

No. 2021-1446

**In the
United States Court of Appeals
for the Federal Circuit**

SMILEDIRECTCLUB, LLC,

Plaintiff-Appellant,

v.

CANDID CARE CO.,

Defendant-Appellee.

Appeal from the United States District Court
for the District of Delaware, No. 1:20-cv-00583-CFC.
The Honorable **Colm F. Connolly**, Judge Presiding.

**BRIEF OF PLAINTIFF-APPELLANT
SMILEDIRECTCLUB, LLC**

KAL K. SHAH
SIMEON G. PAPACOSTAS
BENESCH, FRIEDLANDER, COPLAN
& ARONOFF LLP
71 S. Wacker Dr., Suite 1600
Chicago, Illinois 60606
(312) 212-4949
kshah@beneschlaw.com
spapacostas@beneschlaw.com

*Counsel for Plaintiff-Appellant
SmileDirectClub, LLC*



1. A method of producing aligners for repositioning one or more teeth of a user, the method comprising:

receiving, by an appointment management system, a request to schedule an appointment at an intraoral scanning site, the intraoral scanning site having an intraoral scanner configured to scan a mouth of a user, the appointment being for a technician to conduct an intraoral scan of the mouth of the user at the intraoral scanning site without a dentist or orthodontist physically seeing the user during the scheduled appointment, wherein the technician is not a dentist or an orthodontist;

scheduling, by the appointment management system, the appointment at the intraoral screening site in accordance with the request;

generating and communicating, by the appointment management system, a message to a device of the user, the message including a confirmation confirming the scheduled appointment;

conducting, using the intraoral scanner, the intraoral scan at the intraoral site during the scheduled appointment, the intraoral scan generating three-dimensional data of the mouth of the user;

causing generation, by a treatment plan computing system located at a treatment plan site, of a treatment plan for the user based on the three-dimensional data of the moth of the user;

receiving an indication of an approval of the treatment plan by a dental or orthodontic professional, wherein the approval is received without the dental or orthodontic professional having physically seen the user;

producing, at a fabrication site, a plurality of aligners based on the treatment plan, the plurality of aligners specific to the user and being configured to reposition one or more teeth of the user in accordance with the treatment plan; and

sending the plurality of aligners from the fabrication site directly to the user, wherein the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.

FORM 9. Certificate of Interest

Form 9 (p. 1)
July 2020

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF INTEREST

Case Number 2021-1446

Short Case Caption SmileDirectClub, LLC v. Candid Care Co.

Filing Party/Entity SmileDirectClub, LLC

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box.** Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

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Name: Kal K. Shah

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| 1. Represented Entities. Fed. Cir. R. 47.4(a)(1). | 2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). | 3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). |
|---|--|--|
| Provide the full names of all entities represented by undersigned counsel in this case. | Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. <input checked="" type="checkbox"/> None/Not Applicable | Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. <input type="checkbox"/> None/Not Applicable |
| SmileDirectClub, LLC | | SDC Financial, LLC |
| | | SmileDirectClub, Inc. |
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☐ Additional pages attached

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4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable

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| Kevin M. Capuzzin | Noelle B. Torrie | Theresa L. Starck |

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6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☒ None/Not Applicable

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STATEMENT OF RELATED CASES

There has been no other appeal in or from the same proceeding in the lower court that gives rise to this appeal. Furthermore, counsel for Plaintiff/Appellant is aware of no other case in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

Plaintiff/Appellant SmileDirectClub, LLC (hereinafter, "SDC"), brings this Appeal from the United States District Court for the District of Delaware (the "District Court") to the United States Court of Appeals for the Federal Circuit in accordance with 28 U.S.C. § 1295(a)(1). *See* FED. R. APP. P. 4(a)(4)(B)(i).

The District Court had jurisdiction to hear this action and was authorized to issue an order pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1400(b). The District Court entered final judgment in favor of Defendant/Appellee Candid Care Co. (hereinafter, "Candid") on December 7, 2020. Appx00001. Plaintiff/Appellant timely filed a Notice of Appeal on December 8, 2020 in accordance with 28 U.S.C. § 2107, FED. R. APP. P. 4(a), and FED. R. CIV. P. 4. Appx00347-00348. This Court has appellate jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUES

1. Did the District Court err in granting Defendant Candid Care Co.'s motion to dismiss under FED. R. CIV. P. 12(b)(6) finding all claims of U.S. Patent No. 10,636,522 ("the '522 patent") invalid pursuant to 35 U.S.C. § 101?
2. Did the District Court err in failing to construe facts, including those well pled in the Complaint, in the light most favorable to Plaintiff SDC?
3. Did the District Court err in refusing to apply the presumption of validity to the '522 patent claims?
4. Did the District Court err in holding the '522 patent claims to be directed to abstract ideas?
5. Did the District Court err in finding insufficient meaningful limitations, alone or as an ordered combination, or inventive concepts for transforming any alleged claimed abstract ideas into patent-eligible subject matter?

STATEMENT OF THE CASE

This matter is the appeal of a patent infringement suit involving the '522 patent, in which the District Court rendered judgment on the pleadings—before claim construction, fact discovery, or expert discovery—that all claims of the '522 patent were unpatentable under 35 U.S.C. § 101. Following entry of judgment, Appx00001, SDC timely appealed to this Court. Appx00002-00003.

I. STATEMENT OF THE FACTS

A. The Patent-in-Suit

The '522 patent issued on April 28, 2020, having arisen from an application claiming priority to Application No. 62/522,847 filed on June 21, 2017. '522 patent at 1:7-13.¹ The '522 patent claims are directed to systems and methods for manufacturing clear aligners for the treatment of mild-to-moderate malocclusion, i.e., misalignment of the teeth, based on coordinated and distributed processing of intraoral scan data. Appx00057 at ¶ 3. As explained in the Background of the '522 patent, “[d]ental impressions and associated physical or digital reproductions of a patient’s teeth can be used by dentists or orthodontists to diagnose or treat an oral condition, such as misalignment of the patient’s teeth.” '522 patent at 1:24-27. Those impressions “may then be utilized to produce a physical or digital

¹ Unless otherwise indicated, citations to the column and line numbers, *e.g.*, x:yy, in this brief refer to the '522 patent, found at Appx00027-00050.

reproduction of the patient's teeth and surrounding tissues.” *Id.* at 1:33-37.

However, prior to the inventions disclosed and claimed in the '522 patent,

[t]raditionally, dental impressions [we]re made in a dental office ***and require[d] significant time***. Dental offices typically deliver the dental impressions to an outside vendor that utilizes the impressions to form a positive model of the teeth and surrounding tissue. If the dental impressions include[] any errors (e.g., incomplete impression of the teeth and tissues), ***the patient may be required to return to the dental office to have a second impression made***. Furthermore, if the dental impressions are used by the dental professional in the course of administering a continuing treatment plan, ***the patient is typically required to undergo many check-up appointments at the dental office*** so that the dental professional can track the patient's treatment and modify the treatment plan as necessary. ***Each of these examples results in significant inconvenience to the patient and increases the cost of the treatment plan to both the dental professional and the patient.***

Id. at 1:38-54.² That is, the process for obtaining aligners traditionally required expensive, time-consuming, and repeated co-location and coordination between the patient, the dental professional (orthodontist or dentist), and impression generation systems. *See id.*

By contrast, the '522 patent discloses systems and methods for manufacturing aligners using a distributed impression generation and analysis “without a dentist or orthodontist physically seeing the user,” in which the aligners, once manufactured, are sent “from the fabrication site directly to the user.” *See, e.g., id.* at 20:35-21:7, 21:4-5, 22:31-64. As the '522 patent explains, because a “doctor may approve of

² Unless otherwise indicated, all emphases are added.

the treatment plan for the user without having to physically see the user in person . . . the user may not be inconvenienced with a trip to a doctor's office, which may also save time for the user.” *Id.* at 15:21-26. Similarly, a visual representation of the treatment plan may be sent to the user remotely, obviating the need for yet another in person visit as required in the prior art. *Id.* at 15:28-31, 17:26-36; *see also id.* at 21:25-38 (claim 4), 24:27-33 (claim 22), 24:34-43 (claim 23), 26:9-27 (claims 28-30).

The '522 patent also claims appointment-related aspects of this invention: “the user 104 may access a website (or other network-based portal) associated with the appointment management system 100. The user 104 may book an appointment at an intraoral scanning site 106 on the website.” *Id.* at 5:5-14. The '522 patent further encompasses pre-appointment messaging services. *Id.* at 5:15-39. For example, “one or more messages may be automatically generated to the use 104 (e.g., via respective communications device(s) 114).” *Id.* at 9:60-62. “[T]he message generator 136 can include instructions for generating an appointment confirmation message” and “[t]he appointment confirmation message may be or include a message that indicates that the user's 104 appointment has successfully been reserved.” *Id.* at 10:23-33. “[T]he message generator 136 can include instructions for generating one or more appointment reminder messages.” *Id.* at 10:49-51.

The '522 patent further claims the generation of treatment plans to realign a patient's teeth based on a three-dimensional image scan of the patient's teeth. *Id.* at 1:16-20, 15:44-53, 18:31-53, 20:58-64. After the generation of the draft treatment plan, review and approval of the draft treatment plan by the treating professional, and the generation of a prescription for manufacturing of the aligners, various models, such as positive molds that reflect the progressive travel of the various teeth of the patient, are produced. *Id.* at 15:44-64, 22:58-64. Aligners are then manufactured based on those models, "with a first aligner corresponding to the starting position of the user's teeth in the user's dentition, the second [and subsequent] aligner corresponding to an intermediate position[s], and the final aligner corresponding to the final position of the user's teeth in the user's dentition." *Id.* A thermoforming polymer material may be used to manufacture the aligners "based on the treatment plan data" at a fabrication site which includes equipment "configured to receive data corresponding to the treatment plan." *See id.* at 2:62-65, 6:17-25, 21:59-67. The resulting aligners "are specific to the user and are configured to reposition one or more teeth of the user in accordance with the treatment plan." *Id.* at 2:15-17, 2:65-3:1. Notably, the '522 patent incorporates by reference U.S. Patent Application Nos. 62/522,847, 15/725,430, and 62/648,229, which describe additional details regarding the use of dental impression kits, three dimensional scans, and the generation and fabrication of aligners. *Id.* at 15:66-16:9.

In short, the methods and systems claimed in the '522 patent include several concrete and detailed elements directed to the manufacture of a tangible, finished product, i.e., aligners for repositioning teeth unique to the user, confirming that the claims are directed to patent eligible subject matter. Those specific steps include:

- “receiving, by an appointment management system, a request to schedule an appointment at an intraoral scanning site having an intraoral scanner configured to conduct an intraoral scan of a mouth of a user, the appointment being for a technician to conduct an intraoral scan of the mouth of the user at the intraoral scanning site without a dentist or orthodontist physically seeing the user during the scheduled appointment, wherein the technician is not a dentist or an orthodontist”
- “scheduling, by the appointment management system, the appointment in accordance with the request”
- “generating and communicating, by the appointment management system, a message to the user, the message including a confirmation confirming the scheduled appointment”
- “conducting, using the intraoral scanner, the intraoral scan at the intraoral scanning site during the scheduled appointment, the intraoral scan generating three-dimensional data of the mouth of the user”
- “causing generation, by a treatment plan computing system at a treatment plan site, of a treatment plan for the user based on the three-dimensional data of the mouth of the user”
- “receiving an indication of an approval of the treatment plan by a dental or orthodontic professional, wherein the approval is received without the dental or orthodontic professional having physically seen the user”
- “producing, at a fabrication site, a plurality of aligners based on the treatment plan, the plurality of aligners specific to the user and being configured to reposition one or more teeth of the user in accordance with the treatment plan”

- “sending the plurality of aligners from the fabrication site directly to the user, wherein the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.”

See Appx00065-00066 at ¶ 38 (quoting the ’522 patent at claim 1).

In other claimed embodiments, the ’522 patent claims a “fabrication system” that includes “one or more fabrication computing systems” and “equipment configured to produce a plurality of aligners based on the treatment plan data.” *See* ’522 patent at 23:65-24:8 (claim 20). The aligners are created using a set of molds comprised of “thermoforming polymer material” whereby “each positive mold of the plurality of positive molds correspond with a specific step of the treatment plan” to create the aligners. *Id.* at 21:59-67 (claim 7). The treatment plan created from the three-dimensional data of claim 1, for example, can consist of “defining movement of one or more teeth of the user from a starting position at the time of the intraoral scan to ending position following treatment using the plurality of aligners.” *Id.* at 21:13-24 (claim 3). A plurality of aligners may be created that correspond to at least three separate treatment steps that are administered in a “predetermined sequence” for at least three “durations.” *Id.* at 23:5-21 (claims 15 and 16). As discussed above, each of these steps is performed without the patient physically seeing the approving dental or orthodontic professional. *See, e.g., id.* at 21:4-7.

B. The District Court Proceedings

On April 29, 2020, SDC filed a patent infringement suit against Defendant/Appellee Candid alleging infringement of the '522 patent. Appx00057-00076. On June 19, 2020, Candid filed a Rule 12(b)(6) motion to dismiss SDC's Complaint for failure to state a claim, arguing that the asserted patent was invalid under § 101. Appx00077-00079, Appx00080-00108. On July 31, 2020, Candid submitted a request for oral argument on its motion. Appx00271-00272.

Separately, on October 27, 2020, SDC brought a motion for preliminary injunction³ against Candid, after finding out that despite its initial denials, Candid was rapidly expanding its retail businesses on a national scale and utilizing SDC's patented systems and methods to do so. Appx00273-00275, Appx00276-00303. The next day, on October 28, 2020, the District Court issued an Oral Order setting a date for a teleconference regarding SDC's motion for preliminary injunction. *See*

³ In its opening brief in support of its motion for preliminary injunction, SDC brought the Court's attention to the USPTO's recent grant of SDC's U.S. Patent Application No. 16/859,950, a continuation of the '522 patent containing the same specification and similar claims to those of the '522 patent. *See* Appx00291-00292. Germane to this proceeding, SDC submitted Candid's Rule 12(b)(6) briefing to the USPTO as part of the prosecution of that pending application. *Id.* at 00292. The Examiner allowed the claims to issue after considering Candid's motion papers, expressly concluding that they met the requirements of 35 U.S.C. §§ 101, 102, and 103. *Id.* Although SDC briefed the issue as part of its motion for preliminary injunction and brought it to the District Court's attention during the parties' November 4 hearing, *see* Appx00315 at 12:5-25, the District Court was silent on this evidence in its ruling on the '522 patent.

Appx00054 (10/28/2020 docket entry reading: “ORAL ORDER re 22 MOTION for Preliminary Injunction filed by SmileDirectClub, LLC, ORDER Setting Teleconference . . .”).

On November 4, 2020, the District Court held a hearing, ostensibly noticed to discuss SDC’s pending motion for preliminary injunction. Appx00304-00353. But early on during the hearing, the District Court turned to the issue of the pending motion to dismiss, and then gave an unprompted soliloquy expressing its belief that the ’522 patent was not patent eligible:

THE COURT: . . . This patent is by far, of all the patents I have come across, the one that strikes me as suspect. ***I just find it really hard to understand how this patent is an allowed patent.***

Appx00313 at 10:10-13. The District Court repeated its skepticism several times throughout the hearing:

THE COURT: . . . One thing I'm kind of inclined to do these days is to avoid adjudicating 101 by motions to dismiss and to have an opportunity for, when I see a patent like this, which, you know, ***I mean the idea that is somehow patentable to, among other things, schedule appointments by appointment management system. I realize that is only one limitation, but that kind of limitation is what, when I put them together, really leaves me to question the patent . . .***

Appx00316 at 13:3-12. The District Court also had several exchanges with Candid’s counsel discussing the merits of its motion and signaling support for Candid’s position, even though its Oral Order scheduling the hearing gave no indication that the § 101 issue would be a topic for discussion, let alone addressed at all:

THE COURT: So Mr. Sandonato, *give me a little help here because my inclination is generally with you, but I also know how easy it is for a patentee to essentially throw out lots and lots of arguments, and then that, you know, it just takes a long time to parse through.* I'll give you an example. You know, one of the arguments is that you failed to meet the burden of justifying treatment of claim 1 as representative of the patents remaining 29 claims. Okay? You know, how do I get through the 29 claims? Help me there. How do I get to claim 1 as representative of them all?

Appx00319-00320 at 16:16-17:2. Throughout these exchanges, the District Court discussed factual questions with Candid's counsel and indeed looked to Candid's counsel for factual conclusions, over the disagreement of SDC's counsel:

THE COURT: Hold on. Let me just stop you there. *Does the patent expressly identify those components as well known?*

MR. SANDONATO: Yes. Yes, Your Honor. At column 1, lines 24 to 42 where it refers to positive molds traditionally used in the prior art, and in the prosecution history where it refers to positive molds and -- disclosing positive molds and thermoforming polymeric material to fabricate aligners. *So, yes, both the prosecution history and the specification show that those things are well known.* And we cite that in our reply brief at page 6.

THE COURT: All right.

MR. MEHTA: Your Honor, this is Mr. Mehta. If I may?

THE COURT: Sure.

MR. MEHTA: In addition to claim 7, Your Honor, we identified dependent claim 3, which is one of the specific -- well, dependent claim 3 and dependent claim 15 and dependent claim 16 and other claims as well that have additional structure. I mean, Your Honor, to the extent that, you know, this -- these other limitations, *we would contest that, as taken as a whole, that these claims do impart novelty such that it brings it out of the notion of a 101. So I just want to, I just want to*

specify and explain that we disagree with the notion that looking at these limitations in isolation is the appropriate way of trying to assess a 101 motion.

Appx00328-00329 at 25:8-26:12. When the discussion finally turned back to the topics of scheduling the briefing and hearing schedule for SDC's motion for preliminary injunction, the District Court made clear that it had a very busy docket, and that addressing the issues presented in this particular case was a low priority:

THE COURT: Yes. I just think that is virtually impossible given the caseload we've got. ***And this is not like somebody's, you know, somebody's life is at stake, on a cancer drug.*** And I do think that there has got to be sufficient time for Candid to prepare for a hearing. And I would imagine it would want to -- it may want to put up expert testimony about not just 101 but other validity issues, or invalidity issues.

* * *

THE COURT: . . . ***And keep in mind you're one of more than 500 cases that I personally have to deal with, and, you know, about 300 patent cases.*** So I'm just trying to balance the Court's resources, I'm trying to balance the equities in this case, and I think that is the most efficient way to do it.

Appx00329-00330 at 26:24-27:15; Appx00331-00332 at 28:21-29:3. According to the District Court, SDC would be limited to two representative claims for its motion for preliminary injunction in order to streamline those proceedings. Appx00339-00340 at 36:2-37:23.

The District Court also indicated that the case warranted a more fulsome analysis of the full slate of invalidity issues, including expert testimony, than what would typically be considered at the motion to dismiss stage:

THE COURT: . . . And the reality is when you have 29 claims,⁴ what Mr. Mehta is going to do, as he did today, is going to say, you know, he is going to point to dependent claims, and you all aren't going to brief for me in a way that I could feel, you know, ***I could get through it and feel confident that that is the most efficient way to resolve the case. What I have learned is that the most efficient way to resolve these cases is to try to deal with all the validity issues in a summary judgment context on an expedited basis and not limiting them to the 101*** and then also to, if it turns out that you persuade me by clear and convincing evidence that the patents are invalid, then to entertain applications for your fees and costs. And that seems to me to be the more efficient way to address these difficult issues.

* * *

THE COURT: . . . So I'm not saying you can't go forward with your 101, just the opposite. You can do it, ***but I think you may as well get your expert to opine on any other invalidity issues you want to raise***, and then to try to get the PI teed up as quickly as we can, and do all those at the same time. That is kind of where I'm coming from.

Appx00331-00332 at 28:4-20, 29:4-9. The hearing concluded with the District Court asking the parties to jointly submit a schedule for discovery and the remaining briefing. Appx00336-00342 at 33:20-34:21; 38:12-39:12. The District Court then set a hearing date of January 21, 2021. Appx00158-00160 at 00159. But on December 4, 2020, well over a month before the parties' scheduled hearing, the

⁴ The '522 patent has 30 claims.

District Court held a teleconference during which the District Court advised that it planned to grant Candid's motion to dismiss. *See* Appx00054. Notably, no meaningful fact discovery had taken place, no expert reports had been exchanged, and no claim construction proceedings had taken place when the District Court summarily dismissed the case. On December 7, 2020, the District Court issued its memorandum opinion rendering judgment that all claims of the '522 patent were unpatentable under 35 U.S.C. §101. Following entry of judgment, Appx00001, SDC timely appealed to this Court. Appx00347-00348.

SUMMARY OF THE ARGUMENT

The District Court erred in finding all claims of the '522 patent to be unpatentable under 35 U.S.C. § 101 and committed reversible error in several distinct regards.

As an initial matter, the District Court failed to apply the appropriate legal standards to Defendant/Appellee's motion to dismiss. Indeed, the court accepted Candid's uncorroborated factual allegations, which were based on nothing more than *post hoc* attorney argument which contradicted the intrinsic record. The court also conducted its own factfinding and impermissibly substituted it for the well-pleaded facts in SDC's complaint. Finally, the court failed to take into account the presumption of validity that attached to the '522 patent the moment the USPTO

issued it. The District Court's failure to apply the proper legal framework tainted its entire analysis, a clear case of legal error that mandates reversal for this reason alone.

Moreover, the District Court described the '522 patent's claims at such a high level of abstraction, without regard to the specifically claimed limitations, as to ensure that the claims would be found patent ineligible. The appealed patent claims cover improved methods and systems for producing a tangible product, i.e., aligners for repositioning teeth, in a manner that significantly reduces the number of steps patients previously were required to go through in order to receive those products, thereby saving these customers both time and money. These claims in no way resemble the type of abstract claims found ineligible by this Court, or the Supreme Court, for that matter. Nor do the claimed systems and methods merely reorganize otherwise human activity. Rather, they improve the process for prescribing, manufacturing, and obtaining aligners in ways that benefit both patients and dental professionals, providing tangible benefits over the prior art processes.

Each independent claim describes a method or system for manufacturing unique aligners based on specific steps and a brand new approach to doing so over the prior art methods. But the District Court disregarded crucial claim elements. The District Court further failed to consider the claims as a whole—especially as an ordered combination of elements—and improperly conducted its own limited factfinding when it erroneously decided that all 30 claims fell under the narrow

exception of an abstract idea and cover routine and conventional activity without any actual record evidence to support its decision. More specifically, the District Court erred by characterizing the claimed invention in an overly simplistic manner that is inconsistent with the claims, the specification, the prosecution history, and—perhaps most importantly—the undisputed factual allegations in SDC’s Complaint that the District Court was required to accept as true. Indeed, the District Court incorrectly deemed the claims abstract by broadly describing the entirety of the invention as “teleorthodontics” or “telehealth business methods.” Appx00011; Appx00019. But while the District Court’s characterizations may echo other cases discussing unsuccessful attempts to patent telehealth business methods, those characterizations bear no resemblance to the claim language in this case. By casting the ’522 patent as merely an abstract idea tied to generic and conventional equipment the District Court improperly applied this narrow exception to patentability and destroyed a patent that claims improved systems and methods for producing aligners. Such an improper approach also disregards the well-settled standard that well pled factual allegations in a complaint are to be accepted as true, and furthermore defies the standards this Court and the Supreme Court have set for patent eligibility. The District Court’s decision must be overturned because it destroyed SDC’s property right based on its improper over-generalization of the claims that deliberately

ignored the record evidence as to the claimed improvements in technology, which is at odds with the well-settled legal framework for the appropriate inquiry.

Finally, the District Court also failed to consider preemption, which was another flaw in its analysis. Had the District Court actually examined the claims to determine if they include “something more” to avoid preempting a fundamental principle, it would have found the systems and methods claimed in the ’522 patent do not come anywhere near preempting the field of teleorthodontics, let alone the field of producing aligners.

At bottom, the District Court’s opinion is rife with reversible legal error, compounded by factual errors that contradict not only the factual allegations in SDC’s Complaint, the ’522 patent, and even the District Court’s own Opinion itself. For all of the reasons discussed below, this Court should reverse the District Court’s improper dismissal of SDC’s Complaint.

ARGUMENT

I. LEGAL STANDARDS

C. Standard of Review

This Court reviews dismissals under FED. R. CIV. P. 12(b)(6) *de novo*. See, e.g., *Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1380 (Fed. Cir. 2011); see also *Phillips v. County of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008) (“The standard of review for a dismissal under FED. R. CIV. P. 12(b)(6) is *de novo*.”).

D. Rule 12(b)(6) motion standards

This Court has observed that § 101 disputes may be amenable to resolution on motions to dismiss, *see, e.g., Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018), and “review[s] a district court's dismissal for failure to state a claim under the law of the regional circuit.” *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat’l Ass’n*, 776 F.3d 1343, 1346 (Fed. Cir. 2014). In the Third Circuit, evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) ***requires the Court to accept as true all material allegations of the complaint.*** *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). Crucially, at this stage of the case, “[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after “accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” *Maio v. Aetna, Inc.*, 221 F.3d 472, 481–82 (3d Cir. 2000) (internal quotation marks omitted).

“To survive a motion to dismiss, a civil plaintiff must allege facts that ‘raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).’” *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555

(2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). At bottom, “[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element” of a plaintiff’s claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

E. 35 U.S.C. § 101

In *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, the Supreme Court formalized a framework to determine whether a patent claims a judicial exception (i.e., an abstract idea, natural phenomenon, or law of nature). 134 S. Ct. 2347, 2355 (2014). Under the test outlined in *Alice*, courts must first ask “whether the ***claims are directed to*** one of those patent-ineligible concepts,” and if so, then “[w]hat else is there in the claims before us?” *Id.* That is, the focus of the *Alice* test is on ***what is claimed as a whole***. “The abstract idea exception prevents patenting a result where ‘it matters not by what process or machinery the result is accomplished.’” *McRO, Inc. v. Bandai Namco Games Amer. Inc.*, 837 F.3d 1299, 1312 (Fed. Cir. 2016) (quoting *O’Reilly v. Morse*, 56 U.S. 62, 113 (1854)); *see also id.* at *8. At Step One, “the claims are considered in their entirety to ascertain whether their character as a whole is directed to excluded subject matter.” *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d

1343, 1346 (Fed. Cir. 2015) (emphasis added); *see also Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016) (stating first step “calls upon us to look at the ‘focus of the claimed advance over the prior art’ to determine if the claim's ‘character as a whole’ is directed to excluded subject matter”).

Crucially, in conducting the Step One analysis, courts should not “oversimplif[y]” key inventive concepts or “downplay” an invention's benefits. *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1337–38 (Fed. Cir. 2016); *see also McRO, Inc.*, 837 F.3d at 1313 (“[C]ourts ‘must be careful to avoid oversimplifying the claims’ by looking at them generally and failing to account for the specific requirements of the claims.”) (quoting *In re TLI Commc’ns LLC Patent Litig.*, 823 F.3d 607, 611 (Fed. Cir. 2016)).

At Step Two, courts must “look to both the claim as a whole and the individual claim elements to determine whether the claims contain an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself.” *McRo*, 837 F.3d at 1312 (internal brackets and quotation marks omitted). The “standard” Step Two inquiry includes consideration of whether claim elements “simply recite ‘well-understood, routine, conventional activit[ies].’” *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016) (quoting *Alice*, 134 S. Ct. at 2359). “Simply appending conventional steps, specified at a high level of

generality, [is] not enough to supply an inventive concept.” *Alice*, 134 S. Ct. at 2357 (internal quotation marks omitted; emphasis in original).

However, “[t]he inventive concept inquiry requires more than recognizing that each claim element, by itself, was known in the art.” *Bascom*, 827 F.3d at 1349-1350 (holding that while “the limitations of the claims, taken individually, recite generic computer, network and Internet components, none of which is inventive by itself,” the ordered combination of those limitations was patent-eligible under Step Two).

The Federal Circuit elaborated on the Step Two standard, stating that “[t]he question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact.” *Berkheimer*, 881 F.3d at 1368. “Any fact, such as this one, that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence.” *Id.*; see also *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018) (“While the ultimate determination of eligibility under § 101 is a question of law, like many legal questions, there can be subsidiary fact questions which must be resolved en route to the ultimate legal determination.”).

Because issued patents are presumed to be valid, one asserting an invalidity defense pursuant to § 101 bears the burden of proving invalidity by clear and convincing evidence. *Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1306, 1319 (Fed.

Cir. 2019). This Court has cautioned that dismissal for lack of patentable subject matter at the pleading stage should be “the exception, not the rule.” *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339 (Fed. Cir. 2013) (explaining that dismissal under Rule 12(b)(6) for lack of patentable subject matter is warranted when “the only plausible reading of the patent must be that there is clear and convincing evidence of ineligibility”), *vacated on other grounds by WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014).

II. THE '522 PATENT CLAIMS ARE PATENTABLE UNDER *ALICE*

A. The District Court Erred in Not Applying the Proper Legal Standards

1. The District Court Failed to Accept SDC's Well-Pleaded Factual Allegations as True

A patent can only be deemed ineligible on a Rule 12(b)(6) motion “when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law.” *Aatrix*, 882 F.3d at 1125. As the District Court even acknowledged, “[w]hen assessing the merits of a Rule 12(b)(6) motion to dismiss, *a court must accept as true all factual allegations in the complaint* and in documents explicitly relied upon in the complaint, *and it must view those facts in the light most favorable to the plaintiff.*” Appx00008 (citing *Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008) and *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014)).

SDC included factual allegations regarding patent eligibility demonstrating that the claimed inventions were directed to non-abstract, technological

improvements in the dental and orthodontics field. But instead of accepting these statements as true as required under FED. R. CIV. P. 12 and the Third Circuit case law, the District Court disregarded—and in certain instances *failed to even acknowledge*—the well-pleaded factual allegations in SDC’s Complaint, as well as the factual statements in the ’522 patent itself.

Indeed, SDC pleaded the following facts relevant to patent eligibility:

- **SDC’s patented concepts were commercially successful and innovative.** See Appx00058 at ¶ 4 (“Indeed, Candid copied SDC’s commercially successful and innovative concepts, including the enormously successful SmileShop® business model that SDC innovated and protected with the ’522 patent.”).
- **SDC’s teledentistry platform, of which its patented inventions play a part, both democratized access for patients and revolutionized the dental industry in the process.** See Appx00059 at ¶ 13 (“SDC introduced its teledentistry platform to democratize access to teeth straightening solutions that revolutionized the dental industry.”), Appx00061 at ¶ 20 (“A consumer can start their clear aligner therapy journey using SDC’s patented platform . . .”).
- **SDC’s inventions significantly lowered costs for patients while eliminating the need for repeated in person visits with a dental professional.** See Appx00059 at ¶ 13 (“SDC enabled state licensed dentists and orthodontists to offer remote direction and management of clear aligner therapy at a fraction of the traditional cost and without necessitating costly, often inaccessible in person office visits.”).
- **The prior art methods required patients to incur multiple in person visits during limited dental professional office hours that were both prohibitively expensive and logistically cumbersome.** See Appx00059 at ¶ 14 (“Prior to SDC’s innovative and revolutionary platform, patients had to visit state licensed dentists or orthodontists in person, on numerous occasions, and during limited office hours, throughout the course of treatment for mild-to-moderate malocclusion (misalignment of the teeth). Not only was this prohibitively expensive for many patients, but the dentist

or orthodontist office was often inaccessible to the patient, whether due to location, scheduling issues such as work obligations or school that made repeat visits an impossibility, or other logistical obstacles.”).

- **The expense and inaccessibility were the biggest roadblocks for patients to receive treatment, leading to underutilization and even foregoing of dental care altogether.** *See* Appx00060 at ¶¶ 15 (“A full 85% of Americans could benefit from orthodontic care, yet because more than 60% (1,972) of all counties in the U.S. do not have an orthodontist’s office and the typical price tag for malocclusion correction is \$5,000 to \$8,000, a mere 1% of these consumers receive the care they need and want each year, with access and cost being the biggest roadblocks.”), 16 (“SDC solved these accessibility and cost problems by developing a teledentistry platform that allows dentists and orthodontists to diagnose, evaluate, and treat patients remotely.”).
- **SDC delivers its patented technology through its SmileShop® locations.** *See* Appx00063 at ¶ 28 (“SDC’s patented technology, delivered through its SmileShop locations, is a key driver in expanding access to care and thereby driving SDC’s revenue.”); *see also* Appx00060-00062 at ¶¶ 18-24.
- **SDC’s patented inventions solved the affordability, accessibility, and efficiency problems plaguing the prior art methods of in-office treatment.** *See* Appx00060 at ¶ 16 (“The treatment is more affordable, accessible, and efficient than traditional methods of in-office orthodontic treatment.”); *see also* Appx00027-00028 at ¶¶ 3-4 (describing the patented aspects of SDC’s platform reflected in the ’522 patent).
- **The methods and systems of the ’522 patent were a key technological contribution to the teledentistry industry.** *See* Appx00057 at ¶ 3 (“An example of one of its key technological contributions is embodied in the ’522 patent. The ’522 patent provides methods and systems for patients to receive treatment to reposition one or more teeth using aligner technology in a cost effective and convenient manner, utilizing SDC’s revolutionary workflow, including its brick-and-mortar facilities—SDC’s SmileShop® locations—and that offer non-clinical, in-person interaction, digital scans, registration, and administrative, non-clinical processing.”).

These factual allegations contained fulsome descriptions of the state of the prior art, the state of the industry and the problems facing it, and the solutions provided for by the '522 patent. But the District Court picked only a few phrases and viewed them in isolation when describing the '522 patent's inventions, as discussed in further detail below.

The required presumption of truth extends to statements about the invention in the '522 patent as well, because it was attached to the Complaint. FED. R. CIV. P. 10(c) (“[a] copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes”). Both steps of the eligibility analysis are informed by the statements and teachings of the patent specification. *See, e.g., Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1299 (Fed. Cir. 2016). Those statements and teachings are not subject to dispute at the pleadings stage. The specification of the '522 patent includes statements such as the following:

- “According to one aspect of the disclosure, a method of producing aligners for repositioning one or more teeth of a user is disclosed.” '522 patent at 1:58-60.
- “The method includes conducting, using the intraoral scanner, the intraoral scan at the intraoral scanning site during the scheduled appointment. The intraoral scan generates three-dimensional data of the mouth of the user.” *Id.* at 2:2-6.
- “The method includes generating, by a treatment plan computing system at a treatment plan site, a treatment plan for the user based on the three-dimensional data of the mouth of the user.” *Id.* at 2:6-9.
- “The method includes producing, at a fabrication site, a plurality of aligners based on the treatment plan.” *Id.* at 2:13-14.

- “The plurality of aligners are specific to the user and are configured to reposition one or more teeth of the user in accordance with the treatment plan.” *Id.* at 2:14-17.
- “According to another aspect of the disclosure, a system for generating aligners for modifying an alignment of a user’s teeth is disclosed. The system includes an appointment management system, an intraoral scanning site, and a fabrication site.” *Id.* at 2:43-47.
- “The intraoral scanning site includes an intraoral scanner configured to generate three-dimensional data from an intraoral scan of the mouth of the user. The intraoral site includes one or more computing systems configured to communicate the three-dimensional data from the intraoral scan for generation of a treatment plan.” *Id.* at 2:55-61.
- “The fabrication site includes thermoforming equipment configured to produce a plurality of aligners based on the treatment plan data. The plurality of aligners are specific to the user and are configured to reposition one or more teeth of the user in accordance with the treatment plan.” *Id.* at 2:61-3:1.
- “The systems and methods described here may have many benefits including, but not limited to, increasing user excitement about the alignment process, increasing the likelihood of a user showing up for their appointment, and increasing the likelihood of a user purchasing aligners at the intraoral scanning site . . .” *Id.* at 3:64-4:2.
- “The aligners may be constructed of a polymer material, such as Polyethyleneterephthalat-Glycol Copolyester (PET-G), which is thermoformed to positive molds (or models) of the user’s 104 dentition at various intervals between a starting position and an ending position. The positive molds of the user’s dentition 1014 may be directed to wear a first aligner during a first month, a second aligner during a second month, a third aligner during a third month, and so on for a treatment period. These aligners may be shipped to the user 104 following production of the aligners (e.g., at a fabrication site which generates or otherwise produces the aligners).” *Id.* at 6:17-31.

Under the proper legal standards, the District Court was bound by the above facts, as well as any other facts that SDC included in its Complaint (including

statements in the '522 patent, attached as an exhibit to the Complaint) relevant to the patent eligibility inquiry. But the District Court failed to follow this standard, dooming its analysis from the start. This alone is reversible legal error.

2. The District Court Improperly Engaged in its Own Factfinding

Indeed, instead of accepting SDC's well pled factual allegations as true, the District Court engaged in its own factfinding in order to justify its erroneous conclusions, which is improper under the Rule 12(b)(6) standard. The District Court also compounded its erroneous approach by making numerous factual errors, rendering its own factfinding not only legally improper but factually incorrect.

For example, the District Court's refusal to acknowledge that the claims cover systems and methods for producing aligners, despite claim limitations explicitly directed to various aspects of fabricating aligners, demonstrated a total lack of understanding of the claimed invention. Indeed, throughout its Opinion, the District Court repeated its erroneous interpretation that "the claims do not disclose a method of manufacturing dental aligners." Appx00020; *see also* Appx00003 ("The #522 patent does not describe how to make an intraoral scanner, aligners, or three-dimensional representations of teeth . . ."), Appx00018 ("There is no particular concrete or tangible form to the claimed invention." (quotation and citation omitted)), Appx00020 ("But the claims do not disclose a method of manufacturing dental aligners."), Appx00023 ("In contrast, the #522 patent does not concern how

aligners are fabricated.”). The District Court committed further error when it erroneously found that “the only references to the actual *methods for fabricating aligners* in the #522 patent *are general statements that aligners may be fabricated by thermoforming a polymer to a mold of the patient’s teeth.*” Appx00020 (citing ’522 patent at 6:17-20, 15:59). The District Court’s statements fail to credit the clear and explicit statements in the Complaint—as well as those in the ’522 patent specification and claims themselves—confirming that the claims are indeed directed to systems and methods for manufacturing aligners. And the District Court’s statements are contradicted by the Court’s own findings elsewhere throughout its Opinion.

In fact, the District Court conceded that “Claim 1 describes a series of steps that enable a patient, who never sees a dentist or orthodontist in person, to arrange for an intraoral scan and *receive aligners based on that scan.*” Appx00012. The District Court further admitted, albeit using the passive voice, that the aligners “are produced,” *see id.*, but conspicuously omitted that claim 1 includes “producing” those aligners “at a fabrication site” as explicit claim limitations, as well as in its preamble, which is limiting. ’522 patent at claim 1 (“A *method of producing aligners for repositioning one or more teeth of a user*, the method comprising: . . . *producing, at a fabrication site, a plurality of aligners based on the treatment plan*, the plurality of aligners *specific to the user and being configured to reposition one*

or more teeth of the user in accordance with the treatment plan”). The District Court further noted that “claim 7 mentions *a fabrication method for aligners*,” see Appx00013, but glossed over the specific limitations of the claim which detail how the aligners are made:

The method of claim 1, wherein *producing the plurality of aligners comprises: generating a plurality of positive molds of a dentition of the user in accordance with the treatment plan*, wherein each positive mold of the plurality of positive molds correspond with a specific step of the treatment plan; *and thermoforming polymer material to each of the plurality of positive molds to generate the plurality of aligners*.

’522 patent at 21:59-67 (claim 7). The District Court also conceded that that “*the claims themselves require either the production of aligners or a system for fabricating aligners*,” Appx00015, only to later reverse course yet again in concluding that “*the claims do not disclose* a method of manufacturing dental aligners.” Appx00020.

Moreover, the District Court’s finding that the ’522 patent only contained three lines of “general statements” on fabricating aligners not only improperly ignores the explicit language of the claims themselves, but also ignores the disclosures of U.S. Application Nos. 62/522,847, 15/725,430, and 62/648,229, disclosing additional details on manufacturing aligners (as well as on three-dimensional scanning techniques) which the ’522 patent specification “incorporated by reference in their entirety.” See ’522 patent at 15:65-16:9; see also *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001) (“When

a document is incorporated by reference into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.”).

Against this backdrop of clear statements in the Complaint, the ’522 patent specification, and the claims themselves, the District Court was not entitled to conclude that the ’522 patent does not disclose or claim a method for producing aligners for repositioning teeth.⁵ Doing so was contrary to the facts, and this type of improper factfinding resulted in legal error that tainted at least the Step One analysis, as discussed in further detail below.

The District Court also cherry-picked statements in SDC’s complaint that it used to then describe the entirety of the invention as a “workflow,” in an apparent attempt to cast the claims as being directed to merely “economic practices and methods of organizing business operations.” Appx00162⁶, Appx00181. However,

⁵ The District Court also improperly placed outsized emphasis on the ’522 patent’s title and abstract, Appx00022, while ignoring the claims and detailed disclosures in the specification. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1312 (Fed. Cir. 1999) (“[T]he purpose of the title is not to demarcate the precise boundaries of the claimed invention but rather to provide a useful reference tool for future classification purposes.”).

⁶ *See also* Appx00007 (“The remaining claims of the #522 patent recite additional permutations of the same general workflow . . .”), Appx00011 (“The dependent claims of the #522 patent simply add steps or conditions to the workflow recited in claim 1.”), Appx00012 (“The additional elements recited in claim 4 . . . do not change the fact that the claim is directed to an abstract workflow . . .”), Appx00013 (“[C]laim 20, as explained above, differs from claim 1 only insofar as it describes

the District Court appears to have misunderstood the context of these phrases—SDC’s complaint actually stated that “one of [SDC’s] key technological contributions is embodied in the ’522 patent” and that the methods and systems set forth in that patent “utiliz[e] SDC’s revolutionary workflow.” Appx00057 at ¶ 3. It ***did not say*** that the ’522 patent itself was ***only*** directed to or claimed merely a “workflow.”

The District Court also misleadingly stated that SDC’s Complaint concedes that the ’522 patent merely claimed a “business model.” *See, e.g.*, Appx00004 (“To use the words of the Complaint, the claimed invention is a ‘business model.’”), Appx00011 (“The independent claims all describe methods or systems that cover the same business strategy”), Appx00022 (“SDC’s insistence that the #522 patent teaches methods and systems for manufacturing is further undermined by its own characterization of Candid’s ‘business model’ as an implementation of the #522 patent ‘workflow.’”). As SDC’s Complaint makes clear, its brick-and-mortar

the claimed workflow as a system as opposed to a method.”), Appx00013-00014 (“In sum, the various dependent claims of the #522 patent specify different options that might be incorporated into the workflow described in claim 1.”), Appx00017 (“Individual claims add additional steps to the workflow or recharacterize it as a system rather than a method . . .”), Appx00019 (“*American Well* is particularly informative, because that patent at issue in the case was directed to a workflow . . .”), Appx00022 (“SDC’s insistence that the #522 patent teaches methods and systems for manufacturing is further undermined by its own characterization of Candid’s ‘business model’ as an implementation of the #522 patent ‘workflow.’”), Appx00024 (“[A]s noted above, the #522 patent does not teach a manufacturing process but instead describes a workflow . . .”)

“direct-to-consumer SmileShop[®] model” is “*part of* SDC’s teledentistry platform.” Appx00060-00061 at ¶ 19. That SDC “innovated and protected” its SmileShop[®] business model “with the ’522 patent,” *see id.*, does not mean that the ’522 patent claims a business model itself. It merely confirms that the ’522 patent claims technological improvements that contribute to SDC’s overall business success. The phrases “workflow” and “business model” do not appear anywhere in the ’522 patent, and the only instances of the word “model” are in reference to the three-dimensional or physical molds of a patient’s teeth that are part of the claimed process of manufacturing aligners. Nonetheless, the court seized on these few isolated phrases devoid of their context to color its analysis of whether all claims, whether asserted or unasserted, were directed to an abstract idea. This too, was an inappropriate finding divorced from the record.

The District Court also erroneously concluded that “[w]hen the #522 patent was filed in 2018, it was routine *to conduct business across geographical distance through the internet, to ship physical goods, and to use other modern information technologies,*” apparently as part of a factual determination that certain claimed features of the ’522 patent were routine or well-known at the time of filing. Appx00025-00026. As an initial matter, the District Court mistakenly relied on the wrong date for its analysis, as the patent claims priority to a prior application filed on June 21, 2017, over a year before the filing date the on which the District Court

relied. *See* '522 patent at 1:7-13. Moreover, the District Court's broad characterization of so-called "routine" elements as "conduct[ing] business across geographical distance through the internet," or "to ship physical goods," impermissibly overgeneralized the claims. Appx00025-00026. But most importantly, the District Court's sweeping conclusion and the broad characterizations on which it is based is directly at odds with the specific facts SDC pled in its Complaint:

Prior to SDC's innovative and revolutionary platform, ***patients had to visit state-licensed dentists or orthodontists in person***, on numerous occasions, and during limited office hours, throughout the course of treatment . . . Not only was this prohibitively expensive for many patients, but the dentist or orthodontist office was often inaccessible to the patient, whether due to location, scheduling issues such as work obligations or school that made repeat visits an impossibility, or other logistical obstacles.

Appx00059 at ¶ 14. That is, while other business may have been generally conducted across geographical distances through the internet, ***the specific business of dentistry or orthodontics was not***, according to SDC's well pled factual allegations in its Complaint. These allegations are consistent with the disclosures in the specification of the '522 patent, *see, e.g.*, '522 patent at 1:38-54, all of which the District Court was required to follow. *See, e.g., Spruill*, 372 F.3d at 223. Here, the District Court's reliance on its erroneous factfinding to inform its *Alice* Step Two analysis of whether all claims were directed to an inventive concept was another instance of clear legal error that it compounded with underlying factual errors.

3. The District Court Failed to Apply the Presumption of Validity

An issued patent is presumed to be valid, a presumption that this Court has extended to the question of patent eligibility. 35 U.S.C. § 282(a); *Cellspin Soft, Inc.*, 927 F.3d at 1319. That is, Candid had the burden to disprove this presumptive validity, and was required to do so under the clear and convincing standard. *Berkheimer*, 881 F.3d at 1368 (citing *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011)). This high burden of proof applies to the entire § 101 analysis, but especially to the underlying fact question of “whether a claim element or combination of elements is well-understood, routine, and conventional to a skilled artisan in the relevant field.” *Id.* For this reason, judgment of invalidity as a matter of law “is generally reserved for extreme cases.” *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1364 (Fed. Cir. 2018) (quotation omitted).

The presumption of validity is derived from recognition of the deference owed to the USPTO. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984), *cert denied*, 469 U.S. 821 (1984); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 97 (2011). This presumption of validity requires the court to employ a decisional approach that starts with acceptance of the patent as valid, and then looks to the party asserting invalidity for clear and convincing proof of the contrary. *Id.* Here, the Examiner for the '522 patent explicitly emphasized that the key features of the patented methods and systems, i.e., generating aligners based on

a treatment plan without the approving professional seeing the patient, and providing the aligners directly from the fabrication site to the patient, were key factors in allowing the patent to issue. *See, e.g.*, Appx00251 (discussing the prosecution history). The USPTO also issued a notice of allowance for U.S. Patent Application No. 16/859,950, the continuation of the '522 patent containing the same specification and similar claims to those of the '522 patent, *after* considering Candid's briefing and arguments made in the District Court. *See* Appx00291-00292.

Not only did Candid not come close to meeting this high burden to disprove validity, but the District Court failed to meaningfully apply this presumption. As discussed above, the District Court either accepted Candid's unsupported attorney argument or substituted its own factfinding in place of the well pled factual allegations from SDC's Complaint, as well as the factual statements in the '522 patent. *See supra*, Argument, §§ II.A.1-2. And in doing so, the District Court failed to even mention the presumption of validity that the '522 patent enjoys, nor did it ever indicate in its Opinion that it would apply the "clear and convincing" standard to whatever ostensible support Candid offered for its positions. And at the motion to dismiss stage, where all facts must be viewed in the light most favorable to SDC and all of its well pled factual allegations must be accepted as true, the District Court was not entitled to disregard those facts absent directly contradictory statements in the '522 patent or elsewhere in the pleadings (which simply do not exist in this case).

This was yet another legal error that should be cause for reversal. *See, e.g., Cellspin Soft, Inc.*, 927 F.3d at 1319.

4. The District Court’s Failure to Apply the Proper Legal Framework is Reversible Error Before Even Reaching the Merits of the *Alice* Analysis

At bottom, the District Court was not entitled to improperly and cavalierly jettison the well-known legal standards governing motions to dismiss. Nor was the District Court’s failure here merely harmless. Indeed, it had the very real effect of tainting its entire analysis, as the District Court improperly relied on its own factfinding and/or Candid’s attorney argument and ignored all record evidence concerning the nature and background of the SDC inventions, which was limited to the well pled factual allegations in the Compliant and in the ’522 patent. This Court has previously cautioned the District Court against “characteriz[ing] the claims without mention of what, for at least some (perhaps all) of the claims at issue, the claim language and specifications make clear are important parts of what the patents assert are the advances in the art.” *Realtime Data LLC v. Reduxio Sys., Inc.*, 831 F. App’x 492, 499 (Fed. Cir. 2020) (Taranto, J., concurring). But just like in *Realtime Data*, “[t]he district court’s truncated characterization of claim 1 . . . and of some or all of the other claims at issue, created an incorrect starting point for the required analysis.” *Id.* at 500. By refusing to recognize the ’522 patent as claiming aspects of a process for producing a tangible product, i.e., custom aligners for repositioning

the teeth of a user, the District Court simply misunderstood and miscast the technology, and used its erroneous reading to conduct a flawed analysis untethered from the language of the claims, the remainder of the specification, or from the factual allegations in SDC's Complaint. The District Court's misapplication of the proper legal standards led to its misunderstanding of the facts. Doing so was clear legal error that should be reversed.

B. The District Court Erred in its *Alice* Step One Analysis

1. The District Court Improperly Oversimplified the Inventive Concepts and Downplayed the Benefits of the '522 Patent

When looking at Step One, “courts ‘must be careful to avoid oversimplifying the claims’ by looking at them generally and failing to account for the specific requirements of the claims.” *McRO, Inc.*, 837 F.3d at 1313 (quoting *TLI Commcn's*, 823 F.3d at 611 and citing *Diamond v. Diehr*, 450 U.S. 175, 189 n.12 (1981)). “[A] court must look to the claims as an ordered combination, without ignoring the requirements of the individual steps,” and determine “whether the claims in these patents focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery.” *Id.* at 1313-14.

Accordingly, “determin[ing] whether the claims at issue are directed to a patent ineligible concept” is a “meaningful one, i.e., that a substantial class of claims

are **not** directed to a patent-ineligible concept.” *Enfish*, 822 F.3d at 1335 (quoting *Alice*, 134 S. Ct. at 2355). As this Court explained:

The “directed to” inquiry, therefore, cannot simply ask whether the claims **involve** a patent-ineligible concept, because essentially every routinely patent-eligible claim involving physical products and actions **involves** a law of nature and/or natural phenomenon—after all, they take place in the physical world. Rather, the “directed to” inquiry applies a stage-one filter to the claims, considered in light of the specification, based on whether their character as a whole is directed to excluded subject matter.

Id. (quotations and citations omitted). This Court went on to explain that “describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule.” *Id.* at 1337. But that is exactly what the District Court did when it declared that “[t]he #522 patent claims are directed to the abstract idea of ‘teleorthodontics.’” Appx00011.

None of the claims of the ’522 patent are directed to an abstract idea. The claimed methods and systems are for “producing aligners for repositioning one or more teeth of a user,” which covers a patent-eligible process. The claims are drawn “to a concrete task . . . [and] the claim[s] require[] specific physical tasks to be performed using specific tangible items in a specific order.” *Borehead, LLC v. Ellingson Drainage, Inc.*, No. 17-cv-5269, 2018 WL 2338806, at *1 (D. Minn. May 23, 2018); *Green Mountain Glass, LLC v. Saint-Gobain Containers, Inc.*, No. CV 14-392-GMS, 2016 WL 7510247, at *1 n.1 (D. Del. Oct. 11, 2016) (manufacturing method patent eligible where the “steps [are] grounded in physical action” and the

claims “describe a manufacturing process for recycling batches of mixed colored cutlet glass into glass bottles with desired properties . . . [requiring] steps that the glass-maker must physically carry out—he cannot simply use his mind or a pen and paper to perform them.”); *Nike, Inc. v. Puma N. Am., Inc.*, CV 18-10876-LTS, 2018 WL 4922353, at *4 (D. Mass. Oct. 10, 2018) (holding patent related to “tangible manufactured items (footwear), physical components thereof (knitted uppers), or the processes for manufacturing such items or components” would “plainly appear” to be directed to patent-eligible subject matter); *see also Diehr*, 450 U.S. at 184 (“Industrial processes . . . have historically been eligible to receive the protection of our patent laws.”).

2. The Claims of the ’522 Patent Are Not Comparable to Other Claims Found to Cover Abstract Ideas

As discussed above, the ’522 patent claims are not “directed to” merely conducting health-related business over the internet. *See supra*, Statement of Facts § I; Argument §§ II.A.1-2. For this reason, the District Court’s reliance on cases with patents claiming methods of “conducting [standard business practice] over the internet” or “telehealth business methods” is inapposite. *See* Appx00018; Appx00019. Unlike the ’522 patent, which claims methods and systems that improve the prior art process of producing a finished product, i.e., aligners, the patents at issue in *Becton-Dickinson* and *American Well* merely claimed using a computer to remotely consult with or supervise others. *See Becton, Dickinson & Co.*

v. Baxter Int'l, Inc., 127 F. Supp. 3d 687, 689, 692-93 (W.D. Tex. 2015) (claims were directed to a pharmacist remotely supervising pharmacy functions performed by non-pharmacist personnel); *Am. Well. Corp. v. Teladoc, Inc.*, 191 F. Supp. 3d 135, 138 (D. Mass. 2016) (claims were directed to using a computer program “for providing broker services” to consumers and service providers to connect patients to doctors).

Similarly, the District Court’s reliance on *Align Techs., Inc. v. 3Shapes A/S* improperly focused on a holding regarding a patent on a structureless workflow. 339 F. Supp. 3d 435, 456-67 (D. Del. 2018). Notably, the District Court ignored a different holding in *Align*, ***one that is more relevant and comparable to the case here***, in which Align’s ’149 patent, titled “Systems and Methods for Fabricating a Dental Template,” was found patent eligible. *Align*, 339 F. Supp. 3d at 456-457. Like the claims of SDC’s ’522 patent, the claims of Align’s ’149 patent are directed to “fabricating a dental template.” *Id.* at 456.⁷

⁷ Similar to the claims of SDC’s ’522 patent, claim 13 of the ’149 patent claims a “system of fabricating a dental template to position a plurality of objects on a patient’s teeth,” in which a computer performs several steps leading it to “output fabrication data for fabricating a template to locate the orthodontic objects on the patient’s teeth.” *Id.*; compare, e.g., with ’522 patent at claim 20 (claiming a “system for producing aligners for repositioning one or more teeth of a user, the system comprising: . . . equipment configured to produce a plurality of aligners based on the treatment plan data, the plurality of aligners being specific to the user and being configured to reposition one or more teeth of the user based on the treatment plan.”).

The accused infringer in *Align* argued that the claims were directed to an abstract idea rather than a process for fabricating aligners, alleging that “fabricating a dental template” was only alluded to “in the preamble and as an intended use of the data ‘output’ by the claimed computer software of asserted claim 13.” *Id.* But the *Align* court rejected that argument, finding that “claim 13 is directed to an improvement over prior approaches to indirect bonding techniques for orthodontic brackets,” relying on disclosures from the ’149 patent specification and claims, which described the problem in the prior art and provided details on how to achieve the claimed solution. *Id.* at 456-457. Because it held that the ’149 patent was not directed to an abstract idea, the *Align* court did not need to address Step Two. *Id.* at 457.

In stark contrast to the *Align* decision, this District Court failed to conduct a similar analysis. The District Court flatly ignored the disclosures from the ’522 patent explaining the problems in the prior art and disclosing the claimed solutions to such problems. Given that the fabrication steps throughout the ’522 patent claims are demonstrably meaningful and tangible claim limitations that reside outside the preamble of the claims, this would not have been a close case if the District Court had applied the same framework from the *Align* case.

Long-standing Supreme Court precedent further confirms that the types of claims recited in the ’522 patent are not foreclosed by § 101. For example, in *Diehr*,

the Supreme Court found that claims directed to using a computer to automate the process of curing rubber were patent eligible. 450 U.S. at 191 (1981). Although the underlying formula was well known and the remaining steps of the claims—such as installing rubber in a press, closing the mold, determining the temperature of the mold, and opening the press—were not themselves novel, the Supreme Court found that the combination of these elements constituted a specific process for molding rubber and not an attempt to patent an abstract idea. *Id.* at 187. The Court recognized that “one does not need a ‘computer’ to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of ‘overcuring’ or ‘undercuring,’ the process as a whole does not thereby become unpatentable subject matter.” *Id.* Like the claims in *Diehr*, the ’522 patent claims are directed to specific processes that use a specific set of special purpose equipment, *e.g.*, intraoral scanners, or specially programmed equipment, *e.g.*, the computing systems that are part of the claimed fabrication system, in an ordered combination of steps to generate and deliver personalized aligners to users without the need for numerous costly, time-consuming in person visits.

Though it only spent a few sentences discussing *Diehr*, the District Court correctly noted that “the patent [in *Diehr*] was subject-matter eligible because the invention was applied as an integral part of an improved manufacturing process.” Appx00023. Similar to *Diehr*, the invention of the ’522 patent also is directed to

non-abstract, technological improvements in the field, as discussed *supra*. The District Court also correctly noted that the claims in *Nike, Inc. v. Puma North America, Inc.* “were subject matter eligible because they were directed to improving the physical process of manufacture itself.” Appx00022. But the District Court’s distinguishing of these cases ostensibly based on its erroneous finding that “the #522 patent does not concern how . . . [or] . . . does not depend on how the aligners are fabricated,” Appx00023, was borne of both legal and factual error, as discussed *supra*. It accordingly follows that the District Court’s disregard and/or misreadings of *Align, Diehr*, and *Nike* (as well as *Green Mountain Glass*, which the District Court failed to even address) was an extension of its original error.

The District Court was required to consider the claims “in their entirety to ascertain whether their character as a whole is directed to excluded subject matter,” *Internet Patents Corp.*, 790 F.3d at 1346. But the District Court instead ignored the plain language of the claims, and at times, ignored parts of its own Opinion. *See, e.g., supra*, Argument, § II.A.1-2 (repeatedly characterizing the claimed invention as merely a “business model” or “workflow” and refusing to recognize that the patents claim a method for manufacturing aligners). That is, the District Court walked right into the erroneous over-generalizing of claim language that this Court in *Enfish* warned against. *See Enfish*, 822 F.3d at 1337; *see also Realtime Data*, 831 F. App’x at 500 (finding reversible legal error where the district court “disregarded

limitations, in at least some of the patent claims at issue, that are part of the focus of the asserted advances”). The District Court’s holding that the ’522 patent claims were directed to an abstract idea was the product of applying the wrong legal standards and conducting improper and incomplete factfinding, as well as ignoring the claims as a whole. This improper approach led to the District Court’s reliance on the wrong line of case law, causing it to arrive at a clearly erroneous result finding the ’522 patent to be directed to an abstract idea. This Court should accordingly reverse the District Court’s holding.

3. The Claims of the ’522 Patent do Not Preempt the Field of Teledentistry

Preemption is “the concern that drives” § 101 jurisprudence. *Alice*, 134 S. Ct. at 2354. As the Supreme Court has explained, courts must ask whether the limitations in the patent claims, *taken as a whole*, “add *enough*” in the way of specific, practical application to differentiate the scope of the claimed invention from the underlying abstract idea itself. *See, e.g., Mayo Collaborative Svcs. V. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012). The claim “must include additional features to ensure that the claim is more than a drafting effort designed to monopolize the abstract idea.” *Alice*, 134 S. Ct. at 1235 (quotation and brackets omitted).

Here, the claims require specific equipment and specific steps to be used in a specific order and distributed arrangement, under the specific condition that the

approving professional does not physically see the patient, resulting in fabrication of aligners at a specific location that in turn are required to be sent directly to the user. In particular, the claims call for a “scanner,” “aligners,” a “treatment plan” that is based on the “three-dimensional data” of a user, and specific material from which the aligners are to be fabricated. *See, e.g.*, ’522 patent at 20:35-21:8, 21:59-67, 22:25-65, 23:5-21, 23:39-25:17. The scanner must produce a three-dimensional image that provides three-dimensional data on which the treatment plan is based on, and claimed “produc[tion] . . . of a plurality of aligners” results in aligners that are “specific to the user” and “configured to reposition one or more teeth of the user in accordance with the treatment plan.” *Id.* at 20:54-57, 20:67-21:3, 22:34-36, 22:58-62. The ’522 patent claims are limited to the production of aligners using a process or platform that includes all of the specifically claimed limitations.

The District Court’s own analogies of “conduct[ing] business across geographical distance through the internet” or even “connecting patients with orthodontists remotely,” *see, e.g.*, Appx00018, Appx00025-00026, provide examples underscoring the lack of any preemption by the ’522 patent. That is, no risk exists that the claims of the ’522 patent would monopolize the entire field of teleorthodontics (a field that encompasses *significantly* more than just aligner-based therapy), or even the processes for producing aligners for repositioning teeth. Indeed, the abstract idea exception has been applied to prevent patenting of claims

that abstractly cover results where the process or machinery does not matter to the result that is accomplished. *See, e.g., Mayo*, 132 S. Ct. at 1301. But here, the independent claims recite specific requirements for an improved process for manufacturing aligners for repositioning the teeth of a user. Indeed, when those claims are viewed as a whole, and in an ordered combination, it becomes clear that the coordinated and distributed process for generating three dimensional scan data and using it to manufacture custom-aligners, all without the user ever having to physically see a dental professional, limit the breadth of the claims and do not prevent persons from producing aligners “by any means whatsoever” otherwise carrying out a known process on a conventional computer.

Record evidence is needed for a court to decide a claim is ineligible under § 101 due to preemption. *See McRO, Inc.*, 837 F.3d at 1315 (“Defendants’ attorney’s argument that any rules-based lip-synchronization process must use the claimed type of rules has appeal, but no record evidence supports this conclusion.”). Here, without evidence to support its finding, the District Court’s decision was a *de facto* conclusion that the claims of the ’522 patent unduly preempt the field of teledentistry. But that cannot be true, because the claims are limited to coordinated and distributed processing of intraoral scan data using specific equipment in a specific order to produce aligners that are custom to each user.

The District Court’s focus on whether or not SDC “invent[ed] the use of intraoral scans to create aligners” or whether or not the specifically claimed process may be implemented using “existing scanners . . . and existing computer processes” misses the point, as is the District Court’s improper disregard of specific claim limitations, such as those directed to manufacturing aligners. Appx00025. In fact, the District Court did not address the issue of preemption at all. That is, the question of whether any of the ’522 patent claims would preempt the “building blocks” of research in this field and “risk disproportionately tying up the use of the underlying ideas,” was not addressed in its Opinion. *Alice*, 134 S. Ct. at 2354-55, 2357 (internal quotation marks, brackets and citations omitted). This is yet another fundamental flaw in the District Court’s Opinion, and one which also mandates reversal. At a minimum, the District Court’s silence as to preemption suggests that even it agreed that the ’522 patent does not improperly tie up all applications of a generic concept.

C. The District Court Erred in its *Alice* Step Two Analysis

Here, the claims are not directed to an abstract idea, and the Court does not need to continue to Step Two. But if this Court were to assume that the patent is directed to an abstract idea, the District Court’s error becomes even more evident, because the claims recite significantly more than the purported ideas of “conducting business over the internet” or “telehealth business methods.” As discussed below, the District Court erred in focusing exclusively on individual components, without

considering the ordered combination, as is appropriate in Step Two. Moreover, and similar to its erroneous Step One analysis, the District Court relied on an incorrect—and incomplete—reading of the claims which it then used to reach cursory conclusions that the claim elements do not transform the allegedly abstract ideas into patent-eligible subject matter. Furthermore, the District Court impermissibly utilized its own factfinding, which is directly at odds with the record evidence, to reach its conclusions in Step Two. Because the District Court applied a flawed legal framework to its own factual conclusions—conclusions that are at odds with the record evidence—the ruling must be reversed.

The District Court’s flawed approach improperly parsed claim 1 into handpicked individual components (while ignoring other key limitations) and declared (without any record support) that each component, individually, was either not invented by SDC or was otherwise routine and conventional. *See, e.g.*, Appx00025 (“SDC did not invent the use of intraoral scans to create aligners.”); *see also* Appx00024 (discussing the elements of the ’522 patent as “using routine scanning technology, generic computers, and routine communication technology”). This was an improper framework from which to analyze whether the claims contain an inventive concept, and impermissibly conflated novelty with the eligibility analysis. *See Bascom*, 827 F.3d at 1350 (“The inventive concept inquiry requires more than recognizing that each claim element, by itself, was known in the art.”).

The District Court further failed to consider the claim limitations as an ordered combination.⁸

But even operating under its legally flawed framework, the District Court did not even analyze each element of the claims or to consider the claims as a whole. Instead, the District ignored claim elements, including those relating to generating a treatment plan based on the actual generation and manufacture of aligners. *See* Appx00024 (“[T]he #522 patent does not teach a manufacturing process but instead describes a workflow ...”). For example, the District Court asserted that “claim 1 says nothing about manufacturing *except that the method includes ‘producing, at a fabrication site, a plurality of aligners based on the treatment plan.’*” Appx00024-00025. That is, the District Court contradicted its own finding in the very same sentence by minimizing or otherwise disregarding a specifically claimed element. Again, the District Court failed to view the claims as a whole, as claim 1 further includes the limitation of “the plurality of aligners” being “specific to the user and

⁸ Nor did the District Court indicate that it conducted anything resembling a serious inquiry into whether or not any of the ’522 patent claims should have been construed as an ordered combination. Rather remarkably, the Court stated that “neither party takes a position on whether the claims should be read to require a particular order,” Appx00016, after previously acknowledging that SDC “argues that it is necessary to determine whether the steps of the claimed methods must be performed in a particular order.” Appx00015 (citing SDC’s Opposition Br. At 7-8); *Cf. Bascom*, 827 F.3d at 1349 (holding that “the limitations of the claims, taken individually, recite generic computer, network and Internet components, none of which is inventive by itself,” but nonetheless determined that an ordered combination of these limitations was patent-eligible under Step Two).

being configured to reposition one or more teeth of the user in accordance with the treatment plan,” for example. ’522 patent at claim 1. The preamble of claim 1 also states that the claim is a “method of producing aligners for repositioning one or more teeth of a user.” *Id.* These types of errors which “disregarded limitations . . . that are part of the focus of the asserted advances,” *see Realtime Data*, 831 F. App’x at 500, permeate the District Court’s entire Step Two analysis.

Moreover, and perhaps most egregious of all, the District Court impermissibly conducted its own factfinding regarding whether the asserted claim elements, alone or in combination, were well-understood, routine, and conventional at the relevant time. *See, e.g.*, Appx00024 (stating, without record support, that “the claims only recite routine and well-understood practices”). But the Federal Circuit's recent decisions in *Berkheimer* and *Aatrix* confirm that any genuine dispute over these activities raises factual issues that cannot be resolved without a fully developed record, rendering dismissal inappropriate at this stage. In *Berkheimer*, the Federal Circuit reversed a finding of summary judgment as to certain claims because there was “a genuine issue of material fact in light of the specification regarding whether [the claims] archive documents in an inventive manner that improves these aspects of the disclosed archival system . . . making summary judgment inappropriate with respect to these claims.” 881 F.3d at 1370. Similarly, the *Aatrix* court applied this same principle to overturn a judgment on the pleadings. There, this Court held that

the plaintiff's "allegations at a minimum raise factual disputes underlying the § 101 analysis, such as whether the claim term 'data file' constitutes an inventive concept, alone or in combination with other elements, sufficient to survive an Alice/Mayo analysis at the Rule 12(b)(6) stage." *Aatrix*, 882 F.3d at 1126. And this Court previously reversed the District Court in a prior case, in part because it displayed "an apparently improper focus on factual questions that are unsuitable for resolution at the pleading stage and a failure to evaluate the claims as a whole." *Realtime Data*, 831 F. App'x at 496.

The District Court's holding plainly fails to take into account that SDC's Complaint alleges that the claimed methods do not simply automate the ordinary practice of healthcare professionals. Rather, the claimed methods and systems improve upon the prior art systems by manufacturing aligners based upon a coordinated process using distributed equipment that eliminates the need for customers to adhere to inconvenient schedules of their providers and for those providers to adhere to a defined limit of patients they can see in a single day. Appx00059-00062 at ¶¶ 13-24. This not only increases patient access and reduces both financial and time-related costs, but also represents a patentable improvement over the previously known methods for generating aligners. *Id.* The claimed process also solved problems such as errors in the mold process that required the patient to return to the dental office to create additional impressions. *Id.*; see also '522 patent

at 1:38-50. It also provided for improved treatment plans and eliminated the need for the patient to return to the dental office for frequent in person visits and potentially additional impressions in the event the treatment plan required modification. Appx00059-00062.

At the motion to dismiss stage, the District Court was required to accept those allegations as true. And because those facts allege improvements in the efficiency of the process for generating and obtaining aligners, the District Court, being bound by those facts, was required to find that Step Two was satisfied. *See, e.g., Berkheimer*, 881 F.3d at 1369 (noting that technology that “eliminates redundancies [and] improves system efficiency” is sufficiently inventive to transform an abstract idea into a patent-eligible concept); *Jaguar Land Rover Ltd. v. Bentley Motors Ltd.*, 388 F. Supp. 3d 665, 681–82 (E.D. Va. 2019) (denying a motion to dismiss where “the only evidence currently before the Court on inventiveness suggests that the technology embodied in the '828 patent improves efficiency and therefore, is inventive”); *Trs. of Columbia Univ. in N.Y. v. Symantec Corp.*, 425 F. Supp. 3d 601, 612 (E.D. Va. 2019) (denying motion to dismiss where patentee alleged its “improv[ed] computer virus scanning in at least two ways: (1) the creation of unique models and (2) improvements in efficiency”).

Finally, contrary to the District Court’s reasoning, the inventions’ potential utilization of already existing computers and equipment for several of the claimed

process steps, *see* Appx00024-00025, does not render them ineligible. *See, e.g., Enfish*, 822 F.3d at 1338. This Court has also rejected the argument that the claims were patent-ineligible because they could be implemented on a general-purpose computer, holding that “a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software.” *In re Alappat*, 33 F.3d 1526, 1545 (Fed. Cir. 1994), *abrogated on other grounds, In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

As discussed above, the District Court was required to accept SDC’s well-pleaded facts regarding the state of the art prior to the ’522 patent and the solutions contained in SDC’s inventions as true. But the District Court not only ignored those factual allegations, it went even further and again conducted its own impermissible factfinding that was central to its erroneous conclusion that the ’522 patent claims lacked an inventive concept. While this Court need not even reach Step Two because the ’522 patent is not directed to an abstract concept, the District Court’s holding here was the result of legal and factual error, and accordingly it should also be reversed.

CONCLUSION AND PRAYER

For the reasons stated herein, the District Court’s erroneous ruling of patent ineligibility under § 101 should be reversed.

Dated: February 22, 2021

/s/ Kal K. Shah

Kal K. Shah

Simeon G. Papacostas

BENESCH FRIEDLANDER

COPLAN &

ARONOFF LLP

71 South Wacker Drive

Chicago, IL 60606

(312) 212-4949

Counsel for Plaintiff/Appellant

SmileDirectClub, LLC

ADDENDUM

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMILEDIRECTCLUB, LLC,

Plaintiff,

v.

CANDID CARE CO.,

Defendant.

Civil Action No. 20-0583-CFC

ORDER

At Wilmington this Seventh day of December in 2020:

For the reasons set forth in the Memorandum Opinion issued this day, **IT IS**
HEREBY ORDERED that Defendant Candid Care Co.'s Motion to Dismiss
Pursuant to Federal Rule of Civil Procedure 12(b)(6) (D.I. 12) is **GRANTED**.


UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMILEDIRECTCLUB, LLC

Plaintiff,

v.

Civil Action No. 20-0583-CFC

CANDID CARE CO.,

Defendant.

Kevin M. Capuzzi, BENESCH FRIEDLANDER COPLAN & ARONOFF, Wilmington, Delaware; Kaplash K. Shah, Manish K. Mehta, Noelle Briana Torrice, Suzanne M. Alton de Eraso, Simeon Papacostas, BENESCH FRIEDLANDER COPLAN & ARONOFF, Chicago, Illinois; Michael S. Weinstein, BENESCH FRIEDLANDER COPLAN & ARONOFF, Cleveland, Ohio

Counsel for Plaintiff

Rodger Dallery Smith, II, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington; Michael P. Sandonato, Sean M. McCarthy, VENABLE LLP, New York, New York; Edmund J. Haughey, VENABLE LLP, Washington, District of Columbia

Counsel for Defendant

MEMORANDUM OPINION

December 7, 2020
Wilmington, Delaware

Crrz22224



COLM F. CONNOLLY

UNITED STATES DISTRICT JUDGE

Plaintiff SmileDirectClub, LLC (SDC) has sued Defendant Candid Care, Co. for infringement of U.S. Patent No. 10,636,522 (the #522 patent). D.I. 1. Pending before me is Candid's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). D.I. 12. Candid argues that I should dismiss SDC's complaint because the asserted patents are invalid under 35 U.S.C. § 101 for failing to claim patentable subject matter.

I. BACKGROUND

SDC and Candid are competitors in the so-called "direct-to-consumer orthodontics" or remote teleorthodontics business. This business was made possible by the development of intraoral scanners that non-dentist technicians use to take images of a patient's teeth and create three-dimensional, digital representations from which personalized aligners are made for self-insertion by the patient to straighten and reposition teeth. D.I. 1 ¶ 22.

The #522 patent does not describe how to make an intraoral scanner, aligners, or three-dimensional representations of teeth; indeed, the patent does not purport to teach any advances in machinery, equipment, devices, or computer technology. Rather, the invention claimed by the #522 patent is, to use the words of the patent's abstract, "[s]ystems and methods for arranging an intraoral scanning

at a selected location.” #522 patent at abstract. To use the words of the Complaint, the claimed invention is a “business model,” D.I. 1 ¶4, and “revolutionary workflow,” *id.* ¶ 3. Specifically, the #522 patent claims systems and methods by which a patient’s intraoral scan is scheduled, performed, and used to create aligners and the patient receives orthodontic treatment without ever interacting in person with a dentist or orthodontist. D.I. 1 ¶ 16.

The patent has thirty claims. The Complaint alleges that Candid infringes the patent’s four independent claims and “various dependent claims.” D.I. 1. ¶ 69. Candid argues that independent claim 1 is representative. D.I. 9–10. It recites

[a] method of producing aligners for repositioning one or more teeth of a user, the method comprising:

receiving, by an appointment management system, a request to schedule an appointment at an intraoral scanning site, the intraoral scanning site having an intraoral scanner configured to scan a mouth of a user, the appointment being for a technician to conduct an intraoral scan of the mouth of the user at the intraoral scanning site without a dentist or orthodontist physically seeing the user during the scheduled appointment, wherein the technician is not a dentist or an orthodontist;

scheduling, by the appointment management system, the appointment at the intraoral scanning site in accordance with the request;

generating and communicating, by the appointment management system, a message to a device of the user, the message including a confirmation confirming the scheduled appointment;

conducting, using the intraoral scanner, the intraoral scan at the intraoral scanning site during the scheduled appointment, the intraoral scan generating three-dimensional data of the mouth of the user;

causing generation, by a treatment plan computing system located at a treatment plan site, of a treatment plan for the user based on the three-dimensional data of the mouth of the user;

receiving an indication of an approval of the treatment plan by a dental or orthodontic professional, wherein the approval is received without the dental or orthodontic professional having physically seen the user;

producing, at a fabrication site, a plurality of aligners based on the treatment plan, the plurality of aligners specific to the user and being configured to reposition one or more teeth of the user in accordance with the treatment plan; and

sending the plurality of aligners from the fabrication site directly to the user, wherein the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.

SDC takes the position that no single claim of the patent is representative.

When I limited SDC to two asserted claims for purposes of deciding its pending preliminary injunction motion, SDC selected claims 4 and 20. D.I. 31 at 2. Claim 4, which depends from claim 1, recites

[t]he method of claim 1, wherein the approval by the dental or orthodontic professional is a first approval, the method further comprising:

responsive to receiving the first approval, providing data indicative of the treatment plan to the user; and

receiving a second approval of the treatment plan,
wherein the second approval of the treatment plan is
received from the user following the first approval being
received from the dental or orthodontic professional;

wherein producing the plurality of aligners is performed
responsive to receiving the first approval and the second
approval of the treatment plan.

Claim 20 recites

[a] system for producing aligners for repositioning one or
more teeth of a user, the system comprising:

an appointment management system configured to:

receive a request to schedule an appointment at an
intraoral scanning site, the appointment being for a
technician to conduct an intraoral scan of a mouth of a
user at the intraoral scanning site without a dentist or
orthodontist physically seeing the user during the
scheduled appointment, wherein the technician is not a
dentist or orthodontist;

schedule the appointment at the intraoral scanning site in
accordance with the request;

generate and communicate a message to a device
associated with the user, the message including a
confirmation confirming the scheduled appointment;

the intraoral scanning site comprising:

an intraoral scanner configured to generate three-
dimensional data from the intraoral scan of the mouth of
the user; and

one or more intraoral scanning site computing systems
configured to communicate the three-dimensional data

from the intraoral scanner for generation of a treatment plan, wherein the treatment plan is approved by a dental or orthodontic professional without the dental or orthodontic professional having physically seen the user; and

a fabrication system including one or more fabrication sites associated with the production and shipment of aligners, the fabrication system comprising:

one or more fabrication computing systems configured to receive treatment plan data corresponding to the treatment plan for the user; and

equipment configured to produce a plurality of aligners based on the treatment plan data, the plurality of aligners being specific to the user and being configured to reposition one or more teeth of the user based on the treatment plan;

wherein the plurality of aligners are sent from at least one of the one or more fabrication sites directly to the user for repositioning the one or more teeth of the user, and the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.

The remaining claims of the #522 patent recite additional permutations of the same general workflow, described either as methods (as in claim 1) or as systems (as in claim 20).

II. LEGAL STANDARDS

A. Stating a Claim

To state a claim on which relief can be granted, a complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.”

Fed. R. Civ. P. 8(a)(2). Detailed factual allegations are not required, but the complaint must include more than mere “labels and conclusions” or “a formulaic recitation of the elements of a cause of action.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). The complaint must set forth enough facts, accepted as true, to “state a claim to relief that is plausible on its face.” *Id.* at 570. A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Deciding whether a claim is plausible is a “context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* at 679 (citation omitted).

When assessing the merits of a Rule 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and in documents explicitly relied upon in the complaint, and it must view those facts in the light most favorable to the plaintiff. *See Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008); *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (internal quotation marks omitted).

B. Patent-Eligible Subject Matter

Section 101 of the Patent Act defines patent-eligible subject matter. It provides: “Whoever invents or discovers any new and useful process, machine,

manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101.

There are three judicially-created limitations on the literal words of § 101. The Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter. *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014). These exceptions to patentable subject matter arise from the concern that the monopolization of “these basic tools of scientific and technological work” “might tend to impede innovation more than it would tend to promote it.” *Id.* (internal quotation marks and citations omitted). Abstract ideas include mathematical formulas and calculations. *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

“[A]n invention is not rendered ineligible for patent [protection] simply because it involves an abstract concept[.]” *Alice*, 573 U.S. at 217.

“[A]pplication[s] of such concepts to a new and useful end . . . remain eligible for patent protection.” *Id.* (internal quotation marks and citations omitted). But in order “to transform an unpatentable law of nature [or abstract idea] into a patent-eligible application of such law [or abstract idea], one must do more than simply state the law of nature [or abstract idea] while adding the words ‘apply it.’” *Mayo*

Collaborative Servs. v. Prometheus Lab 'ys, Inc., 566 U.S. 66, 71 (2012) (emphasis omitted).

In *Alice*, the Supreme Court made clear that the framework laid out in *Mayo* for determining if a patent claims eligible subject matter involves two steps. The court must first determine whether the patent's claims are drawn to a patent-ineligible concept—i.e., are the claims directed to a law of nature, natural phenomenon, or abstract idea? 573 U.S. at 217. If the answer to this question is no, then the patent is not invalid for teaching ineligible subject matter. If the answer to this question is yes, then the court must proceed to step two, where it considers “the elements of each claim both individually and as an ordered combination” to determine if there is an “inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Id.* at 217–18 (alteration in original) (internal quotations and citations omitted). A claim recites an inventive concept “when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known to the industry.” *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018), *cert. denied*, 2020 WL 129532 (U.S. Jan. 13, 2020) (internal quotation marks, alterations, and citations omitted).

III. DISCUSSION

Applying the two-step framework from *Alice*, I find that the claims of the #522 patent recite patent-ineligible subject matter. The #522 patent claims are directed to the abstract idea of “teleorthodontics” and do not contain any inventive concept.

A. All Claims Can Be Considered Together

After reviewing all thirty claims of the #522 patent, I conclude that the claims are all substantially similar and that no individual claim contains limitations that raise distinct issues for determining that claim’s § 101 eligibility. *See Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1348 (Fed. Cir. 2014) (holding that substantially similar claims directed to the same abstract idea can be considered together for subject matter eligibility). The independent claims all describe methods or systems that cover the same business strategy. When the only difference between claims is the form in which they are drafted, it is appropriate to treat them as “as equivalent for purposes of patent eligibility under § 101.” *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1277 (Fed. Cir. 2012).

The dependent claims of the #522 patent simply add steps or conditions to the workflow recited in claim 1. None of these additional limitations affect the *Alice* analysis. For example, claim 2 adds a videoconference between the patient

and the dentist or orthodontist while claim 12 requires that there is no such videoconference. Claim 3 specifies that the generation of the treatment plan uses a treatment plan computing system. Each dependent claim is directed to the same idea and none add any new technological improvements.

The similarity of the claims for the purposes of § 101 can be illustrated by comparing claims 1, 4, and 20. Claim 1 describes a series of steps that enable a patient, who never sees a dentist or orthodontist in person, to arrange for an intraoral scan and receive aligners based on that scan. First, the patient uses an “appointment management system” to arrange for an intraoral scan. Next, the scan is taken, and that scan is used as input for a “treatment plan computing system.” A dentist or orthodontist remotely approves the treatment plan, and the aligners are “produc[ed]” and sent to the patient. #522 patent at claim 1. The additional elements recited in claim 4 merely require that the patient, and not just the treating orthodontist or dentist, approve the treatment plan. They do not change the fact that the claim is directed to an abstract workflow; and the addition of the patient’s approval does not add an inventive feature that affects step two of *Alice*.

Claim 20 describes the same workflow, but as a system. The system has three components that perform the steps described in claim 1: (1) a generic “appointment management system,” (2) an “intraoral scanning site,” and (3) a “fabrication system.” #522 patent at claim 20. As with the other claims, this

system enables a patient to arrange for and receive aligners without ever interacting in person with a dentist or orthodontist. #522 patent at claim 20. Since claim 20 merely restates in a different form the same workflow recited in claim 1, the claims can be considered together.

SDC argues that a representative claim analysis is inappropriate, because Candid did not conduct a meaningful analysis of every claim. D.I. 17 at 8. But Candid explained that the independent claims were different formulations of the same workflow and that none of the dependent claims added limitations that affect subject-matter eligibility. D.I. 9–12. SDC makes specific arguments against representativeness only with respect to claims 3, 7, 15, 16, and 20. SDC argues that these claims include concrete technical improvements not present in the remaining claims.

Claim 3, however, simply expands on the computational process for generating a treatment plan but does not add any technical innovations. And although claim 7 mentions a fabrication method for aligners, it is directed to the same abstract idea as every other claim and the fabrication method it recites is routine and well-understood. Claims 15 and 16 merely add the incidental requirement of having three steps of treatment. And claim 20, as explained above, differs from claim 1 only insofar as it describes the claimed workflow as a system as opposed to a method. In sum, the various dependent claims of the #522 patent

specify different options that might be incorporated into the workflow described in claim 1. None of these options change the focus of the claims from that general workflow, add any technical improvements to the aligner fabrication process, or add inventive features. All the claims can therefore be considered together for the purpose of subject-matter eligibility under § 101.

B. Resolving the Case on a Motion to Dismiss is Appropriate

“[W]hether a claim recites patent eligible subject matter is a question of law [that] may contain underlying facts.” *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). But “not every § 101 determination contains genuine disputes over the underlying facts” *Id.* When there is no dispute of material fact, § 101 arguments may be resolved at the pleading stage. *Id.* For any claim construction disputes, “the court must proceed by adopting the non-moving party’s constructions or the court must resolve the disputes to whatever extent is needed to conduct the § 101 analysis, which may well be less than a full, formal claim construction.” *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018) (internal citations removed). The Federal Circuit has “repeatedly affirmed § 101 rejections at the motion to dismiss stage, before claim construction or significant discovery has commenced.” *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360 (Fed. Cir. 2017); *see also SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1166 (Fed. Cir. 2018) (citing cases);

Epic IP LLC v. Backblaze, Inc., 351 F. Supp. 3d 733, 751–52 (D. Del. 2018)

(Bryson, J.) (discussing when it is appropriate to resolve a § 101 motion on the pleadings).

SDC argues that fact discovery is required before I rule on the motion. D.I. 17 at 21. But it has identified no factual dispute, and the patent itself explains that the technology used in the claimed workflow was routine or well-understood. #522 patent at 13:45–47, 14:4–5, 19:63–65. Thus, discovery is not necessary.

SDC also argues that claim construction is necessary to clarify the scope and meaning of the claims. DI. 17 at 7. It identifies two claim construction issues. First, it argues that the preamble of claims 1, 20, and 24 should be construed as limiting because they describe the claims as directed to systems or methods for “producing aligners.” DI. 17 at 7; #522 patent at claim 1 (20:35–36), claim 20 (23:39–40), claim 24 (24:44–45). Second, it argues that it is necessary to determine whether the steps of the claimed methods must be performed in a particular order. DI. 17 at 7–8.

Neither of these arguments affect my § 101 ruling. First, it is not necessary to determine whether the preambles limit the claims because the claims themselves require either the production of aligners or a system for fabricating aligners. #522 patent at claim 1 (20:66–67), claim 20 (23:65–25:10). Second, the order of the steps in the claims has no bearing on whether they are directed to an abstract idea

or contain an inventive step. Notably, neither party takes a position on whether the claims should be read to require a particular order. D.I. 17 at 7–8; D.I. 18 at 10.

Third, Candid does not oppose SDC’s reading of the claims, and SDC has not clearly articulated why there is a material dispute that needs preliminary resolution. *See* D.I. 18 at 9. In sum, SDC has not established that a claim construction issue affects the subject-matter eligibility analysis.

C. *Alice* Step One

I turn then to whether the claims at issue are directed to a patent-ineligible concept. *Alice*, 573 U.S. at 217. “[C]laims are considered in their entirety [at step one] to ascertain whether their character as a whole is directed to excluded subject matter.” *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015).

“The Supreme Court has not established a definitive rule to determine what constitutes an ‘abstract idea’ sufficient to satisfy the first step of the *Mayo/Alice* inquiry.” *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016) (citation omitted). The Court has recognized, however, that fundamental economic practices, methods of organizing human activity, and mathematical formulae are abstract ideas. *See Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (“fundamental economic practice” of hedging is unpatentable abstract idea); *Alice*, 573 U.S. at 220–21 (“organizing human activity” of intermediated settlement falls “squarely

within realm of ‘abstract ideas’”); *Gottschalk v. Benson*, 409 U.S. 63, 68, 71–72 (1972) (mathematical algorithm to convert binary-coded decimal numerals into pure binary code is unpatentable abstract idea); *Parker v. Flook*, 437 U.S. 584, 594–95 (1978) (mathematical formula for computing “alarm limits” in a catalytic conversion process is unpatentable abstract idea).

To determine whether claims are directed to an abstract idea courts generally “compare the claims at issue to those claims already found to be directed to an abstract idea in previous cases.” *Enfish*, 822 F.3d at 1334. The Federal Circuit has also instructed district courts to consider as part of *Alice*’s step one whether the claims “focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery.” *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016) (citing *Enfish*, 822 F.3d at 1336).

Applying these standards, I find that the #522 patent is directed to the abstract idea of having patients arrange for and receive dental aligners without ever seeing a dentist or orthodontist in person. Candid accurately describes this idea as “teleorthodontics.” D.I. 13 at 12. Individual claims add additional steps to the workflow or recharacterize it as a system rather than a method, but these variations are all still directed to the same abstract idea.

In performing step one of the *Alice* inquiry, I am required to “look at the focus of the claimed advance over the prior art to determine if the claim’s character as a whole is directed to excluded subject matter.” *Affinity Labs of Texas, LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1257 (Fed. Cir. 2016) (quotation marks omitted). Here, the claimed advance is providing dental aligners without any in-person interaction with a dentist or orthodontist. SDC itself describes the “key technological contribution” of the #522 patent as its “revolutionary workflow.” D.I. 1 ¶ 3. The patent claims achieve this advance without any technical improvements to orthodontic methods or communication technology. The invention is simply the abstract idea of connecting patients with orthodontists remotely. There is “no particular concrete or tangible form” to the claimed invention. *Ultramercial, Inc v. Hulu, LLC*, 772 F.3d 709, 715 (Fed. Cir. 2014).

Numerous cases have established that patents that simply take a standard business practice and describe how to conduct it over the internet or with modern information technology are directed to abstract ideas. *See, e.g., Alice*, 573 U.S. at 212; *In re Greenstein*, 778 F. App'x 935, 938 (Fed. Cir. 2019) (affirming the denial of a patent application describing a business method to improve the reliability of online reviews on § 101 grounds); *Affinity Labs*, 838 F.3d at 1258 (finding patent that claimed systems and methods for streaming out-of-region broadcast content to cellphones was directed to an abstract idea); *Intellectual Ventures I LLC v. Capital*

One Bank (USA), 792 F.3d 1363, 1367 (Fed. Cir. 2015) (finding claims directed to budgeting using a “communication medium” abstract); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014) (finding patent directed to “creating a contractual relationship” abstract notwithstanding its invocation of computer technology). Telehealth business methods in particular have been deemed ineligible for patent protection under §101. *See Becton, Dickinson & Co. v. Baxter Int’l, Inc.*, 127 F. Supp. 3d 687, 689, 692–93 (W.D. Tex. 2015) (“The fact that the pharmacist is ‘remote’ is of no added consequence to the abstract nature of the concept.”); *Am. Well Corp. v. Teladoc, Inc.* 191 F. Supp. 3d 135, 143 (D. Mass 2016) (holding that the asserted claims were invalid under § 101, when those claims were directed to connecting patients to available doctors in a telehealth environment).

American Well is particularly informative, because the patent at issue in that case was directed at a workflow for connecting patients to doctors in a telehealth setting. 191 F. Supp. 3d at 138. The *American Well* court concluded that the claimed workflow was abstract because it merely described a “method of organizing human activity” without any “particular concrete or tangible form.” *Id.* at 144 (internal quotation marks and citations omitted). The court emphasized that this result held regardless of whether there was a “pre-internet analog” for the idea. *Id.* The same logic applies here.

Align Technologies, Inc v. 3Shapes A/S is also instructive. 339 F. Supp. 3d. 435 (D. Del. 2018). The court found in that case that a patent directed to a dental workflow that simply updated traditional practice with new computer technology was invalid for claiming ineligible subject matter. As the court explained, efficiency gains due to “routine computer functionality do[] not render a claim non-abstract” and “performing an abstract concept on a generic computer is not an inventive concept.” *Id.* at 452–53. Like the patent in *Align*, the #522 patent takes an established workflow and then emphasizes the benefits of implementing that workflow with generic technology.

SDC asserts that the claims of the #522 Patent are directed to “producing aligners” and improving aligner manufacturing methods. D.I. 17 at 12. But the claims do not disclose a method of manufacturing dental aligners. Rather, they describe methods for streamlining business operations in order to take advantage of improvements in communication technology. *Cf. Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285, 1290, 1292 (Fed. Cir. 2020) (finding a patent claim ineligible under § 101 despite being characterized as a “method for manufacture”). Indeed, the only references to the actual methods for fabricating aligners in the #522 patent are general statements that aligners may be fabricated by thermoforming a polymer to a mold of the patient’s teeth. #522 patent at 6:17–20, 15:59. Claim 1 merely requires “producing, at a fabrication site, a plurality of

aligners.” #522 patent at claim 1 (20:66). Claim 20 requires “a fabrication system,” but explains that such a system requires only a “computing system” to receive the patient’s treatment data and “equipment configured to produce” aligners for the patient. #522 patent at claim 20 (23:65–24:8). Even claim 7, which adds limitations requiring that the aligners be produced by “terraforming polymer material” to “positive molds” does not change the focus of the claim from the idea of teleorthodontics. #522 patent at claim 7 (21:66–67).

The *Alice* test requires looking to the substance of the claimed invention, not to whether the claims are written as a method of manufacturing or as a physical system. *Trading Techs. Int’l, Inc. v. IBG LLC*, 921 F.3d 1378, 1384 (Fed. Cir. 2019) (“[W]e evaluate the focus of the claimed advance over the prior art to determine if the character of the claim as a whole, considered in light of the specification, is directed to excluded subject matter.” (internal quotation marks omitted)). Supreme Court precedent requires that I do not allow the “determination of patentable subject matter [to] depend simply on the draftsman’s art.” *Parker*, 437 U.S. at 593. To accept that the #522 patent claims are subject-matter eligible simply because they require “producing aligners” without looking at the actual claimed invention would go against this teaching and ignore the character of the claims as a whole.

The patent's written description and SDC's characterization of Candid's alleged infringement of the patent are also inconsistent with SDC's contention that the #522 patent is directed to manufacturing methods. The patent's title is "Arrangements for Intraoral Scanning," and its abstract describes the invention as "[s]ystems and methods for arranging an intraoral scanning at a selected location." This acknowledgement that the claimed invention focuses on arrangements—i.e., workflows—as opposed to manufacturing supports the conclusion that the claims are directed to an abstract business plan rather than a manufacturing process or physical system. SDC's insistence that the #522 patent teaches methods and systems for manufacturing is further undermined by its own characterization of Candid's "business model" as an implementation of the #522 patent "workflow." D.I. 1 at 9.

In support of its position that the #522 patent is directed to manufacturing processes, SDC cites *Nike, Inc v. Puma North America, Inc.*, CV 18-10876-LTS, 2018 WL 4922353 (D. Mass. Oct. 10, 2018), and *Diamond v. Diehr*, 450 U.S. 175 (1981). These cases are informative, but not in the way SDC argues. Instead they illustrate why the #522 patent is not directed to the manufacture and production of aligners. In *Nike*, the claims were subject-matter eligible because they were directed to improving the physical process of manufacture itself. *Nike*, 2018 WL

4922353, at *4. In contrast, the #522 patent does not concern how aligners are fabricated.

Similarly, in *Diehr*, the patent was subject-matter eligible because the invention was applied as an integral part of an improved manufacturing process. 450 U.S. at 184. But here the idea claimed by the invention—arranging for a patient to have an intraoral scan and receive delivery of aligners without being in the physical presence of a dentist or orthodontist—does not depend on how the aligners are fabricated.

In sum, the claims are directed to economic practices and methods of organizing business operations, undoubtably a form of human activity. Accordingly, the #522 is directed to an abstract idea.

D. *Alice* Step Two

Having found that the claims are directed to an abstract idea, I must determine whether the claims contain an “‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.” *Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 77). It is insufficient for the patent to “simply state the law of nature while adding the words ‘apply it.’” *Mayo*, 566 U.S. at 72. A claim directed towards an abstract idea must include “‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].’” *Alice*, 573 U.S. at 221 (alterations in original)

(quoting *Mayo*, 566 U.S. at 77). No such additional features exist here, and I find that, whether considered individually or as an ordered combination, the claim elements of the #522 patent do not “transform” the claimed abstract ideas into patent-eligible subject matter.

The #522 patent simply takes an abstract idea and provides several ways in which a business could “apply it” using routine scanning technology, generic computers, and routine communication technology. *Mayo*, 566 U.S. at 72; *see also Intellectual Ventures I v. Capital One Fin. Corp.*, 850 F.3d 1332, 1341 (Fed. Cir. 2017) (finding no inventive concept when the patent claims merely recited how an abstract idea could be implemented on a generic computer). Setting aside the subject-matter ineligible abstract idea itself, the claims only recite routine and well-understood practices. The #522 patent does not describe any “additional features” that “transform” the abstract idea into an invention eligible for patent protection. *Alice*, 573 U.S. at 221.

SDC argues that the claims meet the inventive concept test because they describe an unconventional manufacturing process. D.I. 17 at 19. But, as noted above, the #522 patent does not teach a manufacturing process but instead describes a workflow that enables a patient, without seeing an orthodontist in person, to arrange for an intraoral scan that is subsequently used to manufacture and deliver aligners. For example, claim 1 says nothing about manufacturing

except that the method includes “producing, at a fabrication site, a plurality of aligners based on the treatment plan.” #522 patent at claim 1 (20:66–67); *see also* #522 patent at claim 20 (23:65–24:8) (providing a similarly generic description of a fabrication site). SDC did not invent the use of intraoral scans to create aligners. #522 patent at 14:4–5. The specification makes clear that that the workflow can be implemented with existing scanners, #522 patent at 13:45–47, and existing computer processes, #522 patent at 19:63–65. And SDC has not identified any way that the #522 patent describes improvements to the physical process of manufacturing aligners. The relevant manufacturing process, to the extent that it is discussed at all, is conventional.

SDC also argues that the #522 patent discloses the inventive step of not having the user physically see the approving dentist or orthodontist. D.I. 19. But having the patient never physically see their dentist or orthodontist is simply part of the abstract idea. And § 101 requires that patents claim more than an abstract idea. *Mayo*, 566 U.S. at 72–73 (explaining the inventive concept must be “significantly more” than the abstract idea itself); *BSG Tech LLC v. Buyseasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018) (“a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept”). When the #522 patent was filed in 2018, it was routine to conduct business across geographical distance through the internet, to ship physical goods, and to use other

modern information technologies. The claims describe a method and a system for using these routine practices to implement the abstract idea to which all the claims of the #522 patent are directed. *See, e.g.*, #522 patent at claim 1, claim 4, claim 20.

Claims 4 and 20 provide two particular formulations for how the abstract idea can be applied with well-understood and conventional activities. Claim 4 takes the general workflow and adds the additional step of approval by the user. #522 patent at claim 4. Claim 20 rephrases the business plan described in claim 1 as a system rather than as a method. #522 patent at claim 20. But neither these claims nor the other claims of the patent describe “additional features” that “transform the claimed abstract idea into a patent-eligible application.” *Alice*, 573 U.S. at 221 (internal quotation marks omitted).

IV. CONCLUSION

For the reasons discussed above, I find that all claims of the #522 patent are invalid for lack of subject-matter eligibility. Accordingly, I will grant Candid’s motion to dismiss.

The Court will issue an Order consistent with this Memorandum Opinion.

Exhibit A

(12) **United States Patent**
Katzman et al.

(10) **Patent No.:** **US 10,636,522 B2**
(45) **Date of Patent:** **Apr. 28, 2020**

(54) **ARRANGEMENTS FOR INTRAORAL SCANNING**

(71) Applicant: **SmileDirectClub LLC**, Nashville, TN (US)

(72) Inventors: **Jordan Katzman**, Nashville, TN (US);
Alex Fenkell, Nashville, TN (US);
David Katzman, Nashville, TN (US);
Christopher Yancey, Nashville, TN (US);
Josh Chapman, Nashville, TN (US);
Jessica Cicurel, Nashville, TN (US)

(73) Assignee: **SmileDirectClub LLC**, Nashville, TN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **16/130,762**

(22) Filed: **Sep. 13, 2018**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(Continued)

(51) **Int. Cl.**
G06Q 30/00 (2012.01)
G16H 40/20 (2018.01)

(Continued)

(52) **U.S. Cl.**
CPC **G16H 40/20** (2018.01); **A61C 7/002** (2013.01); **A61C 7/08** (2013.01); **G06Q 10/02** (2013.01);

(Continued)

(58) **Field of Classification Search**

USPC 705/2-4
See application file for complete search history.

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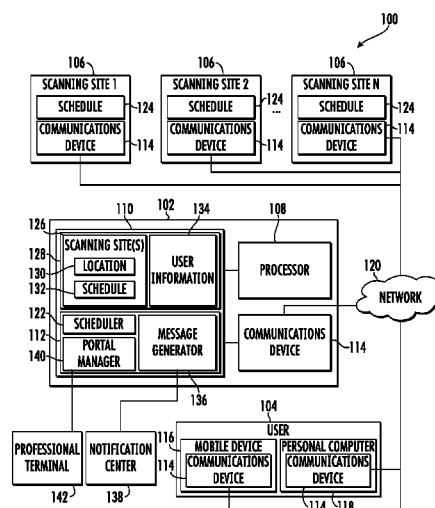
Primary Examiner — Mark Holcomb

(74) *Attorney, Agent, or Firm* — Foley & Lardner LLP

(57) **ABSTRACT**

Systems and methods for arranging an intraoral scanning at a selected location. A user can request an appointment at a selected intraoral scanning site from a plurality of intraoral scanning sites. In requesting the appointment at the intraoral scanning site, the user can provide various information for reserving the appointment. The user can make the request online (e.g., via an internet scheduling website associated with the intraoral scanning site). The request can also include a selected time for the appointment. The schedule for the selected intraoral scanning site can be analyzed to determine that the selected time for the appointment is available. When the appointment is scheduled for the user, one or more automatically generated messages can be communicated to the customer.

30 Claims, 7 Drawing Sheets



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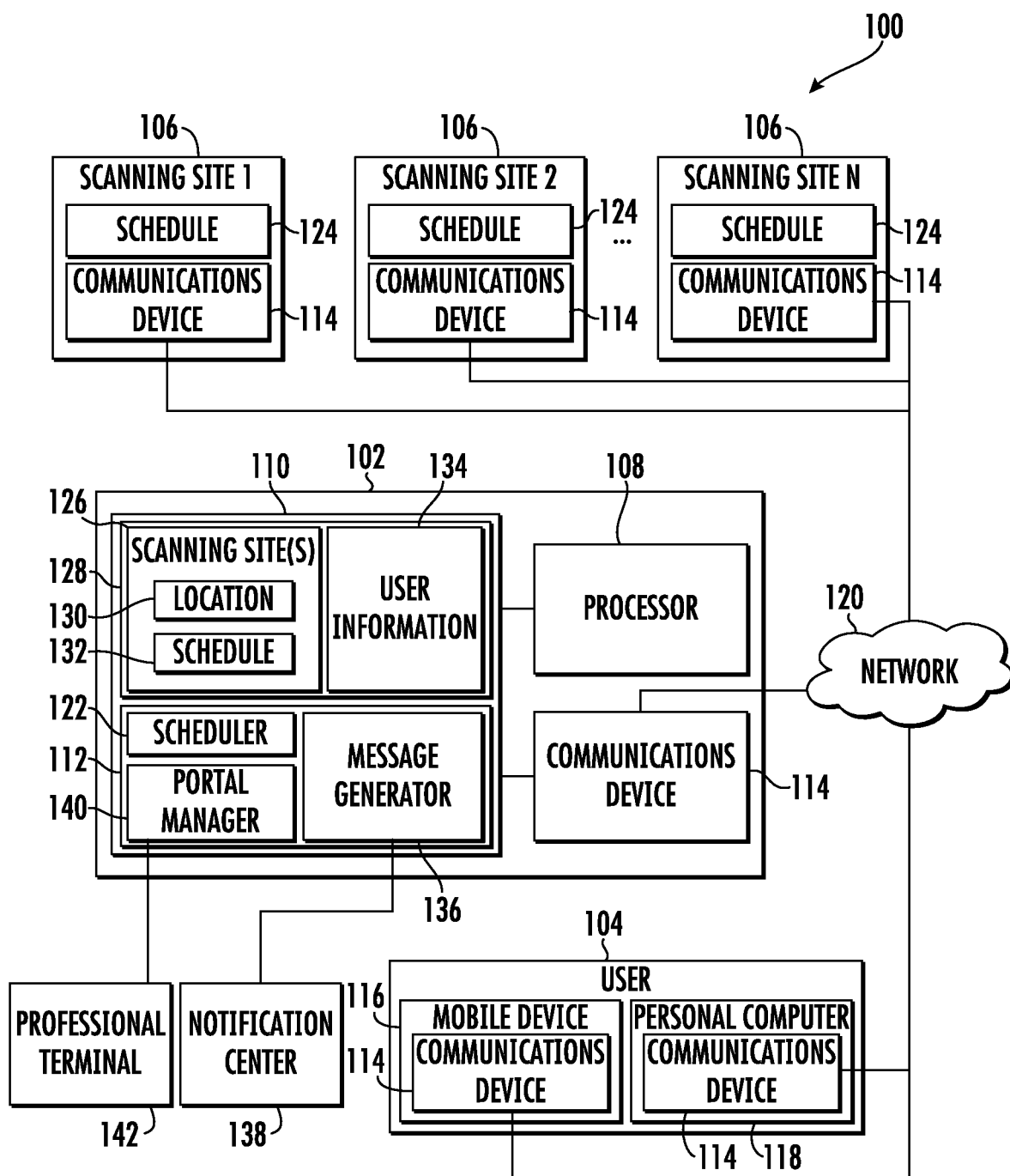


FIG. 1

202

LOCATION

SCANNING SITE 1 (LOCATION) (DISTANCE)

SCANNING SITE 2 (LOCATION) (DISTANCE)

...

SCANNING SITE N (LOCATION) (DISTANCE)

204

DATE

TODAY - FRIDAY, MO. DAY

TOMORROW - SATURDAY, MO. DAY

SUNDAY, MO. DAY

...

DAY, DATE

PLEASE SELECT A TIME:

2:00 PM 2:30 PM 3:00 PM 3:30 PM 4:00 PM

206

200

FIG. 2

302

FIRST NAME

LAST NAME

PHONE NUMBER

E-MAIL ADDRESS

☒ SEND ME MESSAGES WITH MY APPOINTMENT REMINDER, DIRECTIONS, AND DETAILS ABOUT MY NEW SMILE

304

300

ORDER SUMMARY: FREE

| | |
|-------------|--------|
| SUBTOTAL | \$0.00 |
| TAX | \$0.00 |
| GRAND TOTAL | \$0.00 |

BOOK MY SCAN

306

FIG. 3

FIG. 4 is a reservation form. On the left, a bracket labeled 402 groups the following input fields: NAME ON CREDIT CARD, BILLING ADDRESS, CITY, STATE, ZIP CODE, CREDIT CARD NUMBER, MM/YYYY, SECURITY CODE, and E-MAIL ADDRESS. On the right, a text block reads: "DUE TO HIGH DEMAND, WE ASK THAT YOU PROVIDE YOUR CREDIT CARD INFORMATION TO HOLD YOUR RESERVATION. A REFUNDABLE \$25 HOLD WILL BE PLACED ON YOUR CREDIT CARD FOR HOLDING YOUR RESERVATION. THIS HOLD WILL NOT BE BILLED TO YOU UNLESS YOU DO NOT SHOW UP FOR YOUR APPOINTMENT." Below this text are two buttons: "HOLD MY RESERVATION" (labeled 404) and "OPT OUT" (labeled 406).

FIG. 4

500

YOUR RESERVATION HAS BEEN RESERVED!

FIG. 5A

502

WE WILL STILL HOLD YOUR RESERVATION!

EVEN THOUGH YOU DIDN'T PROVIDE YOUR CREDIT CARD INFORMATION, WE WILL STILL HOLD YOUR RESERVATION - JUST FOR YOU!

FIG. 5B

PLEASE PROVIDE THE FOLLOWING INFORMATION SO WE
CAN ACCESS YOUR FILE AND CHECK YOU IN TO YOUR
APPOINTMENT!

FIRST NAME

LAST NAME

PHONE NUMBER

E-MAIL ADDRESS

602

600

FIG. 6 is a schematic diagram of a mobile device 600, such as a smartphone, displaying a registration form 602. The form 602 is presented on the device's screen and contains a request for user information: "PLEASE PROVIDE THE FOLLOWING INFORMATION SO WE CAN ACCESS YOUR FILE AND CHECK YOU IN TO YOUR APPOINTMENT!". Below this instruction are four input fields, each with a label: "FIRST NAME", "LAST NAME", "PHONE NUMBER", and "E-MAIL ADDRESS". The device 600 is depicted with a rounded rectangular shape and a circular home button at the bottom center.

FIG. 6

HEALTH AND CONSENT QUESTIONNAIRE

☐ YES ☐ NO DO YOU HAVE A BONDED RETAINER?

☐ YES ☐ NO DO YOU HAVE CROWNS?

☐ YES ☐ NO DO YOU HAVE ANY BRIDGEWORK?

☐ YES ☐ NO DO YOU HAVE AN IMPACTED TOOTH?

☐ YES ☐ NO DO YOU HAVE VENEERS?

☐ YES ☐ NO DO YOU FEEL ANY PAIN IN ANY OF YOUR TEETH?

☐ YES ☐ NO DO YOU AUTHORIZE US TO ADMINISTER AN INTRAORAL SCAN?

600

FIG. 7

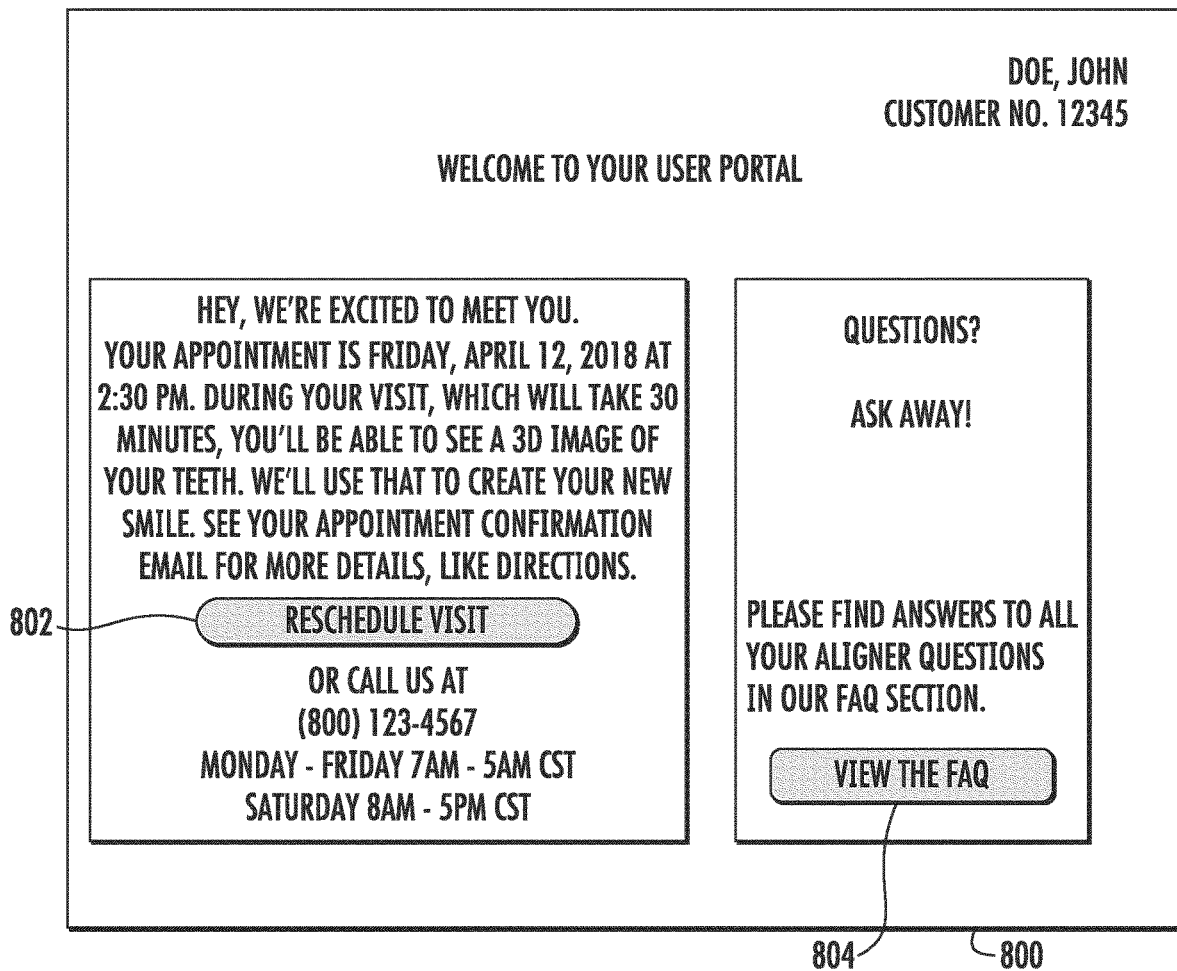


FIG. 8

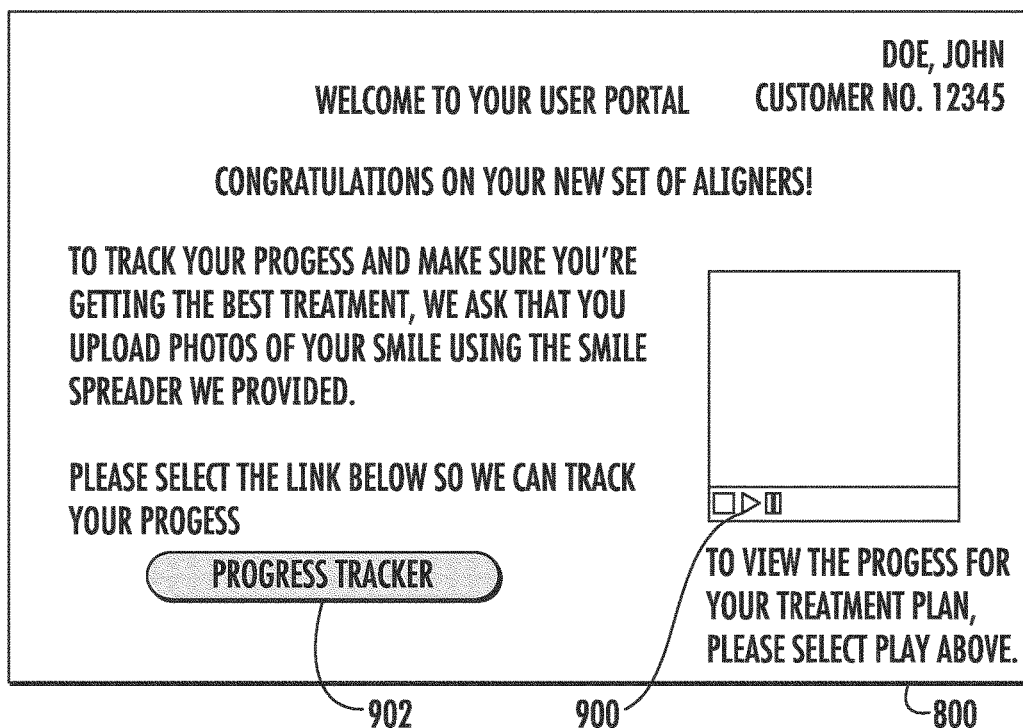


FIG. 9

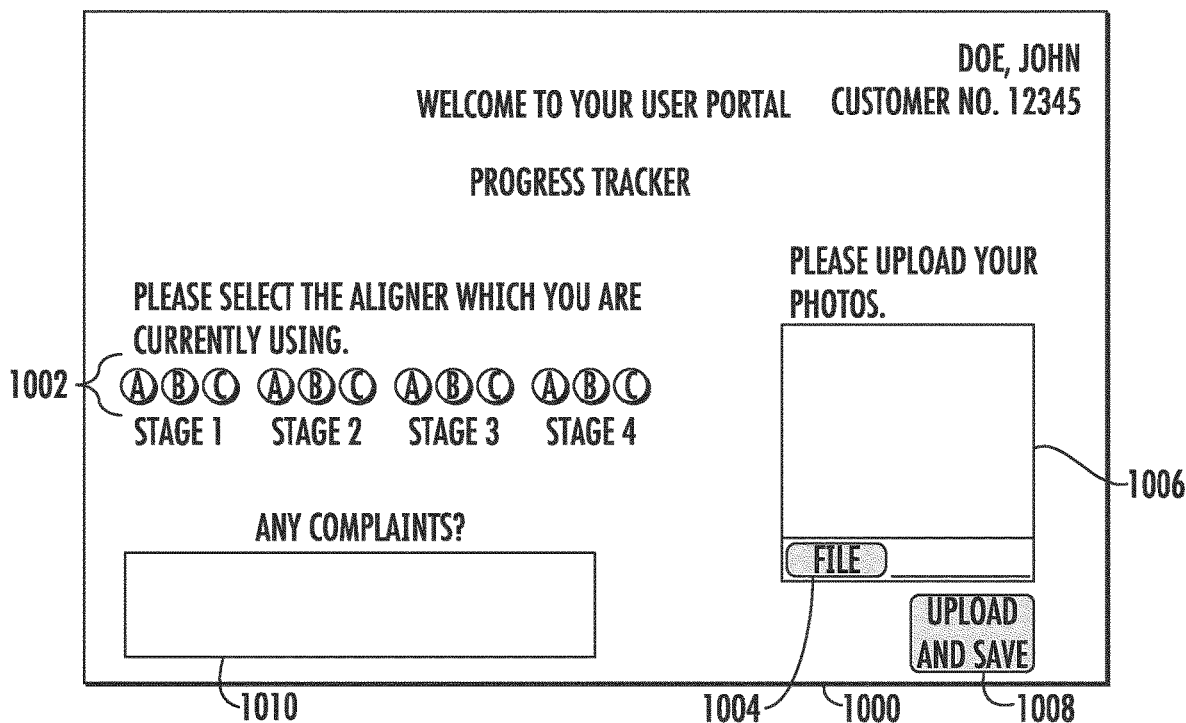


FIG. 10

1

**ARRANGEMENTS FOR INTRAORAL
SCANNING****CROSS-REFERENCE TO RELATED
APPLICATIONS**

This application claims the benefit of and priority to U.S. Provisional Patent Application No. 62/660,141, filed Apr. 19, 2018, and is a continuation-in-part of U.S. patent application Ser. No. 15/725,430, filed Oct. 5, 2017, which claims the benefit of U.S. Provisional Patent Application No. 62/522,847, filed Jun. 21, 2017, each of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

The present disclosure relates generally to the field of intraoral scanning, and more specifically, to intraoral scanning for generating a three-dimensional image of a user's teeth that is used in treating misalignment of the user's teeth.

BACKGROUND

Dental impressions and associated physical or digital reproductions of a patient's teeth can be used by dentists or orthodontists to diagnose or treat an oral condition, such as the misalignment of the patient's teeth. For example, to take a dental impression, a dental tray having a viscous, thixotropic impression material is fit over the dental arches of the patient, and then the impression material sets to a solid over time, thereby providing an imprint of the patient's dental arches once the dental trays are removed from the patient's mouth. The impressions provide a detailed and stable negative of the patient's teeth and tissues in their mouth. The negative impressions may then be utilized to produce a physical or digital reproduction of the patient's teeth and surrounding tissues.

Traditionally, dental impressions are made in a dental office and require significant time. Dental offices typically deliver the dental impressions to an outside vendor that utilizes the impressions to form a positive model of the teeth and surrounding tissue. If the dental impressions includes any errors (e.g., incomplete impression of the teeth and tissues), the patient may be required to return to the dental office to have a second impression made. Furthermore, if the dental impressions are used by the dental professional in the course of administering a continuing treatment plan, the patient is typically required to undergo many check-up appointments at the dental office so that the dental professional can track the patient's treatment and modify the treatment plan as necessary. Each of these examples results in significant inconvenience to the patient and increases the cost of the treatment plan to both the dental professional and the patient.

SUMMARY

According to one aspect of the disclosure, a method of producing aligners for repositioning one or more teeth of a user is disclosed. The method includes receiving, by an appointment management system, a request to schedule an appointment at an intraoral scanning site having an intraoral scanner configured to conduct an intraoral scan of a mouth of a user. The method includes scheduling, by the appointment management system, the appointment in accordance with the request. The method includes generating and communicating, by the appointment management system, a

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message to the user. The message includes a confirmation confirming the scheduled appointment. The method includes conducting, using the intraoral scanner, the intraoral scan at the intraoral scanning site during the scheduled appointment. The intraoral scan generates three-dimensional data of the mouth of the user. The method includes generating, by a treatment plan computing system at a treatment plan site, a treatment plan for the user based on the three-dimensional data of the mouth of the user. The method includes receiving an approval of the treatment plan by a dental or orthodontic professional. The approval is received without the dental or orthodontic professional physically seeing the user in person. The method includes producing, at a fabrication site, a plurality of aligners based on the treatment plan. The plurality of aligners are specific to the user and are configured to reposition one or more teeth of the user in accordance with the treatment plan. The method includes sending the plurality of aligners to the user.

According to another aspect of the disclosure, a method of administering aligners for repositioning one or more teeth of a user is disclosed. The method includes requesting, via a web portal or mobile application, an appointment at an intraoral scanning site having an intraoral scanner configured to conduct an intraoral scan of a mouth of a user. The method includes receiving, from an appointment management system, a confirmation message confirming the scheduled appointment. The method includes receiving, via the intraoral scanner, the intraoral scan at the intraoral scanning site during the scheduled appointment. The intraoral scanner generates three-dimensional data of the mouth of the user. The method includes receiving a plurality of aligners which are generated in accordance with a treatment plan. The treatment plan is generated at a computing system by a dental or orthodontic professional without physically seeing the user. The treatment plan is generated based on the three-dimensional data of the mouth of the user. The plurality of aligners are specific to the user and configured to reposition one or more teeth of the user in accordance with the treatment plan. The method includes administering the plurality of aligners in a predetermined sequence to reposition the one or more teeth of the user in accordance with the treatment plan.

According to another aspect of the disclosure, a system for generating aligners for modifying an alignment of a user's teeth is disclosed. The system includes an appointment management system, an intraoral scanning site, and a fabrication site. The appointment management system is configured to receive a request to schedule an appointment for receiving an intraoral scan of a mouth of a user. The appointment management system is further configured to schedule the appointment. The appointment management system is further configured to generate and communicate a message to a user device associated with the user. The message includes a confirmation confirming the scheduled appointment. The intraoral scanning site includes an intraoral scanner configured to generate three-dimensional data from an intraoral scan of the mouth of the user. The intraoral scanning site includes one or more computing systems configured to communicate the three-dimensional data from the intraoral scan for generation of a treatment plan. The fabrication site includes one or more computing systems configured to receive data corresponding to the treatment plan. The fabrication site includes thermoforming equipment configured to produce a plurality of aligners based on the treatment plan data. The plurality of aligners are specific to the user and are configured to reposition one or more teeth of the user in accordance with the treatment

plan. The one or more aligners are sent to the user for repositioning the one or more teeth of the user.

Various other embodiments and aspects of the disclosure will become apparent based on the drawings and detailed description of the following disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an appointment management system according to an exemplary embodiment.

FIG. 2 shows a reservations screen associated with the appointment management system of FIG. 1 according to an exemplary embodiment.

FIG. 3 shows a booking screen associated with the appointment management system of FIG. 1 according to an exemplary embodiment.

FIG. 4 shows a reservation hold screen associated with the appointment management system of FIG. 1 according to an exemplary embodiment.

FIG. 5A and FIG. 5B show example confirmation windows associated with the appointment management system of FIG. 1 according to an exemplary embodiment.

FIG. 6 shows a check-in screen displayed on a user device for enabling a user to check into an appointment according to an exemplary embodiment.

FIG. 7 shows a health and consent information screen displayed on a user device for enabling the user to provide health and consent information according to an exemplary embodiment.

FIG. 8 is a user portal screen displayed to the user prior to the user's appointment according to an exemplary embodiment.

FIG. 9 is an example of a user portal screen displayed to the user following the user's appointment according to an exemplary embodiment.

FIG. 10 is an example of a user portal screen displaying a progress tracker according to an exemplary embodiment.

DETAILED DESCRIPTION

The present disclosure is directed to systems and methods for conducting an intraoral scan of a user at a location. A user can request an appointment at an intraoral scanning site. For example, the user can request an appointment in advance of the requested appointment time (e.g., online, via a mobile application, via a telephone call) or the user can request an appointment at the time of requested appointment (e.g., a "walk in"). In requesting the appointment at the intraoral scanning site, the user can provide various information for reserving the appointment, such as a reason for making the appointment (e.g., misaligned teeth) or a dental condition of the patient (e.g., having crowns, an impacted tooth). The user can make the request online (e.g., via an internet scheduling website associated with the intraoral scanning site). When the appointment timeslot is held for the user, one or more scheduling alerts can be communicated to the user (e.g., confirmation notification, reminder notification, appointment modification query). Upon arriving at the appointment, the user can provide health history and consent information. The user can receive the intraoral scan, and upon confirmation from the user to purchase the aligners, one or more sets of aligners configured to modify the alignment of the user's teeth can be sent to the user.

The systems and methods described herein may have many benefits including, but not limited to, increasing user excitement about the alignment process, increasing the likelihood of a user showing up for their appointment, and

increasing the likelihood of a user purchasing aligners at the intraoral scanning site, as will be discussed in greater detail below.

Referring to FIG. 1, an appointment management system 100 is shown. The appointment management system 100 includes a computing system 102, a mobile device 116 of a user 104, a personal computer 118 of the user 104, and a plurality of intraoral scanning sites 106.

The computing system 102 includes a processor 108 and memory 110. Processor 108 may be a general purpose or specific purpose processor, an application specific integrated circuit (ASIC), one or more field programmable gate arrays (FPGAs), a group of processing components, or other suitable processing components. Processor 108 may be configured to execute computer code or instructions stored in memory 110 or received from other computer readable media (e.g., CDROM, network storage, a remote server, etc.) to perform one or more of the processes described herein. Memory 110 may include one or more data storage devices (e.g., memory units, memory devices, computer-readable storage media, etc.) configured to store data, computer code, executable instructions, or other forms of computer-readable information. Memory 110 may include random access memory (RAM), read-only memory (ROM), hard drive storage, temporary storage, non-volatile memory, flash memory, optical memory, or any other suitable memory for storing software objects and/or computer instructions. Memory 110 may include database components, object code components, script components, or any other type of information structure for supporting the various activities and information structures described in the present disclosure. Memory 110 may be communicably connected to processor 108 via processing circuit 202 and may include computer code for executing (e.g., by processor 108, etc.) one or more of the processes described herein.

The memory 110 is described below as including various circuits 112. While the exemplary embodiment shown in the figures shows each of the circuits 112 as being separate from one another, it should be understood that, in various other embodiments, the memory 110 may include more, less, or altogether different circuits 112. For example, the structures and functions of one circuit 112 may be performed by another circuit 112, or the activities of two circuits 112 may be combined such that they are performed by only a signal circuit 112. Additionally, it should be understood that any of the functionalities described as being performed by a circuit 112 that is a part of the controller 112 may also be performed by a separate hardware component having its own processors, network interfaces, etc.

As shown in FIG. 1, the appointment management system 100 includes one or more communications device(s) 114. The communications device(s) 114 can be or include components configured to transmit and/or receive data from one or more remote sources. For instance, each of the intraoral scanning site(s) 106 may include a respective communications device 114, the user 104 may have one or more communications device(s) 114 embodied on the user's 104 mobile device 116, personal computer 118, etc., and/or the computing system 102 may include a communications device 114. Each of the respective communications devices 114 may permit or otherwise enable data to be exchanged between the user 104, the intraoral scanning site(s) 106, and/or the computing system 102. The communications device 114 may communicate via a network 120. The network 120 may be a Local Area Network (LAN), a Wide Area Network (WAN), a Wireless Local Area Network (WLAN), an Internet Area Network (IAN) or cloud-based

network, etc. In some implementations, the communications device(s) 114 may access the network 120 to exchange data with various other communications device(s) 114 via cellular access, a modem, broadband, Wi-Fi, satellite access, etc.

Generating an Appointment

In some implementations, the user 104 may access a website (or other network-based portal) associated with the appointment management system 100. The user 104 may book an appointment at an intraoral scanning site 106 on the website. The user 104 may be directed to the website through, for instance, an advertisement on the user's 104 social media account. Additionally or alternatively, the user 104 may search for (e.g., on the internet, etc.) the website associated with the appointment management system 100.

Additionally or alternatively, the user 104 may receive a message directing them to the website to book an appointment at an intraoral scanning site 106. The processor 108 may control the communications device 114 to send the message to the user 104 in response to various conditions. For instance, the processor 108 may determine that the user 104 previously signed up to receive an in-home dental impression kit and never returned the completed kit. The processor 108 may identify a time between an order date (or shipment date) of the dental impression kit and the current date. The processor 108 may compare the identified time to a threshold time indicative of the user 104 likely not returning impressions from the dental impression kit. Where the identified time exceeds the threshold time, the processor 108 may automatically generate and send the message to the user 104. As another example, the processor 108 may determine that the impressions received from the user 104 were, for instance, incomplete. A technician may review the impressions (or a scan thereof) to determine their suitability for manufacturing dental aligners. When the impressions are determined to be incomplete, the technician may flag the impressions as incomplete. When the impressions are flagged, the processor 108 may automatically generate and send the message to the user 104 prompting the user to schedule an intraoral scan.

The website may include a home page, an instructional page detailing how the customer aligner process works, a results page, a locations page, and/or additional or alternative pages. Each of these pages may present different information to the user 104. For instance, the home page may present information pertaining to an overall user experience. The instructional page may present a step-by-step overview starting from an appointment to receiving customized aligners. Additionally, the instructional page may present a video to the user 104. The video may include graphics and/or text that show how the customized aligners reposition the user's 104 teeth, among other information. The video may also show the user 104 what to expect upon arrival at their appointment location, should they choose to book an appointment. The results page may include before-and-after pictures (or a rolling video of before-and-after pictures) of previous users who have used aligners to reposition their teeth. The locations page includes locations associated with each of the respective intraoral scanning sites 102.

Referring now to FIG. 1 and FIG. 2, the user 104 may access the locations page of the website. Specifically shown in FIG. 2 is a reservation page 200 which may be a portion of the locations page or a portion of the home page.

In some embodiments, the computing system 102 may include a scheduler 122. The scheduler can be or include instructions that, when executed by the processor 108, cause the processor 108 to generate and/or manipulate pages and displays for scheduling an appointment at an intraoral scan-

ning site 106. While shown as embodied on memory 110 of the computing device 102, in some implementations, the scheduler 122 may be separate from the computing device 102. For instance, the scheduler 122 may be located remotely from the computing device 102. In instances such as these, the scheduler 122 may have a separate processor 108 and memory 110 (a dedicated processor and memory, for example). A user 104 may schedule an intraoral scan at a particular intraoral scanning site 106 via the website. The website may be controlled by the processor 108 using instructions from the scheduler 122. Following the intraoral scan, the user 104 may, in some instances, order aligners that are customized for the user 104. For instance, the user 104 may be satisfied with the overall process at the intraoral scanning site 106 and results of other users 104. Therefore, the user 104 may purchase aligners for aligning the user's 104 teeth. The aligners may be constructed of a polymer material, such as Polyethyleneterephthalat-Glycol Copolyester (PET-G), which is thermoformed to positive molds (or models) of the user's 104 dentition at various intervals between a starting position and an ending position. The positive molds of the user's dentition 104 may be generated based on the treatment plan. The aligners may be used by the user 104 in stages to move the user's teeth towards the ending position. For example, the user 104 may be directed to wear a first aligner during a first month, a second aligner during a second month, a third aligner during a third month, and so on for a treatment period. These aligners may be shipped to the user 104 following production of the aligners (e.g., at a fabrication site which generates or otherwise produces the aligners). In some instances, the aligners may be shipped in stages, all at once in one box, etc. Each of the aligners may be administered by the user in a predetermined sequence and for a predetermined duration. For instance, a first aligner (which corresponds to a starting position of the user's teeth) may be administered by the user for a duration (e.g., a month, 90 days, etc.), a second (and additional intermediate) aligner(s) may be administered by the user for the same duration, and a final aligner may be administered for the same duration. Each of these aligners may move the user's teeth from the starting position to one or more intermediate positions, and from the one or more intermediate positions to the final positions based on the treatment plan.

As shown in FIG. 2, the reservation page 200 includes locations 202, dates 204, and times 206. Included in the locations 202 is information corresponding to each of the intraoral scanning site(s) 106. While each of the intraoral scanning site(s) 106 are shown as included, in some embodiments, only a subset of intraoral scanning site(s) 106 may be shown. For instance, the intraoral scanning site(s) 106 which are located nearest to the user 104 may be shown. As one example, the processor 108 may receive data from a communications device 114 associated with the user 104 (e.g., the mobile device 114, personal computer 118, etc.). The data may include location-based data associated with the user 104. The processor 108 may use this data to select, from each of the intraoral scanning site(s) 106, a subset of intraoral scanning site(s) 106 to include in the locations 202. As another example, the user 104 may be prompted to provide a zip code. The processor 108 may use the zip code provided by the user 104 to determine intraoral scanning site(s) 106 that are located nearest to (or within) the zip code.

In some implementations, a user 104 may search for specific locations 202 (instead of selecting ones that are nearest to the user's 104 location). The user 104, for instance, may be traveling to a different city than their city

of residence and may want to schedule an appointment at an intraoral scanning site **106** located in that different city. As a result, the user **104** is not limited to scheduling appointments at intraoral scanning sites **106** in their own city, but may schedule appointments at any of the intraoral scanning sites **106**. In implementations such as these, the user **104** may provide a zip code that is different from their current zip code (e.g., the zip code associated with the city to which they are traveling).

In still other implementations, one or more of the intraoral scanning sites **106** may be a mobile intraoral scanning site **106**. For instance, the mobile intraoral scanning site **106** may be implemented in a vehicle (e.g., an automobile, a truck, a van, a bus, etc.), as part of a kiosk (e.g., located within another store or within a shopping mall), or comprise a pop-up location in operation for only a limited time period (e.g., one day, one week, one month). The mobile intraoral scanning site **106** may be included in the locations **202** on the reservations page **200**. As will be described in further detail below, a user **104** may be able to arrange for the mobile intraoral scanning site **106** to travel to a set location (e.g., a location set by the user, such as their home or place of business), and the user **104** may receive an intraoral scan at the set location.

Upon selecting a location **202** of an intraoral scanning site **106** from the list of locations **202** of intraoral scanning sites **106**, the user **104** may select an available date from the list of dates **204**. Each intraoral scanning site **106** may maintain a schedule **124**. The schedule **124** may be maintained locally (e.g., at each respective intraoral scanning site **106**, etc.) and communicated to the computing system **102**. The scheduler **122** can include instructions to access the schedule **124** of the intraoral scanning site **106** selected by the user **104** and determine available days/times for an appointment for the user **105** based on the schedule **124** for the intraoral scanning site. The scheduler **122** can include instructions to display available times and dates for the intraoral scanning site **106** based on the schedule **124** associated with the intraoral scanning site **106**. Additionally or alternatively, the schedule **124** may be a cloud-based schedule that is remotely accessible by the processor **108** and by the respective intraoral scanning site **106**. In implementations such as these, the memory **110** may store intraoral scanning site data **126** corresponding to each respective intraoral scanning site **106**. The intraoral scanning site data **126** may be stored in a database **128** within memory **110**. The intraoral scanning site data **126** may include a location **130** associated with the intraoral scanning site **106** (or other information usable to identify a particular intraoral scanning site **106**) and a corresponding schedule **132** for the intraoral scanning site **106**. The scheduler **122** can include instructions to determine the schedule for the selected location **202** of the intraoral scanning site **106** by cross-referencing data for the selected location **202** with location **130** within the intraoral scanning site data **126**. Following cross-referencing the data for the selected location **202**, the scheduler **122** can include instructions to identify the schedule for the corresponding selected location **202**.

In each of these arrangements, the scheduler **122** can include instructions to identify available appointment times for the intraoral scanning site **106**. These available appointment times may be presented to the user **104** for selection and booking an appointment.

As shown in FIG. 2, the intraoral scanning site(s) **106** may have extended hours (e.g., open nights, weekends, etc.). In implementations such as these, the user **104** may be more likely to schedule an appointment when the hours are

extended due to a lessened likelihood of a scheduling conflict between the user **104** and a given intraoral scanning site **106**.

The processor **108** may access the schedule **124**, **132** for the selected location **202** to determine available dates via the instructions from the scheduler **122**. The processor **108** may display the available dates in the list of dates **204**. Following a selection of an available date from the list of dates **204**, the times available for the selected date may be displayed to the user **104**. The processor **108** may determine the available times in the same manner in which the available dates are determined. The user may select an available time to book their scan from the list of available times **206**.

While described herein as the user first selecting a location, in some embodiments, the user may first select a preferred date and/or time and available locations (and/or dates and locations) may then be displayed based on the selected preferred date and/or time (and/or dates and locations). In each of these implementations, the user **104** may reserve a time at a particular intraoral scanning site **106**, and at the reserved time, the user **104** may arrive at the particular intraoral scanning site **106** and receive their intraoral scan, as will be discussed in further detail below.

In some implementations, the user **104** may select the mobile intraoral scanning site **106**. In implementations such as these, the processor **108** may identify a schedule **124**, **132** associated with the mobile intraoral scanning site **106** using instructions from the scheduler **122**. The user **104** may request a date **204** and time **206** that is available for the mobile intraoral scanning site **106**. The user **104** may then provide a location to arrange the appointment with the mobile intraoral scanning site **106**. The mobile intraoral scanning site **106** may have a predetermined radius (e.g., 10 miles, 20 miles, 25 miles, 50 miles, etc.) within which the mobile intraoral scanning site **106** operates. The user **104** may provide a location within the predetermined radius. At the reserved time, the mobile intraoral scanning site **106** may be driven to the location provided by the user **104**. The user **104** may similarly arrive at the provided location at the reserved time and receive an intraoral scan, as will be discussed in further detail below.

Referring now to FIG. 3, following the user **104** selecting an available time **206** (e.g., as shown in FIG. 2), the scheduler **122** can include instructions to direct the user **104** to a booking screen **300**. At the booking screen **300**, the user **104** may be prompted to provide various personal information **302** (e.g., first and last name, a phone number, an e-mail address, etc.). Additionally, the user **104** may be prompted to opt into (or not opt into) a messaging service by selecting box **304**. The messaging service may provide one or more messages to the user **104** concerning the user's **104** booked appointment, as will be discussed in further detail below. The personal information **302** and data corresponding to whether the user **102** opted into the messaging service may be stored in database **128** in a user file **134**. The user file **134** may be a file associated with the user **104** and may include various types of data associated with the user **104**. The user file **134** may be subsequently used for generating messages to the user **104** before and/or after the user's **104** appointment. The user file **134** may also include the intraoral scan, the treatment plan, progress information, photographs, etc.

As shown in FIG. 3, the appointment may be free to the user **104**. In some implementations, the appointment may have a flat fee (e.g., \$25, \$95, etc.). In still other implementations, the appointment may have a booking hold which is not charged to the user **104**. Following the user **104** provid-

ing their personal information, the user **104** may be prompted to book their scan by selecting button **306**.

Referring now to FIG. **4**, when the user **104** books their scan by selecting button **306** (of FIG. **3**), the scheduler **122** can include instruction to direct the user **104** to a holding page **400**. At the holding page **400**, the user **104** may be prompted to provide credit card information **402**. The credit card information **402** may be requested to hold the available time selected by the user **104** (e.g., as selected on reservations page **200**). The credit card information **402** may be used to place a hold (for instance, \$25) on the user's **104** credit card. In some implementations, the hold may be a refundable hold (e.g., the credit card for the user **104** is not billed or is refunded unless the user **104** does not show up for their appointment at the selected time).

In some implementations, the hold may be optional. For instance, the user **104** may be able to hold the reservation (through selection of button **404**) or opt out of holding the reservation (through selection of button **406**). The user **104** may provide their credit card information **402** and select button **404**. In selecting prompt **404**, confirmation window **500** may be displayed to the user **104** (e.g., indicating that the user's **104** reservation has been confirmed). Additionally, the user **104** may not provide their credit card information **402**, and instead, opt out by selecting button **406**. In some implementations, selecting button **406** may direct the user **104** back to the reservations page **200**. In other implementations, selecting button **406** may cause confirmation window **502** to be displayed to the user **104** (e.g., indicating that the user's **104** reservation is still confirmed despite the user **104** not providing credit card information **402**). By providing credit card information **402**, the user **104** may be more likely to show up for their appointment, despite their credit card never being charged.

In one or more embodiments, following the user **104** reserving (and optionally holding) their appointment, the user **104** may want to reschedule their appointment. To do so, the user **104** may call the intraoral scanning site **106** to reschedule their appointment. Additionally, the user **104** may go onto the website associated with the appointment management system **100**, provide log-in information or other identifying information to look-up their appointment and access, for instance, a user portal (as will be discussed in greater detail below). The user portal may include various appointment-related information including the time, date, and location for their appointment. Following the user's appointment, the user portal may include various treatment plan information (such as a virtual representation of the user's **104** treatment plan at different stages or a simulated representation of the user's **104** teeth through progression of the treatment plan), progress information provided by the user **104**, etc., as will be discussed in greater detail below. The user **104** may select their appointment and reschedule their appointment in substantially the same manner by which the user **104** booked their appointment (e.g., by following the progression from FIG. **2** through FIG. **4**).

Pre-Appointment Messaging Services

Referring back to FIG. **1**, when the user **104** opts into the messaging service (through selection of box **304** of FIG. **3**), one or more messages may be automatically generated and communicated to the user **104** (e.g., via respective communications device(s) **114**). For instance, the computing system **102** may include a message generator **136**. The message generator **136** can be or include instructions that, when executed by processor **108**, cause the processor **108** to generate a message to communicate to the user **104**. The message generator **136** can include instructions to transmit

the generated message to the user **104** via, for instance, the communications device **114** of the computing system **102** to the communications device **114** of the user's **104** mobile device **116** and/or personal computer **118**. The message generator **136** can include instructions to identify a communications device **114** associated with the user **104** (e.g., by identifying the user file **134** associated with the user **104**). The message generator **136** can include instructions to communicate the generated message to the user **104** upon one or more conditions, as will be discussed in further detail below. Accordingly, the various messages described herein may be communicated to the user's **104** mobile device **116** and/or the user's **104** personal computer **118**. Various examples of messages will be discussed in turn below.

In some implementations, one or more messages that are generated via the message generator **136** may be communicated to a notification center **138**. The notification center **138** may be, for instance, a call center. The messages that are communicated to the notification center **138** may be instructions to call a particular user **104** at a particular time to deliver a verbal message, as will be discussed in further detail below.

In some embodiments, the message generator **136** can include instructions for generating an appointment confirmation message. The message generator **136** can include instructions to determine when a user **104** has successfully reserved an appointment. The message generator **136** can include instructions to automatically communicate (e.g., via respective communications devices **114**) the appointment confirmation message in response to the user **104** successfully reserving the appointment. The appointment confirmation message may be or include a message that indicates that the user's **104** appointment has successfully been reserved. In some implementations, the appointment confirmation message may include a link, which the user **104** may select, that causes the appointment to be automatically added to a calendar associated with the user **104**. For instance, the appointment confirmation message may include a plurality of links associated with different types of calendar software. The user **104** may select the link corresponding to whichever type of calendar that is used by the user **104**. Upon selecting the appropriate link, the appointment may automatically be added to the user's **104** calendar. The appointment added to the user's **104** calendar may include contact information associated with the corresponding intraoral scanning site **106**, a location associated with the intraoral scanning site **106**, time, and an expected duration of the appointment (e.g., 30 minutes).

In some embodiments, the message generator **136** can include instructions for generating one or more appointment reminder messages. The message generator **136** can include instructions to determine a current time and an appointment time (e.g., the time of the user's **104** appointment at the intraoral scanning site **106**). The message generator **136** can include instructions to compare a time difference between the current time and appointment time to a threshold time. If the difference in time is less than (or equal to) the threshold time, the message generator can include instructions to automatically generate the appointment reminder message.

In some implementations, the threshold time may be set based on a number of days (e.g., two days, three days, a week, etc.) until the user's **104** appointment. In implementations such as these, the appointment reminder message may be a message reminding the user **104** that they have an upcoming appointment. The appointment reminder message may be generated when the user **104** books an appointment

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well in advanced. Accordingly, where the user **104** books an appointment for a number of days in advanced that is less than a threshold number of days (e.g., two days, three days, a week, etc.), the appointment reminder message may not be generated. As one non-limiting example, the user **104** may book an appointment on a Monday. Where the user **104** books the appointment for the next Friday, the user **104** may be reminded of their appointment through generation of an appointment reminder message on the upcoming Wednesday. However, where the user **104** books the appointment for the next day (e.g., Tuesday), the user **104** may not receive an appointment reminder message. The appointment reminder message that is communicated to the user **104** may include various information including, for instance, directions to the intraoral scanning site **106**, a phone number for the intraoral scanning site **106**, etc. Additionally, the appointment reminder message may include various information pertaining to the user's **104** appointment. For example, the appointment reminder message may include a health and consent questionnaire for the user **104** to fill out. In some implementations, the health and consent questionnaire may have a plurality of Yes/No questions corresponding to various health-related conditions. The responses to the questions may be defaulted to "No", whereby the user **104** may only need to change those answers to the questions that do apply to the user **104**. Referring briefly to FIG. 7, the user **104** may be shown several questions which are defaulted to "No". The user **104**, however, may have an impacted tooth and an indicator on the health and consent questionnaire for an impacted tooth is defaulted to "No". Accordingly, the user **104** may maintain all defaulted answers except for the question relating to impacted teeth, which the user **104** may switch to answer "Yes." Such arrangements may expedite the overall process for the user's **104** experience at the intraoral scanning site **106**. As another example, the appointment reminder may include before-and-after pictures for previous customers (e.g., similar to those described above with reference to the results page). Such arrangements may increase excitement and anticipation of the appointment for the user **104**.

In some implementations, the threshold time may be set based on a location of the user **104** (e.g., as determined based on data provided by the user's **104** mobile device **116** and/or personal computer **118**) with respect to the location of the intraoral scanning site **106**. In implementations such as these, the appointment reminder message may be a message reminding the user **104** to leave for their appointment. The threshold may be determined based on factors in addition to the location of the user **104** including, for instance, a distance between the respective locations, traffic between the respective locations, weather, time of day, day of the week, etc. The appointment reminder message that is communicated to the user **104** may include various information including, for instance, directions to the intraoral scanning site **106**, a phone number for the intraoral scanning site **106**, etc.

In some implementations, the message generator **136** may include instructions to generate multiple appointment reminder messages. For instance, the message generator **136** may generate a first appointment reminder message to remind the user **104** that they have an upcoming appointment and a second appointment reminder message to indicate to the user **104** that they should leave for their appointment (e.g., now, in 15 minutes, in one hour, etc.).

In some embodiments, the message generator **136** can include instructions to identify specific users **104** for voice messages. For instance, where the user **104** does not provide

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credit card information **402** (thus opting out of reserving the appointment), such information may be stored in the user file **134**. Where the user **104** does not provide credit card information **402**, the message generator **136** can include instructions to generate a prompt for a voice message to communicate to the notification center **138**. The prompt may instruct a person at the notification center to initiate a telephone call with the user **104**, in which the user **104** will be informed about the overall process and experience at the intraoral scanning site **106**, and the user **104** may provide one or more concerns regarding their smile. The call may be initiated by the person at the notification center a certain number of days prior to the user's **104** appointment (e.g., three days, five days, etc.). The person may annotate (or record) the conversation, and portions thereof may be saved to the user file **134**. In embodiments such as these, the voice message may increase user **104** excitement for the appointment and increase the likelihood that the user **104** shows up for their scheduled appointment.

Appointment Management at an Intraoral Scanning Site Referring now to FIG. 1 and FIG. 6, upon arrival at the intraoral scanning site **106**, the user **104** may be presented with a user device **600**. The user device **600** may be a tablet, for instance. The user **104** may be requested to provide personal information **602** (e.g., similar to the personal information **202**) for accessing the user file **134**. The processor **108** may retrieve the user file **134** associated with the user **104** and check the user **104** into their appointment. Where the user **104** does not show up within a predetermined timeframe (e.g., at the start time of their appointment, within five minutes after the start time, 10 minutes after their start time, etc.) the processor **108** may automatically indicate the user **104** did not show up for their scheduled appointment. The processor **108** may compare a time difference between the current time and the appointment start time to a predetermined timeframe. If the time difference exceeds the predetermined timeframe, the processor **108** may automatically indicate the user **104** did not show up for their scheduled appointment in the user file **134**. Additionally or alternatively, a receptionist may indicate that the user **104** did not show up for their appointment in the user file **134**. In some embodiments, the message generator **136** can include instructions for automatically generating a message to send to the user when the user is late for their appointment beyond a predetermined time frame (for instance, five minutes late). The message may ask the user to respond with whether they still plan on having an intraoral scan conducted, indicate that they do not need an appointment to receive their scan, prompt them to reschedule, etc.

In some instances, the intraoral scanning site **106** may include a screen (e.g., of a television or other display system) that displays before-and-after pictures of customers who previously used aligners. The before-and-after pictures may be similar to those described above with reference to the results page. The before-and-after pictures may be displayed on a rolling basis. In instances such as these, consumer confidence may be increased by observing historical results.

Referring now to FIG. 1 and FIG. 7, the user file **134** may include the health and consent questionnaire. Where the health and consent questionnaire was previously filled out by the user **104** (e.g., as it was received in an appointment reminder message), the health and consent questionnaire may be saved to the user file **134**. However, where the health and consent questionnaire was not previously filled out by the user **104** (e.g., the user **104** never filled the questionnaire out or the questionnaire was never provided to the user **104**),

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the user 104 may fill out the health and consent questionnaire via the user device 600. In some embodiments, where the user 104 switches an answer, a comment box is automatically generated and displayed to the user 104 prompting the user 104 to provide further details. For instance, where the user indicates that they are experiencing pain in their teeth, a comment box is automatically generated and displayed on the display of the user device 600. The user may provide an input, via the comment box, to elaborate on the pain in their teeth. While two examples of when the health and consent questionnaire are provided (e.g., following a reservation and following an appointment check-in but prior to the intraoral scan), the health and consent questionnaire may be provided to the user 104 to complete at any time throughout the scanning process after they arrive at the scanning location, such as during a break in procedures, following completion of the intraoral scan, etc. Accordingly, the present disclosure is not limited to any particular arrangement regarding when the health and consent questionnaire is completed by the user 104.

As shown in FIG. 7, the user device 600 may present the health and consent questionnaire to the user 104. As discussed above, the health and consent questionnaire may have a plurality of Yes/No questions corresponding to various health-related conditions. In some implementations, at least some of the questions for the health and consent questionnaire may be defaulted to a set response. For instance, the health-related questions for the questionnaire may be defaulted to "NO", whereas the consent-related questions for the questionnaire may be defaulted to "YES". In other instances, all of the questions may be defaulted to "NO". The user 104 can modify the responses to all the questions as needed. For instance, the user 104 may have bridgework and a question inquiring about whether the user 104 has bridgework is defaulted to "No". Accordingly, the user 104 may maintain the default answers to all the questions except for the question pertaining to bridgework. The user 104 may manually switch this answer to "Yes." In each of these implementations, the user's 104 experience at the intraoral scanning site 106 may be improved by expediting the health and consent questionnaire.

Following check-in and providing the responses to the health and consent questionnaire, the user 104 may be directed to a room where the user 104 will receive their intraoral scan. A technician at the scan shop 106 may administer the intraoral scan. The technician may administer the intraoral scan using, for instance, an iTero® scanner. As the technician administers the intraoral scan, the intraoral scanner may produce data which is visually represented on a display. The data may correspond to a three-dimensional scan of the user's 104 mouth. In some embodiments, the technician may administer the intraoral scan in a predetermined position. For instance, the technician may be instructed to administer the intraoral scan from over the user's 104 shoulder with the display in the field of view of the user 104. Accordingly, as the intraoral scanner generates data that is visually represented on the display, both the user 104 and technician may be able to observe the display. Such arrangements and instructions may enhance the user's 104 experience by engaging the user 104 in the scanning process.

In some embodiments, the administration of the intraoral scan may be recorded for quality assurance purposes. For instance, the room in which the user 104 has the intraoral scan administered may have a camera. The user 104 may approve or deny the recording. In some instances, the user 104 may be incentivized to approve the recording by, for instance, one free set of aligners or one free set of retainers.

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In some embodiments, the user 104 may be shown a simulated movement of the user's teeth from the starting position (e.g., as represented by the three-dimensional scan) to a simulated final position. Such capabilities presently exist through use of the iTero® scanner.

Following administration of the intraoral scan, in some embodiments, a quality control technician may review and approve the intraoral scan. The quality control technician may be located at the intraoral scanning site 106. Additionally or alternatively, the quality control technician may be located remotely. The quality control technician may be a manager or other guide who has the authority to approve (or not approve) the intraoral scan. Where the quality control technician does not approve of the intraoral scan, the quality control technician may highlight particular areas on the intraoral scan that need to be re-scanned. The quality control technician may also approve some or all of the information provided by the user 104 (e.g., the personal information 202, the health and consent information provided in the health and consent questionnaire, various other information such as shipping information, etc.). In implementations such as these, the quality control technician may ensure that subsequent visits to the intraoral scanning site 106 or unnecessary calls to the user 104 are avoided by collecting all necessary information during a single appointment of the user 104.

In some embodiments, following administration of the intraoral scan, the technician may take one or more photographs of the user's 104 mouth. The technician may take the photographs of the user's 104 upper and lower jaw (in some instances with a smile spreader). The technician may take a head-on photograph of the user's 104 smile. The technician may take the one or more photographs using a digital camera. Additionally or alternatively, the technician may take the one or more photographs using a camera of the user device 600. In each of these implementations, the photographs may be an initial set of photos that is used for compliance checks. The photographs may be saved to the user file 134.

Once the quality control technician approves of the intraoral scan (and photographing), the user 104 may leave the room where the user 104 received their intraoral scan. The user may go to, for instance, a waiting area or front desk area. At the front desk area, the user 104 may be shown or given various products. For instance, the user 104 may be shown what the aligners generally look like (e.g., substantially transparent, translucent, etc.). The user 104 may also be shown the packaging in which the aligners are delivered and the corresponding instruction manual. The user 104 may be provided with various dental-related items. For instance, the user 104 may be provided with lip balm, teeth whitening kits, a tote bag, etc. Each of these examples may further increase the likelihood of the user 104 purchasing aligners that are custom to the user's 104 teeth. In some embodiments, instead of receiving products at a front desk area, the user 104 may be shown or given various products in the room where they received the intraoral scan. In some embodiments, the user 104 may be shown the aligners/packaging prior to receiving the intraoral scan (e.g., at check-in), during a break, etc.

In some embodiments, the user 104 may be presented with a fast track option for generating a set of aligners from the intraoral scan. The fast track option may be a form that is filled out by the user 104, may be an oral agreement from the user, etc. The fast track option may authorize a provider of the aligners to automatically generate the aligners once

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the treatment plan (or the final teeth position) for the user **104** is approved by a doctor (e.g., a dentist, an orthodontist, etc.).

The user **104** may be prompted to pay at the time of the intraoral scan (or set up a payment plan at the time of the intraoral scan). Once the user **104** pays (or sets up the payment plan), the user **104** may authorize fast tracking the generation of the aligners. In implementations such as these, the user **104** may not be required to authorize the treatment plan. Rather, the treatment plan may be shown in the user portal, as will be discussed in greater detail below. Additionally, once the treatment plan is approved by the doctor, the treatment plan may be automatically used for generating the aligners and automatically uploaded to the user portal.

In some embodiments, the doctor (e.g., the dentist, orthodontist, etc.) may approve of the treatment plan following the doctor seeing the user via a video conference or a video of the user. For instance, the doctor may “see” the user remotely prior to approving the treatment plan. In still other embodiments, the doctor may approve of the treatment plan without the video conference or the video of the user. In each of these embodiments, the doctor may approve of the treatment plan for the user without having to physically see the user in person. Accordingly, the user may not be inconvenienced with a trip to a doctor’s office, which may also save time for the user.

Where the user **104** does not authorize fast tracking the generation of the aligners, the user **104** may authorize the treatment plan once the treatment plan is sent to the user **104** via the user portal. Following authorization of the treatment plan, the aligners may be generated and sent to the user **104**. Additionally, following authorization of the treatment plan, the user **104** may then be prompted to pay for the aligners (or sign up for a payment plan).

In some embodiments, the treatment plan may be generated by a dental professional using a computing system at a treatment plan site. The treatment plan site may be separate from the intraoral scan sites, the fabrication site, etc. In other embodiments, the treatment plan site may be the same as the intraoral scan site and/or the fabrication site. Accordingly, two or more of these sites may be consolidated into one site.

The treatment plan may be generated by manipulating individual teeth in the three-dimensional representation of the user’s mouth. For instance, the dental professional may manipulate one or more teeth of the user’s mouth (as represented in the three-dimensional data) from a starting position (at the time of the intraoral scan) to an ending position (following treatment). Following the teeth being moved to the ending position, the treatment plan may automatically be generated (e.g., by a computer or computing system) in accordance with a set of rules. The set of rules may include rules which constrict an amount of movement of a single tooth between two sequential aligners (for instance, 3.00 mm). Following the treatment plan being generated, various models (e.g., positive molds of the user’s dentition) may be generated which correspond to the position of the teeth at various intervals between the starting and ending position. The aligners may then be generated by thermoforming a polymer material to each of the various models (with a first aligner corresponding to the starting position of the user’s teeth in the user’s dentition, the second [and subsequent] aligner corresponding to an intermediate position[s], and the final aligner corresponding to the final position of the user’s teeth in the user’s dentition).

Following generation of the aligners, all aligners associated with the treatment plan may be sent to the user **104**. In some implementations, the aligners may be generated and

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sent to the user **104** in packaging similar to the packaging described in U.S. Patent Application Ser. No. 62/522,847, filed on Jun. 21, 2017, titled “DENTAL IMPRESSION KITS AND METHODS THEREFOR,” U.S. patent application Ser. No. 15/725,430, filed on Oct. 5, 2017 and having the same title, and U.S. Patent Application Ser. No. 62/648,229, filed on Mar. 26, 2018 and having the same title, each of which are incorporated by reference in their entirety as noted herein.

Post-Appointment

Following the user **104** having their intraoral scan administered at the scan shop **106**, the user **104** may receive one or more messages generated via the message generator **136**. Accordingly, in some embodiments, the message generator **136** can include instructions for generating and communicating one or more messages to the user **104** following the user’s **104** appointment.

In some implementations, the message generator **136** can include instructions to generate a message including various surveys and/or questionnaires. These surveys may be used for evaluating the user’s **104** experience at the intraoral scanning site **106**. In some implementations, the surveys may solicit the user **104** for a review on a customer review website such as Yelp®, Google®, etc. Additionally, where the user **104** receives a whitening kit at their appointment, the message generated via the message generator **136** may include whitening tips for the user **104**. In each of these implementations, the messages generated via the message generator **136** may be used as feedback for subsequent user’s appointments, and to enhance the experience for the user **104**.

In some implementations, the message generator **136** can include instructions for generating various messages specifically when a user **104** does not attend their appointment. For instance, when the user file **134** indicates the user **104** did not show up for their appointment, the message generator **136** can include instructions for automatically generating a message including a survey for evaluating reasons why the user **104** did not showed up for their appointment. The survey generated in these implementations may solicit the user **104** to provide suggestions of what the intraoral scanning site **106** (or website) could do differently. The survey generated in these implementations may also solicit the user **104** to provide information as to how the user **104** would like to be contacted in the future (e.g., via phone call, text message, email, etc.). In some instances, the message generated via the message generator **136** may include an indication to the user **104** that the user **104** does not require an appointment for an intraoral scan and that the user can show up at an intraoral scanning site **106** any time during business hours (e.g., that walk-ins are welcome). In each of these implementations, the messages are provided to the user **104** when the messages may increase the likelihood of the user **104** scheduling or otherwise visiting the intraoral scanning site **104**, and may assist in improvements to the overall experience for other users.

Additionally, where the user **104** misses their appointment, in some instances, the user **104** may be provided a free at-home impression kit (similar to those described in U.S. Patent Application Ser. No. 62/522,847 and U.S. patent application Ser. No. 15/725,430). The at-home impression kit may be sent to the user **104** via first class mail. For instance, when the user file **134** indicates the user **104** did not show up for the appointment, the message generator **136** can include instructions to automatically generate a message to the user **104** that indicates that an at-home impression kit will be sent at no charge to the user **104**. Additionally, the

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message generator **136** can include instructions to generate a prompt that is transmitted to, for instance, a processing or shipping warehouse. The prompt may include an address or shipping label and instructions to send an at-home impression kit to the user **104** at the address.

User Portal

Referring now to FIG. **1** and FIG. **8**, a user portal is generated for the user **104**. Specifically shown in FIG. **8** is an example user portal **800** associated with the user **104**. The example user portal **800** shown in FIG. **8** is generated prior to the user's **104** appointment. The appointment management system **100** may include a portal manager **140**. The portal manager **140** may be or include instructions, that when executed by the processor **108**, cause the processor **108** to generate/modify/change/manage one or more aspects of the user portal **800**. As shown, the user portal **800** may include a brief overview of what to expect at the user's **104** appointment. The user portal **800** may include a button **802** to reschedule the user's **104** appointment. The button **802** may direct the user **104** to a page similar to reservation page **200**. Additionally, the user portal **800** may include a button **804** to view a Frequently Asked Questions (FAQ) page providing answers to questions that the user **104** may have.

Referring now to FIG. **1** and FIG. **9**, the portal manager **140** may include instructions to modify the user portal **800** following the user's **104** appointment. For instance, as shown in FIG. **9**, the user portal **800** is generated following the user's **104** appointment. The user portal **800** shown in FIG. **9** may include a visual representation (shown as a video) of the user's **104** treatment plan. The visual representation may show changes in the user's **104** smile as the user **104** progresses through various stages of the treatment plan. The visual representation may be a series of photos, a video, etc. The user **104** may be able to view the visual representation through selection of a button **900** (e.g., play button).

Additionally, the user **104** may be required (or requested) to provide progress information. As will be discussed in greater detail below, the progress information provided by the user **104** may be used for evaluating compliance and issuing a mid-course correction.

The user **104** may select a button **902** for providing progress information. The user **104** may be required to provide progress information at various stages along the treatment plan. For instance, the user **104** may be required to provide progress information at the outset of the treatment plan, as each aligner is used, following 90 days from the outset of the treatment plan, and/or other stages in the treatment plan. In some implementations, the appointment management system **100** may issue reminders to the user **104** for providing the progress information. For instance, the message generator **136** and/or portal manager **140** can include instructions to automatically generate one or more messages to communicate to the user **104** at various points throughout the treatment plan. As one example, when the aligners are received by the user **104** (e.g., as detected by a delivery notification), the delivery notification may be indicated in the user file **134**. When the user file **134** indicates the delivery notification, the message generator **136** and/or portal manager **140** can include instructions to automatically generate one or more messages for the user **104** instructing the user **104** to provide initial progress data. When uploaded, the portal manager **140** can include instructions to store the initial progress data in the user file **134** as a baseline. The message generator **136** and/or portal manager **140** may include instructions to generate subsequent messages reminding the user **104** to upload progress data at various

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stages of the treatment plan, as described above. The message generator **136** and/or portal manager **140** can include instructions to identify a send date upon which the message corresponding to the initial progress data was communicated to the user **104**. Additionally, the message generator **136** and/or portal manager **140** can include instructions to identify a current date. Based on a difference between the send date and the current date, the processor **108** may generate subsequent messages based on the instructions from the message generator **136** (and/or portal manager **140**). Similarly, the message generator **136** and/or portal manager **140** can include instructions to generate messages directing the user **104** to change which aligners they are using (e.g., directing the user **104** to stop using a first set of aligners and to instead use a second set of aligners, directing the user **104** to stop using a third set of aligners and instead use the second set of aligners, to stop using the aligners altogether and to wait for new aligners to be sent to the user **104**, etc.). Such messages may be generated similar to the messages for providing progress data.

Referring now to FIG. **1** and FIG. **10**, upon selection of button **902**, the portal manager **140** can include instructions to direct the user **104** to a progress tracker page **1000** within the user portal **800**. Within the progress tracker page **1000**, the user **104** is prompted to indicate which aligner the user **104** is currently using (e.g., through selection of a corresponding button **1002**). Additionally, the user **104** is prompted to upload photos of the user's **104** smile. The user **104** may be instructed (e.g., either on the user portal **800**, the progress tracker **1000**, or separate instruction manual) on how to capture photos. For instance, the user **104** may be instructed to capture photos while using a smile spreader (e.g., a device positioned in the user's **104** mouth intended to push back the user's **104** lips and expose a greater area of the user's **104** teeth). The user **104** may be instructed to position the smile spreader in the user's **104** mouth and capture images at various angles. The user **104** may be instructed to capture an image of the user's **104** teeth head-on while biting down. The user **104** may be instructed to capture an image of the user's **104** lower jaw while opening the user's **104** mouth. The user **104** may be instructed to capture an image of the user's **104** upper jaw while opening the user's **104** mouth. The user **104** may be instructed to capture additional/alternative images of the user's **104** teeth. Each of these images may be uploaded by the user **104** using button **1004**. Upon selection of button **1004**, the user **104** may be prompted to search for and locate the image to upload. The image may be previewed (e.g., in display box **1006**) once the user **104** locates the file. The user **104** may then select an upload button **1008** to upload the images to the user portal **800**. When the images are uploaded, the portal manager **140** can include instructions to automatically add these images to the user file **134**.

The user **104** may provide comments regarding the progress or fit of the aligners in comments box **1010**. For instance, the user **104** may indicate that the user **104** is not satisfied with the progress of realigning the user's **104** teeth or how the user's **104** smile looks. As another example, the user **104** may indicate that the aligners do not fit or are uncomfortable. Each of these indications may indicate that the user **104** may require a mid-course correction. As used herein, a mid-course correction is defined as a new treatment plan developed for the user **104** following an indication that the current treatment plan is no longer desirable for the user **104**. Accordingly, the user **104** receives a new intraoral scan, a new set of aligners, etc. In this regard, no cross-reference is made between the first treatment plan and the second

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treatment plan. However, in some implementations, the mid-course correction comprises receipt of at least one new set of aligners, which may be created for the user 104 following new intraoral scan or new impressions to be made of the user's 104 teeth. In some implementations, the mid-course correction may be free to the user 104. For instance, as discussed below, the mid-course correction may be free following a compliance check indicating that the user 104 is correctly following the treatment plan.

The compliance check may be a review of the progress data provided by the user (e.g., via progress tracker 1000). In some implementations, following the user 104 uploading any comments via comments box 1010, the portal manager 140 may include instructions to automatically flag the user file 134 and communicate the file to a professional terminal 142. The professional terminal 142 may be a computer associated with one or more professionals (e.g., doctors, dentists, orthodontists, etc.). The professional terminal 142 may display the user file 134 including the images uploaded by the user 104 and the current aligner which is being used by the user 104. The user file 134 may be evaluated by the professionals to determine whether the user 104 is progressing according to the treatment plan, whether the user 104 is following the treatment plan as instructed, etc. Where the user 104 is not following the treatment plan as instructed, the user file 134 may be flagged as not being in compliance. Where the user 104 is following the treatment plan but is not progressing according to the treatment plan, portal manager 140 may flag the user file 134 for a mid-course correction. Where the user file 134 is flagged as not being in compliance, the user 104 may be required to pay for the mid-course correction. However, where the user 104 is following the treatment plan, the mid-course correction may be offered to the user 104 for free.

In some implementations, when the user 104 is following the treatment plan as instructed and progresses through the treatment plan, the message generator 136 and/or portal manager 140 may include instructions to automatically generate a message (and corresponding flag in the user file 134) indicating that the user 104 is eligible for a free dental check-up and cleaning at a dental clinic or associated dental office.

The construction and arrangement of the systems and methods as shown in the various exemplary embodiments are illustrative only. Although only a few embodiments have been described in detail in this disclosure, many modifications are possible (e.g., variations in sizes, dimensions, structures, shapes and proportions of the various elements, values of parameters, mounting arrangements, use of materials, orientations, etc.). By way of example, the position of elements may be reversed or otherwise varied and the nature or number of discrete elements or positions may be altered or varied. Accordingly, all such modifications are intended to be included within the scope of the present disclosure. The order or sequence of any process or method steps may be varied or re-sequenced according to alternative embodiments. Other substitutions, modifications, changes, and omissions may be made in the design, operating conditions and arrangement of the exemplary embodiments without departing from the scope of the present disclosure.

The present disclosure contemplates methods, systems and program products on memory or other machine-readable media for accomplishing various operations. The embodiments of the present disclosure may be implemented using existing computer processors, or by a special purpose computer processor for an appropriate system, incorporated for this or another purpose, or by a hardwired system. Embodi-

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ments within the scope of the present disclosure include program products or memory comprising machine-readable media for carrying or having machine-executable instructions or data structures stored thereon. Such machine-readable media may be any available media that may be accessed by a general purpose or special purpose computer or other machine with a processor. By way of example, such machine-readable media can comprise RAM, ROM, EPROM, EEPROM, CD-ROM or other optical disk storage, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to carry or store desired program code in the form of machine-executable instructions or data structures and which can be accessed by a general purpose or special purpose computer or other machine with a processor. Combinations of the above are also included within the scope of machine-readable media. Machine-executable instructions include, by way of example, instructions and data which cause a general purpose computer, special purpose computer, or special purpose processing machines to perform a certain function or group of functions.

Although the figures may show a specific order of method steps, the order of the steps may differ from what is depicted. Also, two or more steps may be performed concurrently or with partial concurrence. Such variation will depend on the software and hardware systems chosen and on designer choice. All such variations are within the scope of the disclosure. Likewise, software implementations could be accomplished with standard programming techniques with rule based logic and other logic to accomplish the various connection steps, processing steps, comparison steps and decision step.

What is claimed is:

1. A method of producing aligners for repositioning one or more teeth of a user, the method comprising:
 - receiving, by an appointment management system, a request to schedule an appointment at an intraoral scanning site, the intraoral scanning site having an intraoral scanner configured to scan a mouth of a user, the appointment being for a technician to conduct an intraoral scan of the mouth of the user at the intraoral scanning site without a dentist or orthodontist physically seeing the user during the scheduled appointment, wherein the technician is not a dentist or an orthodontist;
 - scheduling, by the appointment management system, the appointment at the intraoral scanning site in accordance with the request;
 - generating and communicating, by the appointment management system, a message to a device of the user, the message including a confirmation confirming the scheduled appointment;
 - conducting, using the intraoral scanner, the intraoral scan at the intraoral scanning site during the scheduled appointment, the intraoral scan generating three-dimensional data of the mouth of the user;
 - causing generation, by a treatment plan computing system located at a treatment plan site, of a treatment plan for the user based on the three-dimensional data of the mouth of the user;
 - receiving an indication of an approval of the treatment plan by a dental or orthodontic professional, wherein the approval is received without the dental or orthodontic professional having physically seen the user;
 - producing, at a fabrication site, a plurality of aligners based on the treatment plan, the plurality of aligners

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specific to the user and being configured to reposition one or more teeth of the user in accordance with the treatment plan; and
sending the plurality of aligners from the fabrication site directly to the user, wherein the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.

2. The method of claim 1, wherein the approval of the treatment plan is received from the dental or orthodontic professional after the dental or orthodontic professional sees the user via a video of the user or via a videoconference with the user.

3. The method of claim 1, wherein causing generation of the treatment plan comprises:
transmitting, to the treatment plan computing system, the three-dimensional data of the mouth of the user; and
receiving, from the treatment plan computing system, the treatment plan for the user generated based on the three-dimensional data of the mouth of the user, the treatment plan defining movement of the one or more teeth of the user from a starting position at the time of the intraoral scan to an ending position following treatment using the plurality of aligners.

4. The method of claim 1, wherein the approval by the dental or orthodontic professional is a first approval, the method further comprising:
responsive to receiving the first approval, providing data indicative of the treatment plan to the user; and
receiving a second approval of the treatment plan, wherein the second approval of the treatment plan is received from the user following the first approval being received from the dental or orthodontic professional;
wherein producing the plurality of aligners is performed responsive to receiving the first approval and the second approval of the treatment plan.

5. The method of claim 1, wherein generating the treatment plan comprises:
manipulating, by the treatment plan computing system, one or more teeth in the three-dimensional data of the mouth of the user from a starting position at the time of the intraoral scan to an ending position.

6. The method of claim 1, wherein scheduling the appointment comprises
identifying, by the appointment management system, a time and a date associated with the request;
accessing, by the appointment management system, a schedule maintained for the intraoral scanning site indicating available appointments;
determining, by the appointment management system, that the time and date requested in the request is available based on the available appointments; and
adding, by the appointment management system, the appointment to the schedule for the intraoral scanning site in accordance with the request.

7. The method of claim 1, wherein producing the plurality of aligners comprises:
generating a plurality of positive molds of a dentition of the user in accordance with the treatment plan, wherein each positive mold of the plurality of positive molds correspond with a specific step of the treatment plan; and
thermoforming polymer material to each of the plurality of positive molds to generate the plurality of aligners.

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8. The method of claim 1, wherein generating and communicating the message to the user comprises:
generating and communicating a first message to the user confirming the scheduled appointment; and
generating and communicating a second message to the user on a date of the appointment instructing the user to leave for the appointment to arrive at a scheduled time of the appointment.

9. The method of claim 8, wherein the second message is communicated to the user a threshold time prior to the scheduled time of the appointment.

10. The method of claim 9, wherein the threshold time at which the second message is communicated to the user is determined based on (1) a location of the user based on a location of the device of the user with respect to a location of the intraoral scanning site, and (2) at least one of (a) traffic between the location of the user and the location of the intraoral scanning site, (b) weather, (c) a time of day of the appointment, and (d) a day of the week of the appointment.

11. The method of claim 1, wherein the message includes a link for adding an entry corresponding to the scheduled appointment to an electronic calendar on the device of the user, wherein the entry includes a location of the intraoral scanning site and a duration of the scheduled appointment.

12. The method of claim 1, wherein the appointment is for the technician to conduct the intraoral scan of the mouth of the user at the intraoral scanning site without the dentist or orthodontist physically or virtually seeing the user during the scheduled appointment.

13. A method comprising:
requesting, via a web portal or mobile application, an appointment at an intraoral scanning site having an intraoral scanner configured to conduct an intraoral scan of a mouth of a user, the appointment being for a technician to conduct the intraoral scan of the mouth of the user at the intraoral scanning site without a dentist or orthodontist physically seeing the user during the scheduled appointment, wherein the technician is not a dentist or orthodontist;
receiving, from an appointment management system, a confirmation message confirming a scheduling of the appointment;
receiving the intraoral scan at the intraoral scanning site during the scheduled appointment, the intraoral scanner generating three-dimensional data of the mouth of the user; and
receiving, directly from a fabrication site without visiting an office of a dental or orthodontic professional, a plurality of aligners produced in accordance with a treatment plan generated by a treatment plan computing system based on the three-dimensional data of the mouth of the user and approved by the dental or orthodontic professional without the dental or orthodontic professional having physically seen the user;
wherein the fabrication site produces the plurality of aligners based on the treatment plan;
wherein the plurality of aligners are specific to the user and configured to be administered in a predetermined sequence to reposition one or more teeth of the user in accordance with the treatment plan; and
wherein the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.

14. The method of claim 13, wherein the approval of the treatment plan by the dental or orthodontic professional is a first approval, the method further comprising:

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receiving data indicative of the treatment plan, the data being received responsive to the first approval of the treatment plan; and
providing a second approval of the treatment plan.

15. The method of claim 13, wherein the plurality of aligners comprises:

- a first aligner corresponding to a first step of the treatment plan;
- a second aligner corresponding to an intermediate step of the treatment plan; and
- a third aligner corresponding to a final step of the treatment plan.

16. The method of claim 15, further comprising:

administering the plurality of aligners in the predetermined sequence by:

- administering the first aligner for a duration;
- administering the second aligner for the duration following administering the first aligner for the duration; and
- administering the third aligner for the duration following administering the second aligner for the duration.

17. The method of claim 13, further comprising:

providing a pre-approval of the treatment plan during the appointment after the intraoral scan and prior to the treatment plan being generated.

18. The method of claim 13, further comprising:

receiving a departure message on a date of the appointment instructing the user to leave for the appointment to arrive at a scheduled time of the appointment.

19. The method of claim 18, wherein the departure message is received by the user a threshold time prior to the scheduled time of the appointment, the threshold time being determined based on (1) a location of the user based on a location of the device of the user with respect to a location of the intraoral scanning site, and (2) at least one of (a) traffic between the location of the user and the location of the intraoral scanning site, (b) weather, (c) a time of day of the appointment, and (d) a day of the week of the appointment.

20. A system for producing aligners for repositioning one or more teeth of a user, the system comprising:

an appointment management system configured to:

- receive a request to schedule an appointment at an intraoral scanning site, the appointment being for a technician to conduct an intraoral scan of a mouth of a user at the intraoral scanning site without a dentist or orthodontist physically seeing the user during the scheduled appointment, wherein the technician is not a dentist or orthodontist;

schedule the appointment at the intraoral scanning site in accordance with the request;

generate and communicate a message to a device associated with the user, the message including a confirmation confirming the scheduled appointment;

the intraoral scanning site comprising:

an intraoral scanner configured to generate three-dimensional data from the intraoral scan of the mouth of the user; and

one or more intraoral scanning site computing systems configured to communicate the three-dimensional data from the intraoral scanner for generation of a treatment plan, wherein the treatment plan is approved by a dental or orthodontic professional without the dental or orthodontic professional having physically seen the user; and

a fabrication system including one or more fabrication sites associated with the production and shipment of aligners, the fabrication system comprising:

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one or more fabrication computing systems configured to receive treatment plan data corresponding to the treatment plan for the user; and

equipment configured to produce a plurality of aligners based on the treatment plan data, the plurality of aligners being specific to the user and being configured to reposition one or more teeth of the user based on the treatment plan;

wherein the plurality of aligners are sent from at least one of the one or more fabrication sites directly to the user for repositioning the one or more teeth of the user, and the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.

21. The system of claim 20, further comprising:

a treatment plan computing system configured to:

- receive the three-dimensional data corresponding to the intraoral scan from the one or more intraoral scanning site computing systems;
- generate the treatment plan based on the three-dimensional data;

receive, from the dental or orthodontic professional, approval of the treatment plan; and

transmit the treatment plan data to the one or more fabrication computing systems for production of the one or more aligners.

22. The system of claim 20, wherein the message is a first message, and wherein the appointment management system is further configured to generate and communicate a second message to the device of the user after the scheduled appointment, the second message including a representation of the treatment plan generated for the user and for approval by the user.

23. The system of claim 20, wherein the message is a first message, and wherein the appointment management system is further configured to generate and communicate a second message to the device of the user after the scheduled appointment, the second message including an indication that the treatment plan was generated and approved by the dental or orthodontic professional and that the plurality of aligners will be sent to the user, wherein the user pre-authorized the treatment plan during the scheduled appointment.

24. A method of producing aligners for repositioning one or more teeth of a user, the method comprising:

- receiving, by an appointment management system, a request to schedule an appointment at an intraoral scanning site, the intraoral scanning site having an intraoral scanner configured to scan a mouth of a user and generate three-dimensional data of the mouth of the user, the appointment being for a technician to conduct the intraoral scan of the mouth of the user at the intraoral scanning site without a dentist or orthodontist physically seeing the user during the scheduled appointment, wherein the technician is not a dentist or an orthodontist;

scheduling, by the appointment management system, the appointment at the intraoral scanning site in accordance with the request;

generating and communicating, by the appointment management system, a message to a device of the user, the message including a confirmation confirming the scheduled appointment;

causing generation, by a treatment plan computing system located at a treatment plan site following the appointment during which an intraoral scan was performed for generating the three-dimensional data of the mouth of

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the user, of a treatment plan for the user based on the three-dimensional data of the mouth of the user; receiving an indication of approval of the treatment plan by a dental or orthodontic professional, wherein the approval is received without the dental or orthodontic professional having physically seen the user in person; causing production of a plurality of aligners based on the treatment plan, the plurality of aligners specific to the user and being configured to reposition one or more teeth of the user in accordance with the treatment plan; and causing sending, from a fabrication site associated with at least one of the production and shipment of aligners, the plurality of aligners directly to the user, wherein the user receives orthodontic treatment without ever having physically seen the approving dental or orthodontic professional.

25. The method of claim **24**, wherein generating and communicating the message to the user comprises: generating and communicating a first message to the user confirming the scheduled appointment; and generating and communicating a second message to the user on a date of the appointment instructing the user to leave for the appointment to arrive at a scheduled time of the appointment.

26. The method of claim **25**, wherein the second message is communicated to the user a threshold time prior to the scheduled time of the appointment.

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27. The method of claim **26**, wherein the threshold time at which the second message is communicated to the user is determined based on (1) a location of the user based on a location of the device of the user with respect to a location of the intraoral scanning site, and (2) at least one of (a) traffic between the location of the user and the location of the intraoral scanning site, (b) weather, (c) a time of day of the appointment, and (d) a day of the week of the appointment.

28. The method of claim **24**, wherein the message is a first message, the method further comprising: generating and communicating, by the appointment management system, a second message to the device of the user, the second message including information corresponding to a treatment plan generated for the user based on the intraoral scan of the mouth of the user during the scheduled appointment.

29. The method of claim **28**, wherein the information included in the second message includes a representation of the treatment plan generated for the user and for approval by the user.

30. The method of claim **28**, wherein the information included in the second message includes an indication that the treatment plan was generated and approved by the dental and orthodontic professional and that the plurality of aligners will be sent to the user, wherein the user pre-authorized the treatment plan during the scheduled appointment.

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FORM 19. Certificate of Compliance with Type-Volume Limitations

Form 19
July 2020

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2021-1446

Short Case Caption: SmileDirectClub, LLC v. Candid Care Co.

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Date: 02/22/2021

Signature: /s/ Kal K. Shah

Name: Kal K. Shah