IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

JEANETTE PEREZ-MACEIRA, et al.,

Plaintiffs,

v.

CUSTOMED, INC, et al.,

Defendants.

CIVIL NO. 23-1445 (CVR)

OPINION AND ORDER

INTRODUCTION

Plaintiffs Jeanette Pérez-Maceira, Jose Luis Mateo-Pérez, Lilliam M. Ortíz, Danisha M. Ortíz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, Lianibel Colón-Sánchez, Iris M. Rivera-Vargas, Idalia Vargas-Gratacós, and Juana Castro-Moreno (collectively, "Plaintiffs") brought the present case individually and on behalf of all others similarly situated against co-Defendants Customed, Inc. ("Customed"), Medtronic P.R., Inc. ("Medtronic"), Edward LifeSciences Technology Sarl ("Edward LifeSciences"), Steri-Tech, Inc. ("Steri-Tech"), Balchem Corp. ("Balchem") and Mays Chemical Company of Puerto Rico, Inc. ("Mays") (collectively, "Defendants"). According to the pleadings, co-Defendants Customed, Medtronic, Edward LifeSciences, and Steri-Tech operate equipment sterilizer facilities (hereinafter, the "Sterilizer Defendants") in different municipalities in Puerto Rico and use Ethylene Oxide ("EtO"), a known human carcinogen. Co-Defendant Balchem manufactures the product and co-Defendant Mays distributes it. Plaintiffs, who reside or work in the immediate vicinity of the Sterilizer Defendants, proffer they have been harmed by Defendants' negligent handling of EtO, as

they were unaware that they were being exposed to dangerous odorless and colorless EtO gases that for years emanated from the Sterilizer Defendants' facilities.

The original Complaint filed on August 29, 2023 contained claims by only three (3) representative Plaintiffs who resided solely in the vicinity of the Steri-Tech's facility in Salinas, Puerto Rico. (Docket No. 1). On February 9, 2024, an Amended Complaint was filed, naming a total of seventeen (17) Plaintiffs who each resided in the vicinity of one of the sterilizing facilities in Salinas (Steri-Tech), Añasco (Edward LifeSciences), Fajardo (Customed), or Villalba (Medtronic). (Docket No. 65). This complaint was again amended on February 29, 2024 to eliminate some of the lead Plaintiffs and left the operative pleading with ten (10) lead Plaintiffs. (Docket No. 74).

After these amendments, Plaintiffs ultimately brought eleven (11) distinct claims: negligence (Count I); gross negligence (Count II); public nuisance (Count III); strict liability - design defect (Count IV); strict liability – design defect based on negligence (Count V); strict liability - failure to warn and instruct (Count VI); strict liability - failure to warn and instruct based on negligence (Count VII); negligent design defect (Count VIII); gross negligent design defect (Count IX); private nuisance (Count X); and restitution-unjust enrichment (Count XI). (Docket No. 74).

Before the Court are several Motions to Dismiss filed by all Defendants (Docket Nos. 75, 76, 78, and 79); Plaintiffs' Omnibus Opposition (Docket No. 83); and Defendants' Replies and requests for joinder (Docket Nos. 84, 87, 90, and 91). The motions were referred to Magistrate Judge Giselle López-Soler ("Magistrate Judge López-Soler") for a Report and Recommendation ("R&R"). (Docket No. 92).

Magistrate Judge López-Soler recommended in the R&R that the Motions to Dismiss at Docket Nos. 75 (Balchem) and 78 (Mays) be GRANTED, and the Motions to Dismiss at Docket Nos. 76 (Customed, Edward LifeSciences and Medtronic) and 79 (Steri-Tech) be GRANTED IN PART and DENIED IN PART. (Docket No. 104). Specifically, she recommended dismissal of all claims against Balchem and Mays. As to the Sterilizer Defendants, she recommended the dismissal of the following claims: gross negligence (Count II), restitution-unjust enrichment (Count XI) and all product liability causes of action (Counts IV, V, VI, VII, VIII and IX). Finally, she recommended the dismissal of all claims brought by Plaintiff Iris Rivera-Vargas against Edward LifeSciences.[1]

Pursuant to Magistrate Judge López-Soler's R&R, the surviving claims would be:

1. For negligence (Count I):
    a. against Steri-Tech: the claims of Jeanette Pérez-Maceira, José Mateo-Pérez, Lilliam Ortiz, Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez pursuant to the American Pipe's doctrine;
    b. against Medtronic: the claims of Idalia Vargas-Gratacós based on the continuing tort doctrine;
    c. against Customed: the claims of Juana Castro-Moreno based on the continuing tort doctrine.
2. For public and private nuisance (Counts III and X):
    a. against Steri-Tech, Medtronic and Customed.

[1] As will be discussed below, this leaves no actionable claims against Edward LifeSciences and effectively means the dismissal of this Defendant from this action altogether under the holding of American Pipe and Constr. Co., et al., v. Utah, et al., 414 U.S. 538 (1974).

Plaintiffs, Customed, Edward LifeSciences, Medtronic and Steri-Tech timely filed limited objections to the Magistrate Judge's Report and Recommendation, as well as responses to the objections raised by the opposing party. Balchem and Mays did not object to the R&R. Instead, Balchem filed a Response to Plaintiffs' Objections, which Steri-Tech joined. (Docket Nos. 110, 111, 112, 113, 115, and 116).

ANALYSIS

The Court may refer dispositive motions to a Magistrate Judge for an R&R. See 28 U.S.C. § 636(b)(1)(B); Fed. R. Civ. P. 72(b). Within fourteen days of receiving a copy of the R&R, "a party may serve and file specific written objections to the proposed findings and recommendations." Id. Objections must "specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for the objection." Local Rule 72(d); see also Fed. R. Civ. P. 72(b)(2).

Upon filing of a timely objection, a party is entitled to a de novo determination of the portions of the report or specified proposed findings or recommendations to which specific objections are made. 28 U.S.C. § 636(b)(1)(C); Total Petroleum Puerto Rico Corp. v. Fonseca-Marrero, Civil No. 16-2436 (PAD), 2018 WL 6131777, at *1 (D.P.R. 2018); Ponsa-Rabell v. Santander Securities, LLC, Civil No. 17-2243 (CCC), 2020 WL 4219685, at *1 (D.P.R. 2022); United States v. J.C.D., 861 F.3d 1, 6 (1st Cir. 2017). When performing this review, the Court may "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(a)(b)(1). Any portions of the R&R not objected is reviewed under the "plain error" standard. See Torres Negrón v. United States, 18 F.Supp.3d 89, 91 (D.P.R. 2014) ("[a]bsent objection by the plaintiffs,

[a] district court ha[s] a right to assume that [a party] agree[s] to the magistrate's recommendation.").

As an initial matter, the Court agrees with the Magistrate Judge's conclusion that, because the proposed class is limited to "all individuals who have resided, worked and/or attended schools within a four mile radius"[2] of the sterilizing facilities, each of Plaintiff's claims are only actionable against the sterilizing facility within the four (4) mile radius of his or her respective home, work or school. Therefore, only Plaintiffs who resided/worked/or went to school within the radius in Salinas can bring claims against Steri-Tech, only Plaintiffs who resided/worked/or went to school within the radius in Villalba can bring claims against Medtronic, only Plaintiffs who resided/worked/or went to school within the radius in Fajardo can bring claims against Customed and only Plaintiffs who resided/worked/or went to school within the radius in Añasco can bring claims against Edward LifeSciences.

The Court also agrees with the Magistrate Judge's conclusion that the gross negligence (Count II) and unjust enrichment (Count XI) claims must be dismissed as there was no error in said determination.[3] The gross negligence claim is not actionable under Puerto Rico law. See Rivera v. Kress Stores, P.R., Inc., Civil No. 20-1350 (ADC), 2023 WL 6795130 at *5 (D.P.R. Oct. 13, 2023). The restitution-unjust enrichment claim, on the other hand, may not move forward if there are other viable theories of liability asserted, and Plaintiffs bring forth ten (10) additional theories of liability in their Amended Complaint. See Ortiz Andújar v. E.L.A., 122 D.P.R. 817, 822 (1988); In re Fin.

[2] Docket No. 74, ¶ 96.
[3] Plaintiffs did not object to these recommendations in the R&R.

Oversight & Mgmt. Bd. for Puerto Rico, 578 F.Supp.3d 267, 296 (D.P.R. 2021), aff'd, 54 F.4th 42 (1st Cir. 2022). [4]

Finally, the Court also agrees with the Magistrate Judge's recommendation that dismissal of the Defendant-funded medical monitoring program that Plaintiffs seek is premature, as the class has not been certified and the relief for a medical monitoring program is contingent on that certification. The parties are free to revisit this issue after briefs on this issue are filed with the Court in due course, including whether Puerto Rico law supports such relief.

A. Plaintiffs' Objections.

Plaintiffs raised a limited objection to the Magistrate Judge's R&R as to her finding that 2022 started the clock for purposes of the statute of limitations; that she erroneously applied the American Pipe doctrine to exclude certain claims; and her analysis recommending dismissal of the claims against Balchem was in error. Plaintiffs did not object to the dismissal of the claims against Mays.

Upon a de novo review, the Court agrees with the Magistrate Judge's conclusion that the clock started to run in 2022, when the Environmental Protection Agency ("EPA") made an announcement that placed Sterilizer Defendants' facilities in a "red flag" list of sites with higher risk of EtO exposure to Puerto Rico's citizens and for this reason, the original claims brought against Steri-Tech were timely. Although Plaintiffs assert that the Magistrate Judge impermissibly blended the inclusion of scientific background

[4] "Unjust enrichment involves recovery and/or restitution for the value of a benefit retained when there is no contractual relationship and on grounds of fairness and justice, wherein the law compels performance of a legal and moral duty to pay." Stewart v. Husqvarna Const. Prods. N. Am., Inc., Civil No. 11-1182 (CVR), 2012 WL 1590284, at *8 (D.P.R. May 4, 2012).

information to support plausibility with allegations of discovery for statute of limitations purposes, as Defendants rightfully assert, Plaintiffs cannot argue on one hand, that Defendants were well aware of the harmful effects to EtO based on widely disseminated reports but then deny that those same reports failed to provide Plaintiffs with adequate notice of their potential claims.

Additionally, Plaintiffs assert that the EPA offered meetings at the sites where three of the Sterilizer Defendants' facilities are located (Fajardo on January 26, 2023; Villalba on January 24, 2023, and Añasco on June 23, 2021). These actions further establish when the relevant information became publicly available to determine a date certain when Plaintiffs knew or should have known of the cause of their alleged injuries. Taking all this information as true, at this stage, the Court finds that the clock began to run in 2022 with the EPA's announcement.

The undersigned also agrees with the Magistrate Judge's conclusion that the American Pipe tolling doctrine requires the claims to be originally redressable against a defendant to anchor any subsequent claims brought by new plaintiffs against that defendant in an amended pleading. Thus, the claims brought against Edward LifeSciences, Customed and Medtronic by any new Plaintiff after the initial pleading would normally be time-barred because none of the Plaintiffs in the original Complaint lived within the radius of those facilities as they all lived near Steri-Tech. Magistrate Judge López-Soler nevertheless concluded that the claims of Idalia Vargas-Gratacós against Medtronic and Juana Castro-Moreno against Customed survive under the exception of the continuing tort doctrine, which allows for tolling of a tort claim until such time as the unlawful conduct ends.

Under Puerto Rico law, a continuous tort arises from ongoing unlawful conduct and not from a continuing harmful effect of the conduct. See Rivera Ruiz v. Mun. de Ponce, 196 D.P.R. 410, 417 (2016). At this juncture, Plaintiffs have pled that the Sterilizer Defendants have engaged in a continued pattern of unlawful acts or omissions by releasing harmful emissions into the atmosphere and failed to warn the communities where they were located that the residents were routinely and continuously breathing the toxic EtO emissions, which caused them harm. Taking this as true, as the Court must at this stage, this is enough to survive a motion to dismiss.

However, moving forward Plaintiffs bear the burden of proving this alleged continued pattern of unlawful, toxic emissions and their harm. If Plaintiffs fail to do so, they must establish that their injuries and the tortfeasor's identity were known within one (1) year of the date when the complaint was filed. See P.R. Laws Ann. tit. 31, § 9496 (2020); Tokyo Marine & Fire Ins. Co. v. Pérez & Cia., de Puerto Rico, Inc., 142 F.3d 1, 3 (1st Cir. 1998).[5] This is a fact-intensive endeavor due to the multiple avenues that Plaintiffs had available to acquire knowledge of their tortfeasors, and which is premature at this stage.

As such, the Court also concurs with Magistrate Judge López-Soler that this argument may be revisited by Defendants after conclusion of discovery at the dispositive motion stage and with a more fully developed record, where it may well be that some or all of Plaintiffs' causes of actions are found to be time-barred. See Rodríguez-Suris v. Montesinos, 123 F.3d 10, 15 (1st Cir. 1997); Santos Espada v. Lugo, 312 F.3d 1, 4 (1st Cir.

[5] Although a new Civil Code was adopted in 2020, the Puerto Rico general tort statute did not suffer substantial changes. See QBE Seguros v. Morales-Vázquez, Civil No. 15-2091 (BJM), 2023 WL 3766078, at *3 (D.P.R. June 1, 2023). The one (1) year prescriptive period for torts remains unchanged. P.R. Laws Ann. tit. 31, § 9496 (2020).

2002) (noting that because the issues of due diligence and adequate knowledge maybe be up to a jury "so long as the outcome is within the range where reasonable men and women can differ."). At this stage of the case, on the facts as they stand now on this limited record, it is simply too early for the Court to make a determination as to this issue. [6]

The Court also agrees with the Magistrate Judge's conclusion that Iris Rivera-Vargas' claims against Edward LifeSciences must be dismissed because she stopped working near said facility in 2008 and thus, the continuing tort doctrine is inapplicable to her claims. She had one (1) year from the moment she was put on notice of a possible connection between the EtO emissions, to wit, the 2022 announcement made by the EPA regarding EtO emissions in Puerto Rico, and her diagnosis to assert a claim against Defendants. She was joined in this case in February, 2024. Thus, since her claims were not tolled either by the original three (3) Plaintiffs under the American Pipe doctrine[7], her claims are untimely.

As to Plaintiffs' objection to the dismissal of the claims against Balchem, the Court agrees (and Plaintiffs do not dispute) that Balchem does not operate any of the sterilizing facilities. Thus, the negligence and nuisance cause of action from the alleged harmful

[6] Plaintiffs aver that the Magistrate Judge's determination that 2022 was the operative date is unsupported because their pleading alleges that they did not find out "until recently" the extent of the emissions and the risk they posed. See Docket No. 74, ¶ 89. However, Plaintiffs fail to state specifically when they learned the extent of the emissions and the risk posed. Thus, even though the statute of limitations has been raised by the Co-Defendants, it seems that Plaintiffs have not met their burden as this juncture to establish that their claims are timely or that they timely tolled the prescriptive period. Considering the early stage of this case, that discovery proceedings have not ensued and the complexity of this case, the Court will give Plaintiffs the benefit of the doubt and finds they have met the plausibility threshold.

[7] As previously noted, American Pipe requires the claims originally brought to be redressable against an original defendant to anchor any subsequent claims brought by new plaintiffs in an amended pleading. Since none of the original three (3) Plaintiffs had claims against Edward LifeSciences, the causes of action against this Defendant were not tolled.

effects of the emissions emanating from the facilities operated by the Sterilizer Defendants cannot lie against Balchem.

The Court likewise concurs with the Magistrate Judge's conclusion that the design defect claims against Balchem cannot prosper, as there can be no defect in the product because it is 100% EtO. Mendoza v. Cervecería Corona, 97 D.P.R. 499, 512 (1969) (indicating that harm must be caused by a defect in the product).

Finally, the failure to warn claims also fail because Plaintiffs admit that the Sterilizer Defendants, the end-user of the product, were aware of EtO's effects and there are insufficient allegations as to how any purported defect in the warnings of the product caused Plaintiffs harm. Balchem had not additional duty to train or further warn the Sterilizer Defendants. See 29 C.F.R. § 1910.1047(j)(1)(iii) (2024) (imposing product training requirement on employer).

B. Medtronic, Customed and Edwards LifeSciences' Objections.

Co-Defendants Medtronic, Customed and Edwards LifeSciences also raised a limited objection to the R&R as to its conclusion that they did not seek dismissal of the nuisance claims; Plaintiffs failed to plead an actual injury caused by EtO, and thus, the negligence and nuisance claims cannot move forward; and the continuing tort doctrine is inapplicable to this case.

The Court has already found that the clams against Edward LifeSciences must be dismissed, insofar as they were not timely tolled.

Medtronic and Customed argue that no actual injury has been pled and that as result, the negligence and nuisance claims, which go hand in hand, must also fail. After conducting a de novo review, the Court agrees with Magistrate Judge López-Soler that

Plaintiff's allegations, at this stage, are sufficient to adequately plead an injury because of Defendants' actions and thus, the negligence claims survive at this juncture. Nonetheless, the Court reminds Plaintiffs going forward that Puerto Rico law requires them to establish (1) evidence of physical or emotional injury, (2) a negligent or intentional act or omission (the breach of duty element), and (3) a sufficient causal nexus between the injury and defendant's act or omission (in other words, proximate cause). Torres v. KMart Corp., 233 F.Supp.2d 273, 277–78 (D.P.R. 2002); Vazquez-Filippetti v. Banco Popular de Puerto Rico, 504 F.3d 43, 49 (1st Cir. 2007). In the present case, this may present a challenge due to the remoteness of the injuries alleged[8], and it is possible that in a more advanced stage of the litigation, the Court may find these claims wanting. The nuisance claims against Customed and Medtronic are contingent on the actual injury claim and therefore also survive.

Lastly, as to the continuing tort doctrine, the Court finds it is applicable to this case for the reasons previously stated. Under this doctrine, the claims asserted by Idalia Vargas-Gratacós against Medtronic and Juana Castro-Moreno against Customed also remain alive.

C. Balchem's Objections.

Magistrate Judge López-Soler recommended dismissal of all claims against Balchem. Thus, Balchem only responded to Plaintiffs' Objections to the dismissal of the claims against it. As previously noted, the Court agrees with Balchem's arguments and

[8] The years of Plaintiffs' diagnoses range from 1994 all the way through 2022.

with the Magistrate Judge's conclusion that dismissal of all claims against Balchem is warranted.

D. Mays Chemical.

Magistrate Judge López-Soler recommended that the claims against Mays, as provider of freight services for EtO, be dismissed insofar as no claims could lie against it, mainly for the same reasons as to Balchem.[9] First, she concluded that the negligence and nuisance claims could not be asserted against Mays because it did not operate a sterilizing facility. Second, she found that the product liability claims could not move forward because Mays only provided freight services and did not design or manufacture the product at issue or otherwise had any duty to warn, inform or provide proper training to the Sterilizer Defendants about EtO.

This recommendation stands unopposed by Plaintiffs. Absent a proper objection, the Court need only make sure there is no plain error in the Magistrate Judge's findings to adopt the same. López-Mulero v. Vélez-Colón, 490 F.Supp.2d 214, 217-218 (D.P.R. 2007). Finding no error, the Court concludes that the dismissal of all the claims against Mays is appropriate.

CONCLUSION

In view of the foregoing, Magistrate Judge López Soler's comprehensive R&R (Docket No. 104) is ADOPTED in full.[10] Consequently,

[9] The Complaint asserts that Mays distributed EtO, while Mays argues in its motions that it merely provides "freight services" of the product. Plaintiffs failed to oppose the portion of the R&R pertaining to Mays. Therefore, the Court accepts that Mays merely provides freight services for the product in question and did not actually distribute it. See United States v. Maldonado-Peña, 4 F.4th 1, 20 (1st Cir. 2021) (a party failing to file an objection to an R&R waives review); United States v. Díaz-Rosado, 857 F.3d 89, 94 (1st Cir. 2017). The result, however, would still be the same if Mays was an EtO distributor.

[10] "Where, as here, a [Magistrate Judge] has produced a first-rate work product, a reviewing tribunal should hesitate to wax longiloquent simply to hear its own words resonate." Chen v. I.N.S., 87 F.3d 5, 7 (1st Cir. 1996); see also Lawton v.

1. May's Motion to Dismiss (Docket No. 78) is GRANTED and all claims against Mays are DISMISSED WITH PREJUDICE.
2. Balchem's Motion to Dismiss (Docket No. 75) is GRANTED and all claims against Balchem are DISMISSED WITH PREJUDICE.
3. Customed, Edward LifeSciences and Medtronic's Motion to Dismiss (Docket No. 76) and Steri-Tech's Motion for Joinder of the Motion to Dismiss at Docket No. 76 and Supplementing Arguments (Docket Nos. 79) are GRANTED IN PART AND DENIED IN PART. Accordingly, the gross negligence (Count II), restitution-unjust enrichment (Count XI) and all product liability causes of action (Counts IV, V, VI, VII, VIII and IX) against Customed, Edward LifeSciences, Medtronic and Steri-Tech, as well as all claims against Edward LifeSciences, are DISMISSED WITH PREJUDICE.
4. The Motions for Joinder of Motions to Dismiss (Docket Nos. 90 and 91) are GRANTED.

As such, the remaining claims are the following:

a. Claims against Steri-Tech: the negligence, public and private nuisance claims of Jeanette Pérez-Maceira, José Mateo-Pérez, Lilliam Ortiz, Danisha Ortiz-Santiago, Yamel Santiago-Rivera, Elba Meléndez-Figueroa, and Lianibel Colón-Sánchez.

b. Claims against Medtronic: the negligence, public and private nuisance claims of Idalia Vargas-Gratacós.

State Mut. Life Assur. Co. of America, 101 F.3d 218, 220 (1st Cir. 1996); Ayala v. Unión de Tronquistas de Puerto Rico, Local 901, 74 F.3d 344, 345 (1st Cir. 1996); In re San Juan Dupont Plaza Hotel Fire Litig., 989 F.2d 36, 38 (1st Cir. 1993).

c. Claims against Customed: the negligence, public and private nuisance claims of Juana Castro-Moreno.

Partial judgment shall be entered accordingly.

The remaining Co-Defendants shall answer the Amended Complaint by November 13, 2025.

IT IS SO ORDERED.

In San Juan, Puerto Rico, on this 23rd day of October, 2025.

S/CAMILLE L. VELEZ-RIVE
CAMILLE L. VELEZ RIVE
UNITED STATES DISTRICT JUDGE