordingly, Plaintiffs’ individual-capacity antitrust claims must be dismissed under Rule 12(b)(6). *See Feit*, 886 F.2d at 858.

To sum up: All of Plaintiffs’ claims against the Board itself are barred by sovereign immunity. Plaintiffs’ state-law claims against the Board members in their official capacities are likewise barred by sovereign immunity under *Pennhurst*. Additionally, because Plaintiffs’ requested relief would run against the state, not the individual Board members, all of their individual-capacity claims fail to state a claim and are due to be dismissed. However, Plaintiffs’ federal claims for prospective equitable relief against the Board members in their official capacities are not barred by sovereign immunity. The court therefore proceeds to address

whether Plaintiffs have stated a claim against the Board members in their official capacities under the various provisions of federal law they claim the Board members are violating.

**C. Plaintiffs Have Stated a Claim Against the Board Members Under the Sherman Act**

Both Dr. Leeds and SmileDirect assert section 1 Sherman Act claims against the members of the Dental Board. (Doc. # 29 at 1, 29, 32). The Board members respond that these claims should be dismissed because they are entitled to state-action immunity from Sherman Act claims under *Parker v. Brown*, 317 U.S. 341 (1943) and its progeny. For the reasons explained below, the court concludes a definitive ruling on *Parker* immunity would be premature at this time. Plaintiffs' Sherman Act claims, as pleaded, are sufficient to survive a Rule 12(b)(6) motion to dismiss on *Parker* immunity grounds. Further factual development will be required to determine whether the Board members are entitled to *Parker* immunity. The Board members may therefore raise the *Parker* immunity defense at a later stage in this litigation, in a motion for summary judgment, if appropriate.

**1. Legal Framework**

The federal antitrust laws provide an important safeguard for our free-market economy. *North Carolina State Bd. of Dental Examiners v. F.T.C.*, 135 S. Ct. 1101, 1109 (2015) (“*N.C. Dental*”). Indeed, the antitrust laws “are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms.” *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972). To this end, “[t]he antitrust laws declare a considered and decisive prohibition by the Federal Government of cartels, price fixing, and other combinations or practices that undermine the free market.” *N.C. Dental*, 135 S. Ct. at 1109.

Despite the liberal federal policy favoring competition embodied in the Sherman Act, states have long chosen to regulate certain spheres of their economies in ways that restrict competition, in order to promote other important values. For example, states sometimes “impose restrictions on occupations, confer exclusive or shared rights to dominate a market, or otherwise limit competition to achieve public objectives.” *Id.* The Supreme Court has long recognized that “[i]f every duly enacted state law or policy were required to conform to the mandates of the Sherman Act, thus promoting competition at the expense of other values a State may deem fundamental, federal antitrust law would impose an impermissible burden on the States’ power to regulate.” *Id.* For that reason, the Supreme Court in *Parker* “interpreted the antitrust laws to confer immunity on anticompetitive conduct by the States when acting in their sovereign capacity.” *N.C. Dental*, 135 S. Ct. at 1110. This doctrine has come to be known as *Parker* or state-action immunity from the federal antitrust laws.

*Parker* immunity exists to avoid conflicts between the federal policy of robust competition embodied in the Sherman Act and a state’s sovereign authority to regulate local activities (even in anticompetitive ways) to promote the health, safety, and morals of its citizens. *Id.* For that reason, “[a]n entity may not invoke *Parker* immunity unless the actions in question are an exercise of the *State’s* sovereign power.” *Id.* (emphasis added). State legislation automatically qualifies as an exercise of the state’s sovereign power and is “*ipso facto* . . . exempt from the operation of the antitrust laws.” *Id.* (internal quotation marks omitted) (quoting *Hoover v. Ronwin*, 466 U.S. 558, 568 (1984)). But *Parker* immunity does not always apply when a state delegates regulatory authority to a nonsovereign actor, instead of regulating itself by legislation. In that case, anticompetitive conduct by the nonsovereign actor receives *Parker* immunity only if the conduct results “from procedures that suffice to make [the anticompetitive

conduct] the State’s own.” *Id.* at 1111. In other words, the question is whether the nonsovereign actor’s anticompetitive conduct “should be deemed *state* action and thus shielded from the antitrust laws.” *Id.* (internal quotation marks omitted) (emphasis added).

For purposes of *Parker* immunity, “a nonsovereign actor is one whose conduct does not automatically qualify as that of the sovereign State itself.” *Id.* Perhaps counterintuitively,<sup>5</sup> even state agencies may qualify as nonsovereign actors for purposes of *Parker* immunity, particularly where they are controlled by active participants in the regulated market. *Id.* at 1111. Indeed, limits on *Parker* immunity “are most essential” when the state delegates its regulatory power “to active market participants,” because active market participants may be incentivized to regulate in a manner that promotes their own private interests instead of the state’s policy goals. *Id.*

Deciding whether a nonsovereign actor is enforcing state policy or furthering private interests can be a difficult task, especially where the nonsovereign actor is controlled by active market participants. Thus, the Supreme Court has held that a nonsovereign actor controlled by active market participants enjoys *Parker* immunity only if it satisfies both elements of the two-part test set forth in *California Retail Liquor Dealers Ass’n v. Midcal Aluminum, Inc.*, 445 U.S. 97 (1980). *N.C. Dental*, 135 S. Ct. at 1110-12. Under the *Midcal* test, anticompetitive conduct by a nonsovereign actor receives *Parker* immunity only if (1) the state has articulated a clear policy to allow the anticompetitive conduct; and (2) the state provides active supervision of the anticompetitive conduct. *Id.* at 1112.

*Midcal*’s clear-articulation requirement is met “where the displacement of competition is the inherent, logical, or ordinary result of the exercise of authority delegated by the state legislature.” *Id.* (internal quotation marks omitted). And, the active-supervision requirement demands, among other things, “that state officials have and exercise power to review particular

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<sup>5</sup> See *N.C. Dental*, 135 S. Ct. at 1117-18 (Alito, J., dissenting).

anticompetitive acts of private parties and disapprove those that fail to accord with state policy.” *Id.* (internal quotation marks omitted).

The Supreme Court applied these principles in *N.C. Dental* to conclude that the North Carolina State Board of Dental Examiners was not entitled to *Parker* immunity for its regulation of teeth whitening services provided by nondentists. *Id.* at 1116-17. The North Carolina Dental Board was quite similar to Alabama’s Dental Board in its powers, duties, and composition. North Carolina’s Board was empowered by statute to regulate the practice of dentistry. *Id.* at 1107. North Carolina’s Dental Practice Act required six of the Board’s eight members to be licensed dentists engaged in the active practice of dentistry. *Id.* at 1108. Those members were elected by other North Carolina dentists in elections conducted by the Board. *Id.* The other two Board members were a practicing dental hygienist (elected by other licensed hygienists) and a nondentist “consumer” (who was appointed by the governor). *Id.*

North Carolina’s Dental Practice Act authorized the Board to promulgate rules and regulations governing the practice of dentistry in North Carolina, provided they were not inconsistent with the Act and were approved by the North Carolina Rules Review Commission, whose members were appointed by the state legislature. *Id.* The Board was also required to comply with North Carolina’s Administrative Procedure Act, Public Records Act, and open-meetings law. *Id.*

Dentists in North Carolina began offering teeth whitening services in the 1990s. *Id.* By 2003, nondentists began competing with dentists in the teeth whitening market, often charging lower prices for their services than the dentists did. *Id.* Dentists complained to the Board about their new competitors, and the Board opened an investigation into nondentist teeth whitening. *Id.* The investigation did not result in the promulgation of a formal rule or regulation reviewable by

North Carolina's Rules Review Commission, even though the Dental Practice Act did not, "by its terms, specify that teeth whitening is 'the practice of dentistry.'" *Id.* Instead, the Board began issuing cease-and-desist letters to nondentist teeth whiteners. *Id.* The letters directed the nondentists to cease their teeth whitening services because teeth whitening constituted the practice of dentistry, which the nondentists were not authorized to engage in. *Id.* As a result of the Board's actions, "[n]ondentists ceased offering teeth whitening services in North Carolina." *Id.*

When the Federal Trade Commission charged the Board with violating federal antitrust law through these actions, the Board asserted the defense of *Parker* immunity. *Id.* at 1110. The Supreme Court rejected that argument, however. The Court ruled that the Board, despite its status as a state agency, was a nonsovereign actor controlled by active market participants. *Id.* at 1110-11. The Court therefore held that the Board must satisfy both the clear-articulation and active-supervision prongs of *Midcal* to receive *Parker* immunity for its regulation of nondentist teeth whitening. *Id.* at 1110, 1112. The Court assumed without deciding that the clear-articulation requirement was satisfied but held that the Board "did not receive active supervision by the State when it interpreted the Act as addressing teeth whitening and when it enforced that policy by issuing cease-and-desist letters to nondentist teeth whiteners." *Id.* at 1110. Because the Board failed to show active state supervision, it could not invoke *Parker* immunity. *Id.*

In holding that the Board failed to satisfy *Midcal*'s active-supervision requirement, the Court relied heavily on the fact that the statute the Board was purportedly enforcing with its cease-and-desist letters said "nothing about teeth whitening, a practice that did not exist when it was passed." *Id.* at 1116. Additionally, when the Board decided to take action against nondentist teeth whiteners, it "relied upon cease-and-desist letters threatening criminal liability, rather than

any of the powers at its disposal that would invoke oversight by a politically accountable official.” *Id.* at 1116. “With no active supervision by the State,” the Court concluded that state officials “may well have been unaware that the Board had decided teeth whitening constitutes ‘the practice of dentistry’ and sought to prohibit those who competed against dentists from participating in the teeth whitening market.” *Id.* In short, because there was “no evidence [ ] of any decision by the State to initiate or concur with the Board’s actions against the nondentists,” the North Carolina Dental Board failed *Midcal*’s active-supervision requirement.

In reaching this conclusion, the Court explained that the active-supervision inquiry “is flexible and context-dependent.” *Id.* The key question “is whether the State’s review mechanisms provide realistic assurance that a nonsovereign actor’s anticompetitive conduct promotes state policy, rather than merely the party’s individual interests.” *Id.* (internal quotation marks omitted). The “few constant requirements of active supervision” are that the state supervisor: “review the substance of the anticompetitive decision, not merely the procedures followed to produce it”; “have the power to veto or modify particular decisions to ensure they accord with state policy”; and “not itself be an active market participant.” *Id.* at 1116-17 (internal quotation marks omitted). Beyond that, however, “the adequacy of supervision . . . will depend on all the circumstances of a case.” *Id.* at 1117.

## **2. N.C. Dental Applies to the Alabama Dental Board**

The rule announced in *N.C. Dental* -- that certain state entities must satisfy *Midcal*’s two-part test to claim *Parker* immunity -- applies to “nonsovereign actor[s] controlled by active market participants.” 135 S. Ct. at 1110. In *N.C. Dental*, the Supreme Court squarely held that North Carolina’s Dental Board was such a nonsovereign actor, despite its status as a state agency. *Id.* at 1110-11. The powers, duties, and composition of Alabama’s Dental Board are

nearly identical to those of the North Carolina Dental Board the Supreme Court considered in *N.C. Dental*. Both Boards are created by state law and empowered by the state to regulate the practice of dentistry and enforce the state’s prohibition of the unauthorized practice of dentistry. Ala. Code §§ 34-9-40, 34-9-43; *N.C. Dental*, 135 S. Ct. at 1107. Both Boards are comprised of a controlling number of active participants in the market for dental services, who are in turn selected by other members of the dental profession. Ala. Code § 34-9-40; *N.C. Dental*, 135 S. Ct. at 1108. Neither North Carolina’s nor Alabama’s Dental Practice Act creates a mechanism by which Board members may be removed from office by other state officials. Ala. Code § 34-9-40; *N.C. Dental*, 135 S. Ct. at 1108. And both Boards are empowered to promulgate rules and regulations governing the practice of dentistry, provided those mandates are not inconsistent with a state statute. Ala. Code § 34-9-43.2(c); *N.C. Dental*, 135 S. Ct. at 1108. The similarities between the two Boards compel the conclusion that the Alabama Board is also a “nonsovereign actor controlled by active market participants” for purposes of *Parker* immunity, and that the principles set forth in *N.C. Dental* therefore apply to it. *Id.* at 1110.

There might appear to be some tension in treating Alabama’s Dental Board as a *nonsovereign* actor for purposes of *Parker* immunity while simultaneously holding, as discussed above, that the Board is an arm of the state entitled to *sovereign* immunity under *Versiglio*, 686 F.3d at 1291. But that tension is simply a consequence of the fact that different tests govern whether an entity is considered “sovereign” for purposes of *Parker* immunity and Eleventh Amendment immunity, and of the reality that this court is bound by both the Supreme Court’s decision in *N.C. Dental* and the Eleventh Circuit’s decision in *Versiglio*.

The Supreme Court has provided little guidance on what entities qualify as “nonsovereign actors” for purposes of *Parker* immunity. But in *N.C. Dental*, the Court did cite

*Hoover*, 466 U.S. at 567-68 for the following proposition: “For purposes of *Parker*, a nonsovereign actor is one whose conduct does not automatically qualify as that of the sovereign State itself.” 135 S. Ct. at 1111. The portion of *Hoover* cited by the Court identified two state entities that were “sovereign” for purposes of *Parker* immunity and whose conduct therefore automatically qualified as the conduct of the state: the state legislature and the state supreme court when acting legislatively rather than judicially. *Hoover*, 466 U.S. at 567-68. The *Hoover* Court expressly left open the question “whether the Governor of a State stands in the same position as the state legislature and supreme court for purposes of the state-action doctrine.” *Id.* at 568 n.17. Thus, sovereign actors for purposes of *Parker* immunity appear to be limited to governmental bodies like a state legislature or supreme court (or perhaps the governor) that constitute the apex of a coequal branch of state government. But whatever the limits of that category, as *N.C. Dental* makes abundantly clear, “[s]tate agencies are not simply by their governmental character sovereign actors for purposes of state-action immunity.” 135 S. Ct. at 1111. Accordingly, their actions are not automatically cloaked in *Parker* immunity.

The test for determining what state entities are “arms of the state” entitled to sovereign immunity under the Eleventh Amendment is different. As described above, the Eleventh Circuit employs a four-factor test to determine whether a state agency is an arm of the state with respect to a particular function it performs. *See Manders*, 338 F.3d at 1309. Because of the different tests that apply, it is possible for a state agency to be “sovereign” for purposes of Eleventh Amendment immunity but “nonsovereign” for purposes of *Parker* immunity. And, that is precisely the position the Alabama Dental Board is in. As explained above, the Board is an arm of the state entitled to sovereign immunity under the Eleventh Circuit’s controlling decision in

*Versiglio*. But, under the equally binding *N.C. Dental* decision, the Board is a “nonsovereign actor” for purposes of *Parker* immunity.

What is the effect of *Versiglio* and *N.C. Dental* on this case? As explained above, suit against the Board itself is barred by sovereign immunity under *Versiglio*. None of Plaintiffs’ claims, including their antitrust claims, may proceed against the Board itself. However, under *Ex parte Young*, Plaintiffs’ federal claims for prospective relief against the Board members, including specifically their antitrust claims, are not barred by sovereign immunity. Those claims may therefore proceed, *if* they are not barred by *Parker* immunity. The court therefore turns to the *Parker* immunity issue. Because the Board members are active market participants in the dental profession, the court must analyze their assertion of *Parker* immunity under *N.C. Dental*.

### **3. A Rule 12(b)(6) Dismissal on *Parker* Immunity Grounds Would Be Premature**

In light of *N.C. Dental*, it is clear that the Board members’ Rule 12(b)(6) motion<sup>6</sup> to dismiss Plaintiffs’ Sherman Act claims as barred by *Parker* immunity is premature. There are two possible scenarios in which the Board members might be entitled to *Parker* immunity. But under either scenario, the factual record on a Rule 12(b)(6) motion is insufficient for the court to determine whether the Board members may in fact claim *Parker* immunity for their challenged conduct in this case. The Board members’ motion to dismiss Plaintiffs’ official-capacity Sherman Act claims must therefore be denied.

First, the Board members may be entitled to *Parker* immunity if the Alabama Dental Practice Act by its terms specifies that using an iTero without a dentist on site constitutes the

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<sup>6</sup> Defendants have moved to dismiss Plaintiffs’ claims pursuant to both Rule 12(b)(1) (lack of subject-matter jurisdiction) and Rule 12(b)(6) (failure to state a claim). (Doc. # 32). Because *Parker* immunity is a waivable, nonjurisdictional affirmative defense, *Bolt v. Halifax Hosp. Med. Ctr.*, 874 F.2d 755, 756 (11th Cir. 1989) (en banc), the court construes Defendants’ request to dismiss Plaintiffs’ Sherman Act claims as a motion under Rule 12(b)(6) rather than Rule 12(b)(1).

unauthorized practice of dentistry. In *N.C. Dental*, the Supreme Court repeatedly emphasized that, while North Carolina’s Dental Practice Act prohibited the unauthorized practice of dentistry, it never mentioned teeth whitening, a practice that did not exist when the Act was passed. 135 S. Ct. at 1108, 1110, 1116. The Act was simply silent on whether teeth whitening constituted the practice of dentistry. *Id.* at 1110. But North Carolina’s Dental Board nonetheless interpreted the Act to apply to teeth whitening and enforced the Act by issuing cease-and-desist letters to nondentist teeth whiteners who competed with dentists. *Id.* Because the Board’s interpretation and enforcement of the state’s broad ban on unauthorized dental practice presented the opportunity for “private self-dealing,” the Court required the Board to show its anticompetitive conduct was actively supervised and approved by the state in order to claim *Parker* immunity. *Id.* at 1112. In other words, to claim *Parker* immunity, the Board had to show that its prohibition of nondentist teeth whitening was really the *state’s* prohibition of nondentist teeth whitening. *Id.* at 1111.

Had North Carolina’s Dental Practice Act expressly defined teeth whitening as the practice of dentistry, the Dental Board would plainly have been entitled to *Parker* immunity in enforcing the state’s clear statutory prohibition of nondentist teeth whitening. *See id.* at 1116. After all, state legislation is “*ipso facto* . . . exempt from the operation of the antitrust laws.” *Id.* at 1110 (internal quotation marks omitted); *see also Hoover*, 466 U.S. at 567 (“We find nothing in the language of the Sherman Act or in its history which suggests that its purpose was to restrain a state or its officers or agents from activities *directed by its legislature.*”) (internal quotation marks omitted, emphasis added) (quoting *Parker*, 317 U.S. at 350-51). If North Carolina’s legislature had expressly defined teeth whitening as the practice of dentistry and directed the state’s Dental Board to take action against nondentist teeth whiteners, there would

have been no risk of private self-dealing by the Board. Rather, the Board's actions in carrying out the legislature's express directive would have been "an exercise of the State's sovereign power" and therefore cloaked in *Parker* immunity. *N.C. Dental*, 135 S. Ct. at 1110. As *N.C. Dental* explained, *Midcal*'s active-supervision requirement could have been satisfied by evidence of a "decision by the State to initiate . . . the Board's actions against the nondentists." *Id.* at 1116. Such a decision -- enshrined in statutory text -- would have shown beyond all dispute that the state had "approve[d]" the Board's actions against the nondentist teeth whiteners, thus cloaking them in *Parker* immunity. *Id.* at 1112.<sup>7</sup>

The Alabama Board members argue that, by sending a cease-and-desist letter to SmileDirect, they were merely enforcing an express, specific statutory directive of the Legislature that forbids unsupervised nondentists from using a digital imaging machine to make dental digital images. (Doc. # 29 at ¶¶ 2, 62-68). The Alabama Dental Practice Act provides that any person who "[u]ses a roentgen, radiograph, or *digital imaging machine* for the purpose of

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<sup>7</sup> *N.C. Dental* is susceptible of two different readings concerning when state agencies must show active supervision to claim *Parker* immunity. On the first reading, if a state entity (even one controlled by active market participants) is engaged in anticompetitive conduct mandated by the express statutory instructions of the legislature, that entity need not establish *Midcal*'s active-supervision requirement to claim *Parker* immunity. See *Hoover*, 466 U.S. at 569 ("Where the conduct at issue is in fact that of the state legislature . . . , we need not address the issues of 'clear articulation' and 'active supervision.'"). That reading is based on the fact that the statute the Board was enforcing in *N.C. Dental* said nothing about teeth whitening, a practice that did not exist when the statute was enacted. In other words, the Board in *N.C. Dental* had to show active supervision because the state had never expressly instructed it to prohibit teeth whitening by nondentists. But if the state *had* expressly instructed it to prohibit teeth whitening by nondentists, there would have been no need for the Board to show any further active supervision.

On the other hand, *N.C. Dental* could instead be read broadly to mean that state agencies controlled by active market participants must *always* show active supervision to claim *Parker* immunity, no matter how clear and specific the statutory mandate they are enforcing is. But even on that reading, the *N.C. Dental* decision makes clear that a state agency controlled by active market participants can show active supervision by pointing to a "decision by the State to initiate . . . the [specific anticompetitive conduct at issue]." 135 S. Ct. at 1116. An express statutory mandate directing the active market participants to engage in the specific anticompetitive conduct at issue would surely qualify.

The court need not pick between those two readings of *N.C. Dental* because, in either case, the result is the same. Whether the active-supervision requirement *does not apply* when a state agency controlled by active market participants is enforcing an express, specific statutory mandate of the legislature, or whether such a mandate *satisfies* the active-supervision requirement, the result is the same: the agency receives *Parker* immunity.

making dental roentgenograms, radiographs, or *digital images*” “shall be deemed to be practicing dentistry.” Ala. Code § 34-9-6 (emphasis added). The only exception to this rule is if the person makes dental digital images “under the supervision of a licensed dentist or physician.” *Id.*, § 34-9-7(a). In that case, the Act does not apply. *Id.*

The Board members contend the iTero device is a “digital imaging machine” and that the images it produces are “digital images” within the meaning of Alabama Code § 34-9-6. They therefore assert the Act permits nondentists to use the device only “under the supervision of a licensed dentist or physician.” *Id.*, § 34-9-7(a). And they further take the position that the term “supervision” in Alabama Code § 34-9-7(a) requires the physical presence of a licensed dentist at facilities where an iTero is used.

The Board members might be entitled to *Parker* immunity under this analysis, but only if the iTero and the images it produces clearly qualify as a “digital imaging machine” and “digital images” as those terms are used in Alabama Code §§ 34-9-6 and 34-9-7(a).<sup>8</sup> To make this determination, a factual record is necessary. The court cannot determine whether the iTero is a “digital imaging machine” (as that term is used in § 34-9-6) unless it has more information about the iTero. What type of imaging mechanism does the iTero use? How does that mechanism compare to the mechanisms of roentgens and radiographs, the other two means of creating dental images listed in § 34-9-6? What was the meaning of the term “digital imaging machine” when § 34-9-6 was adopted? Did it have a specialized meaning in the field of dentistry? Did the technology used in the iTero even exist when § 34-9-6 was adopted? These and numerous other factual questions must be answered before the court can determine whether the iTero counts as a

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<sup>8</sup> The Board members would also have to show that the term “supervision” in Alabama Code § 34-9-7(a) requires a dentist’s physical presence at the facility where the digital imaging is performed.

“digital imaging machine” under § 34-9-6 and whether the images the iTero produces are “digital images” as that term is used in §§ 34-9-6 and 34-9-7(a).

To be sure, in their papers, both Plaintiffs and Defendants have offered their answers to some of these questions. But the answers are either contained in pleadings (Doc. # 29 at ¶¶ 29-30, 32, 64) or are derived from matters outside the pleadings that the court may not consider on a Rule 12(b)(6) motion (Doc. # 33 at 9-11). *See* Fed. R. Civ. P. 12(d). Fact discovery will be necessary to determine the veracity of Plaintiffs’ and Defendants’ competing claims about the nature of the iTero procedure and whether it is covered by the Alabama Dental Practice Act. The ultimate question for purposes of *Parker* immunity is whether the Alabama Legislature clearly proscribed the use of an iTero without a dentist physically present when it enacted the Alabama Dental Practice Act. That question cannot be answered on the record accompanying a Rule 12(b)(6) motion to dismiss.

Second, even if the Alabama Dental Practice Act does not expressly authorize the Board’s challenged conduct in this case, the Board members may still be entitled to *Parker* immunity if the state actively supervised their decision to interpret and enforce the Act as prohibiting the use of an iTero without a dentist physically present.<sup>9</sup> Unlike the Board in *N.C. Dental*, which never issued “a formal rule or regulation reviewable by the independent Rules Review Commission,” *id.* at 1108, 1116, Alabama’s Dental Board did promulgate a formal regulation forbidding nondentists from performing any intraoral procedures unless under the direct supervision of a dentist. *See* Ala. Admin. Code 270-X-3-.10. Additionally, the Board’s regulation received some type of statutorily authorized review and approval by the Legislative Services Agency, though the parties dispute the nature and extent of that review. *See* Ala. Code

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<sup>9</sup> Of course, in this scenario, the Board members must also establish *Midcal*’s clear-articulation requirement to receive *Parker* immunity. *N.C. Dental*, 135 S. Ct. at 1110. The court does not address that requirement at this time because the Board members cannot show active supervision on the limited Rule 12(b)(6) record.

§ 41-22-22.1; (Docs. # 29 at ¶ 56; 33 at 6-9). These procedures may “suffice to make [the Board’s anticompetitive conduct] the State’s own” and therefore immunize the Board from antitrust liability. *N.C. Dental*, 135 S. Ct. at 1111. But making that determination will require a factual record that is simply not present on a Rule 12(b)(6) motion to dismiss.

Although *Midcal*’s active-supervision inquiry “is flexible and context-dependent,” one of its “few constant requirements” is that the state supervisor must “review the substance of the anticompetitive decision, not merely the procedures followed to produce it.” *Id.* at 1116. Here, Plaintiffs have alleged that “any review pursuant to an Alabama statute of the Board’s [challenged] regulation, . . . if it occurred at all, was perfunctory, ministerial, and non-substantive.” (Doc. # 29 at ¶ 56). That allegation is enough to defeat the Board members’ claim to *Parker* immunity at the motion-to-dismiss stage. The court must accept Plaintiffs’ plausible factual allegations as true when considering a Rule 12(b)(6) motion to dismiss. *Iqbal*, 556 U.S. at 678-79. If Plaintiffs’ allegation turns out to be true and no state supervisor in fact reviewed the substance of the Board’s anticompetitive policy, the Board members will not be entitled to *Parker* immunity. Dismissal on *Parker* immunity grounds would therefore be improper at this time.

The Board members attach to their motion to dismiss certain documents that they claim establish *Midcal*’s active-supervision requirement. (Doc. # 33-1). The parties dispute whether the court may properly consider these extrinsic documents in ruling on the Board members’ motion to dismiss. (Docs. # 41 at 12-14; 46 at 2-3). But the court need not resolve that issue because, even if it were to consider the documents, they are insufficient to establish that the Board members are entitled to *Parker* immunity.

The documentary evidence submitted by the Board members includes certified records relating to the promulgation of the Board regulation that prohibits taking intraoral digital images without a dentist on site. (Doc. # 33-1 at 3-13). It also includes a “memo to file” showing that the Legislative Services Agency (“LSA”) conducted an antitrust review of the regulation and found it would not affect competition. (*Id.* at 14-16). Finally, an affidavit of the director of the LSA’s Legal Division authenticates the documents. (*Id.* at 2).

Even assuming the LSA qualifies as a “state supervisor” under *N.C. Dental*, 135 S. Ct. at 1117 (and, to be clear, the court takes no position on that question at this time), the “memo to file,” standing alone, cannot establish that the LSA “review[ed] the substance of the [Board’s] anticompetitive decision, not merely the procedures followed to produce it.” *Id.* at 1116. The memo to file spends a mere four sentences discussing the Board’s challenged regulation, Alabama Administrative Code 270-X-3-.10. Indeed, in its entirety, the memo’s discussion of the challenged provision reads as follows:

Rule 270-X-3-.10, Duties of Allied Dental Personnel, lists the procedures that may be performed by dental hygienists, dental assistants, and dental laboratory technicians. The amendment adds to the list of procedures the making of digital images. . . . [The Rule] do[es] not significantly lessen competition. [It] do[es] not affect competition at all.

(Doc. # 33-1 at 15-16). These four sentences alone do not establish that the state reviewed and approved the substance of the Board’s anticompetitive policy in this case. In fact, because the LSA found the regulation would “not affect competition at all” (Doc. # 33-1 at 16), the regulation apparently never reached the stage of Alabama’s statutory review process at which its substance would have been reviewed.

In 2016, shortly after the Supreme Court’s 2015 *N.C. Dental* decision, the Alabama Legislature enacted Alabama Code § 41-22-22.1. *See* S.B. 80, 2016 Leg., Reg. Sess. (Ala. 2016).

The statute requires the LSA's Legal Division to "review each rule certified to it by a state board or commission that regulates a profession, a controlling number of the members of which are active market participants in the profession." Ala. Code § 41-22-22.1(a). The LSA must "determine whether the rule may significantly lessen competition." *Id.* If it concludes the rule will not decrease competition, no further action is required. *Id.* But if it finds that the rule "may significantly lessen competition," it must "determine whether the rule was made pursuant to a clearly articulated state policy to displace competition" and then "certify those determinations" to a legislative committee. *Id.*, § 41-22-22.1(b). The chair of the committee must then "call a meeting of the committee to *review the substance of the rule*, determine whether the rule may significantly lessen competition, and if so, whether it was made pursuant to a clearly articulated state policy to displace competition." *Id.* (emphasis added). The committee shall then "approve, disapprove, disapprove with a suggested amendment, or allow the agency to withdraw the rule for revision." *Id.* If the committee fails to act on a rule, "the rule shall not become effective and shall be placed on the agenda of the committee at each subsequent meeting until the committee disposes of the rule." *Id.*

The memo to file submitted by the Board members suggests that the challenged regulation in this case never received the substantive review by a legislative committee provided for in Alabama Code § 41-22-22.1(b). Instead, the LSA determined that the Board's regulation would "not affect competition at all," and that determination evidently ended the review process. (Doc. # 33-1 at 16). In other words, the LSA did not understand the policy embodied in the Board's regulation to have any anticompetitive effects. The memo to file, standing alone, is therefore insufficient to show that the Board received active state supervision when it interpreted the Dental Practice Act as applying to SmileDirect and enforced that policy by issuing a cease-

and-desist letter. For that reason, the Board members have not yet shown they are entitled to *Parker* immunity. Their motion to dismiss Plaintiffs' Sherman Act claims on that basis is accordingly due to be denied.

**D. Plaintiffs Have Stated a Claim Against the Board Members Under the Dormant Commerce Clause**

Pursuant to 42 U.S.C. § 1983, both Dr. Leeds and SmileDirect assert claims under the Dormant Commerce Clause against the members of the Dental Board. (Doc. # 29 at 26-27). They claim the Board members' interpretation and enforcement of Alabama Code § 34-9-6 and Alabama Administrative Code 270-X-3-.10 burden out-of-state economic interests without serving any legitimate local purpose. Because Plaintiffs have adequately alleged a Dormant Commerce Clause violation, the Board members' motion to dismiss this claim will be denied.

The Commerce Clause grants Congress the power “[t]o regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. Though the Clause only expressly speaks of powers granted to Congress, the Supreme Court has long held that the Clause also has a “dormant” aspect, which imposes “substantive restriction[s] on permissible state regulation of interstate commerce.” *Dennis v. Higgins*, 498 U.S. 439, 447 (1991) (internal quotation marks omitted). The dormant or negative aspect of the Commerce Clause “prohibits economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.” *New Energy Co. of Indiana v. Limbach*, 486 U.S. 269, 273 (1988).

The Eleventh Circuit evaluates Dormant Commerce Clause challenges using a two-tiered analysis. *Bainbridge v. Turner*, 311 F.3d 1104, 1108 (11th Cir. 2002). The first tier applies if a state regulation “directly regulates or discriminates against interstate commerce, or has the effect of favoring in-state economic interests.” *Island Silver & Spice, Inc. v. Islamorada*, 542 F.3d 844,

846 (11th Cir. 2008) (internal quotation marks omitted). If that showing is made, the regulation is invalid unless “shown to advance a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives.” *Id.* (brackets omitted). The second tier applies if the regulation “has only indirect effects on interstate commerce and regulates evenhandedly.” *Bainbridge*, 311 F.3d at 1109 (internal quotation marks omitted). In that case, a court applies the balancing test of *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), which asks “whether the State’s interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.” *Bainbridge*, 311 F.3d at 1109 (internal quotation marks omitted). “[T]he two tiers of analysis are not clearly distinguishable.” *Id.*; *see also Amerijet Int’l, Inc. v. Miami-Dade Cty.*, 627 F. App’x 744, 752 (11th Cir. 2015). Under either tier, “the critical consideration is the overall effect of the [regulation] on both local and interstate activity.” *Bainbridge*, 311 F.3d at 1109 (internal quotation marks omitted).

Plaintiffs argue the allegations of their Amended Complaint are sufficient to survive a Rule 12(b)(6) motion under either tier of analysis. The court concludes Plaintiffs have adequately alleged a Dormant Commerce Clause violation under the second tier. It therefore need not address the first tier at this time.

The regulation Plaintiffs challenge requires a licensed dentist to be physically present at facilities where nondentists perform intraoral procedures, including using an iTero to make digital images of teeth. Plaintiffs allege that the regulation burdens interstate commerce: it prevents out-of-state dentists like Dr. Leeds from serving patients across state lines, and it impedes SmileDirect’s ability to offer a platform to out-of-state dentists who wish to serve Alabama patients. (Doc. # 29 at ¶¶ 68, 71-72, 79, 83-85, 90-91). According to Plaintiffs, requiring SmileDirect to employ highly paid licensed dentists at its SmileShops would prove

prohibitively expensive and would effectively prevent SmileDirect from partnering with out-of-state dentists to serve Alabama patients. (*Id.*). In other words, Plaintiffs argue, the regulation burdens the practice of dentistry across state lines and protects those in-state dentists who provide clear aligner therapy at their offices from competition by out-of-state dentists who, using SmileDirect's platform, could provide the same treatment to Alabama patients at a lower cost. (*Id.*).

Plaintiffs also allege that the regulation serves no legitimate state interest and produces no local benefits. They allege that using an iTero to make digital images of a person's teeth is a simple, safe procedure. (*Id.* at ¶¶ 86-88). The iTero is the size and shape of a pen and is covered with a disposable sheathe to ensure that no germs are transmitted between patients. (*Id.* at ¶ 86, 95). SmileDirect staff also wipe the iTero wand with a disinfecting wipe after each use. (*Id.* at ¶¶ 95-96). The iTero does not use any radiation, but instead uses digital camera technology to create a digital model of a person's teeth and gums. (*Id.* at ¶¶ 92-94). Additionally, SmileDirect staff wear non-allergenic nitrile gloves when using the iTero. (*Id.* at ¶ 97). SmileDirect has performed hundreds of thousands of digital scans nationwide, and hundreds of scans in Alabama alone, without receiving a single complaint of physical injury, infection, or other adverse patient outcome associated with the use of the iTero. (*Id.* at ¶ 99). Based on these allegations, Plaintiffs claim that the use of an iTero presents no risk to consumers that would be eliminated by a dentist's physical presence at SmileDirect's facilities. (*Id.* at ¶ 980). Plaintiffs therefore argue that the state has no legitimate interest in imposing the regulation besides economic protectionism and that the burdens on interstate commerce imposed by the regulation clearly exceed any local benefits it affords.

The Board responds that its regulation provides important health and safety benefits to Alabama consumers and that Plaintiffs therefore have failed to state a claim under the Dormant Commerce Clause. (Doc. # 33 at 25-26). The Board argues that requiring the physical presence of a licensed dentist when the iTero is used provides the following local benefits: (1) dentists can ensure that sterilization procedures are followed to prevent the spread of illness; (2) dentists can use their skill and training in the event of a sudden medical emergency, such as a patient experiencing an allergic reaction from contact with latex gloves, or the iTero inadvertently dislodging a patient's crown; (3) dentists can diagnose preexisting conditions that contraindicate the use of clear aligner therapy in the first place, such as gum disease; and (4) dentists can verify in real time that a patient's oral cavity is being accurately imaged by the iTero device. (*Id.* at 24).

In Dormant Commerce Clause challenges, “bona fide safety regulations” bear “a strong presumption of validity.” *Kassel v. Consol. Freightways Corp. of Delaware*, 450 U.S. 662, 670 (1981). Under the tier-two *Pike* balancing test, “[i]f safety justifications are not illusory, [federal courts] will not second-guess legislative judgment about their importance in comparison with related burdens on interstate commerce.” *Locke v. Shore*, 634 F.3d 1185, 1194 (11th Cir. 2011) (quoting *Kassel*, 450 U.S. at 670). But a state's mere “incantation of a purpose to promote the public health or safety does not insulate a state law from Commerce Clause attack.” *Kassel*, 450 U.S. at 670. Even regulations designed to promote public health and safety “may further the purpose so marginally, and interfere with commerce so substantially, as to be invalid under the Commerce Clause.” *Id.* Courts must therefore weigh the state's asserted safety purpose against the degree of interference with interstate commerce, giving “sensitive consideration” to the “weight and nature of the state regulatory concern in light of the extent of the burden imposed” on interstate commerce. *Id.* at 670-71 (internal quotation marks omitted).

The court cannot conduct the “sensitive” balancing test mandated by the Supreme Court’s Dormant Commerce Clause precedents without a factual record. *Id.* at 670. The state’s asserted safety justifications for requiring the physical presence of a dentist at SmileDirect’s facilities may well not be illusory, but Plaintiffs have plausibly alleged that they are, and that the real reason for the regulation is economic protectionism. Discovery will be necessary to determine whether the Board’s regulation serves its asserted safety purposes and how severely the regulation burdens interstate commerce. Only then will the court be able to determine whether the Board’s regulation passes muster under the Dormant Commerce Clause. A state’s mere incantation of a rational basis for a regulation does not preclude Dormant Commerce Clause scrutiny. *Id.* Accordingly, dismissal of Plaintiffs’ Dormant Commerce Clause claims on Rule 12(b)(6) review would be improper.

**E. Plaintiffs Have Failed to State an Equal Protection or Substantive Due Process Claim**

Pursuant to 42 U.S.C. § 1983, both Dr. Leeds and SmileDirect assert claims under the Fourteenth Amendment’s Equal Protection and Due Process Clauses. (Doc. # 29 at 36-37, 39-40). Dr. Leeds claims the Board’s regulation unlawfully distinguishes between Alabama-licensed dentists practicing in Alabama and Alabama-licensed dentists practicing out of state, without a rational basis for such a distinction. (*Id.* at ¶ 153). Dr. Leeds also argues that he has a substantive due process right to practice his profession across state lines and that the Board’s regulation burdens this right without any rational basis for doing so. (*Id.* at ¶¶ 167-69). SmileDirect claims the Board’s regulation unlawfully distinguishes between persons who use an iTero without a dentist physically present and persons who use an iTero with a dentist physically present, without a rational basis for that distinction. (*Id.* at ¶¶ 160-62). SmileDirect also argues that it has a substantive due process right to offer a teledentistry platform to dentists who wish to remotely

provide clear aligner therapy and that the Board's regulation burdens this right without any rational basis for doing so. (*Id.* at ¶¶ 174-76). For the reasons explained below, Plaintiffs' equal protection and substantive due process claims are due to be dismissed.

The parties agree (correctly) that rational basis review applies to Plaintiffs' equal protection and substantive due process claims. Under equal protection doctrine, rational basis review applies unless the classification at issue "infringes fundamental rights or concerns a suspect class." *United States v. Castillo*, 899 F.3d 1208, 1213 (11th Cir. 2018) (internal quotation marks omitted). Similarly, rational basis review applies to substantive due process challenges to state professional regulations "because the right to practice a particular profession is not a fundamental one." *Locke*, 634 F.3d at 1195. As neither fundamental rights nor suspect classifications are at issue in this case, rational basis review applies.

Under rational basis review, state policies enjoy "a strong presumption of validity." *Castillo*, 899 F.3d at 1213 (internal quotation marks omitted). Courts ask only whether "the enacting government body *could* have been purs[u]ing a legitimate government purpose" in enacting the measure. *Id.* (internal quotation marks omitted). If a legitimate goal for the law conceivably exists, courts "ask only whether a rational basis exists for the enacting governmental body to believe that the legislation would further the hypothesized purpose." *Id.* (internal quotation marks omitted). "This inquiry occurs entirely in the abstract because the actual motivations of the enacting governmental body are entirely irrelevant, as is whether the legitimate basis was actually considered by the legislative body." *Id.* (internal quotation marks and brackets omitted). "[T]he government has no obligation to produce evidence to sustain the rationality" of the challenged measure, "and the complaining party has the burden to negate every conceivable basis which might support it." *Id.* (internal quotation marks and brackets

omitted). “Unsurprisingly, almost every statute subject to the very deferential rational basis standard is found to be constitutional.” *Id.* (internal quotation marks and brackets omitted).

Plaintiffs cannot possibly mount a successful challenge to the Board’s regulation under the deferential rational basis standard, and their equal protection and substantive due process claims therefore necessarily fail. Defendants and their *amicus* have identified several legitimate goals for requiring the physical presence of a licensed dentist at facilities where an iTero is used. Using an iTero to make digital images of teeth is an intraoral procedure that involves inserting the device into patients’ mouths. Hypothetical legitimate goals for requiring a dentist’s physical presence at facilities where an iTero is used include: (1) ensuring proper sterilization procedures are followed to prevent the spread of illness; (2) ensuring that a skilled, trained dentist is available in the event of a sudden medical emergency caused by the iTero inadvertently dislodging a patient’s crown; (3) ensuring that a licensed dentist has the opportunity to diagnose preexisting conditions that contraindicate the use of clear aligner therapy in the first place, such as gum disease; and (4) ensuring that a dentist can verify in real time that the iTero is accurately capturing a patient’s oral cavity, to avoid having the procedure repeated and to prevent patients from receiving clear aligners that were fabricated based on inaccurate images. (Docs. # 33 at 24; 47-1 at 21).

All of these purposes are legitimate state interests that *could* justify the Board’s regulation. Moreover, a rational basis undoubtedly exists for believing that the regulation would further those hypothesized purposes. Rational arguments exist that requiring a licensed dentist to be physically present at facilities where an iTero is used would advance each of the interests identified above. And importantly, that is all that is required under rational basis review. It does not matter if the challenged law is based only on “rational speculation unsupported by evidence

or empirical data” or even if the law “seems unwise or if the rationale for it seems tenuous.” *Locke*, 634 F.3d at 1196 (internal quotation marks and ellipses omitted). The challenged regulation in this case readily meets the low bar of rational basis review.

Because the rational basis inquiry occurs entirely in the abstract, no evidentiary record is necessary for the court to assess this challenge. And, no evidence that Plaintiffs might uncover through discovery could change the court’s analysis above. Plaintiffs have simply failed to plausibly allege an equal protection or substantive due process claim, and the Board members’ Rule 12(b)(6) motion to dismiss those claims will therefore be granted.

#### **IV. Conclusion**

For the reasons explained above, Defendants’ motion to dismiss (Doc. # 32) is due to be granted in part and denied in part. Plaintiffs’ Sherman Act and Dormant Commerce Clause claims against the Board members in their official capacities may proceed. But all claims against the Board itself are barred by Eleventh Amendment sovereign immunity. Plaintiffs’ state constitutional and statutory claims against the Board members in their official capacities are likewise barred by Eleventh Amendment sovereign immunity under *Pennhurst*. And though Plaintiffs’ federal claims for prospective relief against the Board members are not barred by sovereign immunity, their equal protection and substantive due process claims fail to state a claim upon which relief may be granted. Finally, all of Plaintiffs’ individual-capacity claims fail to state a claim upon which relief may be granted. A separate order will be entered.

**DONE** and **ORDERED** this April 2, 2019.

  
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**R. DAVID PROCTOR**  
UNITED STATES DISTRICT JUDGE