Enbrel, Part 2 – A Sequel Within A Sequel

Tuesday, February 21, 2012

As promised, we have a second Enbrel case from last week to report on. So we teased it as a sequel. And, as it turns out, this case is itself a sequel. We reported on the first dismissal of plaintiff's complaint in Salvio v. Amgen Inc., 2011 U.S. Dist. LEXIS 92558 (W.D. Pa. Aug. 18, 2011) here. The court gave plaintiff a chance to try again and like with so many sequels – plaintiff should have left it alone. So, that got us thinking about the worst ever movie sequels. Unlike yesterday's list, this one could go on for pages. Generally speaking, sequels are never as good as the original. For instance, we can start at the same place we started yesterday, The Godfather. While there is ample ammunition for either side of the debate over whether Godfather 1 or Godfather 2 is better, nobody disputes that Godfather 3 is the quintessential franchise killer. While most critics like to attack Sofia Coppola, she is far from the worst thing about that movie.

Here is just a short-list (consider it a sampling), in no particular order, of sequels that are so bad, they might even make you forget what you loved about the original (we're sure you can all add to the list):

The Sting II – with all due deference to Jackie Gleason's comic genius, he and Mac Davis were no match for Redford and Newman.

The Matrix Reloaded and **Revolutions** – too long, too tedious, just a complete let down in every way.

Legally Blonde 2: Red, White and Blonde – In the original a ditzy blonde takes the legal profession by storm in a funny and charming way. In the sequel she goes looking for her pet Chihuahua's birth mother. Huh?

Dumb and Dumberer: When Harry Met Lloyd – only good thing was a fairly spot-on impersonation of Jim Carey.

Jaws the Revenge – The original is one of the best horror movies ever made. In this one, as if the plot – a shark that has already been blown to bits seeks revenge on the widow of the man who killed it – isn't bad enough, the shark also roars.

Dirty Dancing: Havana Nights – somebody should definitely have put this movie in a corner.

Speed 2: Cruise Control – Isn't Keanu supposed to be the not too bright one? So, what was Sandra's excuse?

Blues Brothers 2000 – Where was Jim? Not that having a Belushi in it would have saved it. We are just happy brother John wasn't around to witness this travesty.

Caddyshack II – who ever thought Jackie Mason and Robert Stack could fill the shoes of Dangerfield, Murray, Chase and Knight? They headed in the right direction by casting Aykroyd, but that's about it.

Staying Alive – In this sequel to the unforgettable Saturday Night Fever, Sylvester Stallone directs John Travolta in a movie about a Broadway musical featuring the music of his brother Frank Stallone. Need we say more?

Now for Salvio II. Unlike the movies listed above that had their origins in greatness, Salvio II suffers from all the same plot pitfalls as the original. As described in Scream 2 – there are rules to making a successful sequel (at

least a horror sequel) – "Number one: the body count is always bigger. Number two: the death scenes are always much more elaborate - more blood, more gore - carnage candy. And number three: never, ever, under any circumstances, assume the killer is dead." Salvio II breaks all the rules.

Plaintiff took Enbrel to treat her rheumatoid arthritis. She allegedly contracted a fungal infection of the sinuses, brain, and lungs, and died from complications related to her infection. Salvio v. Amgen, Inc., 2012 U.S. Dist. LEXIS 19009, *2-3 (W.D. Pa. Feb. 15, 2012). After the dismissal of her first complaint and being afforded an opportunity to amend, plaintiff filed an amended complaint alleging claims for negligent failure to warn, negligent design/manufacture, and punitive damages. Id. at *4.

Rule Number 1 – A bigger body count. In this case, that meant plaintiff needed to identify feasible, safer alternatives to maintain her negligent design claim. Putting aside our dislike of the fact that Pennsylvania law even allows a negligent design claim in a prescription pharmaceutical case (see prior comments on Lance v. Wyeth, 4 A.3d 160 (Pa. Super. 2010) here), the Salvio II decision correctly identifies the key question for this claim: whether "an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered." Salvio II, 2012 U.S. Dist. LEXIS 19009, *21 (citation omitted). Plaintiff thought she'd get there by pointing to other antirheumatic drugs that were on the market and which could have been prescribed to plaintiff.

But other products are just that – other products. They are not alternative designs of the product at issue. Pennsylvania hasn't yet addressed this issue, but the court found plenty of precedent from other federal courts which all agree that "an alternative design must not be an altogether essentially different product." Id. (citations omitted). What plaintiff did here was essentially list a series of other drugs that that the plaintiff could feasibly have taken, "an allegation that is immaterial for the purpose of a negligent design/manufacture claim." Id. at *22. Even if they could be "alternatives," those products were made by other companies, and thus were not alternatives that this defendant could use. Id. So, without the bodies – here the feasible alternative safer designs – the plaintiff's negligent design claim was dismissed.

Rule Number 2 – More, More More. In a horror movie, that means more gore. In a complaint that's already been dismissed once, it means more facts. Or any facts, as the case might be. Salvio II is full of phrases such as: "Plaintiff does not aver specific facts to show" or "Plaintiff has not pleaded any facts tending to" or "Plaintiff has failed to allege." So Salvio II violates the rules for a successful sequel and the rules of Twiqbal.

For instance, in trying once again to state a claim for punitive damages, the plaintiff made a boilerplate allegation that the defendant acted with reckless disregard and then recited the elements of a claim for punitive damages. Id.at *23. Plaintiff "again failed to allege any conduct that would rise to the level of seriousness necessary for imposing punitive damages and to satisfy the pleading standard of *Twombly, Fowler*, and *Phillips.*" Id. at *24. Definitely not more elaborate. As for punitive damages, the court also went on to state that

> *" claims for punitive damages are unfounded where a manufacturer-defendant warns of the potential danger that resulted in injury to a plaintiff. . . . [E]ven if Plaintiff could show that "[m]ore could have been done or said," the Defendants did not display indifference toward the public's safety and therefore punitive damages are not warranted."*

Id. at *24-25 (citations omitted). That's a good standard to follow.

We now need to depart briefly from our discussion of the sequel rules, because we can't quite fit a discussion of plaintiff's failure to warn claim into the formula. The court recognized that the only failure to warn claim is for failure to warn the prescriber. Id. at *9. But Enbrel was accompanied by a large, bold-faced warning of the risk of serious infections, including fatalities. Id. at *12. Plaintiff's first attempt to circumvent the package insert was to argue that "that there is no evidence that [the] prescribing doctors actually received the Enbrel Package Insert." Id. at *9. So, defendant has to prove the doctor did get the warning? The court didn't buy it:

> *"This argument is not persuasive. Contrary to Plaintiff's contention, he -- not the Defendants -- has the burden of pleading sufficient factual matter to show that the claim is facially plausible. Plaintiff has not pleaded any facts tending to make it plausible that the particular packages of Enbrel sent to Decedent's doctors did not have a Package Insert, which Plaintiff concedes typically accompanied Enbrel during the period in which Decedent took the drug. To the contrary, he merely alleges that Plaintiff's medical records make no mention of a warning and therefore baldly concludes that Decedent's doctors must not have received such an insert."*

Id. at *10. Thus, plaintiff's package insert argument is unlikely to warrant a sequel.

Plaintiff's next attempt is the more recognizable "the warning wasn't good enough" argument. Under Pennsylvania law, "a prescription drug manufacturer has a duty to exercise reasonable care to inform those for whose use the article [was] supplied of the facts which make [the product] likely to be dangerous." Id. at *13. So what was unreasonable about defendant's Enbrel warning? According to the plaintiff, it was the fact that while the package insert warned about infections generally, it did not warn about **fungal** infections specifically. According to the court, such specificity was unnecessary to an adequate warning:

> *"[T]he manufacturers of Enbrel issued a broad warning of the risk of infection and highlighted some specific risks, i.e. sepsis and tuberculosis. Furthermore, the warning specifically informed prescribing doctors of the risk of prescribing Enbrel to patients who, like the Decedent, had diabetes . . . . Therefore, the Court finds that the Enbrel Package Insert in effect when Decedent was prescribed the drug adequately warned doctors of the risk of serious infections, such as the one which allegedly led to Decedent's death."*

Id. at *17 (citation omitted). The court took judicial notice of the warning, and held it adequate as a matter of law.

Finally, plaintiff argued that the warning was inadequate because five months after plaintiff stopped using Enbrel, the defendant changed the warning to include a "black box" warning for invasive fungal infections. "However, it is well established that such a revision cannot be relied on to establish the inadequacy of Defendants' warning." Id. at *18. A subsequent remedial measure could not prevent dismissal of the plaintiff's failure to warn claim.

Rule Number 3 – never assume the killer is dead. In a horror movie this is what allows for the type of jump-out-of-your seat moment like when Glenn Close pops out of the tub at the end of Fatal Attraction. Or, it is what leaves open the option for movies such as Halloween 2, 4 and 5 (Michael Myers isn't the killer in Halloween 3 so we'll

leave that one out). But, again that rule doesn't apply to Salvio II, because having given plaintiff two tries to get it right, the court didn't allow a third. Plaintiff's motion to again amend her complaint was denied. Id. at *26-27.

If Salvio II broke all the rules for making a successful sequel, it adhered to the one rule for making a horrible sequel – do a follow-up to a movie that was bad to begin with (hmmm, Wrath of the Titans is due out next month).