

[DO NOT PUBLISH]

In the
United States Court of Appeals
For the Eleventh Circuit

No. 24-13095

Non-Argument Calendar

HYBRID PHARMA LLC,

Plaintiff-Appellant,

versus

MATTHEW KNISPEL,
MARK WHITTEN,
ROBERT DIFIORE,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Florida
D.C. Docket No. 0:22-cv-61136-DSL

Before JORDAN, ABUDU, and KIDD, Circuit Judges.

PER CURIAM:

Hybrid Pharma LLC (“Hybrid”) appeals the district court’s order adopting a Magistrate Judge’s report and recommendation (“R&R”) and granting summary judgment to Matthew Knispel, Mark Whitten, and Robert Difiore, in Hybrid’s suit brought under 42 U.S.C. § 1983. After careful review, we affirm.

I. FACTUAL BACKGROUND & PROCEDURAL HISTORY

Hybrid brought this suit in June 2022, and, in September 2023, it filed an amended complaint. The amended complaint alleged that Knispel, Whitten, and Difiore selectively enforced laws regulating pharmaceutical outsourcing facilities by intentionally treating Hybrid differently than other similarly situated facilities with no rational basis for that disparate treatment. Hybrid brought a “class-of-one” claim under the Equal Protection Clause of the Fourteenth Amendment against each defendant. Hybrid identified various enforcement actions, both at its facility and at those of “comparator” facilities, to show a difference in treatment, and it identified Olympia Pharmacy (“OPS”), and KRS Global Biotechnology (“KRS”), as relevant comparators.

The defendants moved to dismiss Hybrid’s amended complaint, but, before the district court ruled on that motion, they moved for summary judgment. On summary judgment, the evidence, construed in the light most favorably to Hybrid, showed the following: Hybrid is an outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act of 1938. OPS and KRS

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are the same type of facility. In Florida, such facilities are regulated by both the Federal Food & Drug Administration (“FDA”) and the Florida Department of Health (“FDOH”). Either the FDA or the FDOH can order a recall or investigate deficiencies.¹ Knispel is the FDOH’s Chief of the Bureau of Enforcement, Whitten is the former Chief of the Bureau of Enforcement, and Difiore is the Pharmaceutical Program Manager within the Bureau of Enforcement. All 503B facilities are subject to the same general inspection and regulatory requirements by the DOH and the FDA. Hybrid and OPS had “a similar setup” in their pharmacies, and Hybrid and KRS each “had a pharmacy and production area contained within the same facility.”

The FDOH and the FDA took various enforcement actions against Hybrid, OPS, and KRS. Between 2013 and 2023, the FDOH issued several deficiencies to and filed several complaints against Hybrid. In 2013, the FDOH inspected Hybrid three times and gave Hybrid a deficiency on an inspection form for not certifying its anteroom, even though Hybrid provided proof of certification.²

¹ The parties use the term “deficiency” to refer to “a violation discovered during an inspection.” If the FDOH finds “serious deficiencies” it may file “a formal administrative complaint.” We write only for the parties, so, throughout our opinion, we use the parties’ terminology.

² An anteroom is part of the overall “cleanroom” of a compounding facility. Hybrid’s inspection form reflects a comment in the “remarks” section related to the condition of the anteroom that reads, in part: “the buffer room was tested at rest so it is unknown if the room maintains [appropriate standards] under opera[t]ional conditions. There is no Ante room. The plastic

Following the 2013 inspections, FDOH initiated an investigation, which led to a complaint being filed against Hybrid and one of its employees in 2014. The FDOH cited one of Hybrid's employees for allegedly not having requisite training, even though she did have the necessary training. The FDOH, however, did give Hybrid a "passing designation" with regard to training.

In March 2014, the FDOH issued Hybrid a Special Sterile Compounding Permit ("SSCP"), but it later informed Hybrid that the SSCP had been issued in error. Hybrid was not reissued a SSCP until 2015. On the other hand, the FDOH only inspected OPS once in 2015, and it did not revoke OPS's SSCP.

OPS issued a national recall for certain pharmaceutical products in 2013. After OPS's 2013 recall, the FDOH did not initiate a formal administrative complaint against OPS. In 2014, the FDA issued a warning letter to OPS regarding manufacturing deficiencies. After the FDA sent its warning letter, the FDOH inspected OPS but issued no deficiencies. In 2016, the FDA issued a warning letter to OPS for manufacturing deficiencies. In March 2022, OPS issued a recall for manufacturing deficiencies, but the FDOH again did not file a complaint against it.

Hybrid, on the other hand, never issued a recall.³ In 2017, the FDOH again investigated Hybrid, but later dismissed the

strips do not comply with requirements for an ante room" OPS's inspection form does not have any remarks relevant to its anteroom.

³ Hybrid's briefing before the district court and on appeal does not explain whether it produced the same products which were recalled at OPS. As

investigation. In 2018, Difiore sent an email requesting an inspection of Hybrid because he wanted to “reach out to [the] FDA . . . to highlight . . . egregious findings.” In 2019, Difiore emailed the FDA with a list of deficiencies from a 2017 inspection and called Hybrid a “threat” to the “public.” In 2019 and 2020, the FDOH gave Hybrid deficiencies for its alleged failure to calibrate instruments despite the production of documents that showed the instruments were properly calibrated. The FDOH did not issue OPS similar deficiencies after its 2019 and 2020 inspections. FDOH inspected Hybrid in 2019, 2020, and 2022, and investigated it for deficiencies, including for not having an independent quality control unit and production personnel.

In support of their motion for summary judgment, the defendants presented several arguments. However, the district court only addressed one: whether Hybrid had identified a valid comparator for its class-of-one claims. As for OPS, the defendants argued that no evidence supported Hybrid’s alleged disparate treatment claim, especially because FDOH’s enforcement activities against OPS and Hybrid were multi-dimensional, involved varied decision-making criteria, and took place over an extended period—undermining any claim of disparate treatment. They also argued that Hybrid’s second proposed comparator, KRS, was insufficient because there was no evidence that KRS was treated dissimilarly to

discussed further below, this is the sort of information that is necessary for Hybrid to show that it was similarly situated with OPS.

Hybrid—the inspection reports for the two entities suggested similar FDOH investigations.

A Magistrate Judge prepared an R&R with a recommendation to grant the motion for summary judgment. The R&R explained that Hybrid’s reliance on OPS and KRS as comparators did not create a genuine dispute of fact. The R&R recognized that the FDOH issued several deficiencies and filed several complaints against Hybrid, whereas it had issued a smaller number against OPS. Even so, it determined that Hybrid failed to present evidence that OPS had engaged in the same deficient performance and yet received different, more favorable treatment from the enforcement agency. Thus, according to the R&R, Hybrid did not establish that OPS was a proper comparator.

First, the R&R concluded there was “no evidence” to “demonstrate that the circumstances concerning [Hybrid]’s and OPS’s anteroom and personnel training were similar, such that either OPS should have received the deficiencies as Hybrid did” in 2013, or vice versa. FDOH also gave Hybrid other deficiencies in June 2013—besides the anteroom deficiency and personnel training—and Hybrid presented no evidence that OPS had violated the same FDOH requirements. Next, the R&R concluded that, based on the record, there was no evidence “that the circumstances concerning [Hybrid]’s and OPS’s compounding were similar, such that either OPS should have received the” deficiencies Hybrid received in 2015 for “compounding related matters” or that Hybrid “should not have received the deficiencies as OPS did not.” The R&R next

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explained that, while the FDOH filed a formal complaint against Hybrid in 2017, there was no evidence about “what this complaint was about or evidence that could demonstrate that OPS had similar circumstances” as Hybrid. The R&R explained that Hybrid’s deficiencies in 2019, 2020, 2022, and 2023—regarding calibration of instruments and a quality control unit—presented no similarity with OPS, and Hybrid did not cite to evidence that suggested otherwise.⁴ Further, it explained that Hybrid pointed to no evidence that could demonstrate “that the FDOH should have investigated OPS as it did [Hybrid]” in 2022 for altering an inspection form, or that it “should not have investigated [Hybrid] as it did not investigate OPS.” Turning to the SSCP, the R&R explained that Hybrid failed to present evidence that OPS’s permit was similar, that FDOH should have revoked OPS’s SSCP, or that the FDOH should *not* have revoked Hybrid’s permit. Accordingly, the R&R concluded that there was no reason to think that the FDOH’s actions reflected disparate treatment.

The R&R recognized that the FDA issued warning letters to OPS in 2014 and 2016, and OPS issued national drug recalls in 2013 and 2022, but Hybrid was subjected to none of these actions. However, because these OPS actions at the federal level were not equivalent to actions toward Hybrid at the federal level, “any FDOH

⁴ While Hybrid alleged their quality control unit set up was the same as OPS’s, the R&R concluded that no evidence in the record supported that contention, and conclusory allegations or speculation were insufficient to survive summary judgment.

action or inaction in response to the federal actions” was not comparable. The R&R concluded that, even taking as true Hybrid’s assertions that it was inspected more frequently and that the investigations lasted longer, there was no evidence that Hybrid and OPS were investigated for similar issues. It concluded that because the FDOH found deficiencies at Hybrid and not OPS, the two entities were not similarly situated with respect to the need for re-inspections. The R&R also addressed FDOH’s statement which referred to Hybrid as a threat to the public. The R&R explained that when the FDOH made the statement, it had issued deficiencies and complaints against Hybrid but had not issued such against OPS, and thus Hybrid and OPS were not similarly situated with regard to being called a threat to the public. Last, the R&R rejected Hybrid’s second proffered comparator, KRS. It concluded that the evidence about KRS suggested that the FDOH never issued complaints against it and KRS did not have a similar history of deficiencies or FDOH inspections.

Hybrid objected to the R&R, raising many of the same arguments it raises on appeal. At bottom, it argued that it had valid comparators, as it was similarly situated to OPS and KRS because OPS and KRS were both:

- (i) located within the *same* regulatory jurisdiction as [Hybrid]; (ii) engaged in the *same* business as [Hybrid]; (iii) hold or held the *same* state licenses and federal registrations as [Hybrid]; . . . (iv) have the *same* facility setups as [Hybrid]. . . (v) subject to the *same* regulations; (vi) subject to the *same* type of inspection

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using the same inspection form and criteria; and
(vii) inspected by the *same* regulatory agencies and inspectors.

It went through each FDOH action and argued the R&R had defined “similarly situated” too strictly, as it was sufficient that it, OPS, and KRS were subject to the same requirements and the FDOH only took action against Hybrid.

The district court adopted the R&R. It explained that Hybrid’s objections showed that it “fundamentally misunderstand[ed]” the correct test for whether a comparator is similarly situated. It reasoned that Hybrid was using a “too broad” definition of “similarly situated” and that if it were to use Hybrid’s standard, “it would encapsulate nearly *all* drug compounders subject to the same regulations.” Such a test “would only show that a plaintiff was treated differently than a comparator in the same industry *regardless* of whether the underlying actions were the same.” Under the correct standard, there was no evidence that OPS or KRS were valid comparators because Hybrid had not shown that they had the same, or even similar, violations without receiving sanctions. For example, it was conceivable the FDOH gave Hybrid, but not OPS, an anteroom deficiency because Hybrid’s anteroom did not meet regulatory standards while OPS’s anteroom did, and there was no evidence in the record that the anterooms were substantively the same. The court concluded that Hybrid’s understanding of “class of one” claims was “misguided (and border[ed] on frivolous)” because it failed to appreciate that “FDOH treated Hybrid . . . differently than OPS and KRS because Hybrid . . . engaged in worse

conduct than OPS and KRS.” Therefore, the district court granted the motion for summary judgment.⁵

II. STANDARDS OF REVIEW

“We review a district court’s grant of summary judgment *de novo*.” *Poer v. Jefferson Cnty. Comm’n*, 100 F.4th 1325, 1335 (11th Cir. 2024). “Summary judgment is appropriate ‘if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.’” *Id.* (quoting Fed. R. Civ. P. 56(a)). A party who moves for summary judgment bears the burden to demonstrate the lack of genuine issues of material fact. *Id.* “In determining whether the movant has met this burden, we must view the evidence in the light most favorable to the non-moving party” and “draw all reasonable inferences in the non-movant’s favor.” *Id.*

III. DISCUSSION

“The Equal Protection Clause of the Fourteenth Amendment commands that no State shall ‘deny to any person within its jurisdiction the equal protection of the laws,’ which is essentially a direction that all persons similarly situated should be treated alike.” *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985). “When presenting a class of one equal protection claim, a plaintiff

⁵ The district court later granted the defendants’ motion for attorneys’ fees, concluding that the suit was “frivolous, unreasonable, or without foundation.” *Hughes v. Rowe*, 449 U.S. 5, 14 (1980) (quoting *Christiansburg Garment Co. v. EEOC*, 434 U.S. 412, 421 (1978)). The order granting attorneys’ fees has separately been appealed and is not addressed further here.

alleges that it is the only entity being treated differently from all other similarly situated entities, even though it does not belong to a suspect classification.” *PBT Real Est., LLC v. Town of Palm Beach*, 988 F.3d 1274, 1285 (11th Cir. 2021). “[T]o prevail, a plaintiff must show that it ‘has been intentionally treated differently from others similarly situated and that there is no rational basis for the difference in treatment.’” *Id.* (quoting *Campbell v. Rainbow City*, 434 F.3d 1306, 1314 (11th Cir. 2006)). “[W]e apply the ‘similarly situated’ requirement ‘with rigor.’” *Id.* (quoting *Griffin Indus., Inc. v. Irvin*, 496 F.3d 1189, 1207 (11th Cir. 2007)). “The entities being compared must be *prima facie identical in all relevant respects*.” *Id.* (alterations adopted, emphasis in original) (quoting *Irvin*, 496 F.3d at 1204).⁶ That is the case “because ‘[d]ifferent treatment of dissimilarly situated persons does not violate the equal protection clause.’” *Campbell*, 434 F.3d at 1314 (quoting *E&T Realty v. Strickland*, 830 F.2d 1107, 1109 (11th Cir. 1987)). Thus, a plaintiff making a class of one claim must “show that it and any comparators are ‘similarly situated in light of all the factors that would be relevant to an objectively reasonable governmental decisionmaker.’” *PBT Real Est.*, 988 F.3d at 1285 (quoting *Douglas Asphalt Co. v. Qore, Inc.*, 541 F.3d

⁶ Our employment discrimination caselaw—which asks a similar comparator question—has also wrestled with “[t]he obvious question” of “[j]ust how ‘similarly situated’ must a plaintiff and her comparator(s) be?” *Lewis v. City of Union City*, 918 F.3d 1213, 1217 (11th Cir. 2019) (*en banc*). Sitting *en banc*, we held—at least in that context—that a plaintiff must show their proffered comparators to be “similarly situated in all material respects.” *Id.* at 1218. While we express no view on whether that test is identical to the class of one Equal Protection test described above, we note that we have rigorously applied both tests.

1269, 1275 (11th Cir. 2008)); *see also Chabad Chayil, Inc. v. Sch. Bd. of Miami-Dade Cnty.*, 48 F.4th 1222, 1233 (11th Cir. 2022). “[W]hen plaintiffs in ‘class of one’ cases challenge the outcome of complex, multi-factored government decisionmaking processes, similarly situated entities ‘must be very similar indeed.’” *Irvin*, 496 F.3d at 1205 (quoting *McDonald v. Vill. of Winnetka*, 371 F.3d 992, 1002 (7th Cir. 2004)).

Here, Hybrid did not provide sufficient evidence of a similarly situated comparator to defeat summary judgment for the reasons set forth in the R&R and district court’s decision. One factor obviously “relevant to an objectively reasonable governmental decisionmaker,” is whether both parties committed the same misconduct that led to their sanction. *PBT Real Est.*, 988 F.3d at 1285; *Douglas Asphalt*, 541 F.3d at 1275. Hybrid’s failure to show the parties engaged in similar conduct and misconduct means that it did not show that it and its comparators were similarly situated. Such a failure is fatal because “different treatment of dissimilarly situated persons does not violate the equal protection clause.” *Campbell*, 434 F.3d at 1314. We explain in brief why Hybrid’s arguments to the contrary fail to persuade.

First, Hybrid argues that it is similarly situated to OPS in the context of anteroom compliance because Hybrid’s anteroom and OPS’s anteroom are required to be the same by regulation. Still, Hybrid cites no evidence in the record that shows similarity *in fact*. Instead, it cites the inspection reports that show Hybrid received a

deficiency for its anteroom and OPS did not.⁷ It also notes that there was testimony that Hybrid and OPS had the “same setup.” It does not, however, provide any evidence to show it was undeserving of the anteroom deficiency or that OPS *warranted* a similar deficiency such that a factfinder could conclude that the two entities were similar in this respect. *PBT Real Est.*, 988 F.3d at 1285; *Irvin*, 496 F.3d at 1207.

Second, Hybrid argues that it is similarly situated in the context of pharmacist training compliance. This argument faces the same problem as the previous: Hybrid relies on the fact that FDOH gave it a deficiency and not OPS, but cites no record evidence to suggest the deficiency was unwarranted or that FDOH should have given OPS the same deficiency. Thus, there is also no material question of fact about similarity in this respect. *See PBT Real Est.*, 988 F.3d at 1285; *Irvin*, 496 F.3d at 1207.

Third, Hybrid argues that it is similarly situated in the context of calibration of instruments compliance. Yet it cites no evidence that it and OPS had the same calibration of instruments. Though it contends, with no evidentiary support, that all

⁷ The “remarks” on Hybrid’s inspection report state “high risk” Compounding Sterile Preparations had been “dispensed prior to passing sterility test.” Hybrid argues that these remarks are not relevant, but it presents no evidence to suggest that those remarks were irrelevant to the FDOH—and a rational reason for their inclusion is that they had *some* importance. *See Graham v. State Farm Mut. Ins. Co.*, 193 F.3d 1274, 1282 (11th Cir. 1999) (explaining, at summary judgment, that a “nonmovant need not be given the benefit of every inference but only of every reasonable inference”).

outsourcing facilities “utilize the same instruments and conduct the same calibration,” the FDOH did *not* conclude that Hybrid and OPS had the same calibration of their instruments. Thus, Hybrid’s argument that the FDOH treated it differently by issuing it and not OPS a “failed designation” is meritless because there is no evidence suggesting *disparate* treatment of *similar* conduct.

Fourth, Hybrid argues that it is similarly situated in the context of SSCP Application Compliance. It notes that both it and OPS applied for and received SSCP licenses, but that, shortly thereafter, FDOH revoked its license due to an “error.” It asserts that it submitted the same document as OPS and faced the same inspection, yet it lost its license while OPS did not. These allegations approach the similarity necessary for a class-of-one claim. The record, though, does not include information about the circumstances of OPS’s SSCP permit issuance. Instead, all the record reflects is that OPS kept its SSCP but Hybrid did not. This falls far short of evidence that the two entities were similarly situated in all relevant respects. *PBT Real Est.*, 988 F.3d at 1285; *Irvin*, 496 F.3d at 1207.

Several of Hybrid’s other arguments fail because they rely solely on a difference in treatment as evidence of unequal treatment without any reference to the basis for the difference in circumstances. For instance, Hybrid argues that it was treated differently because it faced additional obligations—for example, it received more inspections than OPS—but the record evidence showed that these requirements and inspections were a result of underlying violations that Hybrid received that OPS did not

receive. Hybrid cannot show it received unwarranted *disparate* treatment as it relates to OPS by saying it received additional inspections that were follow-up inspections when OPS did not receive follow-up inspections because OPS did not receive any deficiencies in the initial inspections. The same goes with Hybrid’s argument about the length and manner of inspections.

At bottom, as the district court explained, Hybrid’s suit asserts that the deficiencies it received when other parties did not show an equal protection violation because it and its comparator businesses have the same core characteristics.⁸ All the same, to defeat summary judgment, it needed to come forward with evidence not just of similarity in business, but similarity in *all* relevant respects—not just that they operate in the same regulated field. *PBT*

⁸ As it did before the district court, Hybrid relies heavily on *Mad Room, LLC v. City of Miami*, No. 21-cv-23485, 2023 WL 8598151 (S.D. Fla. Dec. 12, 2023), but its reliance is misplaced. First, *Mad Room* is a district court opinion; so it was not binding on the district court and is not binding on us. *Fishman & Tobin, Inc. v. Tropical Shipping & Const. Co.*, 240 F.3d 956, 965 & n.14 (11th Cir. 2001). Second, *Mad Room* is an order at the motion-to-dismiss stage, which means the court’s inquiry there was different than ours is here. At the motion to dismiss stage, a court takes a complaint’s allegations as true and asks whether the claim is plausible; at the summary judgment stage, a court looks to see whether there is evidence in the record creating a genuine issue of material fact. Compare *Wainberg v. Mellichamp*, 93 F.4th 1221, 1224 (11th Cir. 2024), with *Poer*, 100 F.4th at 1335. In any event, *Mad Room* does not stand for a broad rule—that would contradict our published precedent—that a plaintiff need not present a comparator that is “*prima facie identical in all relevant respects*.” *PBT Real Est.*, 988 F.3d at 1285 (emphasis in original).

Real Est., 988 F.3d at 1285; *Irvin*, 496 F.3d at 1204.⁹ Accordingly, the district court properly granted summary judgment.

IV. CONCLUSION

For the reasons described above, we affirm in all respects.

AFFIRMED.

⁹ A hypothetical illustrates the problems with Hybrid's position. Imagine an employment suit where a plaintiff employee has been terminated, purportedly for tardiness and absence issues. If that plaintiff employee's theory of her case was that she was late and absent but the *real* reason for her termination was discrimination, she might try to prove her case by comparing herself to another employee who was not terminated. However, if she compares herself to another employee who was not terminated *and* who had never been late or absent, she could not show that the disparate treatment was based on anything besides tardiness and absence. Like this hypothetical, Hybrid's evidence does not show anything besides potentially justifiable disparate treatment.