S233898

IN THE

SUPREME COURT OF CALIFORNIA

T.H., A MINOR, ET AL.,

Plaintiffs and Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant and Respondent.

Review of a decision of the Court of Appeal,
Fourth Appellate District, Division One
Case No. D067839

Plaintiffs' Supplemental Brief re: *McNair v. Johnson & Johnson Corp.* (4th Cir. May 30, 2017, No. 15-1806)

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INTRODUCTION

Plaintiffs submit this supplemental brief under California Rules of Court, rule 8.520(d) to advise the Court of recent appellate activity on the issue of whether a brand-name manufacturer may bear tort liability for injuries caused by generic version of the brand-name manufacturer's drug.

In particular, Plaintiffs seek to advise the Court of the Fourth Circuit's recent decision in *McNair v. Johnson & Johnson Corp.* (4th. Cir. May 30, 2017, No. 15-1806) 2017 WL 2333843, requesting that the Supreme Court of Appeals of West Virginia answer the following certified question of law:

> Whether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer.[1]

This is essentially the same question the Fourth Circuit addressed in its seminal decision, *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, which arose under Maryland tort law. The fact the Fourth Circuit has certified the question in *McNair* a state supreme court rather than simply relying on its decision in *Foster* suggests the Fourth Circuit may have doubts about *Foster*'s broader viability, a fact that casts doubt on much of the authority relied on by Novartis and its amici.

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[1] By order dated August 30, 2017, the West Virginia Supreme Court of Appeals accepted the Fourth Circuit's certification and scheduled the case for argument on January 18, 2018. (See Exh. "A.")

DISCUSSION

As this Court may recall from the parties' briefing, the Fourth Circuit's opinion in *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, was the lead case for the view that brand-name manufacturers should be categorically immune from liability for injuries caused by generic drugs. Like Novartis and its amici, virtually every subsequent appellate decision rejecting a claim against brand-name manufacturers by unwitting consumers of generic drugs either relies on *Foster* directly or cites to cases that were themselves inspired by *Foster*. (See, e.g., Pltfs' Consolidated Answer to Amicus Briefs, at pp. 40–47.)

But as this Court may recall from Plaintiffs' briefing, the *Foster* court's decision was largely the result of its belief that manufacturers of generic drugs "are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval." (*Foster*, *supra*, 29 F.3d at p. 170.) Based on this belief, *Foster* held that federal law does not "insulate generic drug manufacturers from liability for misrepresentations made regarding their products" and, therefore, that "[m]anufacturers of generic drugs"—not brand-name manufacturers—"are responsible for the representations they make regarding their products." (*Ibid.*)

But in *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613, the U.S. Supreme Court expressly rejected the core premise underlying *Foster* when it held that federal law *requires* generic drug manufacturers to copy the corresponding brand-name manufacturer's label "verbatim." (See, e.g., *Drager v. PLIVA USA, Inc.* (4th Cir. 2014) 741 F.3d 470, 476 ["[*Mensing* and *Bartlett*] establish that under the FDCA a generic may not unilaterally change its labeling or change its design or formulation."].)

Mensing's holding that generic drug manufacturers must copy the brand-name label "verbatim," and are *prohibited* from changing their labels without prior FDA approval, have led several courts to question *Foster*'s continued viability. (E.g., *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, 670 ["The *Foster* court's finding that manufacturers of generic drugs are responsible for the representations they make in their labeling regarding their products is flawed based on the 'sameness' requirement subsequently discussed in [*Mensing*]."].)

It appears the skepticism about *Foster*'s viability may have come full circle, in light of the Fourth Circuit's recent decision in *McNair v. Johnson & Johnson Corp.* (4th. Cir. May 30, 2017, No. 15-1806) 2017 WL 2333843.

At issue in *McNair* is whether a brand-name manufacturer can be held liable under West Virginia tort law for injuries caused by a generic version of its drug. Arguing that *Foster* was no longer good law, the plaintiffs in *McNair*

asked the Fourth Circuit to certify the question to the West Virginia Supreme Court in lieu of a so-called "*Erie* guess" regarding how the West Virginia Supreme Court would decide the issue. The Fourth Circuit agreed.

In its decision, the court acknowledged that, since *Foster*, some courts have resolved the issue in the plaintiffs' favor:

> The McNairs' theory of liability is not entirely without support. A few courts have held that the brand-name manufacturer may be liable for failure to warn when the plaintiff's injury was caused by the generic drug, basing their decisions largely on the foreseeability of physicians' and patients' reliance upon the brand-name manufacturer's warning label. *See Conte v. Wyeth, Inc.*, 168 Cal.App.4th 89, 85 Cal.Rptr.3d 299, 320–21 (2008) (holding that, under California law, the brand-name manufacturer owes a duty of care to patients who ingest the generic drug)...

(*McNair, supra*, 2017 WL 2333843, at p. 4., additional citations omitted.)

The *McNair* court then explained how its prior ruling in *Foster* is no longer settled law. Noting that "*Foster*'s reasoning, in large part, was that a manufacturer of generic products is responsible for the accuracy of labels, the *McNair* court then acknowledged that "after *Mensing* and *Bartlett*, it is no longer the case that generic manufacturers can alter FDA-approved labels." (*McNair, supra*, 2017 WL 2333843, at p. 4.)

Prudently, the *McNair* court, unlike so many federal courts before it, was unwilling to ignore the impact of *Mensing* by simply "speculat[ing] as to how the Supreme Court of Appeals of West Virginia would rule in an area of

law where it has not spoken directly." (*McNair*, *supra*, 2017 WL 2333843, at p. 5.) Instead, and in light of its belief that West Virginia "precedent leaves open the possibility that brand-name manufacturers may be liable for failure to warn when a plaintiff ingests the generic drug," the *McNair* court certified the question to the West Virginia Supreme Court of Appeals. (*Ibid.*)

It is possible, of course, that the Fourth Circuit, following a ruling from the West Virginia Supreme Court of Appeals, will ultimately reach the same conclusion as it did in *Foster*. If so, its decision will almost certainly be distinguishable from this case, for all the reasons previously explained. (See, e.g., Pltfs' Consolidated Answer to Amicus Briefs, at pp. 40–47.) But the point *here* is that the certified question in *McNair* suggests that the Fourth Circuit itself may no longer regard *Foster* as good law. If so, that would provide ample reason to question the validity of the authorities cited by Novartis and its amici, the vast majority of which either relied on *Foster* directly or were part of the snowball effect of "me-too" jurisprudence that *Foster* set into motion.

CONCLUSION

Novartis and its amici rely heavily on the Fourth Circuit's decision in *Foster* and its progeny in urging this Court to categorically reject any claim against brand-name manufacturers by consumers of mislabeled generic drugs. But the Fourth Circuit's decision in *McNair* to certify that issue to the West Virginia Supreme Court of Appeals instead of simply relying on *Foster* suggests that the Fourth Circuit has serious—and understandable—doubts about *Foster*'s viability in light of the U.S. Supreme Court's decisions in *Mensing* and *Bartlett*.

In addition to unique, outcome-determinative characteristics of California's tort law, *Foster* would provide yet another important basis to reject virtually all of the out-of-state authorities on which Novartis and its amici rely.

September 19, 2017

By: s/ Leslie A. Brueckner
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CERTIFICATE OF COMPLIANCE

As required by California Rules of Court, rule 8.520(d), I certify that, according to the word-count feature in Microsoft Word, this supplemental contains 1,229 words, including footnotes, but excluding any content identified in rule 8.520(c)(3), but that, in any event, the entire brief is less than 2,800 words.

September 19, 2017

By: s/ Benjamin I. Siminou
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THORSNES BARTOLOTTA MCGUIRE LLP

EXHIBIT A

9/07/17

STATE OF WEST VIRGINIA

At the Supreme Court of Appeals, continued and held at Charleston, Kanawha County, on August 30, 2017, the following order was made and entered **in vacation**:

Kimmy McNair and
Larry McNair,
Petitioners

vs.) No. 17-0519

Johnson & Johnson;
Janssen Pharmaceuticals, Incorporated; and
Ortho-McNeil Pharmaceutical, Incorporated,
Respondents

ORDER

The Court has reviewed and inspected the certification order entered in the United States Court of Appeals for the Fourth Circuit on May 30, 2017 (Nos. 15-1806, 2:14-cv-17463).

Upon consideration, the Court is of the opinion that this matter be scheduled for oral argument under Rule 20 of the Rules of Appellate Procedure on Tuesday, January 18, 2018, and this order constitutes the Notice of Argument pursuant to Rule 20(b). Justice Workman not participating.

Counsel for the petitioners is hereby directed to file the petitioners' brief and appendix on or before October 30, 2017.

Pursuant to R.A.P. 17(a)(4), all parties to this matter are hereby directed to assist the petitioners in preparing a joint appendix of items contained in the record of the appellate court that are relevant to this Court's consideration of the certified questions. Pursuant to R.A.P. 7(e), if no agreement is reached on the contents of the appendix, the petitioners must prepare a list of the parts of the record that the petitioners intend to include in the appendix, and serve the list on the respondents on or before October 2, 2017.

The respondents are directed to file a respondents' brief on or before December 14, 2017. Any reply brief deemed necessary shall be filed by the petitioners on or before January 3, 2018.

A True Copy

Attest: //s// Rory L. Perry II
Clerk of Court

Exh A-01

PROOF OF SERVICE

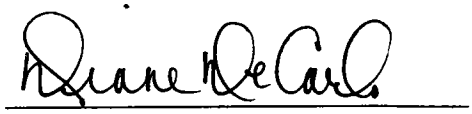
I, the undersigned, say: I am over 18 years of age, employed in the County of San Diego, California, and not a party to the subject cause. My business address is 2550 Fifth Ave., Ste. 1100, San Diego, California, 92103.

On September 19, 2017, I served the attached "**Plaintiffs' Supplemental Brief re: *McNair v. Johnson & Johnson Corp.* (4th Cir. May 30, 2017, No. 15-1806)**," of which a true and correct copy of the document filed in the cause is affixed by placing a copy thereof in a separate envelope for each addressee named hereafter, addressed to each such addressee respectively as follows:

See attached service list.

Each envelope was then sealed, and with the postage thereon fully prepaid, deposited in the United States mail by me at San Diego, California, on September 19, 2017.

I declare under penalty of perjury that the foregoing is true and correct, and this declaration was executed at San Diego, California, on September 19, 2017.



Diane DeCarlo

H. (T.) v. Novartis Pharmaceuticals Corporation
Case Number S233898

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Case Number S233898

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H. (T.) v. Novartis Pharmaceuticals Corporation
Case Number S233898

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