[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 99-11690

D.C. Docket No. 98-02972 CV-DMM

OXFORD ASSET MANAGEMENT, LTD,

Plaintiff-Appellant,

LOWEY DANNENBERG & KNAPP, P.C.
PROFIT SHARING PLAN & TRUST, a.k.a.
Lowey Dannenberg, Bemporad & Selinger
P.C. Profit Sharing Plan,

Plaintiff,

versus

MICHAEL JAHARIS, DANIEL M. BELL,
et al.,

Defendants-Appellees.

No. 00-13220

D. C. Docket No. 98-02972-CV-DMM

OXFORD ASSET MANAGEMENT, LTD,

Plaintiff-Appellant,

LOWEY DANNENBERG & KNAPP, P.C.
PROFIT SHARING PLAN & TRUST, a.k.a.
Lowey Dannenberg, Bemporad &
Selinger P.C. Profit Sharing Plan,

Plaintiff,

versus

MICHAEL JAHARIS,
DANIEL M. BELL,
DUNCAN COCROFT,
JUAN F. RODRIGUEZ,
ROBERT E. BALDINI, et al.,

Defendants-Appellees.

Appeals from the United States District Court
for the Southern District of Florida

(July 16, 2002)

Before EDMONDSON, Chief Judge, FAY and GARWOOD,[*] Circuit Judges.

GARWOOD, Circuit Judge:

In this securities action (our No. 99-11690), plaintiff-appellant Oxford Asset Management, Ltd. (Oxford) appeals the dismissal of its 1933 Act claims.[1] We

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[*]Honorable William L. Garwood, U.S. Court of Appeals for the Fifth Circuit, sitting by designation.

[1]The motions to dismiss were made by defendants-appellees Kos Pharmaceuticals, Inc., Michael Jaharis, Daniel M. Bell, Duncan H. Cocroft, Juan F.

Affirm.

Oxford also appeals (in our No. 00-13220) the district court's award of $520,091.82 in legal fees to the Kos and Underwriter defendants. We affirm in part, reverse in part, and vacate and remand.

Facts and Proceedings Below

1. Appeal of the dismissal (No. 99-11690)

Kos Pharmaceuticals, Inc. (Kos) is a pharmaceutical company that develops and markets prescription drugs. Kos completed an initial public offering of its common stock on March 12, 1997, selling 4,772,500 shares at $15 per share. From October 21, 1997, to October 24, 1997, Kos completed a secondary offering of its common stock. On October 21, 1997, Kos filed the prospectus and registration statement for the secondary offering with the Securities and Exchange Commission. The offering price was $42.75. A total of 3,625,000 shares were sold in the secondary offering. Kos sold 1,085,000 shares. Michael Jaharis, Kos's founder, majority shareholder and chairman, sold 2,390,000 shares. Daniel Bell, Kos's president and chief executive officer, sold 150,000 shares.

Rodriguez, Robert E. Baldini, John Brademas, Steven Jaharis, Louis Lasagna, Mark Novitch, Frederick B. Whittemore (collectively, Kos Defendants) and Cowen & Company, Donaldson Lufkin & Jenrette, Salomon Smith Barney Holdings, Inc., SBC Warburg Dillon Read, Inc. (collectively, Underwriter Defendants).

Kos's only prescription drug product that was publicly available at the time of the secondary offering was an extended release niacin preparation called Niaspan. Niaspan was approved by the Food and Drug Administration in July 1997. Kos began shipping Niaspan to wholesalers in August 1997, and its sales force began detailing physicians in September 1997. On November 12, 1997, a Salomon Brothers analyst, Robert Uhl, released a report in which he slashed Kos's projected revenue for 1998 by half, from $92 million to $46 million, and changed the rating of Kos's stock from buy to hold. The next day, the price of Kos's stock plummeted from $30-15/16 to $16 9/16 per share. Uhl's report was premised on estimates[2] of the numbers of new and refill prescriptions for Niaspan during the first eight weeks that Kos's sales force marketed Niaspan. Uhl's conclusions were based on the assumption (that he and many other pharmaceutical analysts apparently share) that the number of new prescriptions filled during the eighth week of a new prescription drug product's initial marketing is particularly predictive of the market success the product will enjoy. The eighth week of Niaspan's marketing ended on October 31, 1997. Uhl stated that to achieve the original $92 million revenue projection, 5,000 new prescriptions of Niaspan during the eighth week were needed. IMS America estimated that only 708 new prescriptions for Niaspan were filled during the eighth week. Uhl explained that,

[2]These estimates were provided by IMS America.

considering the small size of Kos's sales force and their program of providing sample packs (which contain a three-week supply of Niaspan) to physicians, he would have been satisfied with 4,000 new prescriptions during week eight. Uhl concluded by noting that due to the sampling program and the anti-niacin bias of many physicians, Niaspan could be the first drug for which the "initial weekly prescriptions are not indicative of the product's ultimate success."

Kos's fifty-two page prospectus, filed October 21, 1997, explained the many risks of investing in Kos, among them: 1) "The Company's ability to successfully commercialize *Niaspan* will depend significantly on the acceptance of *Niaspan* by physicians and their patients"; 2) Niaspan has been designed to minimize the severity of the side effect of flushing, but most patients taking Niaspan will experience flushing and "there can be no assurance . . . that patients using Niaspan will not suffer episodes of flushing that they consider intolerable."; 3) Kos's clinical trials indicate that less than one per cent of patients taking Niaspan experience clinically significant elevations in liver enzymes, but physicians have historically been reluctant to prescribe niacin preparations because of such risk and it is possible that the actual incidence of hepatotoxicity will exceed one per cent; 4) Kos has fewer marketing resources than its competitors, a smaller sales force, and "limited" marketing experience, which could prevent Niaspan from achieving "market acceptance"; 5)

"during the initial months following the launch of *Niaspan*, many physicians may start only a limited number of selected patients on *Niaspan"*; 6) physicians' anti-niacin bias combined with the distribution of three-week starter packs (which are dispensed without prescription) may result in only a modest increase in Niaspan prescriptions for the first three to six months of its marketing; and 7) since its inception, Kos had lost about $80 million and there can be no assurance that Kos will ever achieve profitability.

On August 10, 1998, Oxford and Lowey, Dannenberg & Knapp, P.C. (Lowey) filed this suit in the northern district of Illinois. On December 7, 1998, the action was transferred to the southern district of Florida. Plaintiffs brought this action as a proposed class action.[3] Oxford proposed to represent plaintiffs that purchased Kos stock in the secondary offering. Lowey proposed to represent plaintiffs that purchased Kos stock on the open market between July 29, 1997, and November 13, 1997. The complaint alleged violations of sections 11(a), 12(a)(2) and 15 of the 1933 Act, 15 U.S.C. §§ 77(k)(a), 77l(a)(2) and 77(o), sections 10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§ 78(j)(b) and 78(t)(a), and Rule 10(b)(5), 17 C.F.R. § 240.10b-5. The complaint also alleges common law fraud, negligent misrepresentation and breach of

[3]The district court's dismissal of the complaint mooted the class certification issue. Thus, that issue was not resolved.

fiduciary duty. All of the causes of action in plaintiffs' original complaint are based on defendants' alleged material misrepresentations and omissions (in press releases, the prospectus, the registration statement, and other SEC filings) concerning the safety, efficacy, tolerability and sales volume of Niaspan. On January 7, 1999, the Kos defendants moved to dismiss the complaint pursuant to FED. R. CIV. P. 12(b)(6). The Underwriter defendants so moved on February 8, 1999. At the dismissal hearing, the plaintiffs advanced a new basis for recovery, namely that the prospectus should have disclosed the first six weeks of IMS America's estimates of Niaspan's prescription volume. In the interests of justice, the district court considered this as an amended claim. On May 19, 1999, the district court granted the motions to dismiss, holding that the omission of the prescription volume data was immaterial as a matter of law and that plaintiffs' allegations as to the safety, efficacy, tolerability and sales volume of Niaspan were mere legal conclusions masquerading as facts. On August 3, 1999, the district court dismissed the complaint with prejudice.

Oxford appeals the dismissal of its 1933 Act and the common law claims of fraud and negligent misrepresentation, but admits that dismissal of the common law claims was proper if dismissal of the federal claims was proper. Oxford does not appeal the dismissal of its 1934 Act claims. Lowey, which was not named as a plaintiff in the 1933 Act counts, does not appeal to this Court.

2. Appeal of the attorneys' fees award (No. 00-13220)

On July 6, 1999, the Kos defendants moved for sanctions pursuant to the Private Securities Litigation and Reform Act (PSLRA) and Rule 11. On July 16, 1999, the Underwriter defendants so moved. On January 31, 2000, the district court granted the motions for sanctions, finding that the plaintiffs were deliberately indifferent to the lack of factual support for the allegations in the complaint and that, therefore, the complaint was objectively frivolous. On May 22, 2000, the district court awarded $502,576.82 in attorney's fees to the defendants. On June 7, 2000, the district court clarified its earlier order and increased the award to $520,091.82. Oxford appeals the district court's grant of defendants' motions for sanctions and its award of attorney's fees to defendants.

3. Consolidation

This Court subsequently granted Oxford's motion to consolidate the appeals for oral argument.

Discussion

I. Standard of Review

This court reviews *de novo* the dismissal of a complaint pursuant to Rule 12(b)(6). *Harris v. Ivax Corp.*, 182 F.3d 799, 802 (11th Cir. 1999). The plaintiff's factual allegations are accepted as true. *South Florida Water Management Dist. v.*

Montalvo, 84 F.3d 402, 406 (11th Cir. 1996). Dismissal is not appropriate unless it is plain that the plaintiff can prove no set of facts that would support the claims in the complaint. *Id*. However, conclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts will not prevent dismissal. *Id*.; *Fernandez-Montes v. Allied Pilots Ass'n*, 987 F.2d 278, 284 (5th Cir. 1993).

II. District Court's Consideration of Documents Attached to the Kos Defendants' Motion to Dismiss

In resolving the defendants' motions for dismissal, the district court considered the prospectus, which was attached to the complaint; Kos's 10-Q for the period ending September 30, 1997, which was required to be and was actually filed by Kos with the SEC; the Uhl report, quoted in the complaint; a July 29, 1997, press release, quoted in the complaint; a November 12, 1997, press release, quoted in the complaint; a 1996 article about Niaspan, quoted in the complaint; and the Niaspan package insert. All of these documents were attached to the Kos defendants' motion to dismiss. Oxford contends that consideration of such "matters outside of the pleadings" was improper on a motion to dismiss, and that the district court should have converted the motion to dismiss into one for summary judgment. We disagree. In a motion to dismiss a securities action, a court may consider the contents of public disclosure documents which are required to be filed with the SEC and are actually so filed. *Bryant v. Avado*

Brands, Inc., 187 F.3d 1271, 1277-78 (11th Cir. 1999). The documents may only be considered to show their contents, not to prove the truth of matters asserted therein. Neither do we find error in the district court's use of the Uhl report, the press releases or the 1996 article. *See Harris v. Ivax Corp*., 182 F.3d 799, 802 n.2 (11th Cir. 1999). The package insert for Niaspan was not referred to in the complaint, but the district court reasoned that its contents could be judicially noticed because "it is a matter of public record (part of the FDA public file), is included in every package of Niaspan, and also listed in the Physician's Desk Reference." The district court specifically stated it was not accepting the facts asserted in the insert as true, and appears only to have used it to show the bare existence of a clinical study which stated that Niaspan could increase HDL cholesterol by 32%. We find no error in this.

III. Section 11 Claims

Section 11(a) of the 1933 Act, 15 U.S.C. § 77(k), provides a cause of action to purchasers of securities where: "any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading . . . ." Section 11 extends liability to every person who signed the registration statement, the issuer's directors, and every underwriter. Section 12(a)(2)

of the 1933 Act, 15 U.S.C. § 77(l), imposes liability upon one who sells a security "by means of a prospectus or oral communication, which includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading . . . ." Section 15 of the 1933 Act, 15 U.S.C. § 77(o), extends Section 11 and 12 liability to persons who control entities liable under those sections. Thus, to state a claim under any of these sections, Oxford must properly allege a material misrepresentation or a material omission.

A. Omission of Prescription Volume Data

To avoid dismissal of a section 11 omission claim, plaintiffs must properly allege: 1) the prospectus contained an omission; 2) the omission was material; 3) defendants were under a duty to disclose the omitted material information; and 4) that such information existed at the time the prospectus became effective. *Cooperman v. Individual, Inc.*, 171 F.3d 43, 47 (1st Cir. 1999). The complaint (as amended at oral argument before the district court) alleges that: 1) Kos possessed the first seven weeks of Niaspan's prescription volume history; 2) this information was material; 3) issuers have a duty to disclose all material information in the prospectus; and 4) the absence of the prescription volume information rendered the prospectus misleading.

1. Materiality

The district court assumed that Kos was in possession of "several weeks" of information, but held that, because Uhl based his conclusions almost entirely on the number of new prescriptions for Niaspan filled during the eighth week (which occurred after the close of the offering), the partial, preliminary information Kos possessed was not material. The district court also noted the prospectus's mention of several obstacles to the market acceptance of Niaspan, including a specific warning that Niaspan's sales may grow slowly during the first three to six months of its marketing.

The test of materiality is well known. "[T]o fulfill the materiality requirement 'there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available.'" *Basic Incorporated v. Levinson*, 108 S.Ct. 978, 983 (1988) (quoting *TSC Industries, Inc. v. Northway, Inc.*, 96 S.Ct. 2126, 2132 (1976)). The trier of fact usually decides the issue of materiality. *Cooperman*, 171 F.3d at 48-49. Only if the lack of importance of the omission is so plain that reasonable minds cannot differ thereabout is it proper for the court to pronounce the omission immaterial as a matter of law. *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 161-64 (2nd Cir. 2000); *Cooperman*, 171 F.3d at 49.

We are willing to assume, at the dismissal stage, that Kos possessed whatever

prescription volume information existed. We do not know how quickly the IMS America estimates became available, but some delay or lag time seems inevitable. The prospectus was filed October 21, 1997. Oxford purchased its stock on October 24, 1997, the last day of the seventh week of Niaspan's marketing. Thus, Oxford's assertion that Kos possessed seven weeks of data is literally unbelievable. Even though Kos probably did not possess even six weeks of information, for dismissal purposes we will assume that it did.

Realizing that no argument could be made that Kos possessed the critical eighth week of information, Oxford characterizes the partial data as a material trend. During the sixth week, there were 498 new prescriptions for Niaspan. Oxford's point appears to be that, considering the first six weeks of data, it was very unlikely that Niaspan would achieve the Uhl goal of 4,000 to 5,000 new prescriptions per week, and therefore a reasonable investor would consider the total mix of information significantly altered by the data's inclusion. The district court correctly observed that the prospectus explains the several reasons why Niaspan may start more slowly than other drugs. However, the immateriality of the six weeks of prescription information is arguably not so plain that reasonable minds could not differ about it. Accordingly, we will assume for purposes of the motion to dismiss that the six weeks of prescription volume information was material.

2. Duty to Disclose

Oxford asserts three bases for Kos's duty to disclose the prescription data in the prospectus: 1) a general duty to disclose, in the prospectus, all information material to the offering; 2) Item 303(a)(3)(ii) of regulation S-K, 17 C.F.R. § 229.303(a)(3)(ii); and 3) the omission of the prescription data rendered the prospectus materially misleading. We address each of these arguments in turn.

(a.) General Duty

Oxford first argues that issuers have a duty to disclose, in the prospectus, *all* information material to the offering. We disagree. Section 11(a) only makes actionable the omission of a material fact *required to be stated in the prospectus or necessary to make the statements in the prospectus not misleading*. To hold that section 11(a) imposes liability unless the prospectus includes *all* material facts is simply to wholly ignore and render superfluous that section's qualifying language "required to be stated therein or necessary to make the statements therein not misleading." This we may not do. Moreover, considering that materiality will usually be an issue for the trier of fact, to require *all* material information to appear in the prospectus would, like setting the threshold for materiality too low, result in registrants burying the "shareholders in an avalanche of trivial information–a result that is hardly conducive to informed decisionmaking." *Basic Inc. v. Levinson*, 108

S.Ct. 978, 983 (1988) (quoting *TSC Industries, Inc. v. Northway, Inc.*, 96 S.Ct. 2126, 2132 (1976)). We join with the First Circuit in recognizing that the "mere possession of material nonpublic information does not create a duty to disclose it" and that the duty question is properly stated as "whether the defendants had a specific obligation to disclose information of the type that the plaintiffs complain was omitted from the registration statement and prospectus." *Shaw v. Digital Equipment Corp.*, 82 F.3d 1194, 1202 (1st Cir. 1996). If the prospectus contains all of the *material* information specifically required by the securities laws, does not contain an untrue statement of a material fact and if the statements therein are not materially misleading in any respect, there has been no material misrepresentation or material omission.

(b.) Item 303(a)(3)(ii)

In its reply brief, Oxford asserts, for the first time, that disclosure of the prescription volume estimates was required by Item 303(a)(3)(ii) of regulation S-K, 17 C.F.R. § 229.303(a)(3)(ii). While we need not consider this untimely argument, even if we did consider it, it, too, would fail.

Other circuits have considered whether or in what circumstances Section 11 liability may be premised upon the failure to disclose information required by Item 303. *See Oran v. Stafford*, 226 F.3d 275, 288 (3d Cir. 2000); *Steckman v. Hart Brewing Inc.*, 143 F.3d 1293, 1296 (9th Cir. 1998). However, we need not explore

those questions because we conclude that in any event Item 303 did not require that the prospectus disclose the first six weeks' prescriptions.

Item 303(a)(3)(ii) requires registrants to:

> "Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed."

Oxford argues that the prescription data constitutes a known trend that Niaspan was "not selling or being prescribed" and that, therefore, Item 303(a)(3)(ii) requires its disclosure. There are, at least, two independently sufficient reasons why this contention cannot be sustained.

The first element of the Item 303 disclosure test set forth in Securities Act Release 6835 requires management to assess whether the "known trend, demand, commitment, event or uncertainty [is] likely to come to fruition." Securities Act Release No. 33-6835, 1989 WL 192885 at *6 (S.E.C.). As regards trends, we interpret this element to require an assessment of whether an observed pattern accurately reflects persistent conditions of the particular registrant's business environment. It may be that a particular pattern is, for example, of such short duration that it will not support any conclusions about the registrant's business environment. Release 6835

states that management's assessment "must be objectively reasonable, viewed as of the time the determination is made." *Id*. We interpret this language as establishing a negligence standard.

Oxford's complaint says nothing about Item 303. Moreover, it does not allege facts that, if true, would support a finding of negligence as to Kos management's belief that the prescription data did not reflect that the uncertainties identified in the prospectus had been resolved against the marketability of Niaspan. This deficiency is highlighted by Uhl's discussion of Kos management's disagreement with his new projection, in which he specifically notes the experience and competence of Kos's management team and mentions several steps that could be taken to "help bolster awareness of the product." Uhl concludes with a significant admission: "Niaspan could be the first product of which we know where initial weekly prescriptions are not indicative of the product's ultimate success." The complaint alleges that management's assessment was incorrect and repeatedly emphasizes that, as to the issuer, Section 11 imposes strict liability for material omissions. However, in determining the existence of an omission based on Item 303's disclosure requirements, Release 6835 clearly established a negligence standard. Oxford's failure to allege facts from which the objective unreasonableness of Kos management's decision not to include the prescription information in the prospectus could be inferred forecloses

reliance upon Item 303 as a source of a duty to disclose that information.

A second, even clearer, barrier to Oxford's reliance upon Item 303(a)(3)(ii) is that it is primarily concerned with developments that render the registrant's reported results less indicative of the registrant's future prospects, a concern not implicated here. Instruction 3 to paragraph (a) provides:

"3. The discussion and analysis shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition. This would include descriptions and amounts of (A) matters that would have an impact on future operations and have not had an impact in the past, and (B) matters that have had an impact on reported operations and are not expected to have an impact upon future operations."

Item 303(a)(3)(ii) essentially says to a registrant: If there has been an important change in your company's business or environment that significantly or materially decreases the predictive value of your reported results, explain this change in the prospectus. The obvious focus is on preventing the latest reported results from misleading potential investors, thereby promoting a more accurate picture of the registrant's future prospects.

Here, the prescription data was used by a market analyst to make a projection. This projection disappointed the market, which had been very optimistic about Kos because of the market analyst's prior, more favorable projection. However, *the market's disappointment in the changed revenue projection did not render Kos's*

previously reported results unreliable. *See Glassman v. Computervision*, 990 F.3d 617, 632 (1st Cir. 1996). The prospectus stated that Kos had lost almost $80 million since its inception and that there could be no assurance that the company would ever be profitable. If booming Niaspan sales had carried Kos for the previous several reported quarters but suddenly and significantly declined, a potential investor could be mislead by those reported results unless Kos disclosed the importance of Niaspan and discussed the downward trend in Niaspan sales. That is the type of situation Item 303(a)(3)(ii) was designed to address. But that is *not this* case. Because the prescription information did not render Kos's reported results any materially less indicative of the company's future prospects, Item 303(a)(3)(ii) does not require its disclosure.[4]

(c.) Misleading Prospectus

Oxford also argues that Kos had a duty to include the prescription data because the prospectus was materially misleading without it. We conclude that the prospectus

[4]We need not address whether Item 303(a)(3)(ii) required Kos to discuss Niaspan's market acceptance as an uncertainty. Kos clearly did so, and the thrust of Oxford's complaint is that Kos's treatment of Niaspan's future as an uncertainty was misleading. We note, however, that Item 101 of Regulation S-K, 17 C.F.R. § 229.101, appears to require this kind of discussion. Item 101 requires a description of the registrant's business, including a discussion of the registrant's products. Item 101(c)(1)(ii) requires a narrative description of the status of products being developed and new products.

thoroughly explained the risks involved in marketing Niaspan, and specifically warned that Niaspan might have a slow start. The Uhl report mentioned the possibility that Niaspan's first *eight* weeks may not be indicative of its ultimate market success. In view of all of this, the *six* weeks of prescription data, which represents only a *very preliminary* indication that Niaspan was staring slowly, did not have to be included in the prospectus. Such indication did not render materially misleading the prospectus's treatment of the market acceptance of Niaspan as an uncertainty.

In sum, we hold that Kos had no duty to disclose the referenced prescription data in the prospectus.

B. Misrepresentation of Niaspan's Efficacy

The prospectus stated that Niaspan could increase HDL cholesterol by 22% to 32%. Paragraph 47 of the complaint alleges that Niaspan cannot increase HDL cholesterol by up to 32%. The only facts pleaded in support of this bald assertion were the results of two of the four clinical studies relied upon by Kos in stating the 22% to 32% range. These two studies showed that Niaspan could increase HDL by 23% and 26%. Kos claims that one of the four studies shows Niaspan can increase HDL by 32%. A study noting such results is referred to in Niaspan's package insert. At oral argument before this Court, Oxford complained that it had never seen this study and reiterated its view that the 32% claim was false.

The fatal flaw in Oxford's position is the complaint's failure to allege facts that support the conclusion that the 32% claim is false. As mentioned, the complaint only references two studies, both of which are consistent with the 22% to 32% *range* set forth in the prospectus. The district court held that because both numbers from these sources were in the range quoted in the prospectus, neither was evidence that this range was false. We agree. No two clinical trials will produce exactly the same results. Cherry-picking two studies that show average HDL improvement of less than 32%, even significantly less, does not tend to establish that the stated *range* is false.

C. Misrepresentation of Niaspan's Safety

The prospectus stated that only about 1% of patients taking Niaspan experienced clinically significant increases in liver enzymes and that the threshold for clinical significance was three times the normal level.[5] Paragraph 51 of the complaint alleges that "Niaspan use elevated liver toxicity to an intolerable and unsafe level. By defining clinically significant elevations in liver function tests as 'greater than three times the upper limit of normal,' Kos misrepresented the industry standard as to what constitutes tolerable and safe levels of liver toxicity."

The complaint does not plead the existence of facts that would support its

[5]When liver cells are destroyed, certain enzymes that were contained within those cells spill into the bloodstream. Elevation of these enzymes indicates that liver cells are dying at an accelerated rate.

allegation that Niaspan elevates liver enzymes to an intolerable level. The complaint fails to articulate what the proper threshold for clinical significance is, although, after the motions to dismiss were granted, Oxford asserted, in its response to the defendants' motions for sanctions, that it is twice the normal level. No studies are referred to, no specific facts are pleaded that indicate any basis for Oxford's bald assertions that Niaspan elevates liver enzymes to an intolerable level or that Kos employed the wrong standard in its clinical trials.

In its response to defendants' motions to dismiss, Oxford added an additional "safety" claim, which the district court, in the itnerest of fairness, considered. This claim was that the prospectus is misleading because it did not state that 88% of patients taking Niaspan would experience flushing. As regards the flushing issue, the prospectus stated: "Although most patients taking Niaspan will sometimes flush, the formulation and dosing regimen for Niaspan have been designed to maximize patient acceptance and minimize the occurrence of flushing. There can be no assurance, however, that patients using Niaspan will not suffer episodes of flushing that they consider intolerable." In view of this and other candid statements about the side effect of flushing that appear in the prospectus, we hold that the prospectus was not misleading in this respect.

D. Misrepresentations of Niaspan's Tolerability

Paragraph 63 of the complaint observes that subjects in Kos's clinical trials were given 2,000 mg of Niaspan per day and alleges that "only a tiny fraction of the market could tolerate such a high dose of Niaspan." The complaint alleges that the clinical studies were "rigged" because Kos "only administered high doses of Niaspan to subjects who were predetermined to have a high tolerance." The complaint does not even specify what side effect prevents all but a tiny fraction of the market from taking Niaspan. When, at oral argument, the district court asked for an explanation of the charge that the clinical trials the FDA based its approval on were "rigged", Oxford's response was that there must be some reason "why physicians don't prescribe it." We agree with the district court that the complaint fails to plead any factual basis for the charges found in paragraph 63.

E. Misrepresentation of $1.5 Million in September 1997 Sales

The prospectus estimated that Kos reaped $1.5 million in revenue from the sale of Niaspan during the quarter ending September 30, 1997. On November 12, 1997, Kos filed its 10Q for that quarter, which, consistent with the prospectus's estimate, stated that Kos had realized initial product sales of Niaspan in the amount of $1.5 million. Paragraph 57 of the complaint alleges that the claim of $1.5 million in sales of Niaspan was false. The complaint does not allege any facts that support the conclusion that Kos had not sold $1.5 million in Niaspan by September 30, 1997, or

that the $1.5 million figure was inaccurate in any respect. Paragraph 58 of the complaint alleges that, even if $1.5 million in sales did occur, such sales did not result from prescriptions, but rather from pipeline filling sales to wholesalers. The complaint alleges that Kos's statement, in the prospectus, that it "intends to market Niaspan directly to the specialist physicians within the cardiovascular market" somehow rendered the prospectus misleading without a statement clarifying that the $1.5 million in sales was to wholesalers.

The prospectus stated that Kos's sales force was providing "as a promotion item" three-week starter packs of Niaspan to physicians, which "generally are dispensed without a prescription", and that sales to warehouses commenced before the sales force began to market Niaspan to physicians. It is common knowledge in the pharmaceutical industry that "direct marketing" to physicians entails promoting the drug product to physicians and encouraging them to prescribe it for their patients. The prospectus simply does not state or imply that the $1.5 million resulted from prescriptions or direct sales of Niaspan to physicians. The prospectus also plainly stated that Kos was selling Niaspan to wholesalers. The complaint has failed to plead facts that, if true, would constitute a misrepresentation of sales revenue, and does nothing more than offer the legal conclusion that the representation in the prospectus was somehow misleading.

We hold that the dismissal of Oxford's federal claims, with prejudice, was entirely proper.

IV. Attorneys' Fee Award

15 U.S.C. §§ 77Z-1(c) and 78u-4(c) require the district court, upon final adjudication of claims brought under the 1933 and 1934 Acts, respectively, to include specific findings as to each party's and each attorney's compliance with FED. R. CIV. P. 11(b). These subsections also provide for a presumption that the proper sanction for a Rule 11(b) violation is an award, to the opposing party, of the reasonable attorney's fees and costs incurred as a direct result of the violation.

The district court found that Oxford's legal arguments were not frivolous and that Oxford performed an adequate investigation before filing its complaint, but that after such investigation a reasonable attorney would have realized that there was no evidentiary support for any of the allegations in the complaint and that such support was unlikely to be unearthed by further investigation or discovery. The district court concluded that the plaintiffs were deliberately indifferent to the lack of evidentiary support for the conclusory allegations in the complaint and that plaintiffs' claims were objectively frivolous under FED. R. CIV. P. 11(b)(3). The district court awarded $335,686.55 in fees and expenses to the Kos defendants and $184,405.27 to the Underwriter defendants. The plaintiffs and their counsel were each responsible for

half of the award, or $260,045.91.

"An appellate court reviews all aspects of the district court's Rule 11 determination for an abuse of discretion." *WorldWide Primates, Inc. v. McGreal*, 87 F.3d 1252, 1254 (11th Cir. 1996).

The district court concluded that plaintiffs' claim regarding the omission of the prescription data was "not well grounded in fact" because it was essentially an amended claim that was advanced for the first time at the dismissal hearing. In a footnote, the district court observed that: "Just because, 'in the interests of justice,' the Court decided to entertain this 'essentially amended claim' in ruling upon the motions to dismiss, does not mean that the Court has to read Plaintiffs' presentation at oral argument into the Complaint when judging whether Plaintiffs' claims were well grounded in fact." It is true that the complaint's reference to the Uhl report is only in the context of showing that the $1.5 million in Niaspan sales that occurred in September 1997 did not result from prescriptions, and that the plaintiffs did not allege that the prescription data should have been included in the prospectus until the dismissal hearing. The district court appears to have concluded that it is proper to consider such a claim in a motion to dismiss, but then fail to consider the factual allegations advanced in support thereof when resolving a motion for sanctions. The district court certainly did not have to consider the claim in resolving the motions to

dismiss. However, in finding that the thus amended claim was without evidentiary support simply because it was not advanced until the dismissal hearing (and without considering the factual allegations advanced in support of the claim at such hearing), the district court abused its discretion. We conclude that this claim had factual support. The claim fails because we reject Oxford's legal argument as to a registrant's duty to disclose the prescription data under Item 303(a)(3)(ii). This argument, though ultimately rejected, was not frivolous and was adequately supported by the pleaded facts concerning the data and its predictive value.

As to plaintiffs' other claims, we cannot say that the district court's findings as to their lack of evidentiary support represented an abuse of discretion. Therefore, the district court's finding that plaintiffs and their counsel violated Rule 11(b)(3) in advancing these other claims is affirmed.

As to the award itself, plaintiffs complain that: 1) the total number of hours billed by the defendants–1900–was not reasonable considering the claims were dismissed before any discovery took place; 2) some of the defendants' billing records are redacted, vague and do not specify exactly what work the attorney was performing; and 3) the defendants failed to provide hourly rates for a significant portion of the time billed, instead submitting a chart of their average hourly rates.

"[T]he starting point in any determination for an objective estimate of the value

of a lawyer's services is to multiply hours reasonably expended by a reasonable hourly rate." *Norman v. Housing Authority of the City of Montgomery*, 836 F.2d 1292, 1299 (11th Cir. 1988). Our precedent places the burden of documenting the appropriate hours and hourly rates on the fee applicant. *Id.* Oxford does not challenge the reasonableness of the hourly rates submitted by the defendants. As to the number of hours submitted, "fee counsel should have maintained records to show the time spent on the different claims, and the general subject matter of the time expenditures ought to be set out with sufficient particularity so that the district court can assess the time claimed for each activity. A well prepared fee petition also would include a summary, grouping the time entries by the nature of the activity or the stage of the case."[6] *Id.* at 1303 (citation omitted).

Under this standard, both of the fee applications presented to the district court were likely inadequate. Both contain several time entries that are so redacted that it is impossible to tell (beyond "research") what the attorney was doing. Most of the entries contain some description of the work performed, but there is very little information as to which claim the work pertained to. Thus, the district court could not have determined how many hours were spent defending each claim or accomplishing

[6]We view a summary as desirable, but not necessary. We read "activity" as referring to a particular task, such as drafting a motion to dismiss.

any particular task. Therefore, it could not have assessed whether any hours should be excluded (as redundant or unnecessary) or the hourly rate reduced (because the number of hours submitted for a particular activity was excessive). *Id*. at 1301, 1305-06.

Notwithstanding these difficulties, a district court faced with an inadequate fee application must still award a reasonable fee. *Id*. at 1303. Because courts are considered experts in this area, it is usually proper for the district court to award reasonable fees without an evidentiary hearing or additional pleadings. *Id*. Although the district court enjoys wide discretion in determining a reasonable fee, "[t]he court's order on attorney's fees must allow meaningful review–the district court must articulate the decisions it made, give principled reasons for those decisions, and show its calculation." *Id*. at 1304.

Here, the district court found the total number of hours submitted by the defendants to be reasonable. The only explanation for this was that the "factual and legal complexities of this case" rendered "unpersuasive" plaintiffs' argument that the number of hours submitted was excessive. It is true that "[s]worn testimony that, in fact, it took the time claimed is evidence of considerable weight on the issue of the time required in the usual case and therefore [to justify a reduction of the hourly rate], it must appear that the time claimed is obviously and convincingly excessive under

the circumstances." *Perkins v. Mobile Housing Board*, 847 F.2d 735, 738 (11th Cir. 1988). However, in *American Civil Liberties Union of Georgia v. Barnes*, 168 F.3d 423, 430 (11th Cir. 1999), we clarified *Perkins*: "[G]iving weight to sworn statements of fee applicants does not mean accepting those statements as gospel. Courts should not delegate their duty to examine and judge the reasonableness of fee applications to the applicants." Among other things, this means that in order to satisfy *Norman's* "meaningful review" requirement, the district court must respond to s*pecific objections* to a fee application with more than conclusory statements of reasonableness. *Id*. at 428.

We conclude that the district court did not abuse its discretion in refusing to reduce the hourly rate. It is true that the only explanation proffered by the district court–the factual and legal complexity of the case–is less than compelling. However, Oxford's objection to the total number of hours submitted was not specific. *Barnes* rested, in part, on the principle that "[t]he more specific the objections to a fee application are, the more specific the findings and reasons for rejecting those objections can be." *Id*. at 428-29. Oxford did not propose what number of hours would have been reasonable, and therefore could not recommend any particular adjustment to the hourly rate. Oxford simply asserted, in the most general manner, that defense counsel took too many hours getting the case dismissed. Such a

boilerplate objection merits no more of a boilerplate response than that given.

Second, Oxford complains that the redacted time entries made it impossible for it to determine whether any of the work performed by defense counsel was redundant or unnecessary. While some entries were severely redacted, most were not. The district court concluded that surrounding time entries "demonstrate that the time claimed in these entries was spent on this matter, either performing legal research or discussing the case with unidentified individuals." This finding was not an abuse of discretion. The district court did not address the issue of redundance, but we think that where, as here, there is no indication that fee counsel has failed to exercise billing judgment, the total amount of time spent on "research" is reasonable, and the number of entries that fail to contain details about what research is being performed is relatively small, it is within the district court's discretion to include those hours in the award. We caution, however, that where a significant number of entries are severely redacted or it appears that fee counsel has failed to use billing judgment, it may be an abuse of discretion to award fees based on the redacted entries.

Finally, Oxford complains that Kos's counsel has only submitted a chart of average hourly rates for a significant part of the time billed. Oxford advanced this argument before the district court. In response, Kos pointed out that the actual hourly billing rates (along with an unredacted version of most of the time entries) was

contained in Exhibit F of the record. That is indeed the case.

Oxford's other contentions regarding the award are so devoid of merit that it was not an abuse of discretion for the district court to fail to address them.

The only issue requiring remand is the proper apportionment of the award. The district court recognized that opposing parties are only entitled to attorney's fees and costs associated with defending frivolous claims. *Simon DeBartolo Group, L.P. v. Richard E. Jacobs Group, Inc.*, 186 F.3d 157, 166-67, 177 (2nd Cir. 1999). Accordingly, Defense counsel are entitled to fees and expenses incurred in defending against all claims except the claim that Kos should have included the partial, preliminary prescription sales data in the prospectus. We realize that because this claim was not advanced until oral argument at the hearing to dismiss, the amount of fees and expenses incurred in defending against it is probably small. Nevertheless, the law requires that the award not include such fees and expenses. The district court has wide latitude in determining how to apportion the award, but it must explain its decision such that it is capable of meaningful review.

Conclusion

For the reasons stated, the district court's dismissal of Oxford's federal claims, with prejudice, is affirmed. It follows that the district court's dismissal of Oxford's state and common law claims must also be affirmed.

The district court's finding that the plaintiffs and their counsel violated Rule 11(b)(3) by being deliberately indifferent to the lack of factual support for the claims asserted in the complaint is affirmed, except as to the amended claim concerning the omission of the preliminary prescription sales data, which is reversed. The district court's award of fees and expenses is vacated and remanded so that the district court can properly apportion the award, i.e. exclude fees and expenses incurred in defending against the lone non-frivolous claim.

In No. 00-11690, the judgment is AFFIRMED;

In No. 00-13220, the judgment is VACATED and the

matter is REMANDED for further proceedings consistent herewith