SYRACUSE UNIVERSITY

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Duty of Disclosure:

Comparison of Securities Regulations between U.S. and S. Korea by Cases in Bio-Pharmaceutical Industry

Visiting Scholar Paper

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Abstract

This paper introduces the concept of false and misleading statements or omissions regarding companies in the bio-pharmaceutical industry, based on court decisions. Due to essential problem of stock market, "asymmetry of information," if company's public statements about material information are not trustworthy, the investors who purchased the company's shares due to misleading information might lose their assets, and the confidence in and the soundness of the stock market would be damaged as a result.

This paper attempts to clarify violations of §10(b) of the Securities Exchange Act of 1934[2] and the corresponding rule of the Securities and Exchange Commission, 17 C.F.R. §240.10b-5 ("Rule 10b-5), particularly, (1) a material misrepresentation or omission, and (2) scienter[3] through reviewing recent cases of bio-pharmaceutical companies, *Aratana* case and *Chelsea* case.

In the Republic of Korea[4], *Hanmi Pharm'*s case[5] represents how the late public announcement or omission would affect investors' half-baked decision and damage the stock market. Pursuant to §391 of the Financial Investment Services and Capital Market Act, Korea Exchange[6] announced a law "Negative Disclosure Regulations on Material Information,"[7] on May 2, 2016. Nevertheless, the regulation does not appear to be effective guideline for investors and stock market.

In the proposed scienter tests, this paper introduces ImClone stock trading scandal to represent the relatively easy scienter case in the bio-pharmaceutical industry. Also, this paper illustrates two hypothetical cases, *Brandon Therapeutics, Inc.* in the United States, and *Hoon Biosimilar Co., Ltd.* case to suggest the better solution to solve scienter cases in the bio-pharmaceutical industry.

In conclusion, this paper compares both American and Korean cases and related regulation, and then proposes a supplement that will promote a sound stock market.

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[2] 10(b) (codified in 15 U.S.C. 78j) is the primary anti-fraud provision. DAVID L. RATNER, SECURITIES REGULATION 130 (2nd ed. 1982).

[3] BLACK'S LAW DICTIONARY (3rd ed. 2006), "A mental state consisting in an intent to deceive, manipulate, or defraud."

[4] The Republic of Korea is a Civil Law Country.

[5] Hanmi Pharmaceutical Co., Ltd.

[6] In 2006, South Korean government planned to draft the integrated capital market law, and the bill was promulgated in August 2007, after passage through the National Assembly in July 2007. Afterwards, Financial Investment Services and Capital Markets Act was effective on February 4, 2009. SOO HYUN AHN, FINANCIAL SERVICES AND CAPITAL MARKET ACT IN KOREA 47 (2012).

[7] Compared to positive system, the negative system is defined to distinguish the regulation, and permit the rest of the regulation. Negative disclosure regulations on material information were enacted to supplement the existing positive disclosure regulation. The negative disclosure regulation belongs to periodic disclosure. *See* text page 23, *supra*.

Text

I. Introduction

1. Overview

The Securities and Exchange Commission (the "SEC")'s regulation of false and misleading statements or omission from companies in bio-pharmaceutical industry has been developed with the courts' decisions for soundness of stock market. It is expected and fair for investors to depend on the target company's public announcements for investment judgment; therefore, the contents of the company's announcement, or "disclosure" should be accurate and transparent. In regard to bio-pharmaceutical companies; which are dealing with important medicine or prospective technology, the disclosure is maybe uncertain due to industry's features. The case of $ 9 billion start-up company's collapse, Theranos' founder, Elizabeth Homes' fraudulent behavior[8] and Turing Pharmaceuticals' Martin Shkreli[9], a founder and now a convicted felon of securities fraud, the bio-pharmaceutical industry can be vulnerable to misguided information. Therefore, it is important for the government to examine and review bio-pharmaceutical companies' public announcements. Also, the court's decision of the bio-pharmaceutical company's false and misleading announcements or misleading must be understandable and accurate for investors in the stock market.

In the United States, to state a securities fraud claim, a plaintiff must adequately plead i) a material misrepresentation or omission by defendant; ii) scienter; iii) a connection between the misrepresentation or omission and the purchase or sale of a security; (iv) reliance upon the misrepresentation or omission; (v) economic loss; and (vi) loss causation.[10] Even though the elements of the judgment regarding the case is legitimate, the burden on the plaintiff appears to be too heavy. The fact that the company issued misleading and fraudulent information to the public means the company already damaged the soundness of the stock market. Nevertheless, the fact that the judiciary does not have a solid understanding of the plaintiff's burden to prove "scienter" of defendant raises the doubt whether the judiciary understands workings of the stock market.

In the Republic of Korea, the Financial Supervisory Commission ("FSC")[11]'s disclosure regulations divide into two prongs: mandatory disclosure and voluntary disclosure.[12] In the event of a matter, other than to mandatory disclosure, the company that the Korean Composite Stock

[8] In re Arizona Theranos, Inc., Litigation, 308 F. Supp. 3d 1026, (D. Ariz. 2018). Elizabeth Holmes, the founder of Theranos, was indicted on charge of defrauding investors out of hundreds of millions of dollars as well as deceiving hundreds of patients and doctors. Elizabeth raised $7 billion for developing revolutionary blood tests, but truly she used very small portion of blood for the tests.

[9] United State of America v. Shkreli, 260 F. Supp. 3d 247, (E.D.N.Y. 2017). Martin Shkreli, CEO of Turing Pharmaceuticals, was sentenced seven years for securities fraud. Martin raised the price of drug, "Daraprim" more than 5,000 percent from $12.50 to $ 750.

[10] *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38, 131 S. Ct. 1309, 179 L.Ed.23 398 (2011), Securities Exchange Act of 1934.

[11] FSC is a South Korean government agency that supervises, investigates the financial institutions and is equivalent to the U.S. Securities and Exchange Commission.

[12] *See* text page 23, *supra.*

Price Index ("KOSPI")[13]-stock-listed companies report the details to the Korean Exchange voluntarily. The problem is that mandatory disclosure is too narrow. Investors would easily be harmed by the company's voluntary disclosure or omission, since it's not against law.

This article outlines the current jurisprudence of major cases in the United States and the Republic of Korea. Part II explains the statutory background of scienter, the Securities Act of 1933 and the Securities Exchange Act of 1934. It then addresses the main issues that courts considered and reviewed the securities fraud with *Cady, Roberts & Co.*[14] and *Texas Gulf Sulphur Co.,*[15] respectively. Part III studies how the Congress heightened pleading standard of scienter by enacting Private Securities Litigation Reform Act of 1995("PSLRA"). Then, it addresses an important case of scienter, *Ernst & Ernst v. Hochfelder.*[16] *Ernst* not only defines the requirement of elements of a private damages action under §10(b) and Rule 10b-5, but also several subsequent court decisions relied upon *Ernst*'s decision process until the Congress enacted the PSLRA. Also, Part III compares the pleading standard of scienter between the Second Circuit and PSLRA. Part IV illustrates the bio-pharmaceutical industry's recent cases, *Aratana*[17] and *Chelsea*[18] after PSLRA's enactment. An interesting factor about the case study of *Aratana* and *Chelsea* is that both cases involved false and misleading statements from companies to public, but the court decisions were different because of the accuracy of filing statements with Securities and Exchange Commission. Part V introduces the Republic of Korea's disclosure regulation in securities law, "Negative Disclosure Regulations on Material Information,"[19] and analyzes the weakness of voluntary disclosure regulation through reviewing *Hanmi*'s case. Part VI proposes the scienter tests for the bio-pharmaceutical industry both in the United States and the Republic of Korea. Finally, Part VI concludes whether the government or the courts must consider the adoption of improved rule or analysis for soundness of stock market.

II. Background

1. Statutory Background; Antifraud Provisions

1.1 The Securities Act of 1933 and the Securities Exchange Act of 1934

Trading corporate securities occurs in two basic markets:[20] (1) the primary market where an issuer of the securities sells the securities to investors; and (2) the secondary market where investors trade the securities among themselves. For an instance, initial public offering ("IPO") takes place on the primary market, on the other hand, the New York Stock Exchange ("NYSE") is the one of the most highly organized secondary market.

[13] KOSPI is a stock market index of the common stocks and securities listed on the Korean Exchange, equivalent to NASDAQ Composite in the U.S.
[14] In the Matter of Cady, Roberts & Co., 40 SEC 807, No. 8-3925 (Nov. 8, 1961).
[15] *Securities and Exchange Commission v. Texas Gulf Sulphur Co,* 401 F. 2d 833, (2nd Cir. N.Y.,1968).
[16] *Ernst & Ernst v. Hochfelder,* 425 U.S. 185 (1976).
[17] *In re Aratana Therapeutics Inc. Securities Litigation,* 315 F. Supp. 3d 737, (S.D.N.Y., June 11, 2018).
[18] *Zak v. Chelsea Therapeutics International, Ltd*., 780 F.3d 597, 4th Cir., (N.C., Mar. 16, 2015).
[19] *See* footnote 6, *infra.*
[20] WILLIAM A. KLEIN, J. MARK RAMSEYER & STEPHEN M. BAINBRIDGE, BUSINESS ASSOCIATIONS: CASES AND MATERIALS ON AGENCY, PARTNERSHIPS, AND CORPORATIONS 399 (8th ed. 2012).

The beginning of the regulation of the primary market was the Blue Sky Law[21] in 1911. These statutes had flaws such as many interests were exempted, and the states had not given enough resource to enforce the regulation.

The Securities Act of 1933 ("1933 Act") regulates public offerings of securities.[22] The 1933 Act prohibits i) the sale or purchase of for the securities by public unless the securities are registered in Securities Exchange and Commission, and ii) the 1933 Act prohibits fraudulent or deceptive practices in any offer or sale of securities. The main purpose of the 1933 Act is that the public receives correct and trustworthy information about the securities so that public trades the securities confidently.

Due to the crisis of manipulation of the security market in 1920s, Congress wanted to enact the strong antifraud provisions so that public could rely upon the disclosure of the regulated companies. The antifraud provisions of 1933 Act and the Securities Exchange Act of 1934 ("1934 Act") protect investors and the capital market through the imposition of regulations and specified civil liabilities.

1.2 The Comparison of §17 (a) of 1933 Act to §10(b) and Rule 10b-5 of 1934 Act

The 1934 Act covers behavior of the secondary market. The beginning point of the securities regulation starts from §10(b) of the 1934 Act. §10(b) is a catch-all provision and makes it unlawful for any person to use the mails or facilities of interstate commerce:[23]

> (b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

It is important to understand that §10(b) itself does not actually make anything illegal unless the Commission has adopted a rule prohibiting it. Section 10(b)'s legislative purpose of Congress can be understood by Congress using the phrase "in connection with."

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[21] The name's origin was that the statues protect investors from "speculative schemes which have no more basis than so many feet of blue sky." *Hall v. Geiger-Jones Co.*, 242 U.S. 539, 550, 37 S.Ct. 217, 61 L.Ed. 480 (1917).

[22] To achieve the object, an issuer is required to file "Registration Statement" with SEC. Registration statement consist of two principal parts; Part I is the "prospectus," a copy of legal offering to every purchaser. In the prospectus, the company must address business operations, audited financial statements, results of operations, risk factors, and management. In Part II, the company contains the additional information and exhibits which does not need to be furnished to purchasers, but must to be filed with SEC. The company may use Form S-1 to prepare a registration statement. In Form S-1, the company needs to disclose any information that makes the disclosure not misleading. DAVID L. RATNER, SECURITIES REGULATION 34-35 (2nd ed. 1982)., https://www.sec.gov/smallbusiness/goingpublic/registrationstatement.

[23] DAVID L. RATNER, SECURITIES REGULATION 130 (2nd ed. 1982).

Corporations do not violate §10(b) to issue misleading announcements to the public unless corporations are engaged in related securities transactions with wrongful motives.[24]

Section 17(a) of the 1933 Act and 10(b) and Rule 10b-5 of the 1934 Act share similar basic structure of antifraud provision. However, while §17(a) prohibits fraud and misstatements in the sale of securities, there was no comparable provision prohibiting such practices in connection with the purchase of securities. When the SEC modified §17(a) and presented to the Commission as Rule 10b-5, Rule 10b-5 was approved unanimously.

Section 17(a) prohibits fraud and misrepresentation in the offer or sale of securities. It provides:

> It shall be unlawful for any person in the offer or sale of any securities or any security-based swap agreement by the use of any means or instruments of transportation or communication in interstate commerce or by use of the mails, directly or indirectly-
>
> (1) To employ any device, scheme, or artifice to defraud, or
> (2) to obtain money or property by means of any untrue statement of material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
> (3) to engage in any transaction, practice, of course of business which operates or would operate as a fraud or deceit upon the purchaser.

Rule 10b-5 states:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality, by the use of any means or instrumentality of interstate commerce, or of the mails, or of any facility of any national securities exchange,
>
> "(1) to employ any device, scheme, or artifice to defraud,
> "(2) to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of circumstances under which they were made, not misleading, or
> "(3) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
> in connection with the purchase or sale of any security."

[24] *Texas Gulf Sulphur*, 401 F.2d 833, 860.

1.3 Analysis

Rule 10b-5 applies to any purchase or sale by any person of any security. No matter whether the company is publicly-traded or closely-held, whether the securities is registered or not registered, the rule applies to the entity. The rule even applies to "exempted securities," as defined in the 1934 Act, §3(a)(12), (including federal, state and local government securities).[25]

With respect to insider trading, the essence of Rule 10b-5 is that anyone who has "directly or indirectly" access to undisclosed information which is only available for company use and not for personal benefit may not take advantage of the people who do not have the undisclosed information.[26]

The rule is antifraud provision. The Supreme Court has held that to prove the person had violated Rule 10b-5, SEC or private litigant must prove the person have acted with "scienter."[27] Regarding the scienter requirement, the courts' decisions are divided into two methodologies; i) strong inference of scienter from Second Circuit,[28] ii) recklessness. Unlike to Rule 10b-5, regarding violations of Clause (2) or (3) of the 1933 Act §17 (the similar provision to Rule 10b-5), the Supreme Court held that SEC or private litigant does not have to prove "scienter" requirement. *Aaron v. SEC*.[29]

1.4 Rule 10b-5 Cases of disclosure of material information

A. *In the Matter of Cady, Roberts& Co*.[30]

a. Synopsis

When Robert M. Gintel ("Gintel"), a selling broker and partner of the Cady, Roberts & Co., the registered broker-dealer firm, received undisclosed information of Curtiss-Wright Corporation, client's company, Gintel executed orders for discretionary accounts on the exchange for the sale of shares without waiting for a public announcement of the information.

b. The Chronology

Curtiss-Wright Corporation ("Curtiss-Wright") invited 2,000 people to promote a new type of internal combustion engine on early November 1959. On November 24, 1959, the press announcement of the new engine was released to public. During the day, the stock

[25] DAVID L. RATNER, SECURITIES REGULATION 132 (2nd ed. 1982).
[26] *In the Matter of Cady, Roberts & Co.,* 40 SEC 907, 912 (1961).
[27] *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, (U.S. III., 1976).
[28] *See* text page 12-13, *supra.*
[29] *Aaron v. Securities and Exchange Commission*, 446 U.S. 680, (U.S.N.Y., 1980).
[30] *In the Matter of Cady, Roberts & Co.,* 40 SEC 807, No. 8-3925.

price was increased to 35 ¼, up 3 1/4. From November 6 through 23, Gintel purchased about 11,000 shares of Curtiss-Wright for about 30 discretionary account of clients. November 25, the stock price was still high and it was up to 40 ¾.

On the morning of November 25, the board of directors in Curtiss-Wright consulted and authorized to cut the dividend from $.625 per share to $.375 per share. This information was supposed to be released at 11 am by telegram, but due to typing problem of telegram, the information did not transmit to the New York Stock Exchange (the "Exchange") until 12:29 pm. During the delay, one of the directors, J. Cheerver Cowdin ("Cowdin"), called Gintel about the cut of dividend. After Gintel confirmed the information was not released to the public, he executed sell orders on the Exchange.

When the dividend announcement appeared on the Dow Jones at 11:48 am, the Exchange had to suspend trading in Curtis-Wright due to the huge volume of sell orders. The stock price was 34 7/8 at closing on November 25, 1959.

c. Analysis

This case holds that using the omission or misrepresentation of the material information by the people who had the correct information violates Rule 10b-5. Gintel should not have traded the securities after he learned of the material information from an insider of Curtiss-Wright. Regardless the tipper and tippee[31] are liable for the violation of 10b-5, the information was not released to public and it was material to make a decision. Even though the Commission accepted a settlement and Gintel was fined $3,000 by the Exchange and suspended for 20 days from the Exchange, Commissioner Frear dissented from the settlement believing the violation was so severe that the sanction should be greater.

B. *Securities and Exchange Commission v. Texas Gulf Sulphur Co.*[32]

a. Synopsis

After aerial geophysical surveys, the mining firm, Texas Gulf Sulphur Company ("TGS")'s key officers and directors decided not to disclose to the public material information about the high possibility of mining rare mineral, "Kidd-55." Even though TGS tried to keep the information from the public, rumors of the exploratory activity about Kidd-55 spread and several newspapers dealt with the news. TGS's officers issued misleading announcements to deny the speculation.[33] However, in a week, very positive press reports about the drilling of rare materials were released. During the period of denial, insiders bought large amounts of stock.

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[31] *See* text page 25, *supra*.

[32] *Securities and Exchange Commission v. Texas Gulf Sulphur Co.,* 401 F.2d 833 (1968).

[33] On April 11, 1964, various press released the rumors of TGS's finding a major discovery. However, TGS executives did not respond accurately to the public by consulting with officers. Lamont who was passed away during the appeal, advised to Stephens that TGS should not make any action due to short of sufficient information. Also, Holyk, chief geologist reported to Mollison that the results of the drilling were not completed. After the discussion, Stephens and Mollison made a business decision and have Dr. Fogarty make an announcement of misleading information on April 12, 1964.

b. The Chronology

Beginning in 1957, TGS had conducted exploratory activities to acquire the "Kidd 55 segment" of land located near Timmins, Ontario. On November 12, 1963, after Richard H. Clayton, an electrical engineer and geophysicist sent the data of possibility of existence of Kidd 55, Claude O. Stephens, a president of TGS, wished to acquire the land and instructed the exploration group to keep the results in confidential and undisclosed even to other officers, directors and employees in TGS. The hole was concealed and the core of Kidd 55 had been shipped to Utah. After reviewing the core of the material, the results were so remarkable that the core of Kidd 55 was unusually good and it was worth it to purchase the land. By March 27, 1964, TGS decided to proceed to land acquisition, and to resume drilling on that property.

Between the period of the reviewing the data of the core of Kidd 55 and resuming the drilling, there were several securities transactions inside of TGS. TGS stock options were issued to officers and employees; there were tips between the certain officers and employees who were defendants of this lawsuit.

After resuming drilling, and before successfully acquiring the entire material, April 11, 1964, the New York Herald Tribune and New York Times released the articles that TSG discovered the massive amount of useful material in Canada. After discussing with executives and a public relations consultant, on April 12, Charles F. Fogarty, executive vice president of TSG, released a statement to the public that the report and article about TGS's exploratory activities were exaggerate, and the results so far were of no value and not conclusive. On April 13, a previously-invited reporter for the Northern Miner, a Canadian mining industry journal, visited the drillsite and prepared the official article after interviewing engineers and officers of TGS. This report was drafted and submitted to Richard D. Mollison, a mining engineer and vice president of TGS, and returned to the reporter unamended on April 15, was published on April 16.

Between the first public announcement of TSG, April 12, to the official report, on April 16, 1964, Clayton and David M. Crawford, and Francis G. Coates, director of TGS, consummated the transactions of the TGS stock.

In April 12 through April 16, 1964, between the first press release and the TGS official statement, Clayton, Crawford, and Coates traded TSG stock. Clayton ordered the broker to purchase 200 shares on April 15; Crawford ordered 600 shares; and Coates called a broker, Haemisegger, also Coates' son-in-law to order 2,000 shares for family trust account. Additionally, Haemisegger purchased another 1,500 shares for him and other clients.[34]

During the drilling period, the stock price of TGS fluctuated, but overall increased. When the drilling begun on November, 1963, the price closed at 17 3/8. When the drilling was resumed, the price was up to 30 1/8 by April 10. After first TSG's statement was released, the price was closed at 30 7/8. And after the official statement was released, the price was closed at 36 3/8. By May 15, 1964, the stock was selling at 58 ¼.

c. Analysis

[34] *Id.* at 847.

The Second Circuit reversed the district court, which was decided in favor of the TGS and remanded. Judge Waterman held that i) even if the information was substantial and material[35] for investors to make a decision to purchase the company's shares, there was no duty for the company to disclose if there were reasonable business reasons,[36] and ii) however, if officers or employees possess the undisclosed material information, the insider must either disclose the material information to public, or abstain from trading until the information has been disclosed.

As the Second Circuit correctly pointed out, the timing of disclosure is a matter for business judgment or disclosure requirements by SEC. During the related period, TGS had no affirmative duty to disclose the material information about exploratory activity. The issue was whether officers or directors ("insiders") traded TGS stocks after insiders obtain the undisclosed information. As stated in the prior paragraph, if TGS's insiders obtained the undisclosed information, the insiders must either disclose the knowledge to the public, or abstain from trading until the information has been disclosed. TGS case created the famous theory, "disclose or abstain" or "classical theory."[37]

III. Scienter

Congress enacted the Private Securities Litigation Reform Act of 1995 ("PSLRA") with the intention of balancing two incompatible objectives: the promotion of investors' confidence in capital markets and limiting the cost of capital from frivolous lawsuits. Even though Congress understood private securities litigation was an indispensable method to recover damages for defrauded investors and achieve confidence in capital markets, it needed to limit abusive law suits such as "strike suits"[38] by lawyers. To achieve that intention, PSLRA revised and amended existing antifraud provisions of Act 1933 and Act 1934.

Section 21D(b)(1) and (2) of PSLRA states the requirements of private fraud litigation. Section 21D(b)(2) tries to limit strike suits during the pleading stage of litigation.[39] Section 21D(b)(2) states that to recover money damages, the plaintiff must prove the defendant acted with a particular state of mind. The complaint needs to state with particularity facts giving rise to a "strong inference" of the defendant had the required state of mind, "scienter."

Before PSLRA, the Supreme Court held that merely negligent wrongdoing was insufficient to demonstrate civil liability under Section 10(b) and Rule 10b-5 in *Ernst & Ernst*. Unfortunately, *Ernst & Ernst* did not give a clear answer whether complaint must include recklessness or not, to prove scienter. The circuits differed how to define scienter. The Second Circuit's standard, motive and opportunity test[40] affected a number of decisions.[41]

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[35] Material insider information is defined that information insider is required to disclose to SEC before trading the company's securities not only "disclosing earnings and distributions of company but also those facts which affect probable future of corporation and those which may affect desire of investors to by, sell, or hold company' securities." *Texas Gulf Sulphur Co.*, 410, F.2d 833, 848.

[36] Judge Waterman stated, "the timing of disclosure is a matter for the business judgment of the corporate officers entrusted with the management of the corporation within the affirmative disclosure requirements promulgated by the exchanges and by the SEC. *Id.* at 850, footnote 12.

[37] Donna M. Nagy, *Beyond Dirks: Gratuitous Tipping and Insider Trading,* 42 J. CORP. L. 1, 6 (2016).

[38] BLACK'S LAW DICTIONARY (3rd ed. 2006), "A suit (esp. a derivative action), often based on no valid claim, brought either for nuisance value or as leverage to obtain a favorable or inflated settlement."

[39] Michael B. Dunn, *Pleading Scienter After the Private Securities Litigation Reform Act: or, a Textualist Revenge,* 84 CNLLR 193, 200.

[40] *See* text page 12-13, *supra.*

[41] *See* text page 12-13, *supra.*

1. *Ernst & Ernst v. Hochfelder*[42]

In *Ernst & Ernst v. Hockfelder*, the Supreme Court held that scienter is a required element of a private damages action under Section 10(b) and Rule 10b-5. Subsequently, the Court decided *Aaron v. SEC,*[43] which applied the analysis used in *Ernst & Ernst* and held that scienter is a necessary element in an SEC injunctive action brought under Section 10(b) and Rule 10b-5.[44]

a. Synopsis

Customers of the brokerage firm sued an accounting firm, Ernst & Ernst ("Ernst"), which audited the brokerage firm, and alleged Ernst's negligence. The Supreme Court, Mr. Justice Powell, held that "the private action for damages will not lie under §10(b) of Act 1934 and Rule 10b-5 in the absence of an allegation of intent to deceive, manipulate, or defraud." And, the Court stated that the customers' allegation of negligence of Ernst was not enough to prove Ernst's liability.

b. The Chronology

From 1946 through 1967, petitioner, Ernst & Ernst ("Ernst"), an accounting firm, was retained by First Securities Company of Chicago ("First Securities"), a brokerage firm for auditing of the First Securities' books and records. Respondents were customers of First Securities. Leston B. Nay, president and majority shareholder (92 percent) of First Securities, induced respondents to invest on fraudulent securities scheme. From 1942 to 1966, respondents sent their checks payable to Nay, rather than designated bank account. Nay assured respondents that he would transmit the investment to "escrow account," which never reflected the investment's transaction. Since Nay promised high returns, the respondents followed untraditional procedure of transmittance of the checks. The scheme was revealed after Nay's suicide and First Securities' bankruptcy in 1968. Subsequently, respondents filed suit against Ernst that Ernst had "aided and abetted" Nay's fraudulent securities scheme by Ernst's failure to conduct proper audits. Respondents' cause of actions relied on a theory of negligent nonfeasance.

In the Supreme Court, Mr. Justice Powell held that in the absence of an allegation of intent to deceive, manipulative practice and behavior, or intent to defraud, there is no scienter. Respondents maintained that liability arose from mere negligence. This private action would not lie under Section 10(b) and Rule 10b-5 as scienter was regulated. The judgment of the Court of Appeals was reversed.

2. The Second Circuit's Pleading Standard

After *Ernst & Ernst*, plaintiffs must prove scienter in securities fraud actions under Section 10(b) and Rule 10b-5. However, *Ernst & Ernst* did not state whether plaintiff must include an

[42] *Ernst & Ernst v. Hochfelder.*, 425 U.S. 185, (U.S. III., 1976).
[43] Aaron v. SEC, 446 U.S. 680. (S.D.N.Y. 1980).
[44] WILLIAM K. S. WANG & MARC I. STEINBERG, INSIDER TRADING 158 (3rd ed. 2010).

element of "recklessness" in the scienter. The Second Circuit held, in *Shields v. Citytrust Bancorp, Inc.,*[45] plaintiffs may plead scienter by alleging either (1) motive and opportunity on the part of the defendant to commit fraud; or (2) facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness. In other words, the plaintiffs who tried to allege a strong motive, including personal gain for scienter, need to be concerned with "concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." On the other hand, plaintiffs who tried to allege a strong opportunity for scienter need to concern "the means and likely prospect of achieving concrete benefits by the means alleged."

Many courts follow the Second Circuit's pleading standard of motive and opportunity test. Also, a number of courts interpreted the PSLRA's intention of heightened pleading standard of standing. *In re Advanta Corp,*[46] the court held that "although the PSLRA established a uniform pleading standard, it did not purport to alter the substantive contours of scienter." Also, *in Phillip v. LCI Int'l, Inc.,*[47] the court held that "to establish scienter, a plaintiff must still prove that the defendant acted intentionally, which may perhaps be shown by recklessness." *In re PLC Sys., Inc.,*[48] Judge Stern stated that Congress in enacting the PSLRA intended to eliminate recklessness as an alternative means of establishing scienter." *In re Aetna Inc.,*[49] the Court held that "it reaches the same conclusion that the PSLRA codified the Second Circuit pleading standards." In *Marksman Partners, L.P. v. Chantal Pharmaceutical Corp.,*[50] the court held that unusual insider trading during the class period and a violation of Generally Accepted Accounting Principles ("GAAP") may permit an inference of fraud under the PSLRA.[51]

3. PSLRA's Pleading Standard of Scienter

After Congress enacted the Private Securities Litigation Reform Act of 1995 ("PSLRA"), there has been much analysis and confusion to interpret scienter. Did the PSLRA heighten the standard of scienter? Is the Second Circuit's pleading standard sufficient to address scienter under the PSRLA? The PSLRA requires the complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Even though the language of the statute is consistent with the Second Circuit's pleading standard of "motive and opportunity test," the Conference Report clearly addressed that since the Committee's intent is to strengthen existing pleading requirements, it does not intend to codify the Second Circuit's case law interpreting this pleading standard."[52]

Congress's intention of heightening the pleading standard of scienter is clear: even though Congress acknowledges its desire to protect the investors at stock market, Congress may prefer to limit frivolous strike suits and judicial costs. However, with Congress's effort to promote two incompatible goals by enacting PSLRA, investors had more difficulty in proving scienter of the company. Also, the PSLRA has enabled companies to abuse the heightened standard and release

[45] *Shields v. Citytrust Bancorp, Inc.* 25 F. 3d 1124, 2nd Cir. (Conn., 1994).
[46] *In re Advanta Corp. Securities Litigation,* 180 F. 3d 525, (3rd Cir. Pa., 1999).
[47] *Phillips v. LCI International, Incorporated,* 190 F. 3d 609, (4th Cir., 1999).
[48] *In re PLC Systems, Inc. Securities Litigation,* 41 F. Supp. 2d 106, (D. Mass., 1999).
[49] *In re Aetna, Inc. Securities Litigation,* 617 F. 3d 272, (3rd Cir., Pa., 2010).
[50] *Marksman Partners, L.P. v. Chantal Pharmaceutical Corp.* 927 F. Supp. 1297, (C.D.Cal., 1996).
[51] Nicholas E. Chimicles, *The Future of Securities Litigation Under the Private Securities Litigation Reform Act of 1995*, Q253 ALI-ABA 33, 5 (1996). *Marksman* adopted Second Circuit's test as most stringent way and had no difficulty to achieve the Congress purpose to heighten the bar of scienter.
[52] H.R. Conf. Rep. No. 104-369, at 48 n.23 (1995).

false and misleading statements to the public. Ultimately, this undermines the soundness of the stock market.

IV. Bio-Pharmaceutical Industry

1. Background

Around the world, bio-pharmaceutical market's constant growth and success are hard to ignore. The global bio-pharmaceuticals market was valued in $162 billion in and is expected to reach $278 billion by 2020.[53] Unfortunately, many biotechnology companies fail because of the expensive clinical research and development program.[54] The period of clinical research and development for obtaining approval of the drug is long and difficult. To get FDA's approval of the right to market the drug or treatment, a sponsor or a manufacturer needs to complete a lengthy period of drug development and demonstrate the studies of pre-clinical and clinical stage to FDA. The studies are extremely long and costly. The cost of developing new drug may exceed $2.5 billion.[55] Beginning from discovery, the process typically goes through non-clinical testing, pre-clinical testing with animals, IND submission or application, Phase 1, 2, 3 clinical trials and NDA submission and review, and finally receiving marketing approval of the drug. The whole process usually takes twelve to fifteen years to complete.

1.1 FDA approval process[56]

(a) Discovery and Development

When a sponsor/researcher finds the symptoms, disease, or condition, he or she starts to test with substances to develop the most effective therapy against the disease. At discovery, robust research of compounds is conducted, and a few selected compounds advance to next stage. With selected candidates, researchers conduct thorough and profound experiments typically relating to the potential benefits, best dosage, side effects, and interaction with other drugs, etc.

(b) Pre-Clinical Stage

Prior to human clinical trials, a sponsor needs to test the drug with laboratory animals to determine toxicity. During the pre-clinical stage, the sponsor/researchers need to conduct tests pursuant to 21 C.F.R. Part 58: Good Laboratory Practice for Nonclinical Laboratory Studies, the regulation required for researchers to provide information such as study conduct, personnel, facilities, equipment, operating procedures, and study results.

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[53] Persistence Market Research, *Global Market Study on Biopharmaceuticals: Asia to Witness Highest Growth by 2020,* http://birac.nic.in/webcontent/BIPP-SBIRI-SPECIAL-CALL.pdf.
[54] Kris Grohn et al., Lean start-up: *A case study in the establishment of affordable laboratory infrastructure and emerging biotechnology business models,* Journal of Commercial Biotechnology 21(2), 64 (2015).
[55] Rick Mullin, Chemical Engineering News, Scientific American, *Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B*(November 24, 2014) https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/.
[56] Development & Approval Process (Drugs), FDA U.S. Food & Drug, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm.

(c) IND Application

Prior to clinical research, a sponsor needs to submit an Investigational New Drug ("IND") application to the FDA. The FDA requires all drugs to be approved at each step even before the sponsor completes studies. For a successful New Drug Application ("NDA"), the sponsor is required to provide a complete NDA that includes chemistry-manufacturing controls along with all of the data from each phase of the clinical trials and additional supportive data as elucidated in FDA guidance documents.

(d) Clinical stages

Researchers or manufacturers of the drug design the clinical stages by three phases. Phase 1 tests twenty to one hundred healthy volunteers and volunteers with target disease or conditions over several months. The purpose of the Phase 1 stage is to gain results of safety and appropriate dosage of the drug. Phase 2 tests additional people with the target disease or conditions and it may take one or more years. The main reason to conduct the Phase 2 is to obtain the efficacy data and identify any side effects of the treatment or drug. In Phase 3, several volunteers who have target disease or condition go through therapy regimen. The purpose of the Phase 3 is to achieve the final safety and efficacy of the drug.

1.2 FDA approval for an animal pharmaceutical treatment

A sponsor seeking approval for a veterinary pharmaceutical must apply for an Investigational New Animal Drug with the FDA's Center for Veterinary Medicine ("CVM"). After a pre-development meeting with the CVM and the successful completion of the required clinical trials, the sponsor needs to prepare the New Animal Drug Application ("NADA"). For a successful NADA, the sponsor is required to provide sufficient data to CVM. Once CVM reviews the data and deems it satisfactory, CVM sends a technical section complete letter to the sponsor. Once a drug is approved by FDA, the sponsor is required to report to CVM any material changes that may affect "identity, strength, quality, purity, or potency of drug." Regarding *Aratana,* the company needed to change the manufacturing site which was a material change. To secure the approval for a major change, the company must file a Prior Approval Supplement ("PAS"). According to FDA. a PAS is subject to a 120-day review period.

2. Case Study

There are similarities and differences between *in re Aratana Therapeutics, Inc. Securities Litigation* and *Zak v. Chelsea Therapeutics International, Ltd*. Both bio-pharmaceutical companies were sued by investors due to the companies' misleading announcements. However, the courts' decisions were clearly different because of the contents of official statements filied with SEC.

A. In re Aratana Therapeutics, Inc. Securities Litigation[57]

a. Synopsis

Aratana Therapeutics, Inc., a development-stage bio-pharmaceutical company that develops biomedical therapeutics for animals, was sued by investors who purchased Aratana's shares between March 16, 2015 and March 13, 2017("Class Period"). In this putative class action,

[57] *In re Aratana Therapeutics Inc. Securities Litigation* 315 F. Supp. 3d 737, (S.D.N.Y., 2018).

the plaintiffs alleged that Aratana made a false and misleading press release so that the fraudulent information damaged the plaintiff who bought Aratana's stock during the Class Period. During the time, Aratana's stock price was about $20 at the peak in September 2015; now the stock price is $5.50.

b. The Chronology

Over the class period, Aratana's executives, Steven St. Peter and Craig A. Tooman, issued frequent announcements to the public about Aratana's future plans for commercialization of the product, ENTYCE, an appetite stimulant for dogs.

b-1 Anticipated 2016 or mid-2016 release

On March 16, 2015, Aratana filed Form 10-K with the SEC. Domestic companies are required to file current status information annually using Form 10-K, quarterly using Form 10-Q, and current important events using Form 8-K. In Form 10-K, Aratana included cautious statements, using terms such as "risks, uncertainties and assumptions, that, if they never materialize or if they prove incorrect, could cause our consolidated results to differ materially from those expressed or implied by such forward-looking statements."[58] Forward-looking statements are defined as statements that include, "a projection of revenue, income, or earnings," "plans and objectives of managements for future operations," or "a statement of future economic performance."[59] Also, Form 10-K attached the "Risk Factor," as stated, "we may be unable to obtain regulatory approval for our existing or future product candidates under applicable regulatory requirements."[60]

On August 6, 2015, Aratana published a press release with Form 8-K which explained the favorable result of ENTYCE research. The press release said that because of the positive results of the research, Aratana could start commercialization of ENTYCE in mid-2016.

b.2 Delay of launch for commercialization

On May 17, 2016, Aratana announced that FDA approved ENTYCE for dogs. Also, in the same press release, Aratana revealed the commercialization would be launched in February 2017.

On August 5, 2016, Aratana made an announcement that it intended to file a Prior Approval Supplement ("PAS") regarding the transfer of ENTYCE manufacturing. The announcement appeared to be that the FDA's approval would be delayed, but St. Peter assured investors the launch would be on schedule at conference call meeting at the same day.

On November 4, 2016, Aratana filed Form 10-Q and addressed the positive prospect, "So we're not changing the timing of what we expect…"

On February 6, 2017, Aratana issued a press release with Form 8-K,and stated that the commercial availability of ENTYCE would be delayed to late 2017. After the announcement, the stock price dropped 17.93%.

On March 14, 2017, during the fourth-quarter 2016 earnings call, Tooman stated that Aratana lost $ 2 million worth of purchase commitments. On this statement, Aratana's stock price dropped another 24%.

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[58] The PSLRA amended the Exchange Act to provide a safe harbor for forward-looking statements. *See* 15 U.S.C. §78u-5(c).

[59] *In re Aratana Therapeutics Inc. Securities Litigation* 315 F. Supp. 3d at 755.

[60] *Id.* at 746.

b.3 Officers' stock trading

St. Peter, CEO and founder of Aratana, sold 50,000 shares before the Class Period. During the Class Period, St. Peter sold 300,000 shares, with total proceeds of $1,664,925. Tooman, CFO and Treasurer, never made sales before the Class Period, however, during the class period, he sold $314,175 worth of shares of Aratana.

The Court held that: i) investors did not adequately allege falsity; ii) investors' allegations of motive did not raise a strong inference of scienter. The court reviewed the cautious language on statements for deciding falsity. And, the court considered the Aratana officer's trading of company shares during the Class Period when the court decided the strong inference of scienter.

c. Analysis

c.1. Falsity

The court's decision that the plaintiffs did not properly address falsity of defendants was mainly focused on forward-looking statements. A forward-looking statement is not actionable if it "is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading."[61] To satisfy meaningful cautionary language, cautionary language must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements. Even though Aratana issued a series of positive prospects of commercial launch of ENTYCE, Aratana clearly stated in the forward-looking statements that "we may be unable to obtain regulatory approval for our existing or future product candidates under regulatory requirements…"[62] The statement seems to suffice, using meaningful cautionary language.

c.2. Scienter

To plead scienter, plaintiffs may allege either (1) motive and opportunity on the part of the defendant to commit fraud; or (2) facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.[63]

c.2.1 Motive

Plaintiffs alleged that individual defendants sought personal benefit from suspicious stock trading. The court rejected the allegation for three reasons. First, the trading stocks of officers did not appear severe manipulative, deceive fraud. The court quoted, *the Glaser* case that "sales representing less than 11% of defendant's holdings did not support strong inference of intent to deceive."[64] During the class period, St. Peter's holdings declined by 9%, while Tooman's holdings increased by 34%. Second, the court held that the timing of the trade of stock did not give strong inference of scienter. St. Peter sold 150,00 shares in August and December before August 5, 2016 press release. Tooman sold 30,000 shares in September 2016, after August 5, 2016 disclosure. Third, the court stated, "trades made pursuant to a Rule 10b5-1 trading plan do not give rise to a

[61] *Slayton v. American Express Company*, 604 F. 3d 758,766, (2nd Cir. N.Y., 2010)
[62] *See* footnote 60, *infra.*
[63] *See* text page 8, *infra.*
[64] *Lawrence F. Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 593 (S.D.N.Y., 2011).

strong inference of scienter."[65] Complaint stated the officers merely entered into the trading plain during the class period. Mere fact of trading plan did not raise the strong inference of scienter.

c.2.2 Conscious Misbehavior of Recklessness

Since the court decided that the plaintiffs did not successfully allege a motive of scienter, the plaintiffs bore a greater burden on the allegation of recklessness with defendants. The court held that even though Aratana issued several positive statements of the prospect of the commercialization of ENTYCE, there was no evidence of scienter that defendants knowingly withheld or used misleading information. For instance, the complaint should have contained internal documents which demonstrated Aratana is intent to deceive the shareholders.

The District court decision on this class action was made by relying on federal civil procedure regulation, rather than factual incidents. But, the insiders dumping their stock seems to demonstrate they knew of the problems. Aratana's statements contained meaningful cautious language. Also, investors' complaints did not properly argue Aratana's strong inference of scienter due to lack of internal documents. However, the court decision doesn't seem to consider material facts. During the class period, holdings of St. Peter and Tooman were changed dramatically and insider trading did occur. As a result, the officers gained personal benefit through trading. Furthermore, the court's decision of the timing of the officers' selling stocks was also problematic. St, Peter and Tooman sold their stocks after August 5, 2016 disclosure which was material change information about changing the manufacturing site. In August 2016, investors still had much expectation of ENTYCE and the stock price was high. The stock price began to drop finally from February 2017 disclosure. As the court pointed out, the market did not respond to only one misleading bad news. Aratana officers clearly abused the fact and waited until the fuss had been calmed down. The court should have considered more closely the actual insider trading. Because insider trading itself can represent the officer's evil mind of damaging the stock market.

B. Zak v. Chelsea Therapeutics International, Ltd.[66]

a. Synopsis

A development-stage bio-pharmaceutical company issued a series of announcements to the public regarding the FDA's approval of market rights. The company's statements with the SEC were not properly filed, and did not contain accurate information about corporate officer's stock trades. The appellate court held the stockholders properly alleged strong inference of scienter.

b. The Chronology

In 2006, Chelsea Therapeutics International, Ltd. ("Chelsea") started to obtain approval from the Food and Drug Administration ("FDA") to market a drug, "Northera," which is a treatment for symptomatic neurogenic orthostatic hypotension ("NOH").[67]

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[65] *In re Lululemon Securities Litigations*, 14 F. Supp. 3d 553, 585 (S.D.N.Y., 2014).
[66] *Zak v. Chelsea Therapeutics International, Ltd*., 780 F.3d 597, (4th Cir., N.C., 2015).
[67] Peter A. McCullough, *Treatment of Orthostatic Hypotension Due to Autonomic Dysfunction (Neurogenic Orthostatic Hypotension) in a patient with Cardiovascular Disease and Parkinson's Disease,* Cardiology and Therapy (Jan. 9, 2019), https://doi.org/10.1007/s40119-018-0124-z. "NOH is medical condition that occurs when blood pressure decreases too much when a person changes from a seated or lying position to

After considering the "significant unmet need" for a clinically beneficial treatment of symptomatic NOH, the FDA assigned Northera "orphan drug status." FDA defines an orphan drug as "the safe and effective treatment, diagnosis, or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,0000 people but are not expected to recover the costs of developing and marketing a treatment drug."[68] Orphan drug exclusivity is guaranteed by the Orphan Drug Act ("ODA"), which defines that once the product was approved with orphan drug status by the FDA, the drug will have seven years of exclusive marketing rights.[69]FDA's designation of Northera as having orphan drug status was a very profitable status for Chelsea, because during the exclusive period, FDA cannot accept or approve another version of the same drug for NOH.

From 2008 to 2010, Chelsea conducted four clinical trials (Studies 301, 302, 303 and 306) to demonstrate Northera's efficacy and safety before Chelsea submitted a New Drug Application ("NDA").[70] While Study 301 was successful, the testing period was conducted during only one week. For the other studies, 302, 303, and 306, even though the clinical period was substantially longer than Study 301, the results did not meet the drug's significant endpoints or goals.

On December 10, 2010, Chelsea had a meeting with FDA officials about approval of the NDA for Northera with the Study 301 result. FDA officials warned that typically, it would be difficult to get approval with only one study. However, Chelsea announced that the FDA agreed that Chelsea could submit an NDA for Northera based on study 301 (which had only a one week period), and study 302 which did not meet the endpoints of the test.

After meeting with FDA officials, during a conference call meeting with investors, Dr. Simon Pedder, Chelsea's Chief Executive Officer, explained the meeting with the FDA was very successful and that FDA did not require an additional study to get approval of the NDA for Northera. Also, at the same conference call, Dr. William Schwieterman, Chelsea's vice president and chief medical officer, assured the investors that Chelsea was very pleased with FDA's response to Chelsea's inquiry regarding the NDA for the treatment.

Chelsea made an announcement that with "robust" efficacy data from study 301 and 302, they submitted the NDA to the FDA. The FDA acknowledged, however, that the efficacy data included only a one week period.

Pursuant to the FDA's initial evaluation process, one of the FDA staff members drafted a briefing document to submit to an advisory committee regarding Northera's NDA. The staff member affirmed the denial of the NDA because of the relatively short period of the study in the briefing document.

Prior to the briefing document's release to the public, Chelsea made a press release on February 13, 2012. Chelsea revealed the fact regarding FDA's concern, but Chelsea did not release the fact that FDA considered not approving the NDA. After the press release, Chelsea's stock price

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an upright position. People who are older or have medical condition related to nervous system failure, such as Parkinson's disease, are at greater risk of having NOH."

[68] Emily Marden & Anna Sims, *Gene Therapy – FDA takes steps toward clarifying scope of orphan drug exclusivity*, Food and Drug Law Institute Update, December 2018/January 2019, at 30.

[69] *Id*. at 30.

[70] *See* text page 14-15, *infra.*

dropped about 37.5 percent. When the briefing document was released to the public, Chelsea's stock price dropped an additional 21 percent.

On February 23, 2012, the FDA's advisory committee issued a non-binding recommendation that FDA would approve Northera's NDA. The chairperson of the committee who was initially in favor of approving the NDA, stated that "virtually all agree that the failed studies do not provide confirmatory evidence of benefit. And the primary study, study 301, also did not provide evidence regarding the duration of effect in any direct ways."

Finally, on March 28, 2012, the FDA denied Northera's NDA. In a complete response letter, the FDA stated it needed a longer study period of the time of the study in order to approve the drug.

On appeal, Chelsea submitted three documents as exhibits. Chelsea submitted two documents of "Form 4 reports,"[71] and one "Definite Proxy Statement."[72] A Form 4 report is required by the SEC, when any officer of the firm trades the firm's stock, that he or she has to file with the SEC, including relevant information such as the officer's name, job title, the date of the transaction, the number of the shares traded, the price of the shares, and the officer's total shares after transaction. A Definite Proxy Statement, otherwise known as DEF 14A, is required by the SEC. Pursuant to § 14(a) of 1934 Act, the firm should file the proxy statement with SEC prior to the annual or special stockholder meeting. Definite Proxy Statements disclose the usual voting procedure and information, board compensation, executive compensation, bonus, and any potential conflicts of interest between the firm and officers, executives and directors.

Chelsea's two Form 4 reports disclose that Dr. Schwieterman, as the reporting person, had purchased Chelsea stock twice during the class period. On a Definite Proxy Statement, Dr. Pedder owned 2.8 percent of all shares of Chelsea, but did not represent any changes of Dr. Pedder's stock during the class period.

On hearing the motion to dismiss, the defendants argued that no officers traded the stock during the class period. They addressed the fact that no trades during the class period represented the absence of scienter. At the conclusion, the district court granted the defendants' motion to dismiss and held that the plaintiffs did not properly raise allegation to support a strong inference of scienter.

The Fourth Circuit vacated and remanded the district court's decision. It held that i) Chelsea's filings of two documents with SEC did not properly reflect the factual basis, and ii) plaintiffs adequately alleged that Chelsea's actions produced a strong inference of scienter.

c. Analysis

c.1 The Exhibit: The Form 4 exhibits and the Definitive Proxy Statement

Even though plaintiffs often assert securities fraud claims based on unusual stock trading among officers, there were no such allegations from the plaintiffs in *Chelsea*. Instead, the

[71] 17 C.F.R. § 249.104, Form 4 is required to a company to be filed for statements of any changes in beneficial ownership of securities of the company.
[72] 17 C.F.R. §240.14a-1(g), "Proxy statement means the statement required by §240.14a-3(a) whether or not contained in a single document."

defendants argued that the very fact that there were no suspicious stock sales between officers during the class period represented the absence of a strong inference of scienter. However, unusual stock trading is not required to prove a strong inference of scienter in securities fraud claims.[73] So, the defendants' argument of absence of scienter was not persuasive. The problem is that the exhibit documents; the Form 4 and the Definite Proxy Statement, did not properly establish the defendants' argument.

Form 4 merely addressed that Dr. Schwieterman, as a reporting person and corporate officer, executed two purchases of Chelsea stock during the class period. On the other hand, the Definitive Proxy Statement indicated only "a snapshot in time" of stock shares owned by several officers as of February 29, 2012. The records did not adequately reflect material information which the exhibits must contain such as how many shares of officers changed during the class period. Or did any officers transfer Chelsea shares with each other?

Therefore, the issue of the exhibit was not that the defendants did not trade Chelsea shares during the class period, but the low accuracy of the exhibits, the Form 4, and the Definite Proxy Statement. The defendants could not argue that there was an absence of a strong scienter because the exhibits were not properly documented.

c.2 Concealment of FDA's warning

Bio-pharmaceutical companies can make announcements about the positive prospect of achieving the company's goal and endpoints, which are usually the FDA's approval of market right of the drug or treatment. There is no affirmative duty for companies to disclose any or all material information by §10(b) and Rule 10b-5. Investors cannot rely on mere company announcements about positive prospects for the company. However, the problem occurs when the company files official documents with the SEC or met with the FDA. At a minimum, these documents need to be properly factual. The Supreme Court stated that companies can control what they have to disclose under 10(b) and Rule 10b-5 by controlling what they say to the market.[74]

When Chelsea's officers met with FDA officials, the FDA officials clearly warned that the one study, Study 301, which was too short, only a one week testing period, would not be enough to gain FDA approval. Without disclosing FDA official's warning, Chelsea released the positive announcement of commercialization of Northera. Chelsea concealed the fact of the FDA action. Chelsea kept the warnings from the public. This represents a strong inference of scienter.

3. Summary of *Aratana* and *Chelsea*

Scienter is the heightened pleading standard of evil intent that plaintiffs must prove in private securities fraud litigation. Congress enacted the PSLRA and raised the bar of scienter to limit frivolous strike suits. However, another important intention of Congress, protection of the investors and soundness of the stock market, became more difficult to obtain because of the heightened standard of scienter.

Both in *Aratana* and *Chelsea*, investors were damaged because of the companies' false and misleading announcements. In *Aratana*, the court did not find the investors' made a strong

[73] *Mizzaro v. Home Depot, Inc.*, 544 F. 3d 1230, 1253, (11th Cir. Ga., 2008).
[74] *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45, (U.S., 2011).

inference of scienter because Aratana's filing with SEC was accurate. Also, the court did not seem to consider well enough the transactions of insiders. It clearly showed the cautious language to investors. In *Chelsea*, the Fourth Circuit held that the plaintiffs alleged properly a strong inference of scienter. Even though Chelsea released the Form 4 and the Definitive Proxy Statements, those exhibits did not reflect the accurate status of the company. Armed with material and accurate information, investors can use their own judgment in deciding whether to invest.

V. The Republic of Korea

The South Korean bio-pharmaceutical industry had developed and had expanded into the global market. Throughout the world, various South Korean bio-pharmaceutical companies have succeeded in business. Celltrion[75] created a key product, "Remsima™," a biosimilar[76] product for rheumatoid arthritis treatment. It exceeded fifty-two percent of market share in Europe as of the end of 2017.[77] Regulation of the disclosure of material information is, however, somewhat equivocal and needs to be improved.

1. Statutory Background

The corporate disclosure system regulates that a company discloses material information so that investors understand the company's reality. The corporate disclosure system can resolve the asymmetry of information between investors and the company; in addition, the system can prove the transparency for the stock market, ultimately protecting the investors and capital market.

If the disclosure or announcement is misleading or omission of the material facts, the investors' financial judgment would be damaged. Therefore, the disclosure must be accurate and the company provides entire information to the public. At the same time, the company should disclose not only good news, but provide bad news to the public.

Pursuant to §391 of the Financial Investment Services and Capital Market Act ("FISCM Act"),[78] the Korean Exchange regulates the disclosure system of the corporate information. FSCM act requires the KOSPI[79]-stock-listed corporations to disclose properly and timely material information; prospects and description of the corporate stock, business information regarding assets and management conditions, or the corporation's financial status. The Korean disclosure system[80] is divided into primary market disclosure system and secondary market disclosure system.

1.1 Primary market disclosure system

The Primary market is the same as the American primary market.[81] It is the place where transaction between the issuer and the first purchaser occurs. Primary market disclosure system is concerned with issuance of the company stock and requires the issuer of the stock to deliver all

[75] Celltrion Inc is a South Korean bio-pharmaceutical company that manufactures biosimilar products. https://www.celltrion.com/en/aboutus/philosophy.do.
[76] *See* footnote 110, *supra.*
[77] Han-Na Park, *Celltrion's Remsima overtakes Remicade in Europe*, The Investor, Mar. 28, 2018, 4:48 pm), http://www.theinvestor.co.kr/view.php?ud=20180328000816.
[78] *See* footnote 16, *infra.*
[79] *See* footnote 12, *infra.*
[80] *See* footnote 7, *infra.*
[81] *See* text page 5-6, *infra.*

information about the company's stock and issuers of the stock to investors. Under the primary market disclosure system, the corporation needs to file public securities registration statements,[82] and deliver business prospectuses, and records of securities issuances.

1.2 Secondary market disclosure system

Secondary market disclosure system addresses the disclosure of the trading of company stock. Secondary market disclosure system requires, the company to disclose the business management regarding trading of the issued stock among investors in the second market. There are periodic disclosures, timely disclosures, and fair disclosures in the secondary market disclosure system.

Periodic disclosure requires a company disclose material information along with company's financial status in a certain period. To protect investors, timely disclosure requires a company to provide the material information anytime the company obtains the information. Also, since a subsidiary company's material business management information (such as bankruptcy, merger & acquisition, or transfer of company shares) affects the parent company's business, the timely disclosure system requires the parent company to disclose the subsidiary company's material information. The fair disclosure system supplements the timely disclosure system and prevents the unfair trading of stocks. When the company tries to provide the undisclosed material information to limited investors or insiders, the fair disclosure system requires the company to provide the undisclosed material information to the public. The fair disclosure system supplements the timely disclosure system and prevents the unfair trade of stocks.

1.3 Voluntary disclosure system

Besides the above-referenced disclosure systems (1.1 and 1.2), which are mandatory, there is voluntary disclosure system, as well. In cases where a company explains the rumors or news regarding affecting the company's stock or material business matters about the company, the company may voluntarily report to the Korean Exchange. The voluntary disclosure system requires the company to report the details by the day following the date of occurrence of the ground for reporting. Unscrupulous companies often abuse the weakness of the voluntary disclosure system. In the U.S. this type of reporting, such as breaking news, requires companies to file Form 8-K.[83]

2. In re Hanmi Pharmaceutical Co., Ltd.[84]

a. Synopsis

Hanmi Pharmaceutical Co., Ltd., a Korean bio-pharmaceutical company ("Hanmi"), issued a positive announcement about exports of new technology to a U.S. bio-pharmaceutical company. At the same day, the officers of the Korean company received the "bad news" from a German bio-pharmaceutical company of the termination of $ 750 million contract. Hanmi did not release the bad news until the following morning. Twenty-nine minutes after the stock market began, Hanmi released the bad news. While investors who did not hear the bad news purchased Hanmi's stock, the insiders and investors who received the bad news from foreign news media sold Hanmi's stock

[82] *See* footnote 22, *infra*.
[83] *See* Exhibit A, *supra*.
[84] Based on column in Korean, Youngdae Kim, *Belated disclosure*, Midas (Nov. 2016).

and bought the puts Unfortunately, for investors, Hanmi's belated release was not against Korean voluntary disclosure system.

b. The Chronology

On September 29, 2016, at 4: 33 pm, Hanmi Pharm announced to the public, that Hanmi received approximately $ 1 billion from U.S. company, Genentech for anti-cancer technology. The Korean Stock market had closed at 3:30 pm. Needless to say, it was very good news for Hanmi, and investors. However, the very same day, Hanmi received the termination letter of the $750 million contract from Boehringer-Ingelheim ("Boehringer") It was very bad news. Even though this kind of termination of contract would be occurred thorough due diligence of both sides, the termination of the contract was not important in this issue. The matter is that the officers and directors did not issue the announcement until the following day, September 30. Moreover, Hanmi released the bad news about termination of the contract at 9:29 am (29 minutes after the stock market opened). Hanmi announced that Hanmi received the termination letter of about $750 million from German company, Boehringer. Less than 24 hours, the company's announcement was drastically different, the investors who purchased Hanmi's shares because of good news from September 29, lost substantial money. When Hanmi announced the good news from Genentech, Hanmi called the Korean Exchange by phone. On the contrary, when Hanmi announced the bad news from Boehringer, Hanmi's employee personally came to the Korean Exchange and shared the news, which resulted in a delayed announcement.

Hanmi revealed that they received the termination letter from Boehringer by email on September 29, at 7:06 pm. Under the Korean Exchange's policy for fair disclosure, companies can disclose anytime by phone after stock market closing. The reason Hanmi's then CEO, Lee, Kwan Sun said, Hanmi waited until September 30, after the Korean Exchange opened, was because the executive committee needed to consult for 29 minutes. However, Hanmi apparently had enough time to discuss the disclosure of the material information on prior day. Also, as Hanmi called to the Korean Exchange to report the good news on September 29, Hanmi could have called to the Korean Exchange by phone on 9 am when the stock market began. However, on September 30, instead of calling to the Korean Exchange, Hanmi sent an employee to report in person after beginning of the stock market. During the 29 minutes, there were many sales of Hanmi stock from institutional investor and foreign investor who would have known Hanmi received the termination letter by monitoring international news. However, the individual investor who just received the good news on September 29, would have purchased Hanmi's shares on September 30 for 29 minutes. The sales of Hanmi's short-sales was 50,566 for 29 minutes and it was more than 10 times for one day average short sale[85] of Hanmi. Obviously, some insiders were short-selling.

After the Financial Supervisory Commission ("FSC"),[86] a Korean financial committee conducted an investigation, it was learned the employees of Hanmi leaked the information of termination letter from Boehringer to friends and close-investors. On May 24, 2017, Securities & Futures Commission ("SFC")[87] announced that SFC decided to fine 24 defendants who were

[85] 17 C.F.R. §242.200(a), short sale is defined as "any sale of a security which the seller does not own or any sale which is consummated by the delivery of a security borrowed by, or for the account of, the seller." "A short sale is a term of art used for a security trading practice in which a party speculates that a particular stock will go down in price and seeks to profit from that drop." *Lapidus v. Hecht,* 232 F .3d 679, 680-81 (9th Cir. 2000).

[86] FSC is a South Korean government agency that supervises, investigates the financial institutions and is equivalent to the U.S. Securities and Exchange Commission.

[87] Subsidiary agency under FSC.

employees of Hanmi and the recipients of the undisclosed information (tipper and tippee) for $2.2 million. One then-employee of Hanmi tipper was sentenced to one year in jail with a stay of execution for two years. And one of the recipients, also an employee of Hanmi, a tippee, was sentenced to six months in jail with a stay of execution for two years. However, Hanmi did not receive a monetary punishment or suspension of trading company stock because pursuant to §448 of FISCM Act, when an employee of the company commits an illegal act, the company will get fined only if the company did not fulfill own duty to supervise the employee.

c. Analysis

Hanmi's case represents the moral hazard of the company and the officers and, also the weakness of voluntary disclosure system. Instead of reporting to the Korean Exchange, the officers decided to wait the following day and tried to obtain the personal and corporate monetary benefit. It clearly represents the violation of fiduciary duty to stockholders of Hanmi, and insider trading.

An insider is not always foreclosed from trading his own company stock merely because the insider may have more confidence with the company operations than outside investigators. Insider trading only happens when an insider receives the undisclosed material information of the company, and the insider trades the company's securities without disclosing the information to public.[88] Tipping or insider tipping is the communication by anyone of material nonpublic information about the issuer or about the market for the security to another person. The government seriously needs to regulate insider trading because the insider would have informational advantage compared to the public and the insider could gain unjustified personal profit from the trade. In Korea, §174 of FISCM regulates insider trading. Section 174. 1 states that the officers or directors (insiders) cannot use undisclosed material information to trade the company stock or use the undisclosed information to public. In *Hanmi*, the employees of Hanmi clearly violated the regulation, §174 of FISCM. The insiders of Hanmi used the undisclosed information to trade stock and spread the information to only certain investors. This behavior not only violated the insider trading, but also violated the fiduciary duty.

In *Dirks v. SEC*,[89] the U.S. Supreme Court addressed a "special relationship" between the insider trader and the outsider on the other side of the trade. An insider or tipper will be held liable under Rule 10 b-5 for insider trading when the insider fails to disclose material information before trading the company securities. A tippee will be held liable if the insider gains personal benefit directly or indirectly because of the disclosure. In addition, a tippee assumes a fiduciary duty to shareholders of the company only when the tippee knew or should have known the insider had breached the fiduciary duty to shareholders.

In recent case, *Salman v. U.S.,*[90] the U.S. Supreme Court applied *Dirks* to affirm Salman's conviction. Suzie Salman ("Salman") was tipped the material information from Michael Kara ("Michael") who was engaged to Salman. Michael was tipped from his brother, Maher Kara ("Maher") who was former investment banker at Citigroup. Maher obtained material information about client's pharmaceutical company and shared the undisclosed information to Maher, further

[88] Fleischer, *Securities Trading and Corporate Information Practices: The Implications of the Texas Gulf Sulphur Proceeding,* 51 VA.L. REV. 1271, 1289.
[89] *Dirks v. Securities and Exchange Commission*, 463 U.S. 646, 656, (U.S. Dist .Col., 1983).
[90] *Salman v. U.S.*, 137 S. Ct. 420, U.S., 792 F. 3d 1087, 9th Cir, 2015, 196 L.Ed.2d 351 (2016).

to Salman. Supreme Court held that meaningful close relationship that the tippee knew that tipper was making a gift to close family member of insider information could betray the client company.[91]

In addition to liability of insiders and tippees of Hanmi, the regulation of disclosure was also liable for the case, as well. As explained earlier, when there were rumors or news about the company stock or material information, a company voluntarily reports to the Korean Exchange by the following day. Many Korean companies run international business in Korea. The news from foreign countries can happen after closing of the stock market or even at midnight. If the information is material and can influence investors' business judgments, the disclosure should be reported to the public by before the opening of the stock market of the following day. The disclosure of the material information should be mandatory rather than voluntary.

There is another example that the Korean government appears not to fully understand the protection of investors in the bio-pharmaceutical industry. Financial Supervisory Service ("FSS") set up the model example last August for the bio-pharmaceutical industry. FSS suggested stock-listed companies disclose material information regarding human resources for research, progress, and accounting process of R&D, equivalent to Risk Factor or cautionary language. However, 50 of the 143 companies in the bio-pharma industry do not follow FSS's recommendation. FSS stated that even though the recommendation of model example requires voluntary disclosure of companies, in it's beginning stage of the system, the FSS tries to have companies understand the system fair and square through conference or brochure.

That is another indication how the government does not appreciate investors' confusion and lack of knowledge about the bio-pharmaceutical industry. To the investors who depend on the government's policy and the company's disclosure, the information referenced by the models in Part VI. would be useful to make a decision. However, FSS's recommendation or suggestion is mere example, the investors' loss would be widen.

VI. Proposed Scienter Tests for the Bio-Pharmaceutical Industry in the U. S. and in S. Korea

A lot of scienter cases are easily understood because scienter is resolved based on facts that everyone understands. Companies lost a big contract, companies developed a new product, or a company had a product that's going to cause it great harm because of product liability. We can look to the behavior of people who know this information and trade. Some representative scienter cases follow. This section will propose how to discover scienter and regulate wrongful behavior in the bio pharmaceutical industry.

In re ArthoCare Corpporation Securities Litigation,[92] Judge Sam Sparks held that "compelling inference of scienter was raised by complaint on the part of chief executive officer (CEO) with respect to any misstatements he made after he was confronted by red flags that began appearing in the media and on the part of chief financial officer (CFO) for any misstatements made

[91] *Salman's* decision was different from *Newman*. In Newman, the Ninth Circuit held that *Dicks* did not apply to infer a personal benefit to the tipper from a gift of material information to a trading relative or friend, unless there is "proof of a meaningful close personal relationship" between tipper and tippee "that generates an exchange that is objective, consequential, and represents at least a potential gain of a pecuniary or similarly valuable nature," *U.S. v. Newman*, 773 F.3d 438, 452, (2nd Cir. N.Y., 2014).
[92] 726 F. Supp. 2d.696, 718, (W.D.Tex., 2010).

by CEO in his presence which he knowingly failed to correct." *In Lee v. Active Power, Inc.,*[93] Judge Sparks held that "the allegation regarding CEO and CFO created strong inference of scienter." *In re MicroStrategy, Inc. Securities Litigation,* Judge Ellis,[94] held that, scienter could be inferred because of "magnitude and repetitiveness of alleged early revenue recognition, and other factors including insider sales." *In Phillips v. Scientific-Atlanta, Inc.,*[95] Circuit Judge Anderson held that "factual allegations may be aggregated to infer scienter and must be inferred for each defendant with respect to each violation." *In re Daou Systems, Inc.,*[96] Circuit Judge Brunetti held that "with the exception of one executive who was not involved in the company's day-to-day operations, investors' allegations were sufficient to create a strong inference that executives acted with requisite degree of scienter." *In Gebhart v. SEC.,* Circuit Judge Fisher held that a salesperson acted with scienter by recklessly making false statements."[97]

The bio-pharmaceutical industry, however, is very, very different because the science is very complex. Very few people have a good understanding of the complexity of the science or of the diseases or ailments being treated. They know about cancer; they know about heart disease, they know about broken bones, and so on. But most lay people who are investors don't have the scientific background knowledge. Furthermore, guessing what's going to happen in the future is much more complicated because it's much harder to predict how a drug will work than it is to predict whether this is going to be a big mine as in *Texas Gulf Sulfur*, or to predict unlike *Texas Gulf Sulfur* that there's no copper there because we had a lot of borings and we couldn't find any copper. It's very, very difficult to know if this new cancer drug is actually going to retard cancer, or possibly cure cancer. What are the side effects? It might be really good on cancer but it might give you a heart attack.

Insiders know more about bio-pharmaceuticals, which are further complicated by the various stages and various tests that the drugs have to go through. Insiders are more likely to have very sophisticated knowledge that the investor needs to have in order to assess how the particular drug therapy is proceeding along the highway from testing to approval. Furthermore, the people who understand this mechanism are the regulators like the FDA and presumably the scientists in the drug industry. But both the FDA and the drug industry scientists, product developers and so on are still, in many instances, making educated guesses that a new drug therapy will either work or not work. The clinical trials determine the efficacy of the preparation.

1. The ImClone Stock Trading Scandal

ImClone stock trading fraud represents relatively easy case of scienter in bio-pharmaceutical industry. Even though the development of the drug was very sophisticated and demanding, it was clear to find scienter of insiders through wrongful trading with knowledge of undisclosed material information.

ImClone System Inc. ("ImClone") was an independent, publicly traded company which was developing a monoclonal antibody drug, "Erbitux™."[98] Before the development of Erbitux,

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[93] *Lee v. Active Power, Inc.,* 29 F. Supp. 3d.876, 889, (W.D. Tex., 2014).
[94] 115 F. Supp. 2d 620, 649, (E.D. Va., 2000).
[95] *Phillips v. Scientific-Atlanta, Inc.,* 374 F. 3d 1015, (11th Cir. Ga., 2004).
[96] 411 F. 3d 1006, 1023, (9th Cir. Cal., 2005).
[97] *Gebhart v. SEC.,* 595 F. 3d 1034, (9th Cir., 2010).
[98] Erbitux is a brand name, and Cetuximab is a generic name. Cetuximab is a drug to treat head, neck, and colorectal cancer. –mab represents a monoclonal antibodies. Monoclonal antibodies are antibodies are that are made by identical immune cells that are clones of a unique parent cell.

ImClone used to develop a drug delivery system.[99] Even though ImClone did not succeed to produce an innovative drug delivery system, ImClone was a bio-pharmaceutical company that operated a first-class laboratory facility in New York City it liked to show to investors. After several failures of development of drug delivery system, ImClone's founder, Samuel D. Waksal, closed a license agreement for Erbitux with MD Anderson Cancer Center.[100] Big bio-pharmaceutical companies had seen little value in Erbitux, however, Waksal saw the potential of Erbitux. Against huge risks, Waksal announced that ImClone would refocus its main work from development of drug delivery system to development of Erbitux. Waksal hired new employees who were in charge of applying for a Biologics License Application ("BLA")[101] to FDA and began clinical trials. Waksal's choice and gamble to focus on Erbitux was truly right. During the clinical trials, many patients were cured with Erbitux. Papers and news media introduced gushing stories about Erbitux's positive prospects. Mid-December, 2001, ImClone was one of the seven bio-pharmaceutical companies on the NASDAQ 100.[102]

However, the problem was that even though the clinical trials were very successful and ImClone proved Erbitux was effective, the BLA was not suitable for FDA standards. One of the FDA officials told an employee of Bristol-Myers-Squibb ("BMS") that ImClone's BLA was so poor that the FDA considered to send a refusal to file ("RTF") letter.[103] The employee of BMS revealed the undisclosed information to ImClone and Waksal directed his family and close investors to sell ImClone's stock before the FDA decision was announced. After Waksal's direction, Waksal's family, close friends and officers of ImClone sold $14 million of ImClone stock on December 27-28, 2001. Martha Stewart,[104] a celebrity and founder of Martha Stewart Living Omnimedia, and girlfriend of one of the Waksal's brothers was convicted on charges predicated upon false statements made to federal investigators within "ImClone stock trading scandal." Stewart was involved in ImClone fraud with her broker, Peter Bacanovic. After Bacanovic tipped her off that ImClone was about to drop due to a negative FDA reviewing of drug candidate ERBITUX, Stewart sold about $230,000 in ImClone shares on December 27, 2001, a day before the announcement of the FDA decision. Stewart was found guilty and sentenced to five months in prison, five months of home confinement, and two years probation for lying about a stock sale, conspiracy, and obstruction of justice in June 2004.

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[99] Drug delivery refers to the process of transporting pharmaceutical compounds to achieve a therapeutic effect in humans or animals. Tiwari, Gaurav et al. *Drug delivery systems: An updated review*, International journal of pharmaceutical investigation vol. 2,1 (2012): 2-11.

[100] University of Texas MD Anderson Cancer Center is the one of the original three comprehensive cancer center in the United States.

[101] Whereas a NDA is used for drug approval under Food, Drug and Cosmetic Act, BLA is required for biological products to be approved under Public Health Service Act (PHS Act). Section 351 of PHS Act defines a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous products, applicable to the prevention, treatment, or cure of a disease or condition of human beings."

[102] Hron, Benjamin M., *Placebo or Panacea: The FDA's rejection of ImClone's Erbitux Licensing Application*, 1, https://dash.harvard.edu/bitstream/handle/1/8889445/Hron.html?sequence=2.

[103] Pursuant to 314.101, Center for Drug Evaluation and Research (CDER) may send the refusal to file letter to applicants. For BLAs, 21 C.F.R. 601.2(a) states that a BLA "shall not be considered as file until all pertinent information and data have been received by the FDA." CDER's manual of policies and procedures states that "Recognizing that, for both drugs and biologics, a complete application is needed for review and that the data needed to support approval of BLAs and NDAs are in many ways similar, CDER may refuse to file a BLA for a biological product under many of the same conditions as it could do refuse to file an NDA." Offices of New Drugs, *Good Review Practice: Refuse to File*, MAPP 6025.4, 1 (2018).

[104] *U.S. v. Stewart*, 433 F. 3d 273, (2nd Cir. N.Y., 2006).

ImClone's stock price hit a high of $75.45 on December 6, 2001, but the stock price was $14.90 on January 25, 2002. Eventually, BMS purchased a stake in ImClone and the BLA and the rights to ERBITUX were licensed to Bristol-Myers Squibb. Using the same data, that originally was unsuccessfully filed by ImClone with the FDA, BMS resubmitted the BLA and received an approval for Erbitux by rearranging the data into the format that FDA was accustomed to reviewing. After 14 years of Erbitux sales, Eli Lilly purchased all of ImClone, which manufactures antibody through its subsidiary ImClone.

2. In the United States

The hypothetical case of *Brandon Therapeutics, Inc.* demonstrates the proposed re-evaluation of scienter for the bio-pharmaceutical industry.

In re Brandon Therapeutics, Inc.

a. Synopsis

Brandon Therapeutics, Inc. ("Brandon Therapeutics") is a publicly-held bio-pharmaceutical company in the State of Crawford. Brandon Therapeutics tried to obtain an approval from the Food and Drug Administration for market rights to the drug, "Armicade." Armicade is a unique treatment for Stargardt's disease,[105] a form of macular degeneration. Brandon Therapeutics' officers issued a series of positive announcements that the FDA officials were satisfied with clinical studies of Armicade, even though the FDA warned Brandon Therapeutics about a denial of the NDA[106] due to GCP.[107] After the release of an official statement by Brandon Therapeutics concerning these issues, the stock price of Brandon dramatically dropped. After the crisis, investors filed a putative class action suit against Brandon Therapeutics for misleading or omission of material information.

b. The Chronology

Stargardt's disease is a very serious genetic disease and there is no effective treatment or drug in the market worldwide. In 2014, Brandon Therapeutics began the process of obtaining the market rights for Armicade which would be the only effective treatment for Stargardt's. Brandon Therapeutics had gone through successful pre-clinical experiments which satisfied GLP standards. After considering the significant unmet need for a clinically beneficial treatment of Stargardt's, the

[105] "Stargardt's disease (also known as fundus flavimaculatus and Stargardt's macular dystrophy) is the most common form of inherited juvenile macular degeneration. It causes a progressive loss of central vision and, in the early stages patients may have good visual acuity, but may experience difficulty with reading and seeing in dim lighting. The progression of vision loss is variable and can start with a visual acuity of 20/40 and decrease rapidly to 20/200 (legal blindness)." *Barbara Cutrera v. Board. of Supervisors of Louisiana State Univ.*, 429 F.3d 108, 109, FN 1 (5th Cir. 2005).

[106] New Drug Application, *See* text page 16-17, *infra.*

[107] Good Clinical Practices, Good Laboratory Practice ("GLP") stands for the principles of pre-clinical studies that are intended to support research for drugs regulated by FDA. GCP stands for the principles of clinical studies that are intended to support research with humans.

FDA assigned Armicade an orphan drug status.[108] Between 2016 and 2018, after obtaining approval of their IND application by FDA, Brandon Therapeutics conducted clinical studies, designated ARMI-101, ARMI-102, ARMI-103, and ARMI-104 which had to satisfy the GCP standards. While study ARMI-101 produced successful efficacy with Armicade, the latter three studies did not give acceptable results. Also, Brandon Therapeutics conducted study ARMI-101 during only a one-week test period.

On June 12, 2018, when Brandon Therapeutics' president, David I. Goodman ("David") and Chief Science Officer, Dr. Scott I. Expertguy ("Scott") had a meeting with the FDA. FDA officials reviewed Brandon Therapeutics' clinical studies compared to the GCP standards. After review of the efficacy data, the FDA officials stated that study ARMI-101 satisfied the endpoint of the test. However, the officials clearly warned David and Scott that the other three clinical studies were not successful, and Study ARMI-101's period was too short to approve the drug.

In spite of FDA's warning, on June 12, Brandon Therapeutics released a public announcement of positive prospects for Armicade. In the announcement, Dr. Scott stated that FDA agreed the study ARMI-101 was successful and market approval of Armicade was on schedule by the end of 2018. Also, on the same day, during the conference call meeting with investors, Mr. David assured investors that the meeting with FDA officials was successful and Armicade would obtain market approval by FDA by the end of 2018.

On June 22, pursuant to the FDA's initial evaluation process, an FDA staff member drafted a briefing document to submit to an advisory committee with respect to Armicade's NDA. On the briefing statement, the staff member clearly stated the recommendation of denial of Armicade's NDA.

On June 26, before the FDA's briefing letter was released to the public, Brandon Therapeutics issued an additional announcement. In the announcement, Mr. David revealed FDA's decision that studies ARMI-102, ARMI-103, and ARMI-104 were not successful. However, the statement did not mention that FDA would not grant the market approval for Armicade. After the announcement was released, Brandon Therapeutics' stock price dropped 20%. On July 8, when the FDA released the briefing documents, the stock price dropped an additional 17%.

On August 28, 2018, the FDA denied Armicade's NDA. In complete response letter, FDA stated that Brandon Therapeutics needed to provide a longer period efficacy study in order to approve Armicade.

On September 14, investors who bought Brandon Therapeutics' stock between June 2018 to August 2018 filed the putative class action against Brandon Therapeutics. Investors alleged that Brandon Therapeutics acted with strong inference of scienter, and two key officers traded the stock without releasing the material information to the public during the class period.

On hearing, two officers, Mr. David and Dr. Scott submitted three documents, two Form 4 report[109] and a Definite Proxy Statement[110] which they filed with the SEC before the suit. Form 4 disclosed that Mr. David, as the reporting person, had purchased Brandon Therapeutics stock twice during the class period. Definite Proxy Statement represented that Dr. Scott owned 7.9% of all

[108] *See* text page 19, *infra*.
[109] *See* text page 20, *infra*.
[110] *See* text page 20, *infra*.

shares of Brandon Therapeutics, but the statement did not represent any changes of Dr. Scott's stock during the class period.

The Crawford district court held that i) Brandon Therapeutics' filings of the three documents with the SEC did not properly reflect the factual basis, and ii) the investors adequately alleged a strong inference of scienter of Brandon Therapeutics.

c. Analysis

c.1 The Form 4 reports and the Definite Proxy Statement

The Form 4 merely addressed that Mr. David, as a reporting person and corporate officer, executed two purchases of Brandon Therapeutics stock during the class period. The Definitive Proxy Statement indicated only "a snapshot in time" of stock shares owned by Mr. David and Dr. Scott as of February 29, 2012. The records did not adequately reflect material information which the exhibits must contain such as how many shares of officers changed during the class periods. Or did any officers transfer shares with each other?

Therefore, the issue with the exhibit was the low accuracy of the exhibit, the Form 4, and the Definite Proxy Statement. Investors argued adequately that there was a strong inference of scienter because the exhibits were not properly documented.

c.2 Concealment of FDA's warning

Bio-pharmaceutical companies can make announcements about the positive prospective of achieving the company's goal and endpoints, which are usually the FDA's marketing approval of the drug or treatment. There is no affirmative duty for companies to disclose any or all material information by §10(b) and Rule 10b-5. Investors cannot rely on mere company announcements about positive prospects for the company. However, the problem occurs when the company files official documents with the SEC or met with FDA. At a minimum, these documents need to be properly factual. The Supreme Court stated that companies can control what they have to disclose under 10(b) and Rule 10b-5 by controlling what they say to the market.[111]

When Brandon Therapeutics' officers met with FDA officials, the FDA officials clearly warned that the one study, study ARMI-101, which was too short, only a one week testing period, would not be enough to gain a FDA approval. Without disclosing the FDA official's negative warning, Brandon Therapeutics released the positive announcement of commercialization of Armicade. The behavior of Brandon Therapeutics was concealing a critical fact of the FDA action. Brandon Therapeutics kept warnings from the public. This represents a strong inference of scienter.

3. Republic of Korea

The scienter regulation for the Republic of Korea is demonstrated in *Hoon Biosimilar Co., Ltd.* Case.

[111] *Matrixx Initiatives, Inc. v. Siracusano,* 131 S. Ct. 1309, 1322, 179 L.Ed.2d 398 (2011).

a. Synopsis

Hoon Biosimilar Co., Ltd. ("Hoon Bio") is one of the bio-pharmaceutical company. Hoon Bio is world-renowned for manufacturing biosimilar,[112] "Hoonimira" for cancer. Hoon Bio issued the good breaking news on the day of a big contract with the U.S. bio-pharmaceutical company, Orange Bio-Pharmaceuticals, Inc. ("Orange Bio"). Hoon Bio confidently issued the good news to the public during the opening of the stock market. On the same day, after the closing of the stock market, Hoon Bio received the bad news about the termination of a contract with a German bio-pharmaceutical company, Gödje Pharmaceutical International, AG[113] ("Gödje Pharma"). Hoon Bio did not disclose the bad news until the opening of the stock market of the next day. Hoon Bio finally delivered the bad news to the stock exchange authority in person 30 minutes after the opening of the stock market. Between the opening of the stock market and the announcement of Hoon Bio's bad news, the volume of short sales of Hoon Bio was ten times more than short sales of an average day sales. Investors who bought Hoon Bio stock during the 30 minutes sued Hoon Bio for violation of mandatory disclosure regulation, and insider trading.

b. The Chronology

On September 29, 2016, at 4: 33 pm,[114] Hoon Bio announced to the public that Hoon Bio received approximately $ 2 billion from U.S. bio-pharmaceutical company Orange Bio for export of biosimilar technology. Needless to say, it was very good news for Hoon Bio and investors. However, the very same day, Hoon Bio received the termination letter of the $1 billion contract from Gödje Pharma. It was very bad news. The matter is that the officers and directors did not issue the announcement until the following day, September 30. Moreover, Hoon Bio released the bad news about termination of the contract on 9:30 am (30 minutes after stock market opened). Hoon Bio announced that Gödje Pharma terminated $1 billion contract. Two announcements were completely different, the investors who purchased Hoon Bio shares because of good news from September 29, lost substantial money. Issue is when Hoon Bio announced the good news from Orange Bio, Hoon Bio called to Korean Exchange by phone. On the contrary, when Hoon Bio announced the bad news from Gödje Pharma, one of Brandon Therapeutics' employee personally came to Korean Exchange and notified the news.

Hoon Bio explained that they received the termination letter from Gödje Pharma by email on September 29, 7:06 pm. Korean Exchange's policy for fair disclosure allows that companies can disclose anytime by phone after stock market closing. Hoon Bio stated that the executive committee needed to consult for 30 minutes. However, Hoon Bio apparently had enough time to discuss the disclosure of the positive material information on prior day. Also, as Hoon Bio called to the Korean Exchange to report the good news on September 29, Hoon Bio could have called to the Korean Exchange by phone on 9 am when the stock market began to report the negative news. However,

[112] A biosimilar is a biological product that is highly similar to and has no clinically meaningful difference from a Reference Product. Reference products is already licensed product by FDA. A biosimilar requires to be applied Abbreviated New Drug Application ("ANDA"). FDCA 351K ANDA can be approved when the new drug is identical in active ingredient, dosage form, strength, route of administration, labeling, and intended use to a previously approved drug (listed drug). ANDA does not require efficacy studies. FDA 505(j); 21 C.F.R. 314.

[113] AG is an abbreviation of Aktiengesellschaft, which means a public limited company in German.

[114] The Korean Stock market opens on 9 am and closes on 3:30 pm.

on September 30, instead of calling to the Korean Exchange, Hoon Bio sent an employee to report in person after beginning of the stock market. During the 30 minutes, there were many sales of Hoon Bio from institutional investors and foreign investor who would have known the fact Hoon Bio received the termination letter by monitoring international news. However, the individual investor who just received the good news on September 29, purchased Hoon Bio's shares for 30 minutes. The sales of Hoon Bio's short-sales was 50,566 for 30 minutes and it was more than 10 times for one day average short sale[115] of Hoon Bio. Obviously, some insiders were short-selling.

After Financial Supervisory Commission ("FSC"),[116] a Korean financial committee's investigation, it was determined the employees of Hoon Bio leaked the information of the termination letter from Gödje Pharma to friends and close-investors. On May 24, 2017, Securities & Futures Commission ("SFC")[117] announced that SFC decided to fine 24 defendants who were the employees of Hoon Bio and the recipient of the undisclosed information (tipper and tippee) for $2.2 million. One then-employee of Hoon Bio, tipper was sentenced to one year in jail with a stay of execution for two years. And one of the recipients, also an employee of Hoon Bio, a tippee, was sentenced to six months in jail with a stay of execution for two years. However, Hoon Bio did not get any monetary punishment or suspension of trading company stock because pursuant to §448 of FISCM Act, when an employee of the company commits an illegal act, the company will get fined only if the company did not fulfill own duty to supervise the employee.

c. Analysis

In *Texas Gulp Sulphur,* when an insider obtains the material information which affects future of corporate and desire of investors to buy, sell, or hold corporate' securities, the investor must disclose the material information or abstain the trading of corporate securities.[118] In Hoon Bio, insiders obtained the undisclosed material information, and executed the trading of their Hoon Bio stock. Hoon Bio represents typical harmful consequences of insider trading, and also points out the limitation of voluntary disclosure system.

Hoon Bio's employees who knew the termination of contract with Pharma did traded Hoon Bio stock against 174 (1) of FISCM Act. Because of fundamental differences, asymmetry of information, the public can be damaged by insider trading. Government must regulate insider trading seriously. Not only an insider, but also a tippee can be liable for insider trading. If a tippee knows the insider can gain personal benefit through the insider trading, the tippee would be liable, too. Furthermore, a tippee assumes the fiduciary duty to stockholders of the company only if the tippee knew or should have known the insider breached the fiduciary duty to stockholder of the company.

In Hoon Bio, the employees objectively traded the Hoon Bio stock against insider trading regulation and fiduciary duty to shareholders of Hoon Bio. Also, the recipients of the undisclosed

[115] 17 C.F.R. §242.200(a), short sale is defined as "any sale of a security which the seller does not own or any sale which is consummated by the delivery of a security borrowed by, or for the account of, the seller." "A short sale is a term of art used for a security trading practice in which a party speculates that a particular stock will go down in price and seeks to profit from that drop." *Lapidus v. Hecht,* 232 F. 3d 679, 680-81 (9th Cir. 2000).
[116] FSC is a South Korean government agency that supervises, investigates the financial institutions and is equivalent to the U.S. Securities and Exchange Commission.
[117] Subsidiary agency under FSC.
[118] *See* text page 11, *infra*.

information, tippees traded Hoon Bio stock, and should have known the breach of fiduciary duty of insiders. Both insiders and tippees are liable for Hoon Bio insider trading.

With respect to the disclosure system, Korea should adopt a regulation of the SEC's Form 8-K.[119] Under Section 13 or Section 15(b) of the Securities and Exchange Act of 1934, SEC requires a public company to file Form 8-K. The company is required to notify investors of current events or irregular breaking news that can influence investors' decision of the company stock trading with filing Form 8-K. Without the proper filing of a Form 8-K, the company will be held liable for the misleading or omission of material information by SEC. Hoon Bio should have disclosed the breaking news from Pharma before opening of stock market of the following day. Instead of proper disclosure, Hoon Bio traded own stocks within 30 minutes until Hoon Bio disclosed to the public.

There was no excuse for belated disclosure, because stock market of S. Korea has a system of an "Extended Hours Trading."[120] For investors' convenience and sound stock market, if there are any breaking news or irregular events after stock market closes, or before stock market opens, the stock market allows investors to offer to buy or sell the stock. The South Korean stock market is open 9 am to 3:30 pm. However, the pre-market begins at 8 am, and after-market ends at 4pm. Even if Hoon Bio received the bad news after the stock market closed, Hoon Bio knew there was plenty of time to disclose the breaking information because there were extended hours trading.

4. Summary of United States and Korean Proposals

In the United States, the proposal is that the courts use a more sophisticated and granular reading of the facts in the biopharmaceutical industry to understand the importance of certain material information that may lead to a finding of scienter. In the Republic of Korea, the Financial Supervisory Commission should adopt insider trading set standards somewhat similar to those of United States and utilize a regulation similar to Form 8-K mandating full disclosure material information. In addition, the hypothetical introduces Form 8-K, which is attached as Exhibit A for Hoon Biosimilar Co., Ltd. that should have filed with SEC if the company was incorporated in the United States.

2. Conclusion

Chelsea suggests that how the bio-pharmaceutical companies report the statements with SEC and issue the announcement to public. The prospect of the company can be fluctuated because of the dynamics of industry and global economy. However, the company's truthful attitude towards investors and the stock market should be maintained well. *Chelsea* did not properly report the documents with the SEC. The documents did not reflect accurately the officer's trading of Chelsea stocks. Also, *Chelsea* did conceal the FDA's warning to the public, that the one study 301 would be not enough to get an approval of drug. With these two facts, investors properly alleged the heightened strong inference of scienter of *Chelsea*. On the other hand, *in Aratana*, the court seemed to rely too much on federal civil procedure regulation rather than factual basis. Similar to *Chelsea*, Aratana's officers did commit insider trading during the class period. However, the court held that investors did not properly allege scienter, not because Aratana did not commit misleading material

[119] *See* Exhibit A. *supra.*

[120] Many advanced countries adapt the extended hours trading to protect investors from breaking news after stock market closing, or before stock market opening. NASDAQ allows that pre-market occurs 4am to 8am, and after hours 4pm to 8pm.

information, but, because the complaint did not contain the enough evidence such as internal documents to prove Aratana's deceive to investors.

Hanmi represents the loophole of South Korean voluntary disclosure system. Even though a few officers were sentenced and fined because of insider trading under 171 of the FISCM Act, the penalty did not cure the damage to the stock market. That could not have happened if the disclosure system for breaking news or explanation of the rumors was properly regulated as mandatory system.

Reviewing both countries' cases dealing with misleading information or the omission of material information of companies in the bio-pharmaceutical industry, it appears the regulations can be more effective for investors. In the United States, the pleading standard of scienter is too high to allege the strong inference of fraud. Even though officers committed insider trading, *Aratana*'s decision was failed the investors because the court focused more on the federal regulation of procedure. In the Republic of Korea, the voluntary disclosure system for breaking news is too weak. If the duty of disclosure were mandatory, the Korean government could have stopped the chaos before the insider trading and short sales happened. Even though FSS had punished a few employees and tippees, investors were already damaged, and particularly stock market in bio-pharmaceutical industry lost investors' trust. Without better regulation, confidence in the bio-pharmaceutical market is undercut.[121]

[121] Recently, Hanmi had done similar belated announcement of bad news, again. March 18, 2019, Hanmi announced that its U.S. partner, Spectrum Pharmaceuticals withdrew BLA filing of ROLONTIS due to FDA's request for additional manufacturing-related information. However, Spectrum Pharmaceuticals announced the news in U.S. on March 15, 2019. Spectrum stock fell more than 7% in pre-market trading on March 15. Even though Hanmi explained Spectrum distributed the news after closing of stock market in Korea, there were enough time between Friday through Monday, Hanmi should have disclosed the bad news to the public. Without the proper disclosure system, this kind of occurrence could happen again and the government's purpose of soundness of stock market still seems a long way.

Exhibit A

FORM 8-K

UNITED STATES
SECURITIES AND EXCHANGE COMMISION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event report): September 30, 2016

Hoon Biosimilar, Co., Ltd.

(Exact name of registrant as specified in its charter)

Crawford	**xxx-xxxxx**	**xx-xxxxxxx**
(State of other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

86 Hoonbio Dr. **Hoon City, Crawford** **(Address of principal executive offices)**	**xxxxx** **(Zip Code)**

Registrant's telephone number, including area code: (xxx) xxx-xxxx

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (240.12b-2 of this chapter).

Emerging growth company □

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

□

Item 1.01. **Termination of Material Agreement**

Termination of Contract

On September 29, 2016, Hoon Biosimilar Co., Ltd. ("Hon Bio") received Termination Letter of Contract with Gödje Pharmaceutical International, AG, a German bio-pharmaceutical company ("Gödje Pharma"). The Termination Letter provides, among other things, that on the terms and subject to the conditions set forth therein, $1 billion contract between Hoon Bio and Gödje Pharma will be terminated by options of ("Gödje Pharma"). Aforementioned Termination Letter is attached as Exhibit 1.1 at this Form 8-K.

***

Important Information For Investors And Stockholders

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval. It does not constitute a prospectus or prospectus equivalent document. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

***

Certain Information Regarding Participants

Hoon Bio, and their respective directors and executive officers may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information about the directors of Hoon Bio is set forth in its Annual Report on Form 10-k for the year ended December 31, 2015, which was filed with the SEC on February 13, 2016, its proxy statement for its 2016 annual meeting of stockholders, which was filed with the SEC on March 21, 2016, and its Current Report on Form 8-K, which was filed with the SEC on August 22, 2016.

***

Cautionary Statement Regarding Forward-Looking Statements

This communication contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can generally identify forward-looking statements by the use of forward-looking terminology such as "anticipate," "believe," "continue," "seek," "should," or "will," or the negative thereof other variations thereon or comparable terminology. These forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond Hoon Bio's control.

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Item 9.01. Financial Statements and Exhibits

Exhibit No.	Description of Exhibit
1.1	Termination Letter

∗Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Hoon Bio hereby undertakes to furnish supplemental copies of any of the omitted schedules upon request by the U.S. Securities and Exchange Commission: provided, however, that Hoon Bio may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedules so furnished.

***

SIGNATURES

Pursuant to the requirement of the Securities Exchange Act of 1934, this registrant has duty caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 30, 2016

Hoon Biosimilar Co., Ltd.

By: /s/ Yeong Hoon Sohn
Name: Yeong Hoon Sohn
Title: Chief Executive Officer