UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	)	
Plaintiff,	)	
v.	)	Civil Action No. 0511805 (NMG)
RICHARD B. SELDEN,	)	
Defendant.	)	

COMPLAINT

Plaintiff Securities and Exchange Commission ("Commission") alleges the following against defendant Richard B. Selden ("Selden"):

SUMMARY

1. This case arises from material misrepresentations by Transkaryotic Therapies, Inc. ("TKT"), a bio-pharmaceutical company based in Cambridge, Massachusetts, and by defendant Selden, TKT's former CEO. Between at least October 2000 and October 2002, TKT and Selden misrepresented that clinical trials for TKT's flagship drug, Replagal, were a success and made positive statements about Replagal's chances of being approved for sale in the U.S. by the U.S. Food and Drug Administration ("FDA"). In fact, beginning in January 2001, the FDA had informed TKT that its principal clinical trial was a failure and that Replagal would not receive FDA approval based on that trial. At all relevant times, defendant Selden was the CEO of TKT and knew the negative information about Replagal. Nevertheless, he made, signed, participated in, or otherwise authorized a series of materially misleading public statements by TKT about the

status of the FDA application for Replagal. In addition, he sold 90,000 shares of TKT stock while in possession of material non-public information about the negative clinical results and other problems with the FDA application, thereby avoiding losses of more than $1.6 million that he would have incurred had he held the stock until October 2002 when TKT finally disclosed some of the negative information about the application and its stock price dramatically declined.

2. In June 2000, TKT filed an application for FDA approval of Replagal, a treatment for Fabry disease, a rare kidney condition in which patients suffer from extreme pain and kidney dysfunction. From at least October 2000 until it issued corrective disclosure in October 2002, TKT and Selden as CEO made a series of public statements and filed several reports to the Commission describing TKT's most important clinical trial (known as the "pivotal trial") as a success and containing positive statements about Replagal's clinical benefits and chances for FDA approval. However, TKT and Selden as CEO knew but failed to disclose material negative information about Replagal's FDA application such as: (1) the pivotal trial had failed to meet its primary objective; (2) the FDA had informed TKT in January 2001 that the pivotal trial was a failed study and that its primary analysis had failed; (3) the FDA had recommended in January 2001 that TKT conduct additional clinical trials; and (4) TKT had informed the FDA, at least as early as April 2001, that it would no longer seek approval of Replagal based on a claim that the drug was effective against pain.

3. After the market closed on October 2, 2002, TKT publicly announced that the FDA viewed the company's pain-related clinical data as "uninterpretable" and that, as a result, TKT had abandoned its claim that Replagal was clinically effective against pain as a basis for seeking FDA approval. During a conference call with investors that evening, Selden falsely

stated that TKT had only recently learned of the FDA's position and had just decided to change its approach to the application, when in fact the FDA had been communicating negative information to TKT since at least January 2001 and TKT had told the FDA in April 2001 that it was changing its approach. On October 3, 2002, the price of TKT stock plummeted 63% – from a closing price of $33.25 per share on October 2 to $12.75 per share on October 3.

4. Between May 2001 and February 2002, Selden sold 90,000 shares of TKT stock while he knew the material, non-public information about the problems with TKT's clinical trial and its FDA application for Replagal. Based on the closing price of TKT stock after the information was publicly disclosed on October 2, 2002, Selden avoided a loss of $1,664,000 and was unjustly enriched by selling his TKT stock during a period when the stock price was artificially inflated as a result of misleading information in the markets.

5. Through the activities alleged in this Complaint, Selden violated the anti-fraud provisions of the federal securities laws, specifically Section 17(a) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. §77q(a)] and Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5]. Selden also aided and abetted TKT's violations of Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20,13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 & 240.13a-13] by causing TKT to file false and misleading annual, quarterly and other reports with the Commission.

6. Accordingly, the Commission seeks: (a) entry of a permanent injunction prohibiting Selden from further violations of the relevant provisions of the federal securities laws; (b) disgorgement of Selden's ill-gotten gains, plus pre-judgment interest; (c) the imposition

of a civil penalty due to the egregious nature of Selden's violations; and (d) entry of an order barring Selden from serving as an officer or director of a public company.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to Section 22 of the Securities Act [15 U.S.C. §77v] and Sections 21 and 27 of the Exchange Act [15 U.S.C. §§78u & 78aa]. Venue is proper in this District because, at all relevant times, TKT's corporate headquarters was in this District, many of the acts and practices alleged in this Complaint occurred in this District, and Selden lives in this District.

8. The Commission seeks a permanent injunction pursuant to Section 22 of the Securities Act [15 U.S.C. §77v] and Section 21(d)(1) of the Exchange Act [15 U.S.C. §78u(d)(1)]. The Commission seeks the imposition of a civil penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. §77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)]. The Commission seeks an officer and director bar pursuant to Section 20(e) of the Securities Act [15 U.S.C. §77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)].

9. In connection with the conduct described in this Complaint, Selden directly and indirectly made use of the mails or the means or instruments of transportation or communication in interstate commerce.

DEFENDANT AND RELEVANT ENTITY

10. **Selden**, age 46, lives in Wellesley, Massachusetts. He founded TKT and served as its CEO and a director from 1988 until his resignation in February 2003.

11. **TKT**, a Delaware corporation, is a bio-pharmaceutical company headquartered in Cambridge, Massachusetts. From 1996 through July 2005, TKT common stock was registered with the Commission pursuant to Section 12(g) of the Exchange Act [15 U.S.C. §78l(g)] and traded on the NASDAQ National Market System. Pursuant to Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 13a-1 and 13a-13 thereunder [17 C.F.R. §§240.13a-1 and 240.13a-13], TKT was required to file with the Commission annual reports on Form 10-K and quarterly reports on Form 10-Q. Pursuant to Rule 12b-20 [17 C.F.R. §240.12b-20], TKT's annual and quarterly reports were required to contain such material information as necessary to make the required statements, in the light of the circumstances under which they were made, not misleading. On or about July 28, 2005, TKT was acquired by Shire Pharmaceuticals Group, PLC ("Shire") and became a wholly-owned subsidiary of Shire. As a result, TKT is no longer a publicly-traded company and no longer files periodic reports with the Commission.

STATEMENT OF FACTS

Replagal and its Significance for TKT

12. Replagal is intended to treat Fabry disease, a genetic disorder caused by the lack of a key enzyme. Fabry disease causes extreme pain, particularly in the hands and feet, cloudiness in the cornea of the eye, and hearing loss, and it may involve potentially life-threatening complications such as progressive kidney disease, heart attack, and stroke. The disease is extremely rare, with a U.S. patient population estimated at a few thousand, but treatment for the disease costs approximately $160,000 per patient annually. Replagal has been approved for use in some other countries and, at all relevant times, sales of Replagal abroad were TKT's only source of product revenue. Accordingly, the possibility that the FDA would approve

Replagal for sale within the U.S. was highly material to TKT.

13. In June 2000, TKT submitted an application for FDA approval for domestic sales of Replagal. TKT's application was based upon clinical trials whose principal objective, TKT hoped, was to demonstrate that Replagal had a treatment effect on the extreme pain suffered by patients with Fabry disease. About one week later, Genzyme Corp. ("Genzyme") filed a competing application for its drug, Fabrazyme. Genzyme's application was based upon surrogate marker data, an approach which is generally seen as a less desirable basis for obtaining FDA approval. Both applicants sought "orphan drug" status which, if granted, would result in a seven-year marketing exclusivity within the U.S. The existence of competing orphan drug applications was unprecedented and, because of the "winner-take-all" effect on the first applicant to receive FDA approval, any information about the FDA's attitude toward approval of Replagal would be watched closely by investors. As one analyst described the situation, "It's an amazingly high stakes poker game [TKT] is playing with [Genzyme] – if either company has a glitch in front of the FDA panel, that company may have to wait seven years for another chance."

Replagal's Clinical Trials

14. TKT's pivotal study, called TKT 003, was conducted at the National Institutes of Health. As indicated above, the primary objective or endpoint of the study was to demonstrate that Replagal had a treatment effect on pain. Prior to the study, TKT and the FDA agreed that the primary efficacy analysis (that is, the primary analysis upon which TKT would rely to demonstrate Replagal's clinical benefit for pain) would be an analysis referred to as "area under the curve" or "AUC".

15. The level of confidence in a statistical result is expressed in terms of probability, often known as a "*p* value". Under statistical principles, the smaller the *p* value, the greater the level of certainty that the observed effect was not randomly induced, and a *p* value of 0.05 or less (indicating a 95% level of certainty that the observed effect was not randomly induced) is generally accepted as persuasive. A *p* value higher than 0.05 is not *per se* evidence of failure, but further analysis is needed to assess whether the drug at issue caused the observed effect.

16. In TKT's pivotal study, the *p* value of the AUC analysis for effect on pain was 0.19 – much worse than the desired level of 0.05 or less. Based on this result, the pivotal study failed to meet its primary objective. Subsequent analysis enabled TKT to reduce the asserted *p* value to 0.08, which was still worse than the desired level of 0.05 or less. Although the AUC analysis did not produce a result with a *p* value of 0.05 or lower, two secondary pain analyses yielded *p* values of 0.02 and 0.05, respectively.

May 2000 Meeting with Institutional Investor

17. In May 2000, Selden and other senior TKT executives met privately with an institutional investor who was considering a substantial investment in TKT. At that meeting, Selden and other TKT executives presented the complete results of the pivotal study, including the fact that the one of the *p* values of the AUC analysis was 0.08. Based on the information provided, the investor had sufficient information to conclude in an investment memorandum that the pivotal study had failed to meet its primary objective. Selden also acknowledged to this investor the significant risk that, in light of these results, the FDA would not approve Replagal. After disclosing this negative information to the institutional investor – who was bound by a confidentiality agreement to keep the bad news secret – Selden and TKT embarked upon a

campaign to mislead the investing public about Replagal's chances for FDA approval.

TKT's Misleading Statements at Conference in October 2000

18. In October 2000, TKT representatives made a presentation concerning the pivotal study to medical professionals and investors at a conference sponsored by the American Society of Human Genetics ("ASHG"). TKT's presentation included a slide show, and Selden had reviewed and approved each slide in advance.

19. TKT's presentation described the successful results of the pivotal study with reference to the secondary pain analyses but never mentioned that the primary efficacy analysis (the AUC analysis) had failed to show a benefit (because its *p* value was 0.19). To the contrary, one of the slides purported to show the results of the primary efficacy analysis with a *p* value of 0.02, much better than the desired level of 0.05 or less for demonstrating statistical significance. Although the pivotal study did produce a secondary pain analysis with a *p* value of 0.02, the presentation omitted to say that the *p* value of the primary efficacy analysis was 0.19, much worse than 0.02. Selden had personally decided that TKT's presentation should not include any account of the AUC analysis.

20. TKT's characterization of the pivotal study at the ASHG conference was materially misleading and created the false impression in the investment community that the pivotal study was an unqualified success. For example, one analyst wrote after the conference that "positive pivotal trial results for Replagal were presented at the [ASHG] in October 2000.... Results showed Replagal to be effective in achieving all primary and secondary endpoints, as well as being safe and well-tolerated."

The FDA's Negative January 2, 2001 Review Letter

21. FDA rules require the agency staff to provide a response, known as a "complete review letter", within six months after the filing of an application for approval of a drug. On January 2, 2001, TKT received a complete review letter from the FDA which explicitly stated that TKT had failed to demonstrate the clinical benefits necessary for FDA approval:

> The clinical study data you have provided do not provide substantial evidence of efficacy for [Replagal].... [A]dditional analyses or otherwise revised analyses of the clinical data you have submitted will be unable to address this deficiency. In order to provide substantial evidence of efficacy, we recommend that you conduct additional clinical studies and submit the results to [FDA].

The review letter explained that TKT had failed to demonstrate the efficacy of Replagal or even a statistically significant difference between the trial groups:

> The analysis of the primary endpoint dataset you submitted using the prospectively designed statistical test did not demonstrate a statistically significant difference between treatment groups (p=0.195). Thus, even if this were a valid analysis..., the trial failed to demonstrate efficacy on the prospective primary analysis.

The review letter also offered fundamental criticisms of TKT's handling of the study data:

> [T]he process used to select which values to include in the primary analytical dataset introduced unmeasurable bias and is both inappropriate and unacceptable. We thus conclude that there is no valid analysis of the primary endpoint of TKT003.

22. The January 2, 2001 review letter thus contained a detailed and unequivocal statement by the FDA that TKT's pivotal study was a failure, its methodology was flawed, its primary analysis had not demonstrated a treatment effect on pain with statistical significance, and TKT should conduct additional clinical trials if it hoped to obtain FDA approval for Replagal.

TKT's Misleading January 3, 2001 Press Release

23. On January 3, 2001, after the stock market had closed, TKT issued a press release announcing that the FDA had issued its complete review letter. The same day, TKT filed a current report with the Commission on Form 8-K incorporating the press release. Selden actively participated in drafting the press release, approved the final version of the release, and was quoted in it.

24. The January 3, 2001 press release stated that the FDA had asked for additional data and that TKT employees were working to provide the requested information. The press release was materially misleading because, among other things, it did not disclose that, far from just asking for more information, the FDA had informed TKT that the pivotal study failed to achieve its primary objective and had recommended that TKT conduct additional clinical trials. Even so, market reaction to the release was negative. On January 4, 2001, TKT shares closed at $33.25 per share, down 9% from the previous day's close of $36.56 per share.

25. Within days of the January 2001 press release, a senior executive in charge of clinical trials told Selden that the FDA's recommendation to conduct new studies was important enough to disclose. However, Selden dismissed those concerns, explaining that disclosure was not part of the executive's job, and refused to authorize disclosure of the FDA's recommendation.

26. On January 11, 2001, the FDA's negative view was reaffirmed when TKT's outside counsel spoke with a senior FDA official. The official reiterated the FDA's position that the clinical study was a failure and that the FDA wanted another study.

TKT's Misleading Form 10-K Filed on April 2, 2001

27. On April 2, 2001, TKT filed its annual report on Form 10-K for the year ended December 31, 2000. Selden participated in preparing the Form 10-K, and he signed it as the CEO of TKT.

28. The Form 10-K contained the same statements about the FDA's complete review letter that had appeared in the January 3, 2001 press release, plus some additional generic risk disclosures. These statements were materially misleading because, among other things, they failed to correct TKT's prior misstatements about the results of the clinical trials and because they failed to disclose that, far from just asking for more information, the FDA had informed TKT that its pivotal study was a failure and had recommended that TKT conduct additional clinical trials.

29. The Form 10-K also incorporated by reference the company's annual report to shareholders. The annual report included a letter from Selden concerning the Replagal application which stated that TKT employees "worked to provide the FDA the requested data," as if TKT had already satisfied the FDA's request for more information. This statement was materially misleading because, among other things, it failed to disclose that the FDA had told TKT that its pivotal study was a failure and had recommended that TKT conduct additional clinical trials.

30. In a sidebar appearing on the same page as Selden's letter to shareholders, the annual report stated that positive pivotal clinical results for Replagal demonstrated a reduction in pain, again failing to correct the prior misstatements about the results of the clinical trials and omitting to state that, in the FDA's view, the pivotal study's primary analysis was a failure.

April 26, 2001 Meeting with the FDA

31. On April 26, 2001, Selden and several other TKT executives met with the FDA staff to discuss the complete review letter. At the meeting, the FDA staff again stated that TKT had not demonstrated that Replagal was effective for the pain of Fabry disease and that its pain data was uninterpretable. The senior FDA official again characterized the pivotal study as a "failed study", criticized the results of a six-month follow-up study which TKT had recently submitted, criticized TKT's proposal for a new study because it contained the same design flaws as the pivotal study, and said that TKT needed to come up with other alternatives.

32. The TKT executives responded that the company was no longer going to seek FDA approval for Replagal on the basis of effect on pain. Contemporary writings by Selden and TKT's outside FDA lawyer, including correspondence to the FDA, used words such as "surrender," "moot" and "out of the picture" to describe TKT's proposed change in approach to the FDA application.

33. The remainder of the meeting focused on other ways in which Replagal might be approved. The FDA staff left open the possibility that additional clinical data from a study that had not then been completed, or surrogate marker data of the type being proposed by Genzyme for its competing drug, could lead to approval for Replagal on the basis of a predicted clinical benefit for kidney function. However, the FDA staff made clear that, as the agency had previously informed TKT, the company should not expect approval on the basis of the clinical data already submitted.

TKT's Misleading Form 10-Q Filed on May 14, 2001

34. On May 14, 2001, TKT filed its report on Form 10-Q for the quarter ended March 31, 2001. Selden reviewed and approved the Form 10-Q.

35. When describing the status of the FDA application for Replagal, the Form 10-Q repeated the grossly incomplete characterization of the FDA's complete review letter from the January 2001 press release and the April 2, 2001 Form 10-K, stating only that the FDA "requested further explanation in several areas and additional data." These statements were materially misleading because, besides failing to indicate that the FDA's complete review letter had labeled the pivotal study as a failure, TKT failed to report on the April 26, 2001 meeting, at which the FDA had dismissed the additional data submitted by TKT and questioned the methodology for its proposed new study, and at which TKT had admitted that it was no longer seeking approval for Replagal on the basis that it was effective for pain.

TKT's Misleading May 29, 2001 Press Release

36. On May 29, 2001, TKT issued a press release to publicize an article concerning the pivotal study which had been published in the *Journal of the American Medical Society*. Selden approved the final version of the press release, which had been prepared by TKT's head of investor relations.

37. The press release stated that patients receiving Replagal had a clinically significant reduction in pain. As a result, *Bloomberg* reported on June 5, 2001 that Replagal "markedly relieves pain and improves heart and kidney function."

38. The May 29, 2001 press release was materially misleading because it failed to include at least four critical and negative facts: (1) the *p* value for the pivotal study's primary

analysis was 0.19, much worse than the desired level of 0.05 or less and much worse than the 0.02 figure which TKT had misleadingly presented at the October 2000 ASHG conference; (2) the FDA had stated that the pivotal study was a failure; (3) the FDA had recommended additional clinical trials; and (4) based on the FDA's criticisms of its clinical trial results, TKT had informed the FDA that it was no longer seeking approval for Replagal on the basis of effect on pain.

May 30, 2001 Conference Call with the FDA

39. On or about May 30, 2001, several TKT executives, including Selden, had a conference call with the FDA staff to discuss their continuing review of data submitted by TKT. During this call, the FDA staff reaffirmed their position that TKT's data had failed to demonstrate a treatment effect and again recommended that TKT conduct additional controlled trials.

TKT's Misleading Public Filings from June 2001 through May 2002

40. On June 25, 2001, TKT filed with the Commission a Form 8-K updating its risk disclosure. On June 26, 2001, TKT filed with the Commission a prospectus supplement in connection with a public stock offering. Selden as the CEO of TKT had overall responsibility for both filings.

41. The Form 8-K and prospectus supplement contained similar language concerning Replagal. With respect to the FDA application, the supplement stated:

> The FDA letter stated that the data that we had provided was not adequate for approval of our BLA [Biologic License Application, the formal name for the Replagal application] at the time and requested additional information. In response to this letter, we have discussed our BLA with

> the FDA and have submitted additional data to the FDA. We expect that after the FDA has reviewed our additional data, it will either approve the BLA or decline to approve it. If it declines to approve our BLA, the FDA may request additional information, possibly including data from additional clinical trials.

These statements were materially misleading because, rather than merely requesting additional information, the FDA had explicitly informed TKT that the pivotal study was a failure and had recommended that TKT conduct additional clinical trials, and because, in light of the FDA's negative response, TKT had informed the FDA that it was withdrawing its claims about Replagal's effect on pain and was now relying on the drug's potential impact on kidney function as the basis for obtaining FDA approval.

42. TKT's subsequent public filings in 2001, for which Selden had overall responsibility as CEO, were similarly misleading. In the reports on Form 10-Q which it filed for the quarter ended June 30, 2001 (filed on August 14, 2001) and for the quarter ended September 30, 2001 (filed on November 14, 2001), TKT stated that, according to the FDA's complete review letter, "our BLA was not adequate for final approval action at the time of such letter" and "[t]here can be no assurance as to whether or when [the] application ... will be approved by the relevant regulatory authorities." These statements were materially misleading because, as shown above, Replagal's chances for FDA approval were actually much worse than indicated and TKT had withdrawn the primary basis for its application (Replagal's effect on pain).

43. TKT filed a prospectus and a Form 8-K updating risk disclosures in connection with other stock offerings on December 13, 20 and 21, 2001. These, as well as the Form 10-K for the year ended December 31, 2001 (filed on March 29, 2002), the Form 10-Q for the first

quarter of 2002 (filed on May 15, 2002), and the Form 10-Q for the second quarter of 2002 (filed on August 14, 2002), contained substantially the same disclosure, each of which was materially misleading for the reasons set forth in the preceding two paragraphs. Selden had overall responsibility for these filings as CEO of TKT.

Selden's Misleading Statements to Analysts from Fall 2001 to Spring 2002

44. From the fall of 2001 through the spring of 2002, Selden expressed unfounded optimism and failed to disclose material negative information about the Replagal application in response to direct inquiries from stock market analysts during quarterly conference calls. The question of whether the FDA had recommended new or additional studies was raised repeatedly during these calls. Each time, Selden provided evasive answers which gave the impression that the FDA had not recommended additional studies and that FDA approval on the basis of existing data was likely.

45. For example, in an October 29, 2001 conference call to discuss results of the quarter ended September 30, 2001, an analyst twice asked Selden whether the FDA had suggested additional clinical trials. Selden responded:

> At this point, we think the data that we've provided is already sufficient. And, we have spent a fair amount of time – and continue to spend a fair amount of time – discussing that data. And so, at this point, I don't believe additional trials are going to be required. I can't absolutely rule it out though – I just don't think they'll be required. I think that we have a great data package as it is.

These statements were materially misleading because, among other things, Selden failed to disclose that the *p* value for the primary analysis in the pivotal study was 0.19, much worse than the desired level of 0.05 or less, and that the FDA had repeatedly informed TKT that its trials

were a failure, that TKT should conduct additional clinical trials, and that TKT could not expect approval of Replagal based on the existing data. Further, Selden failed to disclose that, in light of the FDA's continued criticism of its pivotal trial data, TKT had informed the FDA that it was dropping its claim that Replagal was effective on pain and was now seeking approval only on the basis of effect on kidney function, a claim that would require continuing clinical trials. Moreover, these statements were far more optimistic than the negative information which Selden had disclosed to the institutional investor at their confidential meeting back in May 2000, and Replagal's chances for FDA approval had not improved since that meeting.

46. In a February 11, 2002 conference call to discuss year-end results, an analyst asked Selden whether any new trials had been initiated at the request of the FDA. Selden responded that "no trials have been initiated on FDA requirements." This statement was materially misleading for the same reasons cited in the preceding paragraph.

47. In April 2002, the FDA informed TKT that it was willing to consider approving Replagal using "surrogate markers," a form of approval that would require continuing clinical trials in order to demonstrate the clinical benefits that TKT had publicly reported it had achieved. However, the FDA requested substantial additional information, making clear to TKT management that FDA approval was not assured, even on this alternative basis.

48. In a May 2, 2002 conference call with analysts to discuss results for the quarter ended March 31, 2002, Selden optimistically stated, "We believe that the approval of Replagal in the U.S. remains a 'when,' not 'if', proposition." When asked for a more detailed description of the FDA discussions, Selden stated that the conversations with the FDA were very reasonable and were getting better and better. These statements were materially misleading because, among

other things, Selden failed to disclose that the FDA had been telling TKT since January 2001 that Replagal could not be approved based on existing data and that, as recently as April 2002, the FDA had made clear that approval was not assured.

Postponement of the September 2002 Advisory Committee Meeting

49. In early summer 2002, the FDA scheduled an advisory committee meeting for September 26-27, 2002 to review the competing applications by TKT and Genzyme. Such meetings are typically the last step before an FDA decision on approval, and the meetings involve committee members, guests and advisors. Briefing materials are usually posted on the FDA's public Website the day before the meeting.

50. The FDA's briefing materials, consistent with all of their prior statements to TKT, harshly criticized TKT's clinical data, particularly the pain data, as well as TKT's methodology and results, and indicated that the FDA staff could not interpret the pain data submitted and could not draw any conclusions with respect to effect on pain. The FDA materials concluded that the purported kidney benefits of Replagal depended entirely on a "physiologically improbable" change occurring entirely during the 24th week of the study, and that other analyses, including the cardiac data, generally showed no treatment effect.

51. On September 11, 2002, TKT's outside attorney wrote to the FDA alleging that four invited advisory committee guest experts were biased. On September 20, 2002, the FDA abruptly cancelled the meeting. As a result, the FDA's negative briefing materials concerning Replagal were not made public at that time. The advisory committee meeting was later rescheduled for January 15-16, 2003.

Public Disclosure in October 2002

52. At no time prior to October 1, 2002 did TKT inform the public that: (1) the *p* value for the primary analysis in the pivotal study was 0.19, much worse that the desired level of 0.05 level or less and much worse than the 0.02 figure which TKT had misleadingly presented at the October 2000 ASHG conference; (2) the FDA had stated that the pivotal study was a failure; (3) the FDA had recommended additional clinical trials; (4) based on the FDA's criticisms of its clinical pain results, TKT had informed the FDA that it was no longer seeking approval for Replagal on the basis of pain relief; and (5) TKT was now relying solely on Replagal's potential impact on kidney function, an impact to be demonstrated through surrogate marker data instead of proven clinical benefits.

53. On October 2, 2002 – after the stock market closed – TKT issued a press release announcing that the FDA found its pain data to be "uninterpretable" and that TKT had therefore withdrawn its claim that Replagal was effective against pain as a basis for seeking approval of Replagal. A few minutes later, Selden held a conference call with investors. He was repeatedly evasive when asked for further detail about the press release. However, he stated that discussions with the FDA leading to the announcement had occurred only during the past month. He also characterized the change in TKT's strategy for FDA approval as "moderate", asserting that TKT had decided "not to use the pain data as a basis for seeking approval *at this time*" (emphasis added). These statements were false because TKT had actually informed the FDA at least eighteen months earlier (in April 2001) that it was no longer seeking approval based on Replagal's effect on pain.

54. The stock market reacted strongly to TKT's disclosure of the major problems with its FDA application for Replagal. On October 3, 2002, TKT shares closed at $12.75 per share, down 61% from the prior day's close of $33.25 per share. Trading volume on October 3 was 22.8 million shares, whereas trading volume during the preceding month was typically less than 500,000 shares per day.

Subsequent Events

55. On January 15-16, 2003, the FDA advisory committee met to consider TKT's application for Replagal. By a vote of 15-0, the committee rejected the application on the basis of demonstrated clinical results. By a vote of 8-7, the committee rejected the application on the basis of surrogate markers, although the committee held out some prospect that the issue could be revisited with additional analysis. The FDA approved Genzyme's competing application, and Genzyme received a seven-year marketing exclusivity for its drug Fabrazyme.

56. Later in January 2003, the TKT board of directors established a committee to investigate certain management issues, including the handling of the Replagal application. In February 2003, Selden resigned as CEO, although he continued to receive an equivalent salary pursuant to a consulting agreement.

57. On January 12, 2004, TKT announced that it was ending its efforts to seek FDA approval for domestic sales of Replagal.

Selden's Sales of Transkaryotic Shares

58. During 2001 and the first half of 2002 – when he knew that he and TKT had disseminated false and misleading information concerning Replagal to the investing public –

Selden sold tens of thousands of shares of TKT stock.

59. On May 8, 2001, Selden sold 20,000 shares at $22.90 per share. This sale was only two weeks after the April 26, 2001 meeting at which the FDA staff had characterized TKT's pivotal study as a "failed study", had criticized the results of TKT's six-month follow-up study, had criticized TKT's proposal for a new study because of its design flaws, and had stated that TKT needed to come up with other alternatives.

60. On September 20-21, 2001, Selden sold 20,000 shares: 10,000 shares at $24.43 per share and 10,000 shares at $25.05 per share. These sales were one month after TKT had filed a materially misleading Form 10-Q which failed to disclose that the FDA had told TKT that the pivotal trial was a failure and had recommended that TKT conduct additional clinical trials, and which also failed to disclose that, in light of the FDA's negative response, TKT was no longer basing its application on Replagal's effect on pain and was relying instead solely on Replagal's potential impact on kidney function.

61. On November 1, 2001, Selden sold 30,000 shares at $37.07 per share. This sale was one month after TKT had filed another materially misleading Form 10-Q which failed to disclose that the same negative information.

62. On February 14, 2002, Selden sold 20,000 shares at $37.33 per share. This sale was three days after a conference call with analysts in which Selden had once again concealed the FDA's recommendation that TKT conduct additional clinical trials and TKT's decision to withdraw its claim that Replagal had an effect on pain.

63. As demonstrated by the market reaction to the negative information about Replagal that was ultimately disclosed on October 2, 2002, the false and misleading information

previously in the public realm had kept TKT's stock price artificially inflated since at least October 2000. Thus, Selden benefitted by selling TKT shares at artificially inflated prices before the negative news was made public.

64. Based on the closing price of TKT stock after the first day of trading after the negative news had been announced on October 2, 2002, Selden was unjustly enriched in the amount of $1,664,400.

FIRST CLAIM FOR RELIEF
(Violation of Section 10(b) of the Exchange Act and Rule 10b-5)

65. The Commission repeats and realleges paragraphs 1- 64 above.

66. As set forth above, Selden made direct statements to investors and market participants, authorized other TKT employees to make statements to the public concerning Replagal, exercised control over all significant disclosure decisions by TKT, signed TKT's materially misleading Forms10-K for 2000 and 2001, authorized TKT's offerings of securities using prospectuses that were materially misleading, and offered and sold his own shares to public investors. He knew or was reckless in not knowing that these filings and other public statements were materially misleading because, among other things, they contained false and misleading statements regarding Replagal's clinical results and the FDA application and they omitted material information necessary to make statements made not misleading.

67. By reason of the foregoing, Selden, directly or indirectly, acting intentionally, knowingly or recklessly, by use of the means or instrumentalities of interstate commerce or of the mails, in connection with the purchase or sale of securities: (a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or omitted to state a material fact

necessary to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices or courses of business which operated as a fraud or deceit upon certain persons, including purchasers or sellers of TKT's securities.

68. As a result, Selden violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5], and his violations involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements and resulted in substantial losses or significant risk of substantial losses to other persons, within the meaning of Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)].

SECOND CLAIM FOR RELIEF
(Violation of Section 17(a) of the Securities Act)

69. The Commission repeats and realleges paragraphs 1- 68 above.

70. As set forth above, Selden made direct statements to investors and market participants, authorized other TKT employees to make statements to the public concerning Replagal, exercised control over all significant disclosure decisions by TKT, signed TKT's materially misleading Forms10-K for 2000 and 2001, authorized TKT's offerings of securities using prospectuses that were materially misleading, and offered and sold his own shares to public investors. He knew or was reckless in not knowing that these filings and other public statements were materially misleading because, among other things, they made false and misleading statements regarding Replagal's clinical results and the FDA application, and that material information necessary to make statements made not misleading was omitted.

71. By reason of the foregoing, Selden, directly or indirectly, acting intentionally, knowingly or recklessly, by use of the means or instruments of transportation or communication

in interstate commerce or by the use of the mails, in the offer or sale of securities: (a) employed devices, schemes or artifices to defraud; (b) obtained money or property by means of untrue statements of material fact or omissions to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in transactions, practices or courses of business which operated or would operate as a fraud or deceit upon certain purchasers, including purchasers of TKT's securities.

72. As a result, Selden violated Section 17(a) of the Securities Act [15 U.S.C. §77q(a)], and his violations involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements and directly or indirectly resulted in substantial losses or significant risk of substantial losses to other persons, within the meaning of Section 20(d) of the Securities Act [15 U.S.C. §77t(d)].

THIRD CLAIM FOR RELIEF
(Aiding and Abetting TKT's Violations of
Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13)

73. The Commission repeats and realleges paragraphs 1- 72 above.

74. TKT's annual reports to the Commission on Form 10-K for 2000 and 2001, its quarterly reports to the Commission on Form 10-Q for the first quarter of 2001 through the second quarter of 2002, and certain reports of current events filed as part of Forms 8-K materially misstated facts, and omitted to state material facts necessary to make statements made not misleading, relating to Replagal and the FDA application process. As a result, TKT violated Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 and 240.13a-13].

75. As set forth above, Selden signed certain of TKT's materially misleading filings with the Commission and substantially participated in preparing each of those public filings.

76. By reason of the foregoing, Selden provided knowing and substantial assistance to TKT's filing of materially misleading reports to the Commission.

77. As a result, Selden aided and abetted TKT's violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13.

PRAYER FOR RELIEF

WHEREFORE, the Commission requests that this Court:

A. Enter a permanent injunction restraining Selden and each of his agents, servants, employees and attorneys and those persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in violations of:

1. Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5];

2. Section 17(a) of the Securities Act [15 U.S.C. §77q(a)]; and

3. Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 and 240.13a-13];

B. Order Selden to disgorge all unlawful benefits received, including his unjust enrichment from his sales of TKT shares during the relevant period and, as appropriate, salary, bonus and other compensation received from TKT;

C. Order Selden to pay an appropriate civil penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)];

D. Enter an order, pursuant to Section 20(e) of the Securities Act [15 U.S.C. §77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)], barring Selden from serving as an officer or director of any issuer required to file reports with the Commission pursuant to Sections 12(b), 12(g) or 15(d) of the Exchange Act [15 U.S.C. §§78l(b), 78l(g) and 78o(d)];

E. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

F. Award such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Franklin C. Huntington

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District Administrator

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