

THE PURSUIT OF ELECTRONIC DISCOVERY

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The pursuit of electronic discovery by lawyers and the legal battles that ensue are now a routine part of pharmaceutical litigation. “Today, it is black letter law that computerized data is discoverable if relevant.”³ Attorneys today are faced with new challenges and hurdles in this world of new-age technology and digital discovery. With this progressive electronic evolution, attorneys and their support staff must learn to navigate through various types of computer programs including word processing documents, databases, spreadsheets, personal and business e-mails and other electronic files. However, diligent efforts on the part of an attorney may lead to an abundance of relevant electronic evidence and discovery of “smoking gun” documents illustrating corporate misconduct.

As the business world conducts more and more electronic transactions and communicates electronically, courts have recognized the need to require the exchange of electronic information in the same manner as “traditional” paper information. So why pursue electronic information and data when you have access to “traditional” paper

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³ *Anti-Monopoly, Inc. v. Hasbro, Inc.*, 94 Civ. 2120, 1995 WL 649934 (SDNY 1995), *Seattle Audubon Society v. Lyons*, 871 F. Supp. 1291 (W.D. Wash. 1994)

information and discovery? Electronic information is different in a variety of ways from paper information and could reveal electronically what may be otherwise hidden on paper. Discovery of electronic communication such as personal and business e-mails can often illustrate the “behind the scenes” business philosophies and strategies of corporate officers and their employees. E-mails are often much more informal and may contain “off the record” comments as opposed to formal letters or official office memorandums. Another advantage to electronic discovery is that documents may be significantly easier to search through, utilizing the navigational tools which are part of the computer software. Companies can now provide millions of documents on a relatively small number of CD’s with a searchable index or database, which may include objective coding. Additionally, utilizing this format allows electronic information that is often thought to be deleted or destroyed to be recovered and viewed.

The creation and storage of electronic data is significant in the discovery process. The importance of the environment or software in which the data exists can be just as essential as the electronic information itself. This is an issue which can easily be overlooked or dismissed by lawyers feverishly searching for “hot docs.” This oversight, which can easily occur in mass tort pharmaceutical litigation, may lead to valuable information going unnoticed, while lawyers sift through the proverbial haystack.

As an attorney, it is not necessary to become a “computer whiz” in order to adequately pursue electronic discovery. However, it is imperative that lawyers arm themselves with the knowledge of how a corporate defendant’s computer system is created, a basic understanding of its operation and how that information is processed. One of the most effective ways to ensure a proper understanding of this environment and

the programs and software used by a corporate defendant is through the use of a 30(b)(6) deposition⁴. However, prior to initiating this process, counsel should consider retaining an expert in electronic discovery for consultation, participation in conferences with defense counsel, assistance in drafting 30 (b)(6) notices, and attendance at depositions or hearings on preservation orders.

Fed. R. Civ. P. 30 DEPOSITION UPON ORAL EXAMINATION

(b)(6) A party may in the party's notice and in a subpoena name as the deponent a public or private corporation or a partnership or association or governmental agency and describe with reasonable particularity the matters on which examination is requested. In that event, the organization so named shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. A subpoena shall advise a non-party organization of its duty to make such a designation. The persons so designated shall testify as to matters known or reasonably available to the organization. This subdivision (b)(6) does not preclude taking a deposition by any other procedure authorized in these rules.

Plaintiff's counsel should utilize a 30(b)(6) deposition to gain information from certain key corporate personnel, including the Records Manager, the MIS Manager, the Director of Safety Surveillance Systems and the Director of Sales Force Automation. These four positions comprise the personnel that primarily affect the information systems essential to complex litigation. These depositions should be taken as soon as possible, preferably from the outset of the litigation, even before any documents have been produced. Effective discovery of electronic evidence must begin when the litigation begins. Therefore, serving discovery with the summons and complaint could help to ensure a timely response by your adversary. With these depositions completed at the early stages of litigation, plaintiff's counsel will gain an advantage by having valuable

⁴ See *Steiner v. Bayer Corp., et al.* - exhibits attached

information needed to help complete the litigation plan and future discovery.

The following are descriptions as to what information should be obtainable from each corporate representative at a 30(b)(6) deposition:

Records Manager

The Records Manager is the employee responsible for developing, maintaining, and enforcing records management and policies of the company. The Records Manager is crucial to an understanding of pre-litigation organization of the company's records system and how it functions. This employee should also give an insight into document preservation and organization after the company has been put on notice as to pending litigation. A 30(b)(6) deposition of the Records Manager should include an inquiry as to the corporate records retention policies and procedures, records retention auditing, corporate procedures for complying with discovery requests (in order to establish the company's response to the litigation in terms of preserving and producing electronic information), and corporate records retention policy training and procedures (for informing employees to preserve documents relevant to potential litigation). A thorough deposition should also require the Records Manager to produce certain documents via *duces tecum*⁵ including: the corporate records retention policy manual, corporate documents relating to use of any outside documents storage facilities, corporate document destruction logs and records retention training manuals.

⁵ Fed. R. Civ. P. 30 (b)(5)

Director of MIS

The Director of MIS is the corporate employee responsible for design, implementation and maintenance of computer systems within the organization. This person would be involved in policies and procedures concerning record retention. The Director of MIS should be deposed on several areas including: the use of computers by relevant departments, description of software used by the company, computer backup procedures, system upgrades, use of e-mail (both personal and business) by the company, and, as previously mentioned, implementation of record retention requirements in computer systems used by the company.

The Director of MIS should also be required to produce at deposition all corporate documents relating to computer infrastructure of the company, documents relating to e-mail systems in use, documents related to computer backup procedures, documents concerning the location of backup tapes, documents related to systems and server upgrades and documents related to document imaging systems used in the company.

Director of Sales Force Automation

The Director of Sales Force Automation is the employee responsible for collection and distribution of data in connection with the sales force whether in electronic or non-electronic format. The Director of Sales Force Automation should be deposed on policies and procedures for reporting and tracking of sales call activities by the sales force, which includes the use of any computers in this process. Other areas to explore at deposition would be the method for providing the sales force with sales materials, the use of computers by the sales force and the existence and use of database and/or mailing list in marketing activities. The Director of Sales Force Automation should also be required

to produce certain documents at the deposition including: corporate policies and procedures manuals for sales call reporting, documents relating to purchase and usage of prescription sales data and software manuals for any sales force automation software.

Director of Drug Safety Surveillance

The Director of Drug Safety Surveillance is the employee responsible for collection and distribution of data concerning an adverse drug experience (ADE). The Director of Drug Safety Surveillance should be deposed on policies and procedures for the intake, processing and reporting of ADE reports, use of any computer to process and maintain ADE reports and the company's compliance with the Federal Drug Administration's ADE reporting requirements.⁶

The Director of Drug Safety Surveillance should also be required to produce certain documents at deposition including corporate documents concerning use of computer databases to track ADE's, documents concerning policies and procedures for the intake, reporting and follow up of ADE reports and all documents concerning auditing of the ADE tracking process to ensure compliance.

Conclusion

With a knowledge and understanding of the functions and abilities of these primary corporate personnel, lawyers can greatly advance their position in pharmaceutical litigation, especially during the discovery process. The use of 30(b)(6) depositions can serve as a tremendous tool to gain perspective on company-wide

⁶ 21 C.F.R. § 600.80 (2002)

technology, electronic data retention and procedures using the insight of these information systems employees.

The increase in the use of electronic information in the business world has created the need for more knowledge and better practices related to electronic discovery. These practices include the collection, evaluation and examination of electronic data, through a systematic approach in order to discover information which may be crucial to litigation. Time is of the essence in electronic discovery. In conjunction with a timely filed 30(b)(6) notice, it may also be appropriate to seek a preservation order so as to protect this vital electronic information. The plaintiff should assume that relevant information may be inadvertently destroyed or destroyed in the ordinary course of business by the defendant. A strong preservation order, which addresses specific areas of the lawsuit, may prevent losing valuable information and can help to secure an efficient and complete discovery process.

With the evolution of mass tort litigation, a complete understanding of a corporate defendant's information systems and procedures has become essential to successful mass tort litigation. Timely and effective electronic discovery is essential in order to see the "big picture." Lack of this knowledge and understanding in electronic discovery could result in the oversight or omission of important documents and other crucial evidence.