

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN DIGITAL MODELS, DIGITAL DATA, AND TREATMENT PLANS FOR USE IN MAKING INCREMENTAL DENTAL POSITIONING ADJUSTMENT APPLIANCES, THE APPLIANCES MADE THEREFROM, AND METHODS OF MAKING SAME

Inv. No. 337-TA-833

ORDER NO. 17: GRANTING COMPLAINANT ALIGN TECHNOLOGY INC'S MOTION TO STRIKE CLEARCORRECT'S NINTH AFFIRMATIVE DEFENSE

(January 2, 2013)

On July 18, 2012, complainant Align Technology, Inc. ("Align") filed a motion to strike the Ninth Affirmative Defense contained in the responses of respondent ClearCorrect Operating, LLC and ClearCorrect Pakistan Private, Ltd. (collectively "ClearCorrect") (Motion Docket No. 833-005)¹. Align certifies that at least two days prior to the filing of the motion, it made reasonable good faith efforts to contact the other parties to resolve the matter and notified all other parties in advance of the filing of the motion as required by Ground Rule 3.2. Align states that ClearCorrect indicated it would oppose the motion. On July 30, 2012, the Commission Investigative Staff ("Staff") filed a response opposing striking ClearCorrect's Ninth Affirmative

¹ Although ClearCorrect Operating LLC and ClearCorrect Pakistan Private, Ltd. filed separate responses to the complaint (also described as the corrected complaint), the Ninth Affirmative Defense in the responses is identical in all respects. Consequently, Align argues its motion against the two responses jointly, and this Order will treat them jointly.

Defense; but supporting an order requiring ClearCorrect to supplement their pleadings. On July 30, 2012, ClearCorrect filed its opposition to the motion.

On August 15, 2012, Align filed a motion for leave to file a reply in support of its motion to strike. (Motion Docket No. 833-009) On August 27, 2012, Respondents' filed an opposition to that motion.

Align's Position: Align argues that ClearCorrect's inequitable conduct defense is inadequate under the standards set in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) and relevant ITC precedent, and should be stricken.

More specifically, Align asserts that ClearCorrect has failed to meet the standards of F.R.C.P. Rule 9(b) and fails to answer the basic questions of the "who, what, when, where and how" of the alleged misconduct giving rise to the assertion of inequitable conduct. (Citing *Exergen* at 1327) Align alleges that ClearCorrect has failed to allege facts sufficient to identify the specific person or persons accused of misconduct, facts sufficient to demonstrate that any specific person had both knowledge of specific and material information and made a deliberate decision to withhold such information, and facts that would support a finding that any withheld information was material under the "but for" standard set forth in *Therasense*.

Align contends that Respondents' inequitable conduct allegations omit key details and at times directly contradict the materials quoted and referenced. Align notes that Commission Rule 210.13(b) requires that "[a]ffirmative defenses shall be pleaded with as much specificity as possible in the response."

Align addresses the three allegations of Respondents' inequitable conduct defense, to wit: (1) U.S. Patent No. 5,242,304 (the '304 patent); (2) U.S. Patent No. 5,820,368 (the '368 patent);

and (3) an expert report prepared for Align in another litigation by Dianne Rekow, PhD (the Rekow report).

Addressing the '304 patent, Align argues that Respondents fail to provide any facts to show that anyone at Align or Align's prosecuting attorneys had knowledge of either the materiality of the '304 patent or intended to deceive the PTO by withholding it. Align asserts that Respondents fail to identify the individuals they accuse of misconduct, and does not identify the specific material portions of the '304 patent and relate them to U.S. Patent No. 6,705,863 (the '863 patent).

More specifically, Align notes that Respondents allege that James Heslin, acting as Align's attorney, "conducted a thorough review" of the '304 patent. Align says that Respondents rely solely on the fact that Mr. Heslin continued to act as Align's attorney during the time of the re-examination. Align avers that neither Mr. Heslin nor any member of his firm signed any documents related to the '863 reexamination. Align adds that Respondents provide no basis for alleging that Mr. Heslin knew of the alleged materiality of the '304 patent to the '863 reexamination. Align concludes that Respondents do not and cannot allege that Mr. Heslin was aware of the new re-examination claims to which the '304 patent was allegedly relevant.

Align continues that Respondents do not provide any basis for the allegation that Mr. Heslin passed his knowledge of the '304 patent along to Align's counsel in the '863 patent re-examination. Align admits that Respondents allege:

Members of the Greenberg, Traurig and Paul Hastings firms met with Mr. Heslin and attorneys from Townsend & Townsend & Crew, reviewed the prior art, drafted filings submitted to the PTO, and met with patent examiners.

Align states that nowhere do Respondents allege that the Greenberg and Paul Hastings attorneys knew of the '304 patent.

Align asserts that Respondents' allegations fail to identify "who" exactly are the attorneys from Greenberg and Paul Hastings firms that are accused. Align argues that the pleading must identify the persons involved by name in order to comply with F.R.C.P. 9(b), and Align asserts that Respondents have failed to do this. (Citing *In the Matter of Certain Liquid Crystal Display Devices and Products Containing the Same*, Inv. No. 337-TA-782, Order No. 8 at 5 (Oct. 4, 2011))

Align argues that Respondents fail to identify the claims and the limitations in those claims, to which the withheld references are relevant, and where in those references the material information is found. Align contends that Respondents fail to identify any limitation for any claim of the '863 patent for which the '304 patent would be material. Align concludes that Respondents offer "little more than a cursory description of what the references disclose, citing generally to columns five and six (a full page of the patent) as an 'example' of why the reference is material." Align contends that Respondents must establish the "where" and "how" of alleged misconduct by providing detailed claim charts comparing the claims of the patents-in-suit with the alleged material references. (Citing *Liquid Crystal Display Devices; In the Matter of Certain Devices for Mobile Communication*, Inv. No. 337-TA-809, Order No. 11 at 10 (Dec. 23, 2011); and *In the Matter of Certain Electronic Devices, Including Handheld Wireless Communications Devices*, Inv. Nos. 337-TA-673, 337-TA-667, Order No. 39C at 6 (Sep. 17, 2009))

Addressing the '368 patent, Align argues that Respondents' allegations are similarly deficient. Align says that the Respondents fail to plead sufficient facts to show that anyone at Align or any of Align's prosecuting attorneys knew of the '368 patent's materiality or intended to deceive the PTO. Align asserts that Respondents fail to identify by name the individuals it accuses of misconduct, and where Respondents do identify individuals, they fail to adequately

allege how the individuals had a duty of candor to the PTO. Align concludes that Respondents fail to provide a detailed comparison between the '368 patent and the '863 patent to show materiality.

More specifically, Align states that Respondents base their allegations “upon information and belief” that Align’s legal counsel, including James Heslin and Bao Tran, “reviewed and considered [the] ... '368 patent during or near September 2001” without citing evidence supporting this allegation. Align asserts that Respondents do not allege that Bao Tran was “substantively involved” in the prosecution of the patent or its re-examination² such that he would owe a duty of candor to the PTO. (Citing *Liquid Crystal Display Devices*, Order No. 8 at 6) Align continues that Respondents fail to allege any facts sufficient to suggest a “deliberate decision to withhold a known material reference” beyond the fact that individuals at Align may have known about the '368 patent. (Citing *Therasense* 649 F.3d at 1290) Align adds that Respondents resort to generic allegations against “Align’s legal counsel” and “attorneys who reviewed and considered Dr. Wolk’s '368 patent.” Align reiterates that an inequitable conduct defense is insufficiently pled where it names only a few individuals and then accuses unidentified “others involved in the preparation or prosecution” of a patent-in-suit. (Citing *Liquid Crystal Display Devices*, Order No. 8 at 5)

Align also asserts that Respondents have failed to provide the required “complete and detailed comparison between the asserted claims of the [patents-in-dispute] and the [withheld reference].” Align admits that Respondents cite one claim of the '863 patent as an example of why the '368 patent is material; but says that Respondents do not cite to any allegedly material information in the '368 patent. Align concludes that Respondents’ general comparison of the

² Align asserts that Mr. Tran did not sign any document to the PTO in the '863 file history.

'863 patent and the '368 patent are inadequate to demonstrate how the disclosures in the '368 patent are claimed in the '863 patent.

Finally, Align contends that Respondents do not allege that the '368 patent is not cumulative and does not address whether other art before the PTO discloses any of the same matter contained in the withheld references, and Respondents have not explained how the examiner would have used the allegedly withheld reference, as required by *Exergen*.

Align next addresses the Rekow report and says that Respondents fail to allege any facts to show that anyone at Align or any prosecuting attorney knew of the alleged materiality of the Rekow report and intended to deceive the PTO. Align states that Respondents fail to name the specific individuals it accuses of misconduct. Align continues that Respondents provide no comparison to demonstrate how the Rekow report is material to U.S. Patent No. 7,134,874 (the '874 patent). Align states that Respondents allege that "Align's outside lawyers at the firm, Townsend and Townsend and Crew, LLP" and "Align's in-house lawyers, including Roger George" were "contemporaneously aware" of the Rekow report. Align continues that Respondents allege that Michael Rosato, a Townsend attorney, prepared, and in-house attorney George approved, the office action allegedly contradicted by the Rekow report. Align asserts that Respondents never state that Rosato and George knew of the identified statements from the Rekow report or even read the report.

Align reiterates that Respondents' allegations regarding misconduct fail to name any other individual accused. Align says, instead, the Respondents' allegations center on "Align's in-house lawyers" and "Align's in-house counsel" while identifying only one attorney by name, Roger George. Align concludes that Respondents also accuse Align's outside lawyers at the firm of Townsend and Townsend and Crew, LLP, while identifying only one of them – Michael

Rosato – by name. Align argues this does not meet the standard set in Rule 9(b) and discussed in *Liquid Crystal Display Devices*, Order No. 8.

Align alleges that Respondents provide only a cursory description of the Rekow report and only relate the Rekow report to claim 1 of the '874 patent. Align attacks several assertions of fact by Respondents related to allegations that Align's counsel misstated the state of prior art in connection with the '874 patent. Align also contends regarding materiality, that the portion of the Rekow report to which Respondents refer was referring to the use of computers to design braces and that the discussion of other references by Mr. Rosato noted that those references did not teach segmented dentition, which was true. Align says that the Rekow report did not contradict that position. Align refers to "Bhatia SN, JH Sowray, 'A computer-aided design for orthognathic surgery' British (sic) Journal of Oral and Maxillofacial Surgery, Vol. 22, 237-253, 1984," which Align says was disclosed to the PTO during the prosecution of the '874 patent. Align avers, therefore, references regarding segmented dentition were before the PTO during the prosecution of the '874 patent. Align concludes that Respondents cannot plead that the Rekow report was material to the prosecution of the '874 patent.

Respondents' Position: Respondents argue that they have provided adequate notice to Align of the alleged inequitable conduct. Regarding the '304 patent, Respondents devote most of their argument to copying the language of their Ninth Affirmative Defense verbatim.

Focusing on the '368 patent reference, Respondents address Align's complaint that they base allegations on information and belief and say that this is because Align has withheld discovery of the evidence necessary to prove the defense. Respondents discuss the progress of other cases being disputed in other forums to show Align's lack of response to discovery requests. Respondents continue that Align also argues the lack of proper identification of

individuals in the pleading and that they have failed to establish materiality of the '368 patent to the '863 patent prosecution. Respondents again refer the reader to the language of their Ninth Affirmative Defense and elaborate on the facts cited therein.

Regarding the third allegation of inequitable conduct, Respondents aver that Align argued inconsistent positions in an action accusing Align of infringement and in prosecuting the '874 patent at the PTO. On the one hand, Respondents say, Align used expert testimony to show that asserted claims were invalid because of prior art, and on the other hand they argued that the same prior art was immaterial to the '874 patent's claims. Respondents note that Align argues that Respondents fail to allege "specific individuals involved" and do not allege "the materiality of Align's inconsistent statements" and that Respondents have "taken some of the expert's statements out of context." Respondents disagree and contend that they have adequately identified the persons involved in Align's "efforts to mislead the PTO." Once again, Respondents quote at length from their Ninth Affirmative Defense to support their position.

Staff's Position: The Staff takes the position that the request to strike the Respondents' Ninth Affirmative Defense should be denied; but an order should issue requiring the Respondents to supplement their pleadings.

Staff argues that motions to strike affirmative defenses are generally disfavored and that Commission practice generally gives respondents an opportunity to supplement insufficiently pled affirmative defenses. (Citing *Certain Shirts with Pucker-free Seams and Methods of Producing Same*, Inv. No. 337-TA-517, Order No. 20 at 2 (January 27, 2005); *Certain Light Emitting Diodes and Products Containing Same*, Inv. No. 337-TA-512, Order No. 11, at 2 (August 24, 2004); and *Certain Mobile Telephone Handsets Wireless Communication Devices, and Components Thereof*, Inv. No. 337-TA-578, Order No. 8 at 3 (September 22, 2006))

Staff says that requests to supplement inequitable conduct defenses have been granted where the supplemented defense meets the required pleading standards. (Citing *Certain Electronic Devices, Including Handheld Wireless Communications Devices*, Inv. No. 337-TA-673, Order No. 39C, at 7 (Sep. 17, 2009); *Certain Devices for Mobile Data Communications*, Inv. No. 337-TA-809, Order No. 11, at 10 (Dec. 23, 2011); and *Certain Game Devices, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-757,³ Order No. 9 (Oct. 3, 2006)) Staff adds that the fact that discovery may be necessary to provide actual factual detail may be taken into account when assessing the time required to supplement pleadings. (Citations omitted)

Regarding the '304 patent reference, Staff says that the materiality of the undisclosed reference is inadequately pled, because Respondents do not sufficiently plead how the nondisclosed reference was but-for material, or how the nondisclosed information would have been used by the examiner to find the claim unpatentable. Staff is of the view that the pleading sufficiently pleads the actions of Mr. Heslin and alleging facts supporting an inference that Mr. Heslin knew of the '304 patent and its materiality, and intentionally did not disclose the reference to the PTO. Staff says the Respondents pled that Mr. Heslin reviewed the '304 patent after Align received a notice of infringement, ordered the prosecution history of the patent, filed the application that ultimately issued as the '863 patent, and submitted a product brochure created by Dr. Truax's company that contained none of the material information from the '304 patent. Staff asserts that Respondents insufficiently pled facts supporting an inference that other individuals were aware of the '304 patent and its materiality, or specifically intended to deceive the PTO through their actions. Staff says the allegations regarding Mr. Shimmick's involvement with reviewing the '304 patent and prosecuting the '863 patent application are vague, and there

³ Staff actually cites "338-TA-757" which is an obvious typographical error.

are insufficient allegations to support an inference that Mr. Jones or Mr. Wilson was aware of the '304 patent or its materiality.

Focusing on the '368 patent, Staff opines that the Respondents' pleadings do not adequately allege the materiality of the undisclosed reference. Although the Respondents refer to disclosures in the '368 patent that are "virtually identical" to a "device at the center of claim 21" of the '863 patent, Staff says they do not sufficiently plead how the reference was but-for material, or how the nondisclosed information would have been used by the examiner to find the claim unpatentable. Staff adds that Respondents insufficiently plead facts supporting an inference that Mr. Heslin or Mr. Tran "were aware of the '304 patent's materiality, or had specific intent to deceive the PTO through their actions."⁴

Regarding the allegedly undisclosed expert reports, Staff is of the view that the Respondents have not adequately pled how the Rekow report is material. Staff says that the alleged critical statement in the Rekow report that "the prior art described systems that taught segmented dentition," does not, without more, appear to contradict an attorney statement to the Examiner that "Lemchen does not teach segmented dentition." Staff asserts that Respondents' allegations do not explain which limitations of which claims were at issue in representations to the Examiner and how the nondisclosed expert reports would have led to rejection of specifically-identified patent claims. Staff adds that Respondents allegations are insufficient to the extent that they rely on other unnamed and unspecified expert reports.

Staff contends that the pleading does not adequately plead specific intent to deceive the PTO. Staff notes that Respondents pled that Mr. George, Align's in-house counsel, and "attorneys at Townsend and Townsend and Crew LLP were 'aware' of the expert reports, not

⁴ Inasmuch as this contention is located within the discussion of the '368 patent reference, I will treat the cite to the '304 patent as a typographical error.

that Mr. George or Mr. Rosato had ever read or reviewed the sections asserted to be material.” Staff argues that these allegations do not support an inference that either Mr. George or Mr. Rosato, the only named individuals, had knowledge of the portions of the expert report that Respondents assert are material, or that they acted with intent to deceive the PTO. (Citing *Exergen*, 575 F.3d at 1330 to find that scienter was insufficiently pleaded because “one cannot assume that an individual, who generally knew that a reference existed, also knew of the specific material *information* contained in that reference.”

Legal Standard

Commission Rule 210.13(b) states that “[a]ffirmative defenses shall be pleaded with as much specificity as possible in the response.” The rule further provides that the respondent is encouraged to make the following showing when appropriate:

If the claims of any involved U.S. patent are asserted to be invalid or unenforceable, the basis for such assertion, including, when prior art is relied on, a showing of how the prior art renders each claim invalid or unenforceable and a copy of such prior art. For good cause, the presiding administrative law judge may waive any of the substantive requirements imposed under this paragraph or may impose additional requirements.

19 CFR § 210.13(b)(3).

In prior investigations, I have held that the heightened pleading standard required by Rule 9(b) of the Federal Rules of Civil Procedure shall apply when a respondent asserts an affirmative defense of inequitable conduct. *Certain Bulk Welding Wire Containers & Components Thereof & Welding Wire*, Inv. No. 337-TA-686, Order No. 21 (Dec. 7, 2009); *Certain Electronic Devices, Including Handheld Wireless Communications Devices*, Inv. Nos. 337-TA-673, 337-TA-667, Order No. 39C (Sept. 17, 2009).

Rule 9(b) of the Federal Rules of Civil Procedure states that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.

Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.”

The Federal Circuit has held that an inequitable conduct pleading in district court must comply with Rule 9(b). *Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). In discussing the pleading standard, the Federal Circuit explained that “[a] pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-1327 (Fed. Cir. 2009). The court held that:

to plead the “circumstances” of inequitable conduct with the requisite “particularity” under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Id. at 1328-1329. The Federal Circuit recently clarified that, “as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed Cir. 2011)

In my view, in cases in which inequitable conduct is raised as an affirmative defense in an ITC proceeding, it is appropriate to require a level of pleading equal to the level required by Fed. R. Civ. P. 9(b). The Federal Circuit noted in 1988 that inequitable conduct has been pleaded in “almost every major patent case” with a small percentage of success. *Burlington Indus., Inc., v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The court commented on the “not inconsequential” nature of the charges and their impact upon the bar. *Id.* The purposes of

Rule 9(b) include: providing an opposing party with adequate notice, deterring a party from asserting claims as a pretext for the discovery of unknown wrongs, and protecting those whose reputation would be harmed as a result of being subject to fraud charges. *See, e.g., Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) (listing purposes behind Rule 9(b)); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999) (stating the four purposes behind Rule 9(b)); *Michaels Bldg. Co. v. Ameritrust Co., N.A.*, 848 F.2d 674, 679 (6th Cir. 1988) (noting that “the purpose undergirding the particularity requirement of Rule 9(b) is to provide a defendant fair notice of the substance of a plaintiff's claim[.]”)

Analysis

I find that Respondents’ Ninth Affirmative Defense fails to adequately plead facts sufficient to demonstrate that an allegedly nondisclosed reference was but-for material, or how the nondisclosed information would have been used by the examiner to find the claim unpatentable. I also find that Respondents’ Ninth Affirmative Defense fails to adequately describe the specific who, what, when, where and how of the material misrepresentation or omission alleged by the Respondents to have occurred before the PTO. Finally, I find that Respondents’ Ninth Affirmative Defense fails to allege facts sufficient to infer a specific individual (1) knew of withheld material information or of the falsity of a material misrepresentation, and (2) withheld or misrepresented such information with a specific intent to deceive the PTO.

Addressing the ‘304 patent, the sole reference to any particular language is, “[c]olumns five and six of the ‘304 patent, for example, expressly describe how the attachment devices could be relocated during different stages of treatment to compensate for movement of the teeth or to provide more secure retention of the appliance.” Respondents allege that, if the PTO had been

given the '304 reference, it would have "understood that the invention claimed in Align's application (i.e. the use of devices attached to a patient's teeth to engage a polymeric shell orthodontic appliance) was a virtual copy of the invention" of the '304 patent. Because the Respondents compare the foregoing reference to claim 21 of the '863 patent, considered the two references in tandem.

The cited portion of the '304 patent, columns 5 and 6, describes a dental appliance and the method of mounting said appliance to a patient's teeth. The two columns describe in some detail the use of "surface mounted undercuts" to assist in securing the appliance to the patient's teeth and to "urge the teeth in a particular direction, to compensate for movement of the teeth, or otherwise enhance the operation of the appliance." ('304 patent, 5:15-39; 6:3-21) At column 6, the '304 patent teaches:

A sheet of material is then preferably vacuum formed over the model 44, creating the base layer for the preferred appliance 38 which encloses or covers the model of the undercuts 12 and the patient's teeth 43. In the embodiment illustrated in FIG. 5, the engagement surfaces 66 on the appliance are formed to enclose or cover teeth 43 containing undercuts 12. Preferably, the engagement surfaces 66 cover additional teeth not containing undercuts 12, thereby providing additional stability. As will be discussed below in connection with the alternate embodiment illustrated in FIG. 10, the engagement surface 66 need only engage with a portion of the teeth. It will be understood that the appliance 38 may be formed with small engagement surfaces 66, or the engagement surfaces 66 may be trimmed after the vacuum forming step.

('304 patent, 6:22-37)

Claim 21 of the '863 patent describes:

21. A set of dental positioning appliances, said set comprising a plurality of thin shell removable appliances representing successive stages of an orthodontic treatment wherein at least some of said appliances representing earlier stages of treatment have a first receptacle positioned to receive an attachment device on a patient's teeth when each of said appliances is successively worn over the teeth during the orthodontic treatment and wherein some of said appliances representing later stages of

treatment have a new receptacle not found on the appliances representing earlier stages of treatment.

(‘863 patent, reexamination certificate, 2:18-28)⁵

Respondents have mischaracterized the cited language from the ‘304 patent. Certainly the two references describe dental appliances for orthodontic treatment, and they involve an overlay of some material that is secured to the teeth (e.g. thin shell removable appliances in the ‘863 patent, and a vacuum formed sheet of material in the ‘304 patent). The ‘304 patent does not, however, teach the essence of claim 21 of the ‘863 patent, which describes appliances representing successive stages of an orthodontic treatment using a “first receptacle” positioned to receive an attachment device on a patient’s teeth when each of said appliances is successively worn over the teeth, and wherein some of said appliances representing later stages of treatment have a new receptacle not found on the appliances representing earlier stages of treatment. Nothing offered by the Respondents addresses these differences, and there is no rationale offered to explain why a patent examiner would not have allowed claim 21 had he or she been aware of the allegedly undisclosed prior art described in columns 5 and 6 of the ‘304 patent. Respondents’ Ninth Affirmative Defense fails to adequately plead materiality of the ‘304 patent reference.

Assuming *arguendo* that the Respondents had adequately pled the materiality portion of their Ninth Affirmative Defense, they fail to describe how a specific individual knowingly withheld the alleged prior art with an intent to deceive the PTO. Addressing the ‘304 patent, Respondents repeatedly allege that “Align” was aware of relevant facts and the ‘304 patent’s content rather than a specific individual. Respondents initially point to Mr. Heslin, as having conducted a thorough review of the patent prosecution materials. Respondents shift focus to

⁵ While the Respondents do not refer to the reexamination certificate, it does not appear that the ‘863 patent included a claim 21 until the reexamination certificate was issued.

Ross J. Miller and John K. Shimmick, saying that they received and reviewed a letter from Dr. Truax, the inventor of the '304 patent, asserting that Align infringed that patent.

Respondents then shift back to Mr. Heslin, alleging that on October 29, 2001, he was, “associated with the law firm Townsend & Townsend & Crew, [and] filed the application which ultimately resulted in the '863 patent.” Respondents allege that Mr. Heslin and Mr. Shimmick knew of the '304 patent in great detail; but do not plead facts adequate to establish such “knowledge” by Mr. Shimmick. Respondents allege that Mr. Heslin and Mr. Shimmick⁶ filed an “Information Disclosure Statement by Applicant” on April 16, 2002, which referenced a product brochure by Dr. Truax’s company that contained none of the material information from the '304 patent that would have been of material interest to the Examiner.

Respondents allege that a re-examination process concerning the '863 patent was initiated on June 23, 2005. Respondents aver, “Mr. Heslin continued to represent Align as its attorney during the entire time of the re-examination. But neither he nor Align ever disclosed Dr. Truax’s '304 patent.” The Ninth Affirmative Defense alleges that the law firms Greenberg Traurig, L.L.P. and Paul Hastings, L.L.P. “assisted Mr. Heslin ... with ... representation of Align before the PTO during re-examination of the '863 patent.” That allegation is sufficient to identify Mr. Heslin, and *only* Mr. Heslin, as an individual who represented Align during the re-examination of the '863 patent.

In two paragraphs describing the events of the re-examination of the '863 patent, Respondents consistently refer to the actions of “Align” (*e.g.* “Align filed amendments...”; “Align argued ...”; and “Align knew well ...”, “Align recognized its obligation to notify the PTO about litigation...”; “Align filed with the PTO ...”; and “Align’s concealment of the

⁶ Respondents use the term “these individuals” which includes Mr. Heslin, Mr. Shimmick and “Townsend & Townsend & Crew.” (“Townsend”) I note that reference to Townsend is inadequate to identify any individuals other than Mr. Heslin and Mr. Shimmick.

information ...”). Nowhere in these paragraphs do the Respondents allege any act by any specific individual (including Mr. Heslin) as required by Rule 9(b) and *Exergen*. (See ClearCorrect Pakistan Response at 24 (last paragraph) and 25 (second paragraph). Respondents conclude that “Align, through the individuals described above, intended to mislead ... the PTO ...” Respondents Ninth Affirmative Defense fails to adequately plead facts sufficient to demonstrate that a specific individual (*i.e.* Mr. Heslin), had knowledge of a material reference and knowingly withheld that information from the PTO with an intent to deceive the PTO.

I turn to the allegation of materiality of the ‘368 patent, and I note that the sole focus of Respondents is on the use of a “disposable applicator” to assist an orthodontist in bonding an orthodontic “button” to a surface of a tooth. I note that nowhere in claim 21, is there any reference to a disposable applicator or to an orthodontic “button.” Respondents grossly mischaracterize the content of claim 21, when they assert that “the polymeric attachment device at the center of claim 21 ... is virtually identical to the attachment ‘buttons’ disclosed in [the] ‘368 patent.” The Ninth Affirmative Defense is devoid of any discussion of the rationale upon which one would base a finding that a patent examiner would not have allowed claim 21 had he or she been aware of the allegedly undisclosed prior art described in the ‘368 patent. Respondents’ Ninth Affirmative Defense fails to adequately plead materiality of the ‘368 patent reference.

Assuming *arguendo* that the Respondents had adequately pled the materiality portion of their Ninth Affirmative Defense, they fail to describe how a specific individual knowingly withheld the alleged prior art contained in the ‘368 patent with an intent to deceive the PTO. While Respondents allege that Mr. Heslin and Bao Tran reviewed the ‘368 patent, they shift focus from individuals to Align and its legal counsel generally, when they allege concealment

with intent to mislead the PTO. (See Resp. to Complaint at 28, first two paragraphs) In my view, this portion of the Respondent's Ninth Affirmative Defense is a textbook example of how *not* to plead an inequitable conduct defense. I find that Respondents' Ninth Affirmative Defense fails to adequately plead facts sufficient to demonstrate that a specific individual (*i.e.* either Mr. Heslin or Bao Tran), had knowledge of a material reference and knowingly withheld that information from the PTO with an intent to deceive the PTO.

Focusing on the '874 patent, Respondents only allegation of withheld information refers to comment attributed to Mr. Michael T. Rosato, counsel for Align. Without citing to any specific page or reference in the prosecution history, Respondents aver that Mr. Rosato stated that the prior art "wholly lacks support" for the examiner's contention that "it would have been obvious to one of ordinary skill to modify Martz to include using computer models instead of real models to generate the appliances in order to make use of alternate ways of modeling tooth positions ..." and "Lemchen does not teach segmented dentition, as alleged by the Examiner." Respondents add that Mr. Roger George, Align's in-house counsel, "approved of these statements" made on Align's behalf.

Respondents aver that in the Rekow report "provided [to] Align," Dr. Rekow opined that the prior art described systems that taught segmented dentition.⁷ Respondents do not allege that Mr. Rosato's comment about "Lemchen" is in any way inaccurate, and I note that the language cited by Respondents is a general comment by Dr. Rekow that "the prior art described systems that taught segmented dentition." Respondents' complaint about the stand taken by "Align" and "Align's agent" compares the comment that the record lacks support for the examiner's contention that it would have been obvious to one of ordinary skill to modify Martz to include

⁷ Respondents do not specifically attribute this comment to the report to which reference was made earlier, dated May 18, 2004, and do not state when this particular opinion by Dr. Rekow was stated.

using computer models instead of real models to generate the appliances in order to make use of alternate ways of modeling tooth positions ...” with the opinion Respondents attribute to Dr. Rekow that “computer based systems for individualized orthodontic treatment planning and, ultimately, custom appliance fabrication began appearing in the literature in the 1970’s.” Respondents provide no detail whatsoever regarding the content or date of the “Martz” reference, and do not provide any rationale for why a patent examiner would not have allowed claim 1 of the ‘874 patent⁸ had he or she been aware of the allegedly undisclosed statement by Dr. Rekow. Respondents’ Ninth Affirmative Defense fails to adequately plead materiality of the opinion stated in the Dr. Rekow report.

Assuming *arguendo* that the Respondents had adequately pled the materiality portion of their Ninth Affirmative Defense, related to the Dr. Rekow opinion, they fail to describe how a specific individual knowingly withheld the alleged information contained in the Dr. Rekow report with an intent to deceive the PTO. Respondents, again, refer to the lawyers at Townsend without naming individuals. Respondents allege that Mr. Roger George was aware of the expert reports and contentions, and that he approved of the comments made by Mr. Rosato. Without further discussion, Respondents say that “Align and its attorneys” knew of its expert opinions, yet made contrary statements to the PTO and did not disclose the expert opinions. I find that Respondents’ Ninth Affirmative Defense fails to adequately plead facts sufficient to demonstrate that a specific individual (*i.e.* either Mr. Rosato or Mr. George), had knowledge of a material reference and knowingly withheld that information from the PTO with an intent to deceive the PTO.

⁸ Claim 1 is the only specific claim mentioned in this portion of the Ninth Affirmative Defense.

Based upon all of the foregoing, I find that Respondents' Ninth Affirmative Defense alleging inequitable Conduct fails to adequately plead facts equal to the level required by Fed. R. Civ. P. 9(b). As a result the Respondents' Ninth Affirmative Defense should be stricken.


ORDER

Motion No. 833-005 is hereby GRANTED. Respondents' Ninth Affirmative Defense is stricken in its entirety. Motion No. 833-022 is hereby DENIED as moot. Motion No. 833-009 is DENIED.

Within seven (7) days of the date of this Order, each party shall submit to the Office of the Administrative Law Judges a statement as to whether or not it seeks to have any portion of this document deleted from the public version. The parties' submissions may be made by facsimile and/or hard copy by the aforementioned date.

Any party seeking to have any portion of this document deleted from the public version thereof must submit to this office a copy of this document with red brackets indicating any portion asserted to contain confidential business information. The parties' submissions concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.



Robert K. Rogers, Jr.
Administrative Law Judge

**CERTAIN DIGITAL MODELS, DIGITAL DATA, AND
TREATMENT PLANS FOR USE IN MAKING
INCREMENTAL DENTAL POSITIONING ADJUSTMENT
APPLIANCES, THE APPLIANCES MADE THEREFROM,
AND METHODS OF MAKING SAME**

Inv. No. 337-833

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** was served upon **Vu Bui, Esq.**,
Commission Investigative Attorney, and the following parties via first class mail delivery on

JAN 22 2013



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**CERTAIN DIGITAL MODELS, DIGITAL DATA, AND
TREATMENT PLANS FOR USE IN MAKING
INCREMENTAL DENTAL POSITIONING ADJUSTMENT
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PUBLIC CERTIFICATE OF SERVICE PAGE 2

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