Court Dismisses Class Action Challenge to Marketing of IVF-Related Genetic Testing

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Anderson, et al. v. Genomic Prediction

Three named plaintiffs brought an 11-count, 472-paragraph complaint in the U.S. District Court for the District of New Jersey, asserting claims under the laws of all 50 states and the District of Columbia on behalf of themselves and a putative nationwide class of purchasers of the defendant's pre-implantation genetic testing for aneuploidy (PGT-A).

Case Background

PGT-A is an add-on procedure to the in vitro fertilization (IVF) process. In a nutshell, a biopsy of three to five cells is taken from the outer cell wall of a fertilized embryo and tested for genetic abnormalities. There are many different methodologies used to perform PGT-A.

The plaintiffs alleged that the defendant, Genomic Prediction, falsely and deceptively marketed their PGT-A testing as a proven, accurate, and reliable method to decrease the chance of miscarriage and increase the chance of giving birth to a healthy baby without disclosing that "science does not support" those claims. The plaintiffs cited a constellation of more than 45 scientific papers published across more than two decades and without any regard for the methodology discussed in those studies, claiming PGT-A, broadly, is "unproven, inaccurate, and unreliable." In particular, the plaintiffs took issue with nine categories of alleged advertising statements made by the defendant, including:

- Its PGT-A is the "most advanced" genetic screening.
- Its PGT-A is 98-99% accurate.
- Its PGT-A increases pregnancy rates.

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- Its PGT-A lowers miscarriage rates.
- Its PGT-A reduces the number of IVF cycles needed and results in fewer wasted embryos.
- Its PGT-A increases the chance of a successful pregnancy.
- Its PGT-A increases the chance of a healthy child.
- Its PGT-A leads to more embryos available for transfer.
- Its PGT-A has lower false positive and false negative rate than other PGT-A methodologies.

The complaint said nothing about (1) the plaintiffs' actual test results, (2) their test results' accuracy, (3) their IVF outcomes, (4) the counseling they received, or (5) the defendant's involvement in the counseling process (beyond testing for embryo aneuploidy).

Defendant's Motion to Dismiss

The defendant, Genomic Prediction, moved to dismiss the complaint on multiple grounds. First, it argued that the plaintiffs could not plead any injury-in-fact and therefore lacked Article III standing. While a plaintiff may plead an economic injury by alleging that she bargained for a service worth a given value but received a service worth less than that value (i.e., the benefit-of-the-bargain theory), a plaintiff must allege the specific service she received was defective. The defendant's motion stressed that broad allegations that similar services could be defective were not sufficient to meet that burden.

Notably, in *Huertas v. Bayer US LLC*, 120 F.4th 1169, 1178 (3d Cir. 2024), the U.S. Court of Appeals for the Third Circuit held that allegations that a product was recalled were too general to sustain the complaint, because there was nothing to connect the product's contamination to the specific lot numbers of the products the plaintiffs purchased. The mere fact there was a recall of some of the products without any connection to the specific products the plaintiffs purchased "stopp[ed] short of the line between possibility and plausibility" and was fatal to the claims.

The defendant's motion highlighted for the court that two other courts — the District of Delaware and the District of Colorado —

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considered Article III standing in PGT-A class actions brought by the same law firm with the same theory, and both dismissed the complaints in their entirety for failing to sufficiently plead an injury-in-fact as outlined by the Third Circuit in *Huertas*.

The plaintiffs argued they had Article III standing because they sufficiently "allege[d] a classic benefit-of-the-bargain injury" in that they "paid for — but did not receive — a test represented to be 98%-99% accurate and to provide specific clinical benefits, including improved reproductive outcomes." The plaintiffs tried to distinguish *Huertas* by arguing that they alleged "all of Defendant's PGT-A testing failed to perform as marketed."

Motion to Dismiss Granted

After considering the arguments, the District of New Jersey granted the defendant's motion and followed the holdings of the District of Delaware and the District of Colorado. The court emphasized that the District of Delaware, relying on the Third Circuit's decision in *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Liab. Litig.*, 903 F.3d 278, 283 (3d Cir. 2018), found "the plaintiffs failed to allege that *their own* PGT-A testing failed to 'adequately perform' the intended functions," adding that, in this case, the "[p]laintiffs' complaint fares no better."

The District of New Jersey explained that, while the plaintiffs "point to numerous studies and scientific opinions that purport to undermine the scientific efficacy of the Defendant's PGT-A testing and the representations," the complaint did not "allege facts that would enable this Court to reasonably infer that the specific PGT-A tests purchased by Plaintiffs were defective." The court observed that "[n]one of the Plaintiffs allege, for example, that they failed to become pregnant, suffered a miscarriage, or experienced a medically compromised pregnancy — notwithstanding [the Defendant's] alleged marketing statements that PGT-A mitigates all of those problems." The court added that it is "unclear" from the face of the complaint whether the plaintiffs' results were indeed inaccurate and, "without more, the Court ha[d] no grounds to infer that Defendant deprived Plaintiffs of the benefit of their bargains such that Plaintiffs have asserted an injury-in-fact."

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The court's decision offers an apt illustration of the nuances of the Third Circuit's decisions in *Huertas* and *Johnson & Johnson*. Ninety-six pages of allegations and citations to 45 scientific papers about the potential flaws in a type of service are no substitute for allegations particularized to the service actually purchased. The court, however, afforded the plaintiffs an opportunity to file an amended complaint within 45 days to address the deficiencies identified.

For more information about this decision, please contact the authors or any attorney with FBT Gibbons' Class Actions team.

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