UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MONTANA, MISSOULA DIVISION

Kurt Matt Rosbarsky v. Mira, Inc. and The Schepens Eye Research Institute, Inc., f/k/a Eye Research Institute of Retina Foundation

Rosbarsky · No. CV 25-80-M-DWM · Decided February 27, 2026

SUMMARY

The opinion addresses Defendants' motions to dismiss a strict products liability action arising from the implantation and later degradation of MIRAgel eye implants. The court grants the motions, concluding that it lacks personal jurisdiction over Mira, Inc. and The Schepens Eye Research Institute, Inc., because the allegations do not establish that either defendant took actions directed at Montana.

OPINION

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MONTANA MISSOULA DIVISION KURT MATT ROSBARSKY, CV 25-80-M—DWM Plaintiff, VS. OPINION and ORDER MIRA INC. and THE SCHEPENS EYE RESEARCH INSTITUTE, INC., F/K/A EYE RESEARCH INSTITUTE OF RETINA FOUNDATION, Defendants. This case arises from the 1989 surgical implantation of MIRAgel, a hydrogel product, in both of Plaintiff Kurt Matt Rosbarsky's eyes to repair his detached retinas.

The MIRAgel implant allegedly swelled and degraded over time with its fragments causing many issues including double vision and eye pain, and necessitating removal surgeries, which could not completely extract the MIRAgel fragments. Ultimately, Rosbarsky was left without sight in his right eye.

In June 2025, Rosbarsky filed this strict products liability suit against Defendant The Schepens Eye Research Institute, Inc., f/k/a Eye Research Institute of Retina Foundation ("Institute"), a non-profit Massachusetts corporation, which studied, designed, and developed MIRAgel, and Defendant Mira, Inc. ("Mira"), a Massachusetts corporation, which manufactured, marketed, and sold MIRAgel worldwide under a licensing agreement with the Institute.

Both defendants have moved to dismiss. Because this Court lacks personal jurisdiction over the defendants, their motions are granted. BACKGROUND I. Factual Background The facts below restate nearly every fact alleged in the Complaint to highlight a glaring omission that is dispositive here: failure to show that either defendant took any actions directed at the forum state, Montana. a. MIRAgel MIRAgel, developed as the "MAI Implant," is "a plastic polymer product" that was

principally used in the late 1980s and early 1990s “by retinol surgeons as a scleral buckling material” surgically “implanted into patients who suffered from retinal detachment.” (Doc.

1 at Jf 11, 13, 14, 15, 33.) The MAI implant was developed by the Institute throughout the late 1970s and 1980s. (Ud. F¥ 30, 87, 133.) The Institute performed all scientific research, testing, and design work as to its development. Ud. 730.)

Under a licensing agreement, Mira manufactured, advertised, marketed, and sold the MAI implant as “MIRAgel” worldwide from 1984 to 1994. (id. J 8, 10.) During this time, the Institute and Mira acted as “Joint venturers in concert with one another to develop, design, market and sell MIRAgel, including the MIRAgel” that was implanted into both of Rosbarsky’s eyes.

(Ud. 951.) During all times relevant to this matter, Charles L. Schepens, M.D. (“Dr. Schepens”) was the founder and head of the Institute, and his son, Luc J. Schepens (“Luc Schepens”), was the president and sole owner of Mira. (/d. 18-21.) i. MIRAgel Patent The MAI implant, later marketed and sold as MIRAgel, was designed and developed by the Institute. Ud.

734.) In 1984, United States Patent No. 4,452,776, titled “Hydrogel Implant Article and Method,” was issued to Institute employee Miguel F. Refojo, D.Sc. (“Dr. Refojo”), and assigned to the Institute. (id. Tj 36, 37 (“MIRAgel Patent”).) Dr. Refojo was a biochemist and materials scientist employed by the Institute as a Senior Scientist and Head of its Biomedical Polymers Laboratory.

Ud. | 37.) ii. MIRAgel Licensing Agreement On July 29, 1985, the Institute and Mira entered into an “Exclusive License Agreement Re Hydrogel,” which granted Mira, with minor exceptions, the exclusive worldwide rights to any interest that the Institute had or might acquire in the hydrogel product subject to the MIRAgel Patent. Ud. J] 38-39 (“Licensing Agreement” or “Agreement”).)

Under the Licensing Agreement, if the Institute developed further technical information intended specifically for use with the hydrogel product, it was required to promptly disclose it in writing to Mira. (dd. { 40.) Unless Mira indicated its intent not to accept such technical information, this information and any related rights would be added to the license. (/d. { 41.)

Under the Licensing Agreement, the Institute would receive “license fees” or “royalties” in accordance with a defined schedule based on a percentage of Mira’s net sales of units of MIRAgel. (/d. J] 42-43.) The Institute and Mira also agreed in this Agreement to jointly pursue any FDA approvals. (/d. { 44.)

In his declaration, Dr. Refojo explains that after the Institute licensed the MIRAgel Patent rights to Mira, he entered into a separate consulting agreement with Mira to provide assistance regarding manufacture of MIRAgel. (Doc. 12-11 at 7.) His consulting work was as an independent consultant. (/d.) iii, MIRAgel Marketing and Sale In October of 1986, the FDA approved Mira to

market and sell the hydrogel product referenced in the MIRAgel Patent, which Mira named MIRAgel. (ld.

46-47.) Mira sold MIRAgel “through distributors or otherwise” to customers inside and outside the United States. Ud. 7 10.) The Institute “participated in decisions relating to the marketing of MIRAgel.” (Ud. J 53.)

For example, on March 15, 1990, Luc Schepens sent a letter to Felipe I. Tolentino, M.D. (“Dr. Tolentino”) requesting his input on a new sales brochure. (Id. J 69 (“1990 Letter”).) Dr. Tolentino was employed by the Institute as a “Program Director with respect to Ophthalmic Microsurgery Research.” (Ud. □ 56.)

The draft text for a new sales brochure stated that MIRAgel was developed by the Institute. Wd. { 69.) Dr. Tolentino responded with a “write up about MIRAgel” which he told Luc Schepens, “you may want to use for marketing.” (/d. 9 72.) Mira incorporated some of the language suggested by Dr. Tolentino into the marketing materials it issued in June 1990. (Ud.

J 75.) The 1990 Letter also included a chart of twelve current designs of MIRAgel and stated a thirteenth was being developed. (/d. J 70.) Luc Schepens wrote that Mira wanted to complete the MIRAgel line within the next year and requested Dr. Tolentino provide suggestions for any additional designs. (/d.) Dr. Tolentino responded that his “‘favorite model of MIRAgel is 90277, 90377, and 906.

If 908G is not popular with users, you may want to drop it. The 90277 and 90377 are 7.5 in width. There may be a need for a wider size, such as 9.5 or 10 mm. [And inquired is] it a problem to have these two models wider?’” (/d. { 73.) Dr. Schepens was copied on this correspondence. (/d. J] 71, 74.)

After manufacturing of MIRAgel later ceased in 1994, Mira “continued to advertise, market, and sell its product inventory of MIRAgel until it was exhausted.” (Ud. J 9; see id. § 159.) On June 21, 1996, Mira notified the FDA that it was no longer manufacturing or selling MIRAgel and had deleted it from Mira’s product line. Vd. 9 11.)

On December 3, 2009, MIRAgel was recalled by the Saudi Food and Drug Authority. (Ud. J 12.) iv. MIRAgel Scientific Research and Testing The Institute performed all the scientific research, testing, and design work in the development, (id. J 30), and manufacture of MIRAgel, (id. 752). Once MIRAgel was on the market, the Institute provided scientific research expertise and personnel to Mira on an ongoing basis: in order to respond to and assess adverse events that occurred in patients who had been treated with implants of MIRAgel[;] in order to determine the content of the warnings, if any, that should accompany the product as sold[;] in order to determine the nature of the marketing literature that should be used to advertise the product[;] in order to determine whether certain professional articles and letters to the editors of medical journals should

be prepared to disseminate information concerning the MAI implant and MIRAgel, in lieu of or in addition to warnings provided after October 22, 1986[; and] collaborated with [Mira] in identifying any outside ophthalmologists that would use the MAI implant in their patients as part of the investigational study thereof];] performed all research with respect to MIRAgel or, with respect to outside research[;] directed [Mira] as to what research should be done and where it should be done[;] and... otherwise engaged in actions in concert with [Mira] that were intended to continue the manufacture and sale of [MIRAgel]. (id.

Ff 52-53; see Ff 54-55.) During the design development of the MAI implant, later marketed and sold as MIRAgel, Dr. Tolentino and other Institute employees implanted the MAI implant into rabbits, (id. § 57), and performed or organized clinical trials with human patients, (id. 4 58).!

The records of these clinical trials were not provided 'TIn his declaration, Dr. Refojo testifies that he, as an employee of the Institute, conducted the rabbit tests, and that the human clinical trials were “separate [and] not conducted by [the Institute].” (Doc. 12-11 at 74.) Dr. Tolentino and other surgeons conducted the human trials. (/d. at Jf 4, 6.) to Mira. (/d. | 107.)

In both the rabbit tests and human clinical trials, the implants remained in the treated eyes for no more than five years. (/d. J] 59-60.) During the development period, the Institute did not perform any accelerated aging testing in the rabbit subjects or human patients to determine whether the MAI implant would remain both safe and effective in the long term. (/d.

J] 61-62.) In or around 1990, Mira rejected a proposal from an outside consulting firm to perform accelerated aging studies regarding MIRAgel as cost prohibitive. Ud. {| 63-64.) Neither the Institute nor Mira ever performed any accelerated aging testing, (id. { 65), and Mira “never performed any scientific study, testing, or research to attempt to determine the safety or efficacy of MIRAgel,” (id.

J 66). v. MIRAgel Implant Performance At the time of implantation, it was “generally intended and anticipated by implanting surgeons” that MIRAgel would remain in a patient for their lifetime absent complications. (/d. | 16.) Experience with both the MAI implant and MIRAgel implanted in human patients has generally shown that “symptoms caused by the defective nature of the MAI implant and MIRAgel’ [do not] manifest 2 As explained above, the MAI implant and MIRAgel can refer to the same hydrogel product that was patented in the MIRAgel Patent.

However, the distinction between the two is not always clear. The hydrogel was first developed and designed by the Institute as the MAI implant, which was used in clinical studies; Mira later marketed and sold this product as MIRAgel, which was implanted into patients. (E.g., Doc. 1 at JJ 30, 46-47, 57-58, 87, 133.) There does not appear to be a distinction in formulation. (/d.

J 135 (“‘The MAI Implant is the themselves in human patients until the [hydrogel product] has been implanted in the patient for at least seven years, approximately, and, in many cases, longer.”

(Id. | 67.) Despite this defect, neither defendant ever performed accelerated aging studies or testing on MIRAgel. (Ud. J] 65, 67.) And, as is detailed below, both the Institute and Mira "became increasingly aware through communications from physicians, complaints, and law suits filed by patients that the use of MIRAgel posed serious risk so the health of patients that were not posed by more traditional implants, such as silicone." (/d.

J 209.) On May 31, 1990, Dr. Refojo told Luc Schepens that Dr. Tolentino had recently removed two hydrogel implants from two patients, one had been implanted for seven years, the other for nine years. Ud. J 76.) These removed implants were "swollen, softer, bulging and hydrated,... translucent[, and] friable." Ud. J 77.) Dr. Refojo reported that although the implants were surrounded by an intact capsule, "as soon as the capsule was opened, the implant would break into pieces." (Ud.

J 78.) The origin of these implants was unknown, but Dr. Refojo stated that they were "probably EFI' prototypes" for MIRAgel. (id. 4 79.) Dr. Refojo then "'reminded [Luc Schepens] that the original rabbit tests were must shorter than [the] implant[period] in these two patients.'" (Ud. J 80.) precursor of the present-day MIRAgel; they have the same chemical composition.'"').)

3 "RFI" is not defined in the Complaint. (See generally Doc. 1.) This same day, Luc Schepens arranged a meeting with both Dr. Refojo and Dr. Tolentino to address these matters. (/d. J 81.) Luc Schepens then spoke with Dr. Refojo, and, afterwards, spoke with Dr. Tolentino, Dr. Schepens, and "perhaps other" Institute "clinicians." (Ud. J 82.)

On June 8, 1990, Dr. Refojo and Dr. Tolentino met with Mira employees Jeff Tailing* and Don Moore? ("1990 Meeting" or "Meeting"). (/d.] 84.) At the Meeting, the participants discussed complications that required re-operations in the cases of three patients who had received MAI implants made by Dr. Refojo. (/d.) These implants were performed in "1977, 1979-80, and 1980-81," respectively.

(Id. J 87.) In one of the three cases, "the MAI implant was friable and broke as Dr. Tolentino attempted to remove it and was brownish 'all the way through.'" Cd. 4 88.) Dr. Refojo remarked that he was "'pretty sure' that the MAI implants in the second and third cases were the same as in the MIRAgel formulation." (Jd. J 89.) He then "expressed the view that the friability of an implant was indicative of hydrolysis or oxidation and a change in the polymer while in the patient[,]" (id. { 90), and that this changed polymer "material would have a different, possibly higher, equilibrium content than the original piece causing it to swell,'" (id.

9 91). Such swelling could only expand the implant into the eye. (Ud. { 92.) 4 Tailing was a sales manager at Mira. (Doc. 1 at | 85.) > Moore was a Mira director and consultant who "acted as the 'go between' between" Mira and the Institute. (Doc. | at J 86.) Dr. Refojo further stated that Mira

"'should not be surprised if it sees incidents in which MIRA[gel] hydrolysis [sic] and swells.'" (id.

J] 96), and that because "the body [is] a harsh environment[,]... all implants are subject to calcification and/or alteration,'" (id. § 97). In response, Dr. Tolentino stated that these complications may have been caused by the technique he used when implanting MIRAgel and "that he would now change his procedures." (Jd. { 93.) He then "expressed his intention to call back for observation some eighty patients from his original hydrogel implant study," but noted that observations of these patients "were not 'directly indicative' of MIRAgel performance." (Id.

J 95.) As a result of the 1990 Meeting, Mira and the Institute agreed the following "program" should be implemented: [Mira] should write to a number of ophthalmologists who first used MIRAgel and/or used MIRAgel in large quantities asking them to report to [Mira] any observations of MIRAgel during re-operations and to send to [Mira], the specimen or a portion of [it] if the MIRAgel was removed; A general article should be published "in the Forum," which should not "focus on [MIRAgel] but rather should characterize all implants as likely to have/cause some long[-]range change in the body" and should "highlight the need for continuous observation of implants and being alert to any indication of change."; [Mira] should prepare a circular and/or package insert change calling the reader's attention to the possibility of long[-]term change in MIRAgel and the need to monitor whether any undesirable changes are occurring. "This circular should point out the increased likelihood of erosion in the case of an explant under an implant." 10 [Mira] should analyze the specimens removed by Dr. Tolentino and determine if chemical changes have taken place; and "Tolentino (and Refojo?) will prepare a journal article reporting on the results of the reexaminations of the 80 patients in the original hydrogel study." (Id.

J 98.) Around June 14, 1990, Mira employee, Moore, sent a "'Confidential' memo to Luc Schepens, Jeff Tailing, and Randy Hasslinger® discussing the" 1990 Meeting ("Confidential Memo" or "Memo"). (Ud. | 99.) The Confidential Memo stated that Moore "was not providing copies to Dr. Refojo and Dr. Tolentino because he 'saw no point in causing them to be defensive or to refute the wording of my memo.'" (/d. § 103.)

In the Memo, Moore further stated that in addition to the five-point program, which is articulated above, Mira should do the following: "Review MIRA[gel] process and quality control procedures to assure that any improperly polymerized product would be detected and rejected"; Find out the nature of the testing that had been done by Dr. Refojo on experimental hydrogel implants to see if they were stable in the presence of bodily fluids, according to a telephone conversation that Dr. Refojo had had with Don Moore on June 1, 1990; Review the adequacy of Dr. Refojo's earlier tests; 6 Hasslinger was employed by Mira as the "Director of R&D/Engineering." (Doc.

1 at] 100.) The "primary activities engaged in by the" Mira R&D Department "were drafting blueprints and specifications and building prototypes, and did not include research with respect to

MIRAgel." (Ud. J 102.) 11 Determine if FDA notification was required at the time and, "if not decide if some notification is desirable"; Review the possible chemical mechanisms for polymer failure; Determine tests for detecting change in "specimens" and apply the tests to 'the Tolentino specimen, retains by [Mira] and Refojo, and samples recovered from ophthalmologists during reops'; Examine chemically the "long term MIRA[gel] retains" and "similar retains from [Dr.

Refojo] to determine if any chemical changes have occurred." (Id. | 104.) Moore then acknowledged that "'[t]he implants are packaged in physiological saline and observing stability here is not fully indicative of stability in situ."" Ud. J 105.) Moore concluded the Confidential Memo by stating that Dr. Tolentino "confirms that MIRA[gel] is an excellent material.

There is no indication of any significant problems other than being cautious in applying an implant over an explant. This is a known risk in any case and is the decision of the ophthalmologist to determine whether such a procedure is appropriate or not." (Ud. J 106.) Mira then manufactured and sold all its MIRAgel at the particular hydration level that was specified by Dr. Refojo.

(Id. { 108.) By October 1990, Mira had learned of five patients who had received the MAI implant and "presented with 'symptomatic erosion into the inner eye due to the swollen implant.'" Ud. J 111.) On October 10, 1990, Hasslinger sent a memorandum to Dr. Schepens requesting his "advice and 12 help in pursuing an organized clinical follow-up study of all patients in the Hydrogel collaborative study and subsequent high[-]volume users of the implant." (Ud. § 112.)

Mira also made this request to Dr. Tolentino. (Ud. 4113.) No such study was performed by the Institute and Mira "was not in a position to perform such a study because" it would have required specific training and experience, which was not possessed by any Mira employee. (id. JJ 114-15.)

The names of the ophthalmologists who purchased MIRAgel "were available in records that were maintained or should have been maintained by" Mira. Ud. | 116.) The names of ophthalmologists who used the MAI implant as part of a clinical study "were available in records that were maintained by [the Institute] and... were available to [Mira] upon request." (Id. ¥ 117.)

Around October 10, 1990, Hasslinger sent a letter to the FDA, which stated that Mira "had become aware of complications with the implants that were a predecessor of MIRAgel that were comprised of 'early experimental materials synthesized in a laboratory facility of an independent institute.'" (Ud. 1 118.)

The letter further stated that [Mira] today manufactures and markets an implant material of a common formulation. There are no known cases of our implants having caused any complications in dwelling [sic], nor do we expect any, (emphasis added). All of [Mira]'s implant lots have 13 been manufactured under strict GMP standards with process controls and quality inspections that guarantee structural character and consistency.

(Id. § 119 (alterations in original).) On or about March 15, 1991, Hasslinger sent another letter to the FDA. (/d. q 120.) In this letter he stated that "'[t]here have been no patients to date, implanted with MJRAgel, that have presented with this problem,'" referring to the complications "encountered with respected to implants produced at [the Institute] under a controlled investigative study." (/d.)

Hasslinger then acknowledged that Mira uses "the same formulation for the MIRAgel implant line that we market today," meaning the "same formulation that had been used in [the Institute's] study." Ud. J 121.) As a result of either attending meetings with or communicating with Mira, on March 26, 1991, Dr. Tolentino sent a letter to various ophthalmologists advising them that he had been using hydrogel scleral buckling material since 1978, continued to use it, and was currently performing a follow-up of cases in which the prototype hydrogel implant developed by Dr. Refojo at the Institute had been used. (id.

J 122-23.) He then stated that "several of the cases followed for seven years or longer had shown 'excessive increase in the buckle height' and that in some of those cases 'the implant was eroding through the surgically thinned sclera and choroid.'" (/d. § 124.) He noted that "'such implants were difficult to remove in 14 one piece because they had become friable, breaking easily into small pieces.'" (Id.

4 125.) He also stated that "'Dr. Refojo, who developed th[e] material, and I did not anticipate these changes.'" (/d. § 126.) But he noted that "[n]o such complications [had] been recorded with... MIRAgel." (Ud. J 128.) He then inquired into the ophthalmologists' long-term observations of the hydrogel implants, particularly with respect to "cases that had at least 5 years of follow-up." (id. § 127.)

Lastly, Dr. Tolentino recommended "yearly follow-up of... patients with this implant in order to check up[]on possible increase in the height of the buckle" and requested that he be informed if such an increase was observed, noting that "[s]ince these cases are rare, we could then publish a report on these observations." (Jd. J 129.)

As a result of the 1990 Meeting discussed above, an article was published in the January 1992 volume of the Archives of Ophthalmology,' titled "Long-term complications of the MAI Hydrogel Intrascleral Buckling Implant" ("MAI Article" or "Article"). Ud. J 130.)

The MAI Article was authored by Jesus F. Marin, M.D., Dr. Tolentino, Dr. Refojo, and Dr. Schepens. (Ud. J 131.) A draft of the Article was reviewed by Mira before publication. (/d. J 136.) The Article reported the results of a follow-up study conducted with respect to eighty-two patients who had received MAI implants from 1979 to 1982. Ud. J 133.)

The results included that 7 7 The Article was accepted for publication on May 20, 1991. (Doc. 1 at § 132.) 15 of 82 patients, or 8.5 percent, had developed complications from swelling of the MAI

implant. Ud. J 134.)

The Article concluded that: The MAI implant is the precursor of the present-day MIRAgel; they have the same chemical composition. Hence, potential problems related to swelling of the implant exist and warrant diligent, periodic follow-up of patients for a long time after surgery.

However, to our knowledge, similar complications in patients who receive an episcleral implant have not been reported. We have used MIRAgel as an episcleral implant in a large number of patients since 1986 and have not observed such complications. (id. { 135.)

The January 1992 volume of the Archives of Ophthalmology also published a Letter to the Editor submitted by Hasslinger on behalf of Mira. Ud. 9 137.) This Letter explained that the MAI implants reported on in the Article were "experimental and known to contain variable levels of components that would account for the difference described in the spectra." (Jd.

J 138.) The Letter then stated that "'[t]o date there have been no patients with MIRAgel implants who have developed the complications described in the report by Marin et al. MJRAgel continues to be manufactured according to good manufacturing practice guidelines for strict formulation and process controls."" (/d. § 139.)

In a Reply to this letter, also published in the 1992 volume, the authors of the Article stated that "there was 'no data available to them'" to support Hasslinger's statement, instead asserting that "MAI polymer, made by the same 16 procedure as the retrieved implants, and the currently available MIRAgel implants have the same chemical composition, as is demonstrated by the identical micro- Fourier transform infrared spectra." (/d.

J] 141-42.) Mira and the Institute determined that publication of the MAI Article was "sufficient to communicate to all physicians who had already implanted MIRAgel in their patients all of the risk and hazards of having used MIRAgel to treat their patients." (id. § 143.) Such risks and hazards included that "MIRAgel that remained in the body might swell over time and that such swelling might result in serious injury to the eye of the patient, and that, over time, MIRAgel might become friable such that it might not be able to be removed from the body without causing further injury to the patient." (/d.)

Following this publication, Mira and the Institute continued to receive additional reports from physicians that MIRAgel was swelling and degrading in the eyes of patients with the implant. Ud. J 144.) For example, by letter dated November 11, 1993, Dr. Bruce® reported to Mira that "a MIRAgel implant that had been in place approximately five years crumbled the way that rotten wood would crumble when he tried to remove the implant." (/d.

J 145.) Dr. Bruce's "first name is presently unknown to" Rosbarsky. (Doc. 1 at § 145.) 17 On January 27, 1994, after Mira had received additional reports of "adverse incidents between 1990

and 1994," Luc Schepens sent a memo to Dr. Schepens and Dr. Tolentino, which asked the following questions: How serious is the situation we are facing? Should we issue a caution to all MIRAgel users and potential MIRAgel users explaining the possibility of degradation of the material and perhaps enclosing a copy of [Dr.]

Tolentino's paper from January 1992? Would it be safer to stop selling the material and simply take if off the market? Are there any other courses of action you would like to recommend? (Id. J] 146-47.) Dr. Tolentino responded to this memo with a memo dated February 3, 1994, titled, "MIRAgel Degradation," which was sent to Luc Schepens and copied to Dr. Schepens and Dr. Refojo. (/d.

J 148.) In his memo, Dr. Tolentino stated, "this degradation is serious in eyes with intrascleral implant. [MIRA]gel implants should be removed in all these cases. The risk for episcleral implant is of course less and will need regular yearly follow up." (/d. { 149.)? He advised that "Mira The Complaint does not clarify the difference between episcleral and intrascleral implantation, but consultation with Stedman's Medical Dictionary explains that episcleral is defined as "[o]n the sclera," 298850 (Nov.

2014), which is the "outer envelope of the eyeball," 801660 (Nov. 2014). Thus, the former means implantation on the sclera while the latter is implantation within the sclera. 18 should issue a caution to all [MIRA]gel users that [MIRA]gel may degrade after 5 to 10 years." (/d.) He further opined that he "fe[It] that this product should be taken off the market to avoid further problems." (/d.)

Following Dr. Tolentino's responsive memo, neither Mira nor the Institute took any action to advise users or potential users of the risk of degradation of the MIRAgel or that MIRAgel intrascleral implants should be removed. (/d. 150- 53.)

In March 1994, Mira employee Michael Warren, who worked in the facility that produced and manufactured MIRAgel, sent a memo to Luc Schepens and Mira's head of Quality Assurance, Roger R. O'Brien. (fd. Jf 154-56.) In his memo, Warren stated that "it would be prudent for Mira to make a business decision as to the viability of MIRAgel as a product.

We have added additional warnings to the product labeling. See attached. We may want to make an effort to alert the vitreoretinal community using a mailing or newsletter." (Ud. 157.) Attached to the memo were two letters from surgeons reporting complications in using MIRAgel. (/d.)

In response, Mira did not send such a mailing or newsletter. (Id. 158.) vi. End of MIRAgel Manufacturing In late 1994, Mira ceased to manufacture MIRAgel, which, according to Luc Schepens, was a choice made for "strictly economic reasons." (/d. Ff 159-60.) 19 Around April 25, 1995, Mira's sole manufacturing facility closed pursuant to a consent decree entered by the United

States District Court for the District of Massachusetts in an action pursued by the United States for injunctive relief against Mira, Luc Schepens, and O'Brien.

Ud. J 161.) This action alleged that these Mira defendants "had violated provisions of the Federal Food, Drug, and Cosmetic Act and various federal regulations promulgated thereunder with respect to [another] product and... silicone eye implants used to treat retinal detachments" by "failing to control manufacturing inspections to ensure that devices conformed to their original design, failing to investigate and maintain a written record of investigations of complaints and other incidents in which devices failed to meet performance specifications, and failing to provide personnel with the necessary training to perform assigned responsibilities adequately." Ud.

J] 162- 63.) The consent decree in this action was a result of "negotiations between counsel for the [Mira] defendants" and "counsel for the United States." Ud. J 167.) This consent decree did not reference MIRAgel because Mira had ceased manufacturing this product before April 1995, rendering injunctive relief inapplicable to MIRAgel. (/d. J 168.) This action was preceded by an FDA Regulatory Letter sent to Luc Schepens in 1991 and a Notice of Adverse Findings Letter in 1986 as to Mira's violations of "Good Manufacturing Practices regulations," as well as FDA 20 inspections of Mira in 1991, 1992, and 1993. (la {7 165-66.)

As a result of the consent decree, Luc Schepens did not play a role in the day-to-day operations of Mira after April 1995. Ud. J 170.) The Mira manufacturing facility reopened in the Spring of 1996. Ud. J 169.) Mira did not resume manufacturing MIRAgel, but it continued to sell and market its remaining inventory. Ud. 9 9; see id. | 159.)

In a separate personal injury case regarding MIRAgel, O'Brien testified that Mira had "'looked at regulatory affairs and quality control as an obstacle,' that in the early 1990[]s he became concerned about a 'trend' of increasing complaints that caused him to 'approach people internally,' and that he was concerned that [Mira] 'was not as responsive as they should have been about this problem that {he] was bringing to their attention.'"" (/d. | 164.)

On June 21, 1996, Mira notified the FDA that it was no longer manufacturing or selling MIRAgel and had removed it from Mira's product line. (id. | 11.) Throughout the entire period of manufacture and sale of MIRAgel, Mira did not employ any staff with "education, training, or experience that was necessary to perform clinical trials, testing, or research" regarding MIRAgel or to "assess[| the nature and implications of adverse events that occurred in patients who had been treated with" MIRAgel. (id.

Jf 24-25.) Further, the single employee in Mira's Quality Assurance and Regulatory Affairs Department did not have any education, training, or experience in medicine or science. (/d. J 27.) 21 vii. 1995-1998 Reports of MIRAgel Complications In a letter to Mira dated November 21, 1995, Dr. Weidenthal reported that in the cases of two patients he had operated on eight years

earlier “a corner of the MIRAgel implant had eroded through the choroid and could be seen beneath the retina” and that “[i]t appeared as if the implants had actually expanded in volume.” (id.

1 172.) Dr. Weidenthal then requested Mira respond to specific questions, including: Is the above[-]described problem commonly associated with the [MIRA]gel implant? Does the implant continue to expand or is this a self-limiting problem? Has there been a product recall? Ifso, when and why? Have complications similar to that which I have above described been reported?

(Id. | 174.) It is unknown whether or how Mira responded to Dr. Weidenthal’s letter. Ud. § 175.) In 1997, O’Brien of Mira Quality Assurance, sent a memo to the president of Mira, “D. O’Brien,” that referenced two reports made that year regarding “extruding and fragmentation of MIRAgel.” Ud. | 176-77.) He suggested recruiting Dr. Refojo to prepare ‘an explanation document of what is taking place longer-term that [Mira] can send to past users of [MIRA]gel as some complaints are requesting the next steps they should take after these patients are reop’ed or examined.

An explanatory statement, letter or engineering directive from a 22 knowledgeable developer sent via a sales bulletin to past users and to any future complainants should be considered.’ (Id. J 178.) In response, Mira did not send any such explanatory written statement to past users in or after 1997. Ud. § 179.)

In August 1998, Mira received a letter from its Japanese distributor reporting that three patients who had received a MIRAgel implant six to eight years earlier complained of feeling something foreign in their eyes. (/d. | 182.) When their doctor opened the three patients’ eyes, “it was found that the MIRAgel had become transformed and was fragile.” Ud. J 183.)

The doctor requested from Mira documents or an explanation regarding the possibility of a change in MIRAgel after implementation for long periods of time. (/d. J 184.) It is unknown whether or how Mira responded to this letter. (/d. J 185.) viii. MIRAgel Patient Personal Injury Litigation The first civil action to recover damages against Mira for personal injuries as a result of the MIRAgel implant was filed in 1997 or 1998.

Ud. J 181.) As of July 9, 2003, six additional personal injury actions brought by MIRAgel patients were pending. (/d. 7 186.) After July 9, 2003, at least five more such actions commenced. (Ud. | 187.) Other such actions may have been commenced in or after 1997 and resolved before July 9, 2003. Ud. J 188.) b. Rosbarsky’s Surgeries i. 1989 Implant Surgery 23 Rosbarsky is a resident and citizen of Missoula, Montana.

Ud. □ 1.) In January 1989, he underwent bilateral retinal surgery to repair his detached retinas through the implantation of MIRAgel scleral buckles. Ud. J] 48, 189.) The MIRAgel implanted into Rosbarsky’s eyes was designed by the Institute and manufactured, marketed, and sold by Mira. (/d. § 49.)

The package insert that accompanied the MIRAgel implant did not include any warnings with respect to the use of MIRAgel. Ud.] 50.) The Complaint does not allege where this surgery took place or who the surgeon was that performed the procedure. (See generally id.)

As is detailed below, Rosbarsky eventually underwent a total of six surgeries that attempted to remove the swollen and fragmented MIRAgel from his eyes. However, because the "longer MIRAgel remained in" Rosbarsky's eyes, "the more difficult it became to remove," the surgeries found only limited success. (Ud. J] 205, 212.) ii. 1998 Removal Surgery In 1998, Rosbarsky underwent surgery to remove the MIRAgel scleral explants from both of his eyes. (/d.

JJ 189-90.) Rosbarsky's medical records indicate "diplopia (i-e., double vision), mechanical strabismus, and difficulty in turing eyes, prompting removal of the [MIRA]gel implants." (Ud. □ 190.) The operative report for Rosbarsky's right eye "indicate[d] a preoperative diagnosis of 24 'restrictive strabismus with expanding scleral buckle.'" (Ud. | 191.)

The operative report notes for his right eye state, inter alia, that: Conjunctiva was taken down over the surface of the buckling element in each quadrant. Mattress sutures were removed. The buckling material had become very friable and had to [be] removed piecemeal from around the eye. It was fixed to the sclera with a layer of calcification.

After we removed as much of the buckle as possible irrigation was carried out with balance salt solution. The calcified layer attached to the sclera was left in place. (Id. | 192.) The surgical pathology report for Rosbarsky's right eye states ""SB Component ~ [MIRA]gel' with the specimen labeled as 'scleral buckle component' and consists approximately of twenty fragments of grayish- white, translucent synthetic material having an oval configuration of 0.7 cm in width and approximately 4.0 mm thick." (/d.

J 195.) The operative report's preoperative diagnosis for Rosbarsky's left eye was "restrictive strabismus secondary to [MIRA|]gel episcleral implant." Ud. J 193.) The operative report notes for his left eye state, inter alia, that the scleral explant was exposed in the superior temporal quadrant by rotating the eye and cutting down over the scleral explant with a #69 blade.

The fibrous sheath which was calcified around the [MIRA]gel was then incised and a muscle hook was passed underneath the lateral rectus muscle. We were then able to expose the scleral explant in the inferior temporal quadrant as well. [MIRA]gel had become firmly adherent to the sclera and the Tenon's capsule which surround it. It was calcified.

We were unable to slide the [MIRA]gel out of its canal and therefore it had to removed piece meal using a lens loop and tenotomy hook. This process was continued into each quadrant and the [MIRA]gel was removed piece meal.

In the superior temporal quadrant 25 the implant had partially eroded through the sclera and black choroid was visible. This area was treated with great respect and fortunately no loss of intraocular fluid occurred.... [T]he majority of the material had been removed.... (Id. § 194.)

The surgical pathology report for the left eye states "'[MIRA]gel sponge, O.S.' with the specimen labeled as '[MIRA]gel' sponge' and consists of several fragments of blood-tinged, grayish-white, translucent synthetic material measuring up to 0.8 cm in greatest dimension and being irregularly fragmented; some pieces have an oval configuration 0.7 cm in width and 0.3 cm thick; the cut surfaces are translucent." (/d.

J 196.) The Complaint does not allege where this surgery took place or who the surgeon was that performed the procedure. (See generally id.) iii. 2015 Cataract Surgery Rosbarsky underwent cataract surgery in 2015. Ud. | 197.) His surgery had no complications, he had no vision issues following surgery, and did not need to wear corrective lenses. (/d.) iv. 2024 First Removal Surgery Rosbarsky began to suffer from irritation in his right eye again "[s]tarting around 2022 and continuing into early 2024." (Ud. | 198.)

Although this did not impact his vision, it "caused irritation and drainage," and Rosbarsky "sometimes w[o]ke up in the mornings with his right eye crusted shut." (/d.) Rosbarsky's treating healthcare providers recommended continued observation and use of over- 26 the-counter lubricants. (/d.) When his right eye irritation persisted, Rosbarsky saw an optometrist at the Rocky Mountain Eye Center in Missoula, Montana, around May 2, 2024.

Ud. 7 199.) The optometrist observed "large chunks of scleral buckle that were protruded from the conjunctiva superiorly" and, with forceps, removed the pieces located outside the conjunctiva. (/d. 2024.'°) Following this removal, the optometrist noted that Rosbarsky had large pieces of scleral buckle embedded under his conjunctiva, which required referral to a specialist. (/d.)

Rosbarsky was referred to and saw an ophthalmologist at the same practice that day. Ud. | 200.) The ophthalmologist recommended surgery to remove the remaining pieces of scleral buckle from Rosbarsky's right eye. (/d.)

On June 24, 2024, the Rocky Mountain Eye Center ophthalmologist performed surgery on Rosbarsky "for the retained MIRAgel buckle with scleral erosion in Plaintiff's right eye to remove the extruding MIRAgel buckle placed in 1989." (Ud. J 201.)

Under the buckle there was an area of scleral erosion and some parts of the MIRAgel buckle could not be removed. Ud.) The ophthalmologist's surgical notes state that the "'exposed scleral buckle was removed, coming off in several large chunks.

The [MIRA]gel buckle was quite friable.'" Ud.) Following '0 This paragraph is numbered as "2024;" the paragraph preceding is 199 and the paragraph following is 200. (Doc. 1 at 40.) 27

surgery, Rosbarsky could not see out of his right eye and the ophthalmologist records noted "'guarded visual prognosis.'" (/d.) v. 2024 Four Additional Removal Surgeries Rosbarsky was then referred to the Moran Eye Center in Salt Lake City for continued treatment.

Ud. J 203.) On June 29, 2024, a specialist at this Center performed surgery on Rosbarsky's right eye, which consisted of "open globe exploration and repair; scleral patch graft; and [MIRA]gel scleral buckle explantation." (/d.) Three additional surgical procedures on Rosbarsky's right eye were performed by specialists in Salt Lake City on July 17, 2024, August 28, 2024, and December 8, 2024. (/d. | 204.)

The first of these three surgeries was a "PPV/Retinectomy/PFO/EL/SO"! to treat a "perforating injury following [MIRA]gel buckle removal." (/d.) The second was a "PPV/MP/SO exchange... for recurrent TRD."" (/d.) The third and final surgery consisted of a "25 gauge pars plana vitrectomy; silicone oil removal; and anterior synechialysis." These surgeries saved Rosbarsky's "right eye, but not his vision." (Id.

205.) Now, in lower light, Rosbarsky can only see shapes and some colors. (/d.) He has no peripheral vision at all and is unable to read with that eye. (/d.) In 11 "PPV/PFO/EL/SO" are not defined in the Complaint. (See generally Doc. 1. 12 <PPV/MP/SO" and "TRD" are not defined in the Complaint. (See generally Doc. 1.) 28 bright light, Rosbarsky cannot see anything, and "[t]he specialists do not expect that to change." (/d.)

II. Procedural Background On June 10, 2025, Rosbarsky filed this products liability suit against the Institute and Mira arising from the implantation of MIRAgel into his eyes and the resultant complications. (Doc. 1.) Rosbarsky alleges the following eight causes of action against both defendants: strict product liability for design defect (Count 1), strict product liability for manufacturing defect (Count 2), strict product liability for failure to warn (Count 3), breach of express warranty (Count 4), breach of implied warranty of merchantability (Count 5), breach of implied warranty of fitness for a particular purpose (Count 6), fraudulent concealment (Count 7), and constructive fraud (Count 8). (/d.)

On September 15, 2025, Mira moved to dismiss for want of jurisdiction and failure to state a claim. (Doc. 5.) On September 17, 2025, the Institute moved to dismiss for want of jurisdiction. (Doc. 10.) ANALYSIS Both the Institute and Mira argue that due to a want of personal jurisdiction, all claims must be dismissed pursuant to Rule 12(b)(2) of the Federal Rules of Civil Procedure.

Mira also argues that because all claims are time-barred, they, alternatively, must be dismissed under Rule 12(b)(6) of the Federal Rules of Civil 29 Procedure. Rosbarsky opposes on all fronts. As to jurisdiction, he argues that both defendants are subject to personal jurisdiction in this Court

or that he should be given leave to engage in jurisdictional discovery to "determine [the Institute's] involvement in distribution of MIRAgel to Montana." (Doc.

28 at 32.) As to failure to state a claim, Rosbarsky argues that his claims are timely because they accrued in 2024, which is within the relevant statute of limitations. Ultimately, because exercising personal jurisdiction over either the Institute or Mira would violate due process, both pending motions to dismiss are granted for want of personal jurisdiction, and Mira's alternative argument is not reached.

Rosbarsky's specific request for jurisdictional discovery is denied. I. Personal Jurisdiction It appears from the briefing that Rosbarsky brought this action here because Montana's product liability law does not allow a "state-of-the-art defense" in strict products liability cases. Indeed, Rosbarsky notes that "Montana is the only jurisdiction in which [he] is likely to receive recourse as [his] claims would likely be dismissed in Massachusetts or New York as reflected [in other analogous actions] as those jurisdictions (unlike Montana) allow the state-of-the-art defense in strict products liability claims[,]" which allowed defendants to prevail.

(Doc. 28 at 7.) While this largely explains why Rosbarsky brought suit here, it does not insulate this case from a jurisdictional challenge. Ultimately, this Court lacks 30 personal jurisdiction over both defendants, foreclosing Rosbarsky's suit in this forum. Personal jurisdiction may be challenged under Rule 12(b)(2) of the Federal Rules of Civil Procedure. "Where a defendant moves to dismiss a complaint for lack of personal jurisdiction, the plaintiff bears the burden of demonstrating that jurisdiction is appropriate." Schwarzenegger v. Fred Martin Motor Co., 374 F.3d 797, 800 (9th Cir.

2004). "Where, as here, the motion is based on written materials rather than an evidentiary hearing, the plaintiff need only make a prima facie showing of jurisdictional facts." Jd. (internal quotation marks omitted).

Although the plaintiff "cannot simply rest on the bare allegations of [the] complaint," uncontroverted allegations must be taken as true. Jd. (internal quotation marks omitted). In other words, courts do not assume the truth of allegations in a pleading that are contradicted by affidavit. ZNS Enters. LLC v. Cont'l Motors, Inc., 22 F.4th 852, 858 (9th Cir. 2022).

However, "conflicts between the parties over statements contained in affidavits must be resolved in the plaintiff's favor." Id. (internal quotation marks and alteration omitted). Consistent with the standards applicable to Rule 12(b)(2) motions, the facts are taken from Plaintiffs' Complaint, (Doc. 1), two declarations filed by the Institute, (Docs. 12-2, 12-11), and other relevant jurisdictional evidence submitted by the parties.

See Caruth v. Int'l Psychoanalytical Ass'n, 59 F.3d 126, 128 (9th Cir. 1995). 31 "Federal courts ordinarily follow state law in determining the bounds of their jurisdiction over persons." Picot v.

Weston, 780 F.3d 1206, 1211 (9th Cir. 2015) (quoting Daimler AG v. Bauman, 571 U.S. 117, 125 (2014)).

In Montana, courts apply a two-step test to determine whether they have personal jurisdiction over a nonresident defendant. Milky Whey, Inc. v. Dairy Partners, LLC, 342 P.3d 13, 17 (Mont. 2015). First, courts consider whether personal jurisdiction exists under Montana's long-arm statute, Rule 4(b)(1) of the Montana Rules of Civil Procedure. Rule 4(b)(1) subjects parties to general jurisdiction if they are "found within the state of Montana" and to specific jurisdiction "as to any claim for relief arising from the doing personally, or through an employee or agent, of" certain enumerated acts.

Mont. R. Civ. Pro. 4(b)(1)(A), (B). Second, courts consider whether the exercise of personal jurisdiction comports with due process. Milky Whey, 342 P.3d at 17. Due process "depends on the defendant's having such 'contacts' with the forum State that 'the maintenance of the suit' is 'reasonable, in the context of our federal system of government,' and 'does not offend traditional notions of fair play and substantial justice.'"" Ford Motor Co. v. Mont.

Eighth Judicial Dist. Ct., 592 U.S. 351, 358 (2021) (quoting Int'] Shoe Co. v. Washington, 326 U.S. 310, 316-17 (1945)). "The defendant... must take some act by which it purposefully avails itself of the privilege of conducting activities within the forum State." Jd. at 359 (internal quotation marks and alterations omitted). 32 "Accordingly, exercising specific personal jurisdiction over a defendant is only appropriate when both the defendant and the underlying controversy are appropriately affiliated with Montana." Ford Motor Co. v. Mont.

Eighth Judicial Dist. Ct., 443 P.3d 407, 412 (Mont. 2019). Here, Rosbarsky "concedes" that neither the Institute nor Mira are subject to general personal jurisdiction. (Doc. 27 at 14; Doc. 28 at 15.) Instead, Rosbarsky argues that specific jurisdiction exists over both defendants and comports with due process. While the Institute and Mira disagree on both fronts, the due process analysis is dispositive.

Even assuming that both defendants are subject to specific jurisdiction under Rule 4(b)(1), such exercise is inconsistent with due process. Accordingly, both the Institute and Mira should be dismissed from this action. a. Montana Long-Arm Statute Because Rosbarsky "concedes" that neither the Institute nor Mira are subject to general personal jurisdiction, (Doc.

27 at 14; Doc. 28 at 15), only specific jurisdiction is addressed below. Montana extends specific jurisdiction "to any claim for relief arising from the doing personally, or through an employee or agent, of any" of the following enumerated acts: (A) the transaction of any business within Montana; (B) the commission of any act resulting in accrual within Montana of a tort action; 33 (C) the ownership, use, or possession of any property, or of any interest therein, situated within Montana; (D) contracting to insure any person, property, or risk located within Montana at the

time of contracting; (E) entering into a contract for services to be rendered or for materials to be furnished in Montana by such person; (F) acting as director, manager, trustee, or other officer of a corporation organized under the laws of, or having its principal place of business within, Montana; or (G) acting as personal representative of any estate within Montana.

Mont. R. Civ. P. 4(b)(1). Rosbarsky argues that specific jurisdiction is proper under subparts (A) and (E). As is described in detail below, because the Complaint is devoid of facts that show the Institute or Mira transacted business within Montana, Mont. R. Civ. P. 4(b)(1)(A), or entered into a contract for services to be rendered or for materials to be furnished in Montana, Mont.

R. Civ. P. 4(b)(1)(E), specific jurisdiction cannot be found on these grounds. Rosbarsky also argues that specific jurisdiction is established under subpart (B) because his tort claims accrued in Montana since "all" of his eye "surgeries occurred in Missoula." (Doc. 28 at 18; see Doc. 27 at 15.)

In support of this argument, Rosbarsky cites to the Complaint "at J 5, 48-50, 190-196, 198-202." (Doc. 28 at 18.) None of these specific paragraphs of the Complaint nor any allegation contained therein support his argument. Indeed, the Complaint does not state where Rosbarsky's 1989 implantation surgery or 1998 removal surgery took 34 place nor who the surgeon was that performed these procedures.

(See generally Doc. 1.) In his responses to the motions to dismiss, Rosbarsky does asserts that the 1989 implantation surgery took place at Rocky Mountain Eye Center in Missoula. (Doc. 27 at 9; see Doc. 28 at 18, 21, 32.) He further states that "[w]hile not specifically stated in the Complaint, it can be inferred that the 1989 and 1998 procedures were performed by specialists also affiliated with Rocky Mountain Eye Center." (Doc.

27 at 9 n.1 (citing Doc. 1 at 5 ("a substantial part of the events giving rise to the claim occurred in this district and division")).) Not so. Given that the Complaint specifically states where the first 2024 surgery took place, (Doc. | at | 199 (Rocky Mountain Eye Center, Missoula)), and where the four additional 2024 surgeries took place, (id. {| 203-04 (Moran Eye Center, Salt Lake City)), it does not logically follow that the 1989 and 1998 surgeries occurred in Missoula based upon a boilerplate jurisdictional statement, (see id. 95.)

Nor is it logical to infer that a surgery that occurred in 1989 or 1998 would have been performed at the same place where a surgery was performed about 30 years later. (See id. J 199.) However, with his opposition, Rosbarsky also filed the 1989 implantation surgery and 1998 removal surgery operative reports, (Docs. 27-1 at 28-1 at 4-5), which clearly show that both surgeries took place at the Rocky Mount Eye Center in Missoula.

35 The test for whether a tort accrued in Montana is "highly-fact specific and dependent on the nature of the alleged tort at issue." Groo v. State Eleventh Judicial Dist. Court, 537 P.3d 111, 119

(Mont. 2023). The inquiry “focuse[s] on where the events giving rise to the tort claims occurred, rather than where the plaintiffs allegedly experienced or learned of their injuries.” Tackett v. Duncan, 334 P.3d 920, 928 (Mont.

2014). Rosbarsky frames this analysis as exceedingly simple here: his “claims accrued in Montana [within the meaning of subpart (B)] as all surgeries occurred in Missoula.” (Doc. 28 at 18.) Even if the analysis were this simple and specific jurisdiction over the Institute and Mira could be established under subpart (B), personal jurisdiction is improper here because it fails to comport with due process as explained below. b. Due Process Because “a federal district court is constrained by [] Fourteenth Amendment” Due Process, there are three requirements for establishing specific jurisdiction over a non- resident defendant: (1) the defendant must either purposefully direct his activities toward the forum or purposefully avail himself of the privileges of conducting activities in the forum; (2) the claim must be one which arises out of or relates to the defendant’s forum-related activities; and (3) the exercise of jurisdiction must comport with fair play and substantial justice, i.e. it must be reasonable.

Impossible Foods Inc. v. Impossible X LLC, 80 F.4th 1079, 1086 (9th Cir. 2023) (internal quotation marks omitted). Ifa plaintiff establishes the first two elements, 36 the burden “shifts to the defendant” as to the third element requiring presentation of “a compelling case that the exercise of jurisdiction would not be reasonable.” Id. at 1099 (internal quotation marks omitted).

However, “if the plaintiff fails at the first step, the jurisdictional inquiry ends and the case must be dismissed.” Boschetto v. Hansing, 539 F.3d 1011, 1016 (9th Cir. 2008). “[P]urposeful direction is often the better approach for analyzing claims in tort.” Impossible Foods, Inc., 80 F 4th at 1088 (internal quotation marks omitted). Application of this test “requires that the defendant allegedly have (1) committed an intentional act, (2) expressly aimed at the forum state, (3) causing harm that the defendant knows is likely to be suffered in the forum state.” Dole Food Co. v. Watts, 303 F.3d 1104, 1111 (9th Cir.

2002). This is known as the “Calder effects test.” Id. (referring to Calder v. Jones, 465 U.S. 783 (1984)). “All three parts of the test must be satisfied.” Schwarzenegger, 374 F.3d at 800. i. The Institute Applying the Calder effects test here, Rosbarsky has shown that the Institute has committed an intentional act through its study and development of MIRAgel in conjunction with the execution of the Licensing Agreement.

However, Rosbarsky fails to show that this act was expressly aimed at Montana. a. Intentional Act ““Tntentional act’ has a specialized meaning in the context of the Calder effects test.” Schwarzenegger, 374 F.3d at 806.

The term “act” “denote[s] an 37 external manifestation of the actor’s will... not includ[ing] any of its results, even the most direct, immediate, and intended.” Jd. (quoting Restatement (Second) of

Torts § 2 (1964)). “Intent” here “refer[s] to an intent to perform an actual, physical act in the real world, rather than an intent to accomplish a result or consequence of that act.” Id. As pled, the Institute’s intentional act was the study and development of MIRAgel, (Doc.

1 at | 30), in conjunction with the execution of the Licensing Agreement, (id. 38-39). Accordingly, the Institute committed an intentional act. b. Express Aim The next question then is whether this “intentional act” was “expressly aimed at” Montana. Dole Food Co., 303 F.3d at 1111.

The Institute insists that because the Licensing Agreement only “contemplated development and distribution of the product worldwide,” and the Institute “did not advertise MIRAgel for Montana, ship MIRAgel to Montana, or even place MIRAgel into the stream of commerce,” its intentional acts were not expressly aimed at Montana. (Doc. 12 at 16-17.)

The Institute further asserts that because it and Mira “were at all times separate entities transacting via [the] Licensing Agreement,” the unilateral marketing or sales actions taken by Mira cannot subject the Institute to personal jurisdiction in this Court. (/d. at 18.) 38 Rosbarsky disagrees, asserting that the Institute “knowingly distribut[ed] its product to Montana.” (Doc.

28 at 22.) Rosbarsky insists that the Institute “indirectly made efforts to get its product into Montana for financial benefit.” (/d.) In support of these assertions, Rosbarsky cites to a Mira document filed by the Institute that lists “U.S. MIRAgel Users” by the doctor’s name, their address, and the distributor used, which includes Rosbarsky’s surgeon, Dr. Randall, then-based in Missoula, whose distributor was Apple Medical.

(Doc. 28 at 22 (citing Doc. 12- 17 at 1 (“Doctors List”).) Rosbarsky does not address the Institute’s argument that Mira’s acts cannot impute personal jurisdiction onto the Institute. (See generally Doc. 28.) Ultimately, Rosbarsky fails to carry his burden on both fronts.

The Institute studied, tested, developed, and designed MIRAgel. (Doc. 1 at {{ 30, 87, 133.) The MIRAgel Patent was issued in 1984, (id. J] 36, 37), and the Institute then entered into the Licensing Agreement with Mira on July 29, 1985, (id. J] 38, 39).

Under this Agreement, as outlined in the Complaint, (id. J] 38-45), the Institute did not have control or oversight over the marketing or distribution of MIRAgel. The Complaint expressly distinguishes between the independent obligations of the Institute and Mira, and their joint obligations under the Agreement. Indeed, the only joint obligation alleged is the pursuit of “any Federal Food and Drug Administration (FDA) approvals relating to licensed products ‘on a cooperative effort basis.’” Ud.

J 44.) 39 As to marketing and distribution activities, Rosbarsky’s pleadings have been contradicted by the sworn statement of an Institute officer. It is alleged that the Institute “participated in decisions relating to the marketing of MIRAgel,” “participated with [Mira] in the formulation and

implementation of a plan to devise articles for publication in professional journals to be read by ophthalmologists who might consider using MIRAgel in the treatment of their patients," (id. | 53), and "Jointly [with Mira] determined the nature of any warnings and marketing literature that would be provided to ophthalmologists concerning the use of MIRAgel," (id. { 54).

Although these facts, as pled, assert that the Institute participated in the marketing and distribution of MIRAgel, jurisdictional evidence contradicts the pleadings here. In his declaration, David L. Conlon, Chief Financial Officer and Director of Physical Plant and Risk Management for the Institute,!° testified that the Institute has never engaged in "marking, selling and/or distributing of [its patented and licensed] products and/or medical devices." (Doc.

12-2 at] 5.) He further explains, once a product or medical device like MIRAgel "is licensed to a pharmaceutical company," like Mira, the Institute "does not retain any control over the manner in which said [product or medical device] is manufactured, marketed, sold, and/or distributed." (/d.)

Because Rosbarsky did '3 Conlon held this position in 2005 when the declaration was submitted. (Doc. 12- 2.) 40 not respond with any sworn testimony supporting his pleadings, (see generally Docs. 27, 28),'* his now-contradicted allegations are no longer assumed to be true, LNS Enters. LLCs, Inc., 22 F.4th at 858. But even if Rosbarsky effectively showed that the Institute was involved in the marketing and distribution of MIRAgel, absent from the pleadings is any allegation that this activity was expressly aimed at Montana.

Indeed, such an assertion is only made in response to the motions to dismiss where Rosbarsky alleges for the first time that MIRAgel "was expressly aimed at Montana and Rosbarsky's eye surgeon, James Randall." (Doc. 28 at 21.)

As discussed above, Dr. Randall is not mentioned in the Complaint. (See generally Doc. 1.) With this response, Rosbarsky also filed the operative report of his MIRAgel implantation surgery, (Docs. 27-1 at 4-5; 28-1 at 4-5), which clearly shows this surgery took place in Missoula and was performed by Dr. Randall. Yet this unpled allegation together with the jurisdictional evidence is not enough. "The placement of a product into the stream of commerce, without more, is not an act purposefully directed toward a forum state." Holland Am.

Line, Inc. v. Wartsila N. Am., Inc., 485 F.3d 450, 459 (9th Cir. 2007) (citing Asahi Metal Indus. Co. v. Superior Ct., 480 U.S. 102, 112 (1987)). Indeed, a defendant must have '4 The only sworn statements submitted by Rosbarsky are two foundational declarations by his counsel to authenticate the exhibits attached to his responses to the pending motions to dismiss.

(Docs. 27-1, 28-1.) Al some "expectation that [their products] will be purchased by consumers in the forum state." World-Wide Volkswagen v. Woodson, 444 U.S. 286, 297-98 (1980). Here, no advertisements or design choices targeting Montana, or any other Montana-focused actions, were pled. See Asahi Metal Indus. Co., 480 U.S. at 112. And although the Licensing Agreement had the

“intended purpose” of placing MIRAgel “into the stream of commerce,” and even if the Institute did “play[] a vital role in getting [MIRA]gel into the stream of commerce,” as is highlighted by Rosbarsky, (Doc.

28 at 16-17), that Agreement does not mention any states specifically, let alone Montana. “[A] defendant’s awareness that the stream of commerce may or will sweep the product into the forum state does not convert the mere act of placing the product into the stream of commerce into an act purposefully directed toward the forum state.” Holland Am. Line, Inc., 485 F.3d at 459.

The pleadings also lack any facts indicating that the Institute had any “expectation” that once in the stream of commerce MIRAgel would reach Montana specifically. See World-Wide Volkswagen, 444 U.S. at 297-98. Further, the Doctors List only shows that two doctors in Missoula were MIRAgel users, it does not show that the Institute (or Mira for that matter) expressly sought to distribute MIRAgel in Montana, or that Montana or its doctors were targeted in any way.

See Holland Am. Line, Inc., 485 F.3d at 459. 42 Because the Institute’s intentional act was not expressly aimed at Montana, the final part of the purposeful direction test need not be reached. Accordingly, Rosbarsky fails to show that exercising personal jurisdiction over the Institute comports with due process. ii. Mira Mira argues that “the Complaint is bereft of any allegation as to the basis for the exercise of personal jurisdiction over” it.

(Doc. 6 at 10.) Once again, while Rosbarsky had pled an intentional act, he fails to show that act was expressly directed at Montana. a. Intentional Act As pled, Mira’s intentional act was the manufacturing, marketing, and sale of MIRAgel under the Licensing Agreement. (Doc. 1 at J 8-10); see Schwarzenegger, 374 F.3d at 806. b. Express Aim The next question is whether this “intentional act” was “expressly aimed at” Montana.

Dole Food Co., 303 F.3d at 1111. Mira argues that Rosbarsky does not sufficiently plead express aim here because Mira’s only contacts with Montana alleged in the Complaint are that “Mira’s product was inserted surgically into the eyes of a Montana resident at some unknown locale, and that the Montana resident sustained the injury in Montana.” (Doc. 6 at 13.)

Rosbarsky disagrees, insisting that Mira “placed [MIRA]gel into the stream of commerce, expressly directing 43 [MIRA]gel to Rosbarsky’s surgeon in Missoula, and causing harm to Rosbarsky in Montana.” (Doc. 27 at 17.) Ultimately, Mira has the better argument. Rosbarsky insists that “Mira engaged in affirmative conduct by knowingly distributing its product to Montana.” (Doc.

27 at 17.) This argument is not pled in the Complaint, (see generally Doc. 1), and the only jurisdictional evidence upon which Rosbarsky relies to make this argument at the motion to dismiss stage is the Doctors List, (Doc. 27 at 17-18 (citing Doc. 12-17).) This List, Rosbarsky

asserts, demonstrates that “Mira had a distributor that served at least two Missoula ophthalmologists,” which shows Mira’s “involvement in, and its pecuniary benefit from, an exploitation of the Montana Market.” (/d. at 17.)

Not so. Clearly Mira did have a distributor, Apple Medical, which served two Missoula ophthalmologists, and an ophthalmologist in Phoenix, Arizona, as well as twelve other distributors who together served ophthalmologists in Alabama, California, Florida, Georgia, Hawaii, Idaho, Illinois, Kentucky, Maryland, Massachusetts, Michigan, Missouri, New Jersey, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, and Virginia.

(Doc. 12-17 at 1- 4.) But, a “defendant’s transmission of goods permits the exercise of jurisdiction only where the defendant can be said to have targeted the forum” state. J. McIntyre Machinery, Ltd. v. Nicastro, 564 U.S. 873, 882 (2011).

As explained above, this cannot be said here. The Doctors List merely shows that Mira engaged 44 distributors and that specific ophthalmologists used MIRAgel, it does not show that Mira expressly sought to distribute MIRAgel in any particular state, and certainly does not show that Montana was specifically targeted. See Holland Am. Line, Inc., 485 F.3d at 459.

Further, Rosbarsky has not pled that Mira engaged in any action focused on Montana, such as advertisements or design choices. See Asahi Metal Indus. Co., 480 U.S. at 112. Thus, because Mira’s intentional act was not expressly aimed at Montana, the final part of the purposeful direction test need not be reached.

Accordingly, because Rosbarsky fails to show that the first element of due process is met, exercising personal jurisdiction over Mira does not comport with due process. II. Jurisdictional Discovery Rosbarsky specifically requests jurisdictional discovery to determine the Institute’s involvement in the distribution of MIRAgel to Montana. He insists this is appropriate given the Institute’s production of documents thus far, including the Doctors List.

Because Mira’s distribution of MIRAgel is insufficient to give rise to personal jurisdiction, Rosbarsky’s quest to tie the Institute to those distribution activities would not further his cause. Jurisdictional discovery is therefore denied. “Jurisdictional discovery should ordinarily be granted where pertinent facts bearing on the question of jurisdiction are controverted or where a more satisfactory showing of the facts is necessary.” Yamashita v. LG Chem, Ltd., 62 45 F.4th 496, 507 (9th Cir.

2023) (internal quotation marks omitted). Jurisdictional discovery here may reveal information regarding the controverted fact that the Institute worked jointly with Mira in distributing MIRAgel. However, this disputed fact is not pertinent to the personal jurisdiction analysis. Even if the Institute worked hand-in-hand with Mira to distribute MIRAgel, such distribution was not purposefully directed toward Montana, as is explained above.

Accordingly, Rosbarsky’s request to conduct jurisdictional discovery on this issue is denied. CONCLUSION Based on the foregoing, IT IS ORDERED that the Institute and Mira’s motions to dismiss, (Docs. 5, 10) are GRANTED and the above-captioned case is DISMISSED. All pending motions are DENIED as MOOT and all deadlines are VACATED.

The Clerk is directed to enter a judgment of dismissal and close the case. IT IS FURTHER ORDERED that Rosbarsky’s specific request for jurisdictional discovery is DENIED. DATED this dat Sey of February, 2026. AU A A.W. Dénald W. MoNoy, District Judge it Court 46