

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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CANDACE STOUT,  
  
Plaintiff,  
v.

NOVARTIS PHARMACEUTICALS,  
CORPORATION, NOVARTIS PHARMA  
GMBH, and NOVARTIS AG,  
  
Defendants.

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VICTORIA ANDERSON,  
  
Plaintiff,  
v.

NOVARTIS PHARMACEUTICALS,  
CORPORATION, NOVARTIS PHARMA  
GMBH, and NOVARTIS AG,  
  
Defendants.

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DAWN BERKEY,  
  
Plaintiff,  
v.

NOVARTIS PHARMACEUTICALS,  
CORPORATION, NOVARTIS PHARMA  
GMBH, and NOVARTIS AG,  
ASTELLAS PHARMA US, INC.,  
  
Defendants.

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HON. JEROME B. SIMANDLE

Civil Nos. 08-856, 07-2774,  
09-0095, 09-916, 07-1657, and  
07-655 (JBS/AMD)

**OPINION**

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DON HOWSON & CHERYL HOWSON,

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS,  
CORPORATION, NOVARTIS PHARMA  
GMBH, and NOVARTIS AG,

Defendants.

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KELLY LINKENMEYER,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS,  
CORPORATION, NOVARTIS PHARMA  
GMBH, and NOVARTIS AG,

Defendants.

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ASHLEY MCDONALD,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS,  
CORPORATION, NOVARTIS  
CORPORATION, NOVARTIS PHARMA  
GMBH, and NOVARTIS AG,

Defendants.

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APPEARANCES:

Christopher A. Seeger, Esq.  
David R. Buchanan, Esq.  
SEEGER WEISS, LLP  
550 Broad Street  
Newark, NJ 07102  
Counsel for Plaintiffs

Beth S. Rose, Esq.  
Charles J. Falletta, Esq.  
SILLS CUMMIS & GROSS P.C.  
One Riverfront Plaza  
Newark, NJ 07102  
Counsel for Novartis Defendants

Christopher M. Farella, Esq.  
STAHL, FARELLA & SAROKIN, LLC  
220 St. Paul Street  
Westfield, NJ 07090  
Counsel for Defendant Astellas Pharma US

**SIMANDLE**, District Judge:

Under New Jersey law, in certain circumstances a consumer injured by an FDA-approved pharmaceutical drug may seek punitive damages if the product manufacturer knowingly withheld or misrepresented information required to be submitted under the FDA's regulations, which information was material to the harm in question. N.J. Stat. Ann. § 2A:58C-5(c). The principal issue to be decided here is whether such a claim – as presented in each of these six lawsuits that had been initiated in state court – gives rise to federal question jurisdiction enabling the defendants to remove the cases to federal court. These matters are before the Court on Plaintiffs' motions to remand following Defendants'

removal of the cases from New Jersey state court.<sup>1</sup> As will be explained below, because the Court finds Defendants' alleged basis for federal question jurisdiction insufficient, the motions for remand will be granted.

## **I. BACKGROUND**

These six cases involve state-law products liability actions against Defendants based on Defendants' sale of topical immunosuppressants. There are over a dozen related cases that were filed in New Jersey Superior Court and removed to Camden vicinage. The undersigned has been assigned six of these cases, none of which has facts that would distinguish them from each other for the purposes of assessing subject matter jurisdiction.<sup>2</sup>

Defendants initially asserted multiple bases for removal, alleging that the Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331 based on several aspects of Plaintiffs' complaints. For the purposes of these motions to remand, however, Defendants assert only one basis, that

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<sup>1</sup> Docket Item 23 in Civil No. 08-856; Docket Item 33 in Civil No. 07-2774; Docket Item 18 in Civil No. 09-0095; Docket Item 5 in Civil No. 09-916; Docket Item 40 in Civil No. 07-1657; and Docket Item 48 in Civil No. 07-655.

<sup>2</sup> With one exception, each case is being represented by the same counsel on each side who have attached identical briefs. The exception is Civil No. 09-0095 involving Defendant Astellas Pharm US, Inc., but Astellas asserts the same basis of jurisdiction as that advanced by the Novartis Defendants.

Plaintiffs' request for punitive damages requires the Court to apply federal law in determining whether Defendants failed to comply with Federal Drug Administration (FDA) regulations requiring certain disclosures of information. The provision of New Jersey products liability law providing for these damages states:

Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

N.J. Stat. Ann. § 2A:58C-5(c) (emphasis added).

The only question before this Court is whether Plaintiffs' allegation that Defendants "knowingly withheld or misrepresented information required to be submitted under the [FDA's] regulations, which information was material and relevant to the harm in question," id., provides a sufficient basis on which this Court may assert federal jurisdiction under 28 U.S.C. § 1331.<sup>3</sup>

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<sup>3</sup> Several of these cases have been stayed while first the Third Circuit Court of Appeals and then the Supreme Court decided issues central to their merits. In McNellis v. Pfizer, Inc.,

## II. DISCUSSION

### A. Legal Standard Governing Federal Question Jurisdiction Over State Law Claims

The standard for asserting federal question jurisdiction in the context of a state-law claim that raises a federal issue is stated in Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308 (2005). “[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” Grable, 545 U.S. at 314. A dispute over a federal issue means a dispute over the interpretation of federal law. See Grable, 545 U.S. at 313 (“As

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this Court held that the FDA's regulations regarding pharmaceutical labeling requirements do not conflict with state tort laws that impose liability for a manufacturer's failure to warn of known risks associated with its product because the FDA's regulations “merely set minimum standards with which manufacturers must comply.” No. 05-1286, 2005 WL 3752269, at \*7 (D.N.J. Dec. 29, 2005). The Court reasoned that a finding that the regulations preempted state law in circumstances such as these would run afoul of “Congress' primary goal in enacting the FDCA, which is to protect consumers from dangerous products, as well as Congress' stated intent that the FDCA must not weaken the existing laws, but on the contrary it must strengthen and extend that law's protection of the consumer.” Id. (internal quotations and citations omitted). McNellis was reversed by Colacicco v. Apotex Inc., 521 F.3d 253 (3d Cir. 2008). Colacicco, however, was vacated by the Supreme Court in light of Wyeth v. Levine, 129 S.Ct. 1187 (2009). See Colacicco v. Apotex Inc., 129 S.Ct. 1578 (2009). In Levine, the Supreme Court agreed with the reasoning offered by this Court in McNellis, finding that the tort actions were not preempted. Id. at 1187. Now that Levine has been decided, these cases are again active.

early as 1912, this Court had confined federal-question jurisdiction over state-law claims to those that “really and substantially involv[e] a dispute or controversy respecting the validity, construction or effect of [federal] law.” (internal quotations omitted) (emphasis added).

In Grable, the plaintiff sought to quiet title over land that was subject to a quitclaim deed purporting to convey all of plaintiff's interest in the subject property from the District Director of Internal Revenue to defendant, pursuant to a tax sale. Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg., Inc., 207 F. Supp. 2d 694, 695 (W.D. Mich. 2002). The plaintiff's sole claim was that the quitclaim deed was void because plaintiff never received legally sufficient notice of the seizure of the property in the first place. Id. The plaintiff conceded that it received actual notice by way of certified mail, but claimed that this method of service did not comply with federal law. Id. The dispute, therefore, centered on the meaning of that federal law. Thus, in the words of a subsequent Supreme Court decision contrasting Grable's grant of jurisdiction from its denial, “Grable presented a nearly pure issue of [federal] law, one that could be settled once and for all and thereafter would govern numerous tax sale cases.” Empire Healthchoice Assur., Inc. v. McVeigh, 547 U.S. 677, 700-01 (2006).

The natural reading of Grable's emphasis on the necessity of an "actually disputed" federal law is that jurisdiction exists only when a defendant actually disputes plaintiff's interpretation of a federal law. But a problem with this understanding of Grable is immediately apparent. It seems to be in tension with the well-pleaded complaint rule, which requires that federal question jurisdiction be determined based on the content of a plaintiff's complaint, not a defendant's response. See Louisville & Nashville R. Co. v. Mottley, 211 U.S. 149, 152 (1908); Douglas D. McFarland, The True Compass: No Federal Question in a State Law Claim, 55 U. Kan. L. Rev. 1, 20 n.121 (2006) (describing this apparent contradiction between Grable and Mottley).

One way to resolve this conflict would be to read Grable as creating an exception to the well-pleaded complaint rule.<sup>4</sup> However, the other so-called exceptions to the well-pleaded complaint rule, complete preemption and artful pleading, are not really exceptions. See Franchise Tax Bd. of State of Cal. v. Construction Laborers Vacation Trust for Southern California, 463

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<sup>4</sup> At least two district courts in this circuit have spoken of Grable as creating an exception to the well-pleaded complaint rule. Scott v. Sysco Food Service of Metro New York, L.L.C., Civ. A. No. 07-3656, 2007 WL 3170121, at \*3 (D.N.J. Oct. 26, 2007); Mathes v. Vulcan Materials Co., Civil No. 2006-229, 2009 WL 2614710, at \*3 (D. Virgin Islands Aug. 21, 2009). But neither has discussed the implications of actually viewing Grable as an exception; they merely used the term exception.



U.S. 1, 22 (1983) (explaining complete preemption); Indeck Maine Energy, L.L.C. v. ISO New England Inc., 167 F. Supp. 2d 675, 685 (D.Del. 2001) (explaining artful pleading). Rather, the other putative exceptions are actually corollaries explaining what is meant by well-pleaded. If a plaintiff fails to draft the complaint to make clear the federal issue (artful pleading "exception") or fails to realize that his state claim is subject to complete preemption (complete preemption "exception"), then the complaint simply was not well-pleaded. But a Grable exception would be a genuine exception in the sense that even a perfectly skilled and legally omniscient plaintiff cannot know if the defendant will dispute his interpretation of the law before filing in the same way he could know his claim is preempted or is inartfully pleaded. Moreover, reading Grable as an unintentional and as-yet unrecognized exception to the rule would not resolve the deeper problem. What does the requirement of an actual dispute mean for the scope of federal question jurisdiction given that plaintiffs must have some way of knowing whether their claims are subject to federal question jurisdiction at the time of filing?

As a consequence of Grable's tension with the well-pleaded complaint rule, some commentators have argued that the only choice left to courts applying Grable is to read "disputed" to mean something other than a dispute between the parties in the

action; if the term were read to mean capable of being disputed, there would be no conflict with the well-pleaded complaint rule. See, e.g., Rory Ryan, No Welcome Mat, No Problem?: Federal-Question Jurisdiction After Grable, 80 St. John's L. Rev. 621, 647 (2006). Or the problem might be solved by understanding the requisite dispute to include even a factual dispute or dispute over a state law term so long as federal law is somehow involved, regardless of whether the litigants agree on the meaning of the relevant federal law.

But neither of these interpretations of the actual dispute requirement is tenable. The Supreme Court was talking about an existing dispute between the parties that must be resolved in the case at hand. See Grable, 545 U.S. at 312-315. Grable states that the principle that federal jurisdiction in the context of state-law claims is "confined . . . to those [cases] that really and substantially involve a dispute or controversy respecting the validity, construction or effect of federal law" is traceable to Gully v. First National Bank, 299 U.S. 109, 112-13 (1936), a case in which the Supreme Court stated that what was required was "[a] genuine and present controversy [over a federal issue], not merely a possible or conjectural one." Id. at 313 (internal quotations and brackets omitted); Gully, 299 U.S. at 112-13. Finally, aside from Grable's emphasis that the dispute be actual and not just potential, a rule that turns on a court's judgement

about which provisions of law are capable of dispute and which are not would likely create more problems than it solves.

The proposal that the requisite dispute may include a factual dispute or dispute over a state law term is equally problematic. The Supreme Court has been quite clear that the dispute must be over legal interpretation of federal law, not facts or state law. See Grable, 545 U.S. at 313 (“As early as 1912, this Court had confined federal-question jurisdiction over state-law claims to those that “really and substantially involv[e] a dispute or controversy respecting the validity, construction or effect of [federal] law.”) (internal quotations omitted) (emphasis added). If the dispute is about the facts or state law, then the federal interest in hearing the case simply does not exist. Empire, 547 U.S. at 700-01 (“Grable presented a nearly pure issue of law, one that could be settled once and for all and thereafter would govern numerous tax sale cases. In contrast, Empire's reimbursement claim . . . is fact-bound and situation-specific.”); Adventure Outdoors, Inc. v. Bloomberg, 552 F.3d 1290, 1299 (11th Cir. 2008) (emphasizing the distinction between factual and legal disputes over federal issues); Bennett v. Sw. Airlines Co., 484 F.3d 907, 910 (7th Cir. 2007) (“What the Court said about Grable in Empire Healthchoice can be said here too. We have a fact-specific application of rules that come from both federal and state law rather than a context-free inquiry

into the meaning of a federal law"). See also Singh v. Duane Morris LLP, 538 F.3d 334, 339 (5th Cir. 2008) (finding federal jurisdiction inappropriate where "federal issue [did not require] resolution of an important question of law" but was "predominantly one of fact"). The point of the doctrine allowing assertion of federal question jurisdiction over state law claims that implicate federal law is that such claims "justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." Grable, 545 U.S. at 312. The federal courts have no special experience or interest in uniformity with regard to resolving questions of fact in an individual case or resolving issues of state law. The special characteristics of the federal courts are most useful when there is an actual dispute over how to interpret federal law.

Instead of altering the meaning of "actually disputed" in ways that clearly contradict the controlling precedent, this Court must find a way to uphold both the requirement of an actual dispute over federal law and the requirement that jurisdiction be determined on the basis of a well-pleaded complaint. Without deciding exactly how to do so, the Court is satisfied that this accommodation is possible. Perhaps, for example, the actual dispute requirement means that the dispute respecting the validity, construction or effect of federal law must be apparent from the complaint itself (as opposed to arising from the content

of a defendant's response).<sup>5</sup> Or perhaps the language requiring an actual dispute is limited to the removal context.<sup>6</sup>

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<sup>5</sup> Such a rule would require the complaint to present more than the mere potential for such a dispute. Perhaps under this interpretation of the rule, the Court would find the dispute to be apparent when the only plausible argument for a defendant to make would be about the content of federal law. Though such a jurisdictional rule has many problems, it would also have some advantages. This rule would uphold the principle of the well-pleaded complaint rule by preventing jurisdiction from depending on decisions made by the defendant as to how and what to dispute in the complaint. And, the correct rule should be one in which federal jurisdiction will rarely be found; federal jurisdiction over state causes of action is supposed to be "special and small." Empire, 547 U.S. at 699. It is also one of the few interpretations that can make sense of the word "necessarily" in Grable; if, when drafting the complaint, the plaintiff does not know that any serious dispute will be over plaintiff's construction of federal law, then the state-law claim does not "necessarily raise a stated federal issue, actually disputed and substantial." It would also seem to be consistent with the facts in Grable. While defendant could have conceivably rested its defense in that case on arguing that plaintiff was, in fact, notified by personal service, such a defense was sufficiently unlikely and implausible under the circumstances that the existence of a dispute over the law was certain enough that it could not be called conjectural or speculative.

<sup>6</sup> Under this understanding of the rule, the dispute need only meet some threshold of likelihood from the content of the complaint, but upon removal must be actual. Removal is an action within the control of the defendant and hence within the control of the party who knows whether there will be a dispute over plaintiff's construction of federal law. 28 U.S.C. § 1446. As in the case of complete preemption or the belated discovery that the parties are actually diverse, knowledge that the case is removable may require some research or effort on the part of the defendant, including perhaps a motion for a more definite complaint, a contention interrogatory, or a jurisdictional hearing. The federal statute allows removal when it "may first be ascertained that the case is one which is or has become removable." 28 U.S.C. § 1446. Thus, the argument would go, the requirement of an actual dispute makes sense and applies in removal context, but something less than certainty of actuality is required when a complaint initially filed in federal court.

In summary, the vitality of the well-pleaded complaint rule need not undermine the requirement of a “federal issue, actually disputed and substantial.” The Court acknowledges a certain degree of uncertainty about what the actual dispute requirement will mean for plaintiffs with state law claims originally filed in federal court. For the purposes of this case, it is sufficient to conclude that an actual dispute respecting the interpretation of federal law must be ascertainable at the removal stage in order for the Court to assert federal question jurisdiction. The considered opinion of three circuit courts of appeals as well as the clear implication of the Supreme Court’s subsequent decision in Empire make clear that the unanimous Supreme Court meant what it said in Grable about the necessity of a dispute over the interpretation of federal law, and this Court is not permitted to ignore that command merely because the resulting rule has raised difficult theoretical problems.

**B. Application of Jurisdictional Rule to Facts of This Case**

Upon applying this understanding of Grable to this case, it becomes clear that the Court must remand. Defendants have not identified any actual dispute respecting the interpretation of

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Notably, Empire involved a case initially filed in federal court, and while that case discusses the distinction between a dispute over law and a dispute over fact, it does not reiterate the phrase “actually disputed,” perhaps because, unlike the present cases, it was not a removal case.

federal law in their briefs opposing remand. The only indication that there is any kind of dispute at all on a federal issue is the general denial found in Defendants' answers of any knowing withholding or misrepresentation of information required to be disclosed by FDA regulations, and the allegation in Defendants' briefs that there is some generalized dispute over this issue. There is no information in the record regarding the nature of the dispute. It is not clear whether the parties agree on what information the FDA requires to be disclosed (i.e. agree on the interpretation of federal law), but disagree about the facts of what was disclosed, disagree about whether information required to be disclosed was misrepresented, or disagree about the mens rea involved in any failures to disclose. If the dispute is factual or based on state law meanings of "willfully" or "misrepresent," there would clearly be no "federal issue, actually disputed and substantial." Grable, 545 U.S. at 314. In short, it is far from necessary or inevitable that this Court would have to interpret federal law in order to resolve this case.

Judge Irenas came to a similar conclusion in his opinion addressing the same facts in one of the other Novartis cases removed to this vicinage:

[I]n contrast to Grable, where the facts were undisputed and only the meaning of a federal tax statute was at issue, there is no indication, at present, that this case "depend[s] on the construction or interpretation of

federal law.” Defendant responds that the progression of this case may reveal a latent dispute as to what information it was required to submit under FDA regulations. In other words, Defendant contends that this case may involve embedded issues requiring this Court to perform a legal inquiry into the meaning of one or more FDA regulations.

At present, there is nothing before the Court to suggest that this case will present the legal issues of regulatory interpretation predicted by Defendant. To the contrary, all indications are that the federal aspect of the NJPLA punitive damages claim will depend on a fact-sensitive inquiry into whether material information concerning Elidel was knowingly withheld from, or misrepresented to, the FDA. In the absence of any current indication that this case will require the resolution of disputed federal issues of general application, Grable counsels against the exercise of jurisdiction.

Sullivan v. Novartis Pharmaceuticals Corp., 602 F. Supp. 2d 527, 535 (D.N.J. 2009) (citations omitted). For whatever reason in these cases, Defendants have not informed the Court about the existence of an actual dispute over the interpretation of federal law. Given the fact that Judge Irenas’ March 2009 decision should have put Defendants on notice of the need to identify an actual dispute over the interpretation of federal law in the subsequent briefing on these motions to remand, this Court is inclined to believe that no actual dispute presently exists. Because Defendants have not met their burden of establishing federal jurisdiction on removal, see, e.g., Samauel-Bassett v. KIA Motors Am., Inc., 357 F.3d 392, 396 (3d Cir. 2004),



Plaintiffs' motion to remand must be granted.<sup>7</sup>

### III. CONCLUSION

For the above-stated reasons, this Court holds that the complaints in these cases were not removable based upon federal question jurisdiction because Defendants have not demonstrated that this Court would necessarily be called upon to adjudicate a substantial dispute about federal law in order to resolve these cases. The accompanying order for remand will be entered.

11/30/09  
Date

/s Jerome B. Simandle  
JEROME B. SIMANDLE  
United States District Judge

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<sup>7</sup> In addition to showing an actual dispute respecting the interpretation of federal law, Defendants must also show the dispute implicates a substantial issue of federal law, as seemingly every other district court has required when faced with this very issue. See Sullivan v. Novartis Pharm. Corp., 575 F. Supp. 2d 640 (D.N.J. 2008); Brown v. Organon Int'l Inc., Nos. 07-3092, 07-3456, 08-2021, 2008 WL 2833294 (D.N.J. Jul. 21, 2008); Fields v. Organon USA Inc., No. 07-2922, 2007 WL 4365312 (D.N.J. Dec. 12, 2007); DeAngelo-Shuayto v. Organon USA Inc., No. 07-2923, 2007 WL 4365311 (D.N.J. Dec. 12, 2007); Von Essen v. C.R. Bard, Inc., No. 06-4786, 2007 WL 2086483 (D.N.J. Jun. 18, 2007); In re Aredia and Zometa Prods. Liab. Litig., No. 3:06-MD-1760, 2007 WL 649266 (M.D.Tenn. Feb. 27, 2007). An insubstantial dispute over the interpretation of federal law would not give rise to federal question jurisdiction. Jurisdiction should not be determined based on hypothetical disputes resting on a series of guesses.