UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

IN RE INTUITIVE SURGICAL SECURITIES LITIGATION

Case No. 5:13-cv-01920 EJD (HRL)

ORDER RE DISCOVERY DISPUTE JOINT REPORT NO. 4

Re: Dkt. 170

In this putative class action, plaintiffs sue Intuitive Surgical, Inc. (Intuitive) and several individual defendants for alleged securities fraud. Plaintiffs claim that defendants concealed safety defects in Intuitive's da Vinci Surgical System and lied about the company's business metrics and financial prospects.

In Discovery Dispute Joint Report (DDJR) No. 4, plaintiffs seek an order compelling the production of two categories of documents: (1) exhibits to deposition transcripts from litigation between Intuitive and its insurance carriers; and (2) "Quality Audit" documents. The matter is deemed suitable for determination without oral argument. Civ. L.R. 7-1(b). Upon consideration of the parties' respective arguments, this court grants plaintiffs' request for discovery in part and denies it in part.

A. Deposition Exhibits

The request at issue seeks "[t]ranscripts of all depositions of Intuitive Employees taken in

the Insurance Actions since the date each such action was initiated." (Dkt. 170-2, DDJR No. 4, Ex. B at ECF p. 10). The term "Insurance Actions" refers to two insurance coverage lawsuits filed in this district by Intuitive's carriers against Intuitive.[1] This court is told that in those actions, the insurers claimed that Intuitive's failure to report product liability claims during its application for insurance coverage provided a basis for rescission of certain insurance policies. Plaintiffs point out that, in the present case, they allege that Intuitive's failure to disclose specific information about the number and nature of product liability suits the company faced rendered defendants' statements about safety false or misleading.

Although defendants contend that the Insurance Actions have little or no bearing on this lawsuit, they agreed to produce non-privileged portions of the requested transcripts that have some connection to plaintiffs' claims. Transcripts were produced in redacted form. The specific dispute now presented to this court is whether or not plaintiffs' request for deposition "transcripts" includes the deposition exhibits.

Defendants argue that exhibits are not included because plaintiffs' request only asks for "transcripts" (a term which plaintiffs did not define) and does not expressly say "exhibits." Plaintiffs contend that exhibits are impliedly included in "transcripts." In any event, plaintiffs claim that the requested exhibits fall within the scope of a prior request, which sought "[d]ocuments concerning disputes or reservations of rights as to coverage for any and all claims arising out of the use of or concerning da Vinci including but not limited to Intuitive's litigation with its product liability insurance carriers, Illinois Union Insurance Co. and Navigator Specialty Insurance Company." (Dkt. 170-1, DDJR No. 4, Ex. A at ECF p. 50). As to this earlier request, plaintiffs say that they offered to narrow it to documents Intuitive produced in the Insurance Actions, and that defendants initially agreed, but later reneged, citing relevance, burden, and patient privacy (HIPPA) concerns.

There seems to be no dispute that the transcripts contain at least some information that is relevant under Fed. R. Civ. P. 26(b), defendants having produced portions that they apparently

[1] See Case No. 3:13-cv-04863-JST *Illinois Union Ins. Co. v. Intuitive Surgical, Inc.* and Case No. 3:13-cv-05801-JST *Navigators Ins. Co. v. Intuitive Surgical, Inc.*

determined have some connection to plaintiffs' claims. Accordingly, plaintiffs' request for documents is granted as follows: Defendants shall forthwith produce exhibits referenced in the portions of the transcripts they produced to plaintiffs. However, to the extent any of the exhibits contain patient-specific information protected under HIPPA, defendants may redact that information. Plaintiffs have not shown why discovery of such information is relevant or necessary to this lawsuit.

B. "Quality Audits"

Plaintiffs propounded discovery requests seeking "Annual Third-Party Audits" and "Internal Audit Records" identified by Intuitive's corporate designees during Fed. R. Civ. P. 30(b)(6) depositions. (Dkt. 170-2, DDJR No. 4, Ex. B at ECF pp. 18, 21). Plaintiffs subsequently narrowed these requests to "Quality Audits" as defined in 21 C.F.R. § 820.22. Briefly stated, that regulation provides that medical device manufacturers "shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."[2] Plaintiffs say that in July 2013, the Food and Drug Administration (FDA) sent Intuitive a warning letter, concluding that Intuitive's devices were adulterated because Intuitive failed to fully implement quality system design controls required under 21 C.F.R. § 820.30. Inasmuch as reports of quality audits must be reviewed by management, see 21 C.F.R. § 820.22, plaintiffs say that the requested documents are relevant to management's knowledge of violations identified in the FDA's letter. They claim that they have found no quality audit documents in defendants'

[2] The full text of 21 C.F.R. § 820.22 is as follows:

> Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a reaudit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and reaudit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and reaudits shall be documented.

production.

Defendants, on the other hand, claim that they have already produced quality audit documents. According to them, Intuitive's Fed. R. Civ. P. 30(b)(6) witnesses testified that the company performs a host of internal and third-party audits. The problem, say defendants, is that plaintiffs refused to narrow their request to audits pertaining to relevant systems or activities, and instead sought records of all quality audits Intuitive has performed. Nevertheless, defendants say that they have searched for and produced documents pertaining to quality audits, including any documents that were circulated to the individual defendants (or to any of the agreed-upon custodians of electronically stored information) and which contained agreed-upon search terms. Additionally, defendants confirm that keyword searches of their production database identifies some 200 documents relating to quality audits, including Quality Audit Observation Tracking and Report spreadsheets, Internal Audit Observations, External Audit Observations, Audit Notes, Audit Reports, Audit Plans, Mock FDA Audit Observations, and others.

This court finds no basis on this record to doubt the veracity of defendants' characterization of their production. Moreover, plaintiffs have not sufficiently explained why they believe defendants' document production is deficient. Their request for an order compelling further discovery therefore is denied.

SO ORDERED.

Dated: October 12, 2016

HOWARD R. LLOYD
UNITED STATES MAGISTRATE JUDGE

United States District Court
Northern District of California