

**United States Court of Appeals
for the Federal Circuit**

**COPAN ITALIA SPA, COPAN DIAGNOSTICS INC.,
*Plaintiffs-Appellees***

v.

**PURITAN MEDICAL PRODUCTS COMPANY LLC,
PURITAN DIAGNOSTICS LLC, PURITAN
MEDICAL PRODUCTS COMPANY I LP,
HARDWOOD PRODUCTS COMPANY LLC,
*Defendants-Appellants***

2022-1943

Appeal from the United States District Court for the
District of Maine in No. 1:18-cv-00218-JDL, Chief Judge
Jon D. Levy.

Decided: May 14, 2024

MICHAEL NEWMAN, Mintz, Levin, Cohn, Ferris, Glov-
sky and Popeo, P.C., Boston, MA, argued for plaintiffs-ap-
pellees. Also represented by PETER CUOMO, ANDREW H.
DEVOGD, COURTNEY PATRICE HERNDON, JAMES M.
WODARSKI.

JAMES H. HULME, ArentFox Schiff LLP, Washington,
DC, argued for defendants-appellants. Also represented by

TANIEL E. ANDERSON, JANINE A. CARLAN, KEVIN R. PINKNEY; MICHAEL L. SCARPATI, New York, NY.

Before CUNNINGHAM, BRYSON, and STARK, *Circuit Judges*.
STARK, *Circuit Judge*.

Copan Italia S.p.A. and Copan Diagnostics Inc. (collectively, “Copan”) brought a patent infringement case against Puritan Medical Products Company LLC and its affiliated companies (collectively, “Puritan”) in the United States District Court for the District of Maine. Puritan filed a partial motion to dismiss, alleging that it was immune from liability and suit for a portion of its accused product under a provision of the Pandemic Readiness and Emergency Preparedness Act (“PREP Act”). On June 1, 2022, the district court denied the motion, and Puritan now appeals. We find we lack jurisdiction and, accordingly, dismiss the appeal.

I

Puritan makes “flocked” swabs “for collecting biological specimens.” J.A. 129. A flocked swab consists “of a rod [with] a tip covered with fiber with hydrophilic properties” that can absorb biological specimens. *Id.* The fibers in a flocked swab are deposited by flocking, a process by which the tip of the rod is sprayed with an adhesive so that tiny fibers can attach, creating a fiber layer. Copan holds several patents on flocked swabs and methods of using them.

On June 1, 2018, Copan filed a patent infringement complaint against Puritan in the District of Maine, alleging that Puritan directly and indirectly infringed and infringes several of its swab patents. As relief, Copan sought “damages caused to Plaintiff by Defendant’s unlawful acts of patent infringement,” as well as a permanent injunction. J.A.

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119.¹ The case proceeded normally throughout 2018 and 2019.

Then the COVID-19 pandemic hit. On March 10, 2020, the Secretary of Health and Human Services issued a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, which declared the COVID-19 pandemic a public health emergency. *See* 85 Fed. Reg. 15198, 15201 (Mar. 17, 2020). On May 15, 2020, Copan and Puritan jointly moved to stay this litigation. Both parties requested a stay until after “the crisis passes” because, in part, “all of their resources at this time are best devoted to producing viral testing materials.” J.A. 3848. At that time, demand for flocked swabs had skyrocketed, as they were used in many of the new tests for detecting whether an individual was afflicted with COVID-19. Given the spike in sales, the parties further indicated in their stay motion that they expected “the current pandemic could fundamentally change the contours of this case.” J.A. 3848. On May 18, 2020, the district court granted the stay.

On July 29, 2020, Puritan entered into a contract with the United States Air Force (“Air Force”) in which Puritan agreed to expand its facilities for manufacturing flocked swabs. In a document associated with an amendment to that contract, the Air Force stated:

In accordance with the Public Readiness and Emergency Preparedness Act (“PREP Act”), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. 247d-6e), as well as the Secretary of [Health and Human Services] Declaration Under the Public Readiness and Emergency

¹ Copan later dropped its request for injunctive relief. J.A. 4552-53.

Preparedness Act for Medical Countermeasures Against COVID-19 (the “PREP Act Declaration”), 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), (i) this Agreement is being entered into for purposes of production capability expansion for “Covered Countermeasures” for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration; (ii) Contractor’s performance of this Agreement falls within the scope of the “Recommended Activities” for responding to the COVID-19 public health emergency; and (iii) Contractor is a “Covered Person” to the extent it is a person defined in Section V of the PREP Act Declaration. Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Air Force expressly acknowledges and agrees that Contractor shall be immune from suit and liability to the extent and as long as Contractor’s activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

J.A. 4231-32. Puritan indicates that this contract provided it with the funds necessary to construct a new factory it calls “P3,” where Puritan manufactures some of its flocked swabs.

At the parties’ request, the district court lifted the stay in October 2021, reopening fact discovery. At that point, Puritan asserted it had immunity from certain of Copan’s patent infringement claims by virtue of the PREP Act, 42 U.S.C. § 247d-6d. Puritan sought to amend its answer to include the affirmative defense of PREP Act immunity. Puritan also filed a partial motion to dismiss Copan’s patent infringement claims to the extent they were directed

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at flocked swabs Puritan made at the P3 facility. According to Puritan, the only swabs it was producing at P3 were those required to fulfill the Air Force contract, which expressly recognized Puritan's PREP Act immunity.

Puritan asked the trial court to take judicial notice of the Air Force contract and certain Food and Drug Administration ("FDA") documents. It further requested that the district court find from these materials that Puritan had immunity from "all claims for loss" under the PREP Act, including claims for patent infringement, on the grounds that all flocked swabs made at the P3 factory constituted "covered countermeasures." 42 U.S.C. § 247d-6d(a)(1).

In response, Copan argued that Puritan enjoyed no immunity from liability for patent infringement. In Copan's view, the PREP Act does not apply to claims for patent infringement; instead, the immunity it confers is limited to claims for "loss" due to physical harm (e.g., product liability claims). Alternatively, Copan argued that if the PREP Act's immunity provision reaches patent infringement claims then it is unconstitutional. Finally, Copan insisted that Puritan's "motion to dismiss [was] highly factual" and Copan "should be allowed to explore the factual basis for Puritan's new allegations" of immunity before the district court should consider dismissal. J.A. 4344-45.

The district court denied Puritan's motion to dismiss. It found that Puritan had not shown, as a factual matter, that its flocked swabs were "covered countermeasures" under the PREP Act. The court acknowledged that Puritan had asked that the court take judicial notice of what appeared to be a letter from the FDA regarding an Emergency Use Authorization ("EUA") of a specific antigen test, which Puritan proffered as evidence that its swabs were being used in COVID-19 tests. The trial court found, however, that "the document does not mention Puritan, the P3 factory, or even flocked swabs." J.A. 8. Nor did the letter indicate that any factory had been built, or any swabs

manufactured, pursuant to the Air Force contract. Hence, the trial court concluded that the Air Force contract did not support a conclusion that *all* flocked swabs created at P3 were related to a federal agreement or would be used in COVID-19 tests constituting covered countermeasures. **[J.A. 9-10]** “In light of the evidentiary gaps” noted, the district court held that “dismissal of the amended complaint is not supported because the limited record . . . does not show that the PREP Act affirmative defense has been proven.” J.A. 10. At the same time, the district court did grant Puritan’s motion to amend its answer, allowing it to assert PREP Act immunity as a defense, one that would be subject to further argument.

Puritan timely appealed. Before us, Copan not only defends the merits of the district court’s decision to deny the motion to dismiss. Copan also contends that the appeal must be dismissed for lack of jurisdiction. In response, Puritan argues that we have jurisdiction by virtue of application of the collateral order doctrine.

We have determined that we lack jurisdiction, for reasons we now explain.

II

The collateral order doctrine is a limited exception to the general requirement that appellate jurisdiction arises only after a district court issues a final order. *See Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 103 (2009) (“Although ‘final decisions’ typically are ones that trigger the entry of judgment, they also include a small set of prejudgment orders that are ‘collateral to’ the merits of an action and ‘too important’ to be denied immediate review.”). “Questions of our jurisdiction,” such as the determination of whether the collateral order doctrine applies, “are governed by Federal Circuit law.” *DePuy Synthes Prods., Inc. v. Veterinary Orthopedic Implants, Inc.*, 990 F.3d 1364, 1368 (Fed. Cir. 2021).

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As we have explained, for a district court order to come within the collateral order exception, it must “at a minimum satisfy three conditions: It must [1] ‘conclusively determine the disputed question,’ [2] ‘resolve an important issue completely separate from the merits of the action,’ and [3] ‘be effectively unreviewable on appeal from a final judgment.’” *Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1220 (Fed. Cir. 2013) (alteration in original) (quoting *Richardson-Merrell, Inc. v. Koller*, 472 U.S. 424, 431 (1985)). If any one of these conditions is not met, the collateral order doctrine does not apply, and we lack jurisdiction to review the order in question. *See generally Mod. Font Applications LLC v. Alaska Airlines, Inc.*, 56 F.4th 981, 985 (Fed. Cir. 2022) (discussing two examples where orders failed to meet requirements of collateral order doctrine).

Puritan argues that the district court’s denial of its motion to dismiss meets the requirements for a reviewable collateral order. In Puritan’s view, the district court conclusively determined that Puritan lacks immunity from suit and also lacks immunity from liability under the PREP Act. To Puritan, this is an important issue, as it goes to whether Puritan can be required to defend itself against an allegation of patent infringement and whether it can be held liable for such infringement. It is also, Puritan argues, an issue entirely distinct from the merits of whether, in fact, Puritan infringes. Puritan further contends that the immunity issue is unreviewable on appeal, as it will have been irrevocably deprived of its immunity from suit after the case proceeds through trial to an appeal.

Copan counters that the denial of Puritan’s partial motion to dismiss is not reviewable under the collateral order doctrine. According to Copan, the district court did not conclusively determine that Puritan lacks immunity under the PREP Act; instead, the district court only held that, to this point, Puritan has not demonstrated that it is entitled to immunity. Copan further insists that the immunity issue

is intertwined with the merits of its patent infringement claim and, in fact, is more properly viewed as a damages question (i.e., can Copan recover for infringement by swabs made at the P3 factory or is its recovery limited to damages from infringement by swabs made outside P3?), as Puritan admits the swabs made at P3 are identical to other swabs. Copan also contends the issue on which Puritan seeks review is not particularly important because trial will be necessary on its non-P3 infringement claims regardless of whether Puritan prevails on its P3 immunity motion.

We find that the district court's denial of Puritan's partial motion to dismiss does not conclusively determine any issue. Therefore, Puritan has not shown that the collateral order doctrine's requirements are satisfied. Accordingly, we dismiss for lack of appellate jurisdiction.

III

The first requirement that must be satisfied to invoke our jurisdiction under the collateral order doctrine is to show that the district court's order "conclusively determined" the disputed issue. Here, that requirement would be met by a showing that the trial court conclusively determined that Puritan lacks immunity from patent infringement under the PREP Act. Puritan cannot show that the trial court arrived at such a determination because the record makes plain it did not.

The PREP Act, when applicable, confers two types of immunity: immunity from suit and immunity from liability. *See* 42 U.S.C. § 247d-6d(a)(1). The essence of immunity from suit "is its possessor's entitlement not to have to answer for his conduct in a civil damages action." *Mitchell v. Forsyth*, 472 U.S. 511, 525 (1985). Immunity from liability means that one cannot be held to pay or otherwise be accountable for whatever loss one has caused. *See Wood v. Strickland*, 420 U.S. 308, 319-20 (1975) (discussing differences between immunity from suit and immunity from

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liability), *abrogated on other grounds by Harlow v. Fitzgerald*, 457 U.S. 800 (1982).

The PREP Act’s immunity provision reads as follows (with bracketed numerals added):

[i] a covered person shall be immune from suit and liability under Federal and State law with respect to [ii] all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if [iii] a declaration [of a public health emergency] has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1). Thus, as it relates to the issues presented here, PREP Act immunity extends to (i) covered persons, (ii) for losses² somehow connected to a covered countermeasure, when (iii) a public health emergency has been declared with respect to the countermeasure, and (iv) the covered countermeasures are distributed under certain means specified in the declaration. *See Maney v. Brown*, 91 F.4th 1296, 1298 (9th Cir. 2024). The PREP Act includes among its definition of “covered countermeasures” a

² The Act defines “loss” as

including – (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss.

42 U.S.C. § 247d-6d(a)(2)(A).

“qualified pandemic or epidemic product.” 42 U.S.C. § 247d-6d(i)(1)(A).³

Invoking these provisions of the PREP Act, Puritan moved to dismiss the patent infringement claims as to the accused swabs manufactured at its P3 facility because they sought to recover for “loss” from which Puritan was immune, on the grounds that (i) Puritan is a “covered person,” (ii) the flocked swabs manufactured at the P3 facility were “covered countermeasures” (iii) with respect to which a public health emergency (COVID-19) had been declared, and (iv) the flocked swabs were distributed (based on its contract with the Air Force) under a means specified in the emergency declaration.⁴

The district court found that the record was not adequate to allow it to make a finding as to the “covered countermeasure” and distribution requirements. *See* J.A. 9 (“[T]he Air Force’s statement leaves some doubt as to whether the flocked swabs from P3 are covered countermeasures.”); J.A. 10 (holding that “without a more fulsome record of the relevant facts,” court could not “conclude with certainty that all of the flocked swabs manufactured at the P3 factory are related to a federal agreement”); J.A. 10 (“In light of the evidentiary gaps I have noted, the dismissal of the amended complaint is not supported because the limited record before me does not show that the PREP Act affirmative defense has been proven.”). Referring to the documents Puritan asked it to judicially notice, the court

³ Where immunity applies, the injured individual or their survivors may seek compensation from the Countermeasures Injury Compensation Program. *See* 42 U.S.C. § 247d-6e.

⁴ There is no dispute that the March 10, 2020 HHS declaration was a declaration of a public health emergency with respect to the countermeasure.

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explained: “Puritan’s proposed evidence does not establish that Puritan carried through with its contractual obligations, that it did so at its P3 factory, or that all of the flocked swabs from its P3 factory (as opposed to some subset) are produced in relation to its government contract.” J.A. 10. Therefore, because immunity had not been established, the court denied Puritan’s motion to dismiss, and at the same time permitted Puritan to amend its answer to assert its PREP Act immunity affirmative defense.

Clearly, the district court is contemplating further litigation will be necessary before a conclusive determination can be reached as to whether immunity is available to Puritan in this case. The district court did not make any factual or legal determination that Puritan’s flocked swabs made at its P3 facility are *not* immune. Instead, it simply – and preliminarily – held that it was not in a position to make these determinations at this time. This is not a “conclusive determination” of the immunity issue.

Our conclusion is supported by Supreme Court precedent arising in the similar context of qualified immunity for government officials. In *Ortiz v. Jordan*, 562 U.S. 180, 188 (2011), for example, the Supreme Court explained that “immediate appeal from the denial of summary judgment on a qualified immunity plea is available when the appeal presents a ‘purely legal issue’ However, instant appeal is not available . . . when the district court determines that factual issues genuinely in dispute preclude summary adjudication.” Just as there is a lack of appellate jurisdiction for interlocutory review of a district court denial of a motion for summary judgment of qualified immunity based on “[d]isputed facts relevant to resolving . . . immunity pleas,” *id.* at 191, so, too, here, we lack jurisdiction to review the district court’s denial of Puritan’s PREP Act immunity motion to dismiss, as that denial was based on genuine, material disputed facts. *See also Johnson v. Jones*, 515 U.S. 304, 316 (1995) (holding interlocutory

appeal is not available where “issue . . . at stake” is “the existence, or nonexistence, of a triable issue of fact”).⁵

IV

A

In urging us to reach a different conclusion and find appellate jurisdiction, Puritan principally emphasizes the immunity from suit provided by the PREP Act. According to Puritan, it is losing its immunity from suit each day that the patent infringement claims relating to P3 remain pending, as each such day requires Puritan to mount a defense to this portion of Copan’s claims – even though Puritan expects the courts will ultimately agree that it is immune from any liability for P3 activities. *See, e.g.*, Opening Br. at 5-7; *Puerto Rico Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 143-44 (1993) (“[A]bsent immediate appeal, the central benefits of qualified immunity – avoiding the costs and general consequences of subjecting public officials to the risks of discovery and trial – would be forfeited.”); *In re World Trade Ctr. Disaster Site Litig.*, 521 F.3d 169, 180 (2d Cir. 2008) (describing defendant’s loss of “its asserted right not to stand trial”). Puritan argues that “[t]he PREP Act shields Puritan from pretrial and trial regarding infringement allegations directed to the P3 factory and Puritan has chosen to exercise this right.” Reply Br. at 6-7.

⁵ It is true, of course, as Puritan points out, that not every denial of summary judgment that happens to involve disputed facts is unappealable. *See Behrens v. Pelletier*, 516 U.S. 299, 312-13 (1996); Reply Br. at 2-3. Here, however, the sole basis for the district court’s denial of Puritan’s motion to dismiss was its identification of factual issues that it felt could not be resolved on the present record.

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Not all issues impacting immunity from suit are necessarily subject to collateral order appellate review. *See Johnson*, 515 U.S. at 313-18 (holding that evidentiary sufficiency determinations in qualified immunity cases are not immediately appealable even where they “force[] public officials to trial”); *Digital Equip. Corp. v. Desktop Direct, Inc.*, 511 U.S. 863, 883 (1994) (holding that order vacating dismissal is not appealable collateral order even when parties negotiated for immunity to suit).

We find the circumstances presented here to be most comparable to those in which courts have found immunity-from-suit issues not to be reviewable under the collateral order doctrine. Again, the district court denied Puritan’s motion to dismiss based on its determination that the record revealed a genuinely disputed material fact; it did not deny the motion based on a legal conclusion. It held immunity was not shown to be applicable, but did *not* hold that immunity cannot be available in the circumstances presented. The district court, as we have stressed, did not, therefore, “conclusively determine” any issue, so we have no proper collateral order to review.⁶

To address what it characterizes as a loss of immunity from suit, Puritan proposes as an “alternative [form of]

⁶ Notably, the PREP Act expressly provides for interlocutory appellate review of denials of a particular type of motions to dismiss: when defendants fail to obtain dismissal of allegations of willful misconduct in suits proceeding in the United States District Court for the District of Columbia. *See* 42 U.S.C. § 247d-6d(e)(1), (10); *Cannon v. Watermark Ret. Cmty., Inc.*, 45 F.4th 137, 146-48 (D.C. Cir. 2022) (explaining that subsection (e)(10) does not apply to all assertions of immunity under PREP Act). It is undisputed that Puritan’s motion to dismiss does not come within this statutory authorization of interlocutory review.

relief” other than reversal that we order the district court to limit discovery to the immunity issue, and address its affirmative defense, before proceeding to patent-related discovery. We will not interfere with the district court’s broad case management discretion by ordering it to proceed in this manner. Nevertheless, on remand the district court may wish to consider structuring this litigation in a manner that could allow it to make a conclusive determination on Puritan’s PREP Act immunity defense before this case otherwise proceeds any further.⁷

B

Puritan’s other main attack on the conclusion we have reached is to argue that our disposition is inconsistent with what other circuits have done in PREP Act cases. We are not persuaded.

In *Hampton v. California*, 83 F.4th 754, 761 (9th Cir. 2023), the district court denied the defendants’ motion to dismiss based on PREP Act immunity. There was no dispute that the defendants were “covered persons” and that the COVID tests involved were “covered countermeasures.” *See id.* at 763. All that was contested was whether the claims by the plaintiff – the spouse of a former inmate who had contracted COVID-19 while incarcerated and passed away – were for loss “caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). “The district court rejected all of Defendants’ claims to immunity.” *Hampton*, 83 F.4th at 761. In other words, the district court made a conclusive determination as a matter of law that immunity was *not* available. Here, by contrast, the district court did not conclusively hold that

⁷ At oral argument, Copan agreed that the immunity issue should be placed “front and center” and prioritized on remand. Oral Arg. at 30:31-55, 32:51-33:15.

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PREP Act immunity is unavailable; it only decided that Puritan has not yet made the factual showing required to establish such immunity. That the situation confronted by the Ninth Circuit in *Hampton* involved an appealable collateral order in no way demonstrates that the very different order we are reviewing also meets the requirements of the collateral order doctrine.

Two subsequent Ninth Circuit cases simply follow *Hampton* and add no analysis relevant to the issue of reviewability. See *Maney*, 91 F.4th at 1299 (“We have jurisdiction over Defendants’ immediate appeal of the district court’s denial of PREP Act immunity. *Hampton*, 83 F.4th at 761-62 (holding that a denial of PREP Act immunity is immediately appealable under the collateral order doctrine.)”); *Harris v. Allison*, 2023 WL 6784355, at *1 (9th Cir. Oct. 13, 2023) (“We have jurisdiction under the collateral order doctrine to review a district court’s rejection of immunity under the Public Readiness and Emergency Preparedness (“PREP”) Act, 42 U.S.C. § 247d-6d, at the motion to dismiss stage. See *Hampton v. California*, __ F.4th __, 2023 WL 6406760, at *4-5 (9th Cir. 2023).”).

Nor does *Solomon v. St. Joseph Hospital*, cited by Puritan, change our opinion. 62 F.4th 54 (2d Cir. 2023). In *Solomon*, the Second Circuit concluded it had “appellate jurisdiction to determine whether the district court had jurisdiction,” and, thus, it did “not decide whether Defendants’ interlocutory appeal [based on PREP Act immunity] is proper under the collateral-order doctrine.” *Id.* at 59.

None of these cases dealt with a situation in which, as here, “the district court determines that factual issues genuinely in dispute preclude summary adjudication.” *Ortiz*, 562 U.S. at 188. In cases such as ours, where the district court determines it requires “a more fulsome record of the relevant facts” before resolving the immunity question,

J.A. 10, the “conclusive determination” prong of the collateral order doctrine is not satisfied.

C

Finally, Puritan argues that the questions of fact the trial court relied on in denying its motion to dismiss were forfeited because Copan did not actually dispute them. Relatedly, Puritan contends that the court improperly identified its own disputed issues of fact and then relied on those disputes to deny Puritan’s motion. *See generally United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020) (“[I]n both civil and criminal cases, in the first instance and on appeal . . . , we rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present.”). Puritan is incorrect.

Copan, in its briefing opposing the motion to dismiss, stated its belief that the record contained disputed issues of material fact. J.A. 4344-45. Copan expressly requested that “at a minimum” it be given an opportunity to “explore the factual basis” for Puritan’s allegations before dismissal could even be considered. *Id.* The district court did not act inappropriately in denying the motion to dismiss based on factual disputes and its desire for a more fulsome record.

V

As the first requirement for application of the collateral order doctrine is not present, we need not consider whether the additional factors have been established. Accordingly, we dismiss for lack of jurisdiction.

DISMISSED