March 30, 2021, Judgment Sentenced.

Case Number: 2019 (Heisei 31) (ne) No. 10008

Appeal for injunction and damages based on the Unfair Competition Prevention Law

(First Trial; Tokyo District Court 2018 (Heisei 30) (wa) No. 22646)

Hearings closed on January 26, 2021(Reiwa 3)

JUDGMENT

Appellant (Plaintiff)

100-10, Yanagishima, Fuji City, Shizuoka Prefecture

Kitazato Corporation

Representative director, Tadashi Inoue

Attorney-at-law for Appellant, Nobuo Hino

Appellee (Defendant)

2-5-3, Shinjuku, Shinjuku-ku, Tokyo, AM Building 9th floor

Reprolife Co., Ltd.

Representative director Masashige Kuwayama

Attorney-at-law for Appellee, Kento Matsumoto, Akira Nose

THE MAIN TEXT OF JUDGMENT

1. Intellectual Property High Court revises Tokyo District Court Judgement as follows:

2. The Court orders Appellee not to use the description such as, "100% survival after thawing", "100% survival", "100% Post-warm Survival", "achieving 100%, literally 100%, survival" or the description of meaning that "can achieve 100% survival after thawing vitrified oocytes" on the advertisements, the documents for transactions, web site, and other advertising media, for straw shaped containers for vitrification, and vitrification or thawing media used together with them.

3. The Court orders Appellee delete "100% survival after thawing" from the indications 1 and 2 in the attached description list on the address 1 in the attached internet address list.

4. The Court orders Appellee delete "survival rate" and "100%" from the indications 3 to 5 in the attached description list, and "100% high survival rate" from the indication 6 in the attached description list, on the address 2 in the attached internet address list.

5 The Court orders Appellee delete, "100% survival vitrification!" from the indication 7, all of indication 8, "100% Post-warm survival rates" from the indication 9, "100% survival" from the indication 10 in the attached description list, on the address 3 in the attached internet address list.

6. The Court orders Appellee delete, "100% SURVIVAL" from the indication 11, "achieving 100%, literally 100, survival" from the indication 12 in the attached description list, on the address 4 in the attached internet address list.

7. The Court orders Appellee delete "100% SURVIVAL" from the indication 11, "achieving 100%, literally 100, survival" from the indication 12, "100% survival" from the indication 13, "100% SURVIVAL" from the indication 14, on the advertisements, the documents for transactions, web site, and other advertising media, for straw shaped containers for vitrification, and vitrification or thawing media used together with them.

8. The Court orders Appellee pay Appellant 43,468,397 yen, of which 26,397,539 yen of which 26,397,539 yen with payment delay charge at 5% per year from July 26, 2018, to the day when would be paid, and 17,070,858 yen with late payment charge at 3% per year from November 11, 2020, to the day when would be paid.

9. The Court dismisses appellant's other claims than described above.

10. The quarter of the Court costs through the first and second trials shall be borne by Appellee and the rest shall be borne by Appellant.

11. Paragraphs 2 to 8 of this judgment can be tentatively enforced.

FACTS AND REASONS

I. Claims requested by the party [omitted]

II. Overview of the case [omitted]

III. Judgment of the Court

1. Based on the above premise facts, the evidence below (all cross-examination witnesses at the Court), and both parties' whole argument, the Court has found following facts:

(1) Cryotop method and Cryotec method

Around 2000 Appellee's (Defendant's) representative developed "Cryotop method," a technique of cryopreservation of oocytes and embryos, when he worked for a medical fertility facility. Appellant or its affiliates manufacture and sell straw shaped vitrification devices, vitrification, and thawing media, prepared for Cryotop method. Appellee's representative quit the medical fertility facility in 2010, and established Appellee company (renamed its company name from "Repro Support Medical Research Center Co., Ltd." on October 1, 2015.) In 2012 Appellee's representative developed Cryotec method by improving Cryotop method and started to manufacture and sell straw shaped vitrification devices, vitrification and thawing media.

Defendant's products are different from the Plaintiff's in the equilibrium treatment process (Defendant's has one step, although Plaintiff's has three steps), utilizing natural levitation by specific gravity difference of solutions, and shape of wells, vitrifying straw devices, and media.

(Appellant's Exhibit 2, 14-1 to 3,15-1to2, P18, 28, 33, 44, 99, Appellee's Exhibit 3, 70, Appellee's representative's witness in court)

(2) Defendant's descriptions in the present advertisements

Defendant's descriptions in the present advertisements are those that Plaintiff request to delete, (A. includes the present description 5, and B. is translated into Japanese), as follows:

A. "Product Introduction" on Defendant's website 1[in Japanese] (Appellant's Exhibit 28)

"Cryotec products have special features as follows:

・Survival rate is 100% for blastocysts, divided embryos and oocytes (when the protocol is strictly observed).

・Cryotech's thawing system can be used for embryos and oocytes vitrified by other vitrification methods, and higher survival rates and pregnancy rates can be expected.

・You can thaw oocytes and embryos in a simpler, safer, and easier way, and can obtain higher survival rate, higher pregnancy rate.

・You can also vitrify low-grade embryos and oocytes those were difficult with conventional methods."

"18 points are improved to ensure for anyone with or without vitrification experience or basic knowledge can get the same good results without human errors."

B. Defendant's Web Page, Site 2 "Home " [in English] (Plaintiff Exhibit 12)

"The most effective, easiest and safety."

"Cryotec is a highly simplified vitrification protocol. It is easy for anyone."

(3) Defendant's selling method of its products

Appellee has sold its product to medical fertility facilities by sales representatives to visit them and recommend newly or continuous purchases of Defendant's products.

Appellee has held a technical workshop to educate embryologist of the medical fertility facility to learn how to use its products and protocol. Appellee has sold its products to those facilities that their embryologist that certified as achieved 100 % survival rate in such a technical workshop. Appellee has still sold to those facilities of embryologist learned Defendant's protocol, expecting the certified embryologist might lecture its protocol, even if they do not participate Defendant's workshop.

Further, Appellee has continued to sell its products after the certified embryologist left the facilities.

(Appellee's Exhibit 33~39, 44, 45, 60, and Mano Keishi's witness in court)

(4) Appellee's workshop and "Challenge 100"

A. At Defendant's workshop, participants vitrify and thaw human oocytes that are going to be discarded with its products, and then it certifies that they achieve 100% survival, sometimes it hands certificate of it.

The confirmation of survival at the workshop is as follows:

If contracted oocytes by vitrified are observed as recovered its volume after thawing during five minutes treatment in WS (washing solution), with a microscope of more than 50 magnification, their survival is confirmed.

(Appellee's Exhibit 33~39, Mano Keishi's and Appellee's representative's witness in court)

B. In April 2019 Appellee started "Challenge 100" policy as follows:

Three chosen embryologists of each facility whom Appellee certified achieving 100% survival are aiming to achieve 100% survival in consecutive hundred thaw cycles of oocytes, split embryos or blastocysts at any stage.

The criteria for confirming the survival in "Challenge 100" are as follows.

(A) An oocyte

An oocyte is confirmed "survival", when its cell volume is fully recovered or becoming recovered after five minutes in WS1 in comparison with the memorized shape when immediately put into, observing with strongest extension of the microscope.

(B) A split embryo

A split embryo is confirmed "survival", when 30% or more of the blastomeres are fully recovered or becoming recovered in comparison with the memorized shape after five minutes in WS1 in comparison with the memorized shape when immediately put into, observing with strongest extension of the microscope.

(C) A blastocyst

A blastocyst is confirmed "survival", when blastocoel begins to open again or the blastocoel is reshaped in the embryo after 1 to 3 hours thawing, observing with the strongest extension of the microscope.

(Appellee's Exhibit No. 42-1~2. 43, 70, Appellee's representative's witness in court)

(5) A method for confirming the survival of vitrified oocytes and embryos.

Generally accepted methods in clinical practice for confirming the survival of vitrified oocytes and embryos is as follows:

A. An oocyte

An oocyte is confirmed survival, when its cell volume is recovered to the same morphology as before vitrified, recovered its cell volume in 5 minutes with WS (washing solution), and cultured 2 to 4 hours by the routine method of the thawing facility. The cell volume is observed with an inverted microscope (generally 200x to 400x) before micro- insemination.

B. A Blastocyst

A blastocyst is confirmed survival, when blastocoel, disappeared by vitrification, remodeling is performed, after thawing and diluting, and cultured by the routine method of the thawing facility, observed with a microscope during the recovery culture for 3 hours.

The blastocoel remodeling is observed with an inverted microscope (generally 200x to 400x) before transfer of it.

(Appellant's Exhibit 63-1 to 3, 70, P's and Appellee representative's witnesses in court)

(6) Reports on the survival rate of oocytes and embryos with Defendant's product

A. Research report 2

(A) Research Report 2 is "Examination of Freezing of Unfertilized Human Oocyte with Cryotop and Cryotec" written by Ms.S and 9 people, in "Journal of the Japan Reproductive Medicine

Society, Vol. 59, No. 3". published on July 1, 2014 by Japan Reproductive Medicine Society. (Appellant's Exhibit 16- 1 to 3).

"(Purpose) We report on the vitrification of unfertilized oocytes that is considered lower success rate and obtained clinically useful results. (Method) Protective medias are adopted as follows:

A: Cryotop Safety Kit made by Kitazato Biopharma,

B: Cryotec Kit made by Repro Support Medical Center; embryos are put in 300 μl ES vitrification method in 15 minutes, and place them in the center of VS1, moved to VS2, then confirming contraction of them, and vitrified.) (Result) B: Resuscitation rate 53.9% (7/13) Fertilization rate 71.4% (5/7) Blastocyst arrival rate 57.1% (4/7). (Conclusion) Cryotec: It was difficult to see the embryos since we were not accustomed to the manipulations. The blastocyst arrival rate was high rate as 57.1%. Since the number of executions is not so many, we are going to continue our study."

(B) Ms.S, one of the authors of Research Report 2, participated to Appellee's workshop on the Cryotech method, and received Appellee's Certificate of achieving 100% survival rate of oocytes after thawing (Both parties admitted).

B. Appellant's Exhibit 91

Appellant's Exhibit No. 91 is " Mechanical zona pellucida removal of vitrified-warmed human blastocysts does not affect the clinical outcome" written by Kirienko and Yakovenko, who are working as senior embryologists at AltraVita, published in November 2019, "RBMO Vol. 39, No. 5". Appellant's Exhibit No. 91 has the following descriptions (Appellant's Exhibit 91-1, 2):

" This study was conducted according to the approval of the Ethical Committee of AltraVita IVF Clinic, Moscow, Russia on 21 November 2017."

"On day 5 or 6 after intracytoplasmic sperm injection or intracytoplasmic morphologically

selected sperm injection, vitrification was carried out using Cryotech method (Vitrification Kit 101; Cryotech, Tokyo, Japan). Cryotech method (Warming Kit 102; Cryotech, Tokyo, Japan) was used for warming of the blastocysts on the day of the scheduled embryo transfer. In the zona-free group, mechanical zona removal was carried out while the blastocysts remained collapsed after warming, i.e., within 5–15 min of completing the warming procedure. Subsequently, blastocysts were rinsed and cultured in HTF medium with 15 mg/ml protein supplement (Life Global, USA) until transfer. Zona intact group blastocysts were cultured in HTF medium with 15 mg/ml protein supplement (Life Global) after warming. Post-warming survival, i.e., re-expansion of blastocysts, was evaluated 1–3 h after warming."

"Both groups had similar maternal age, blastocyst rate (calculated by the number of high-quality blastocysts divided by the number of two-pronuclei stages), blastocyst morphology before cryopreservation and mean number of blastocysts per transfer (TABLE 1). The re-expansion rate of the zona-free group (98.1%) was comparable with that of the intact group (96.3%), suggesting that blastocyst viability was not affected by zona removal procedure. Clinical outcomes, including implantation rates, biochemical, clinical and ongoing pregnancies were not statistically different between the zona-free (33.9%, 43.5%, 35.9% and 32.1%) and zona-intact groups (36.4%, 47.6%, 39% and 33.1%) (FIGURE 2). No statistical difference was observed between zona-free and zona-intact groups concerning multiple pregnancy rates per clinical pregnancy (8.0% versus 3.6%), ectopic pregnancy rates per clinical pregnancy (1.3% versus 1.2%) and spontaneous abortion rates (9.3% versus 12.8%)." [original]

C. AFC's website

AFC (Alpha International Fertility Centre), Appellee's Cryotech support center in Malaysia (Appellant's Exhibit 35-3), publishes the following articles on its website regarding the survival rate of cryopreserved oocytes and embryos using Defendant's products.

(A) Outcome of vitrified-thawed oocytes at Alpha International Fertility Centre (AFC). 2015 (Appellant's Exhibit No. 88)

"Oral presentation at the 24th Asian & Oceanic of Congress of Obstetrics and Gynecology,3-6 June 2015, Kuching, Sarawak, Malaysia.

"Introduction:

In 2013, Dr. Masashige Kuwayama introduced Cryotec Method of vitrification and warming of oocytes, claiming a post-thaw survival rate of 100%. AFC adopted the Cryotec Method from August 2013. We hereby present the outcome of vitrified-thawed oocytes using this method in AFC."

"Method:

Following cryopreservation using the Cryotech method, 5 patients had their oocytes thawed."

"Result:

A total of 65 oocytes were thawed. Sixty three oocytes survived (Post-thaw Survival Rate: 96.9%) and had ICSI. Forty six (46) oocytes were normally fertilized (2PN) while 2 were 3PN (Fertilization rate: 76.2%). Of these, 26 embryos formed blastocysts (Blastulation rate: 56.5%).

"Conclusion:

Our experience with cryopreservation of oocytes using the Cryotec Method showed a near 100% post-thaw survival rate; with fertilization rate, blastulation rate, implantation rate and clinical pregnancy rate comparable to cycles using fresh oocytes." [original]

(B) Clinical outcome of vitrified- thawed oocytes at Alpha International Fertility Centre (AFC). 2016 (Appellant's Exhibit No. 89)

"Presented at 24th Congress of Obstetrics and Gynecological Society of Malaysia., 2-5th June 2016, Kuala Lumpur, Malaysia. "

"Objectives:

This study presents the clinical outcome of vitrified-thawed oocytes using the Cryotec method at Alpha International Fertility Centre, Malaysia."

“Result:

A total of 231 oocytes were thawed. Two-hundred and twenty (220) oocytes survived (Post-thaw Survival Rate: 95.2%) and had Piezo-ICSI. One hundred and thirty-nine (139) oocytes were normally fertilised (Fertilisation rate: 63.2%). All 139 zygotes developed to embryos on Day 3, 2 of them were transferred into 1 patient, while the remaining 137 embryos were further cultured to Day 5/6. "

“Of the 137 embryos, 90 developed to blastocysts on Day 5/6 whereby 31 were transferred into 17 patients, 20 were vitrified, and the remaining 39 blastocysts were poor quality. The mean number of embryos/blastocysts transferred was 1.8. Two (2) patients failed to reach ET due to poor blastocyst quality obtained. Of the 18 patients who had embryo transfer, 11 patients were clinically pregnant (Clinical Pregnancy Rate/ Embryo Transfer: 61.1%) with 14 embryos/blastocysts implanted (Implantation rate: 42.4%).”

"Conclusion:

Our experience with the Cryotec Method in the vitrification of oocytes showed 95.2% post-thaw survival rate with good clinical pregnancy and implantation rates. We believe Cryotec is the cryopreservation method of choice to maximise the freeze-thaw survival rate of oocytes.” [original]

(C) Clinical outcome of blastocysts derived from frozen donor oocytes versus fresh donor oocytes in fresh blastocyst transfer cycles. 2017 (Appellant’s Exhibit 90)

"Presented at 25th Congress of Obstetrics & Gynecology Society of Malaysia, 27-30 of July 2017, Kuala Lumpur, Malaysia."

"Objectives:

The Cryotec method has been employed in all frozen-warmed cycles at Alpha Fertility

Centre (AFC) since July 2013. With the Cryotec method, we have consistently achieved 100% post-warmed survival rates of embryos (Lee et al, 2016), and a near 100% post-warmed survival of vitrified oocytes (Lui et al, 2016).

"Methods:

Forty-one women underwent fresh blastocyst transfer using anonymously donated oocytes at Alpha Fertility Centre, Malaysia from March 2014 until December 2016. Nineteen of these patients were allocated with vitrified-warmed donated oocytes (Group A) while 22 patients received donated oocytes from fresh retrievals (Group B).

Oocytes from Group A were vitrified and warmed using the Cryotec method (Cryotech, Japan). All oocytes had Intra-Cytoplasmic Sperm Injection (ICSI) and resultant embryos were cultured to day 5 or 6. ”

"Results:

In Group A, a total of 284 oocytes were warmed. Two-hundred-and-seventy-two oocytes survived (Post-warmed Survival Rate: 95.8%). One patient in Group A failed to reach ET due to poor blastocyst quality obtained, while all patients in Group B progressed to ET. The mean number of blastocysts transferred was 1.8 and 2.0 for Group A and Group B respectively ($p>0.05$). Clinical Pregnancy Rate (CPR) for Group A was 66.7% and for Group B was 63.6%. Implantation Rates (IR) were 46.9% and 51.2% for Group A and B respectively. There was no statistical significance ($p>0.05$) found in CPR and IR between both groups."

"Conclusion:

This study shows that vitrified-warmed donor oocytes using the Cryotec method yield clinical pregnancy and implantation rates comparable to fresh donor oocytes." [original]

(D) 100 % post-warmed survival rate for 1491 blastocysts in Alpha Fertility Center. 2017 (Appellee’s Exhibit 50 1.2, 68-1.2)

"This study demonstrates the post-warmed survival rate for 1491 blastocysts in 1011 frozen blastocyst transfers (FBT). "

"Materials and methods: Since the commencement of the use of Cryotec Method in July 2013 till now (May 2017), Alpha Fertility Centre had vitrified and warmed 1491 blastocysts using the Cryotec Method for 1011 FBT patients. Cryotech method began to be used in July 2013."

"Results:

Of the 1491 blastocysts warmed, all blastocysts survived with morphologically intact inner cell mass and trophectoderm cells with no degradation in quality. "

"Conclusion:

This study shows that by using the Cryotec Method, we consistently achieved 100% post-warmed survival rate in blastocysts." [original]

(E) The Cryotech method consistently achieves a post-thawing survival rate of 100% in blastomeres.2016 (Appellant's Exhibit 69-1and 2).

"(Method:)

Sixty-two (62) cleavage stage day 3 embryos with 502 blastomeres from 28 patients (Age range: 18-43 years old; Mean age: 35.5) were thawed for FET cycles between July 2013 and April 2015. All were embryos with ≥6 cells and with <15% fragmentation. These embryos were vitrified using the Cryotech Vitrification Media and thawed using the Cryotech Warming Media (Cryotech, Japan).

"(Results:)

After Cryotech warming, all 62 embryos survived with a 100% post-thaw survival rate, enabling transfer in all cases. Moreover, the blastomere survival rate was also 100% (502/502) blastomere remains intact) without any incidence of embryos with lysed cells." [original]

(7) Medical Park Yokohama's website

"Culturing Room Blog" on Medical Park Yokohama's website has a topic of "Notice of Vitrification Liquid Upgrade" on January 28, 2020. The topic states, "The vitrification medium at Medical Park Yokohama will be upgraded from February. I hear the upgraded medium has the world's highest class improved composition, and its safety and effectiveness have been the best in vitrification history. I quote the following message from the manufacturer's website." "This is the latest vitrification method of the world's highest-class vitrification ability and can expect 100% survival rate after vitrified- thawing." quoting the graph named "Blastocyst freeze-thaw performance in clinical practice by cryotech method," "100% survival rate suggests the least stress on the oocytes. 100%, not 99%, There is a meaning between them than the number itself.

Medical Park Yokohama's website states, "The director of this clinic Dr. Kikuchi, and Dr. Kuwayama, worked together on oocytes and ovarian[sic] vitrified. I hear Dr. Kikuchi learned much from Dr. Kuwayama. We are going to provide its latest vitrification methods, in principle in all cases from February."

(Appellant's Exhibit 94～97)

(8) The Customer Survey

Appellee conducted a customer survey in June (June-July, 2020) and in November (2020).

The customer survey in June has the following 9 questions, domestic and overseas as follows:

"Q2" is "How did you know about Cryotech products?" "Q4" is "Please check the decisive reason from below for the final decision maker to start to purchasing Cryotech products." "Q4" has 13 choices for an answer as follows:

"Function of the product," "Design," "Quality," "Price," "REPROLIFE's homepage", "It was good when you tried the products at the workshop." "It was better than other competitors' products (including customer services)", "Because REPROLIFE's products," "Introduced by another clinics or labs," "Because Dr. Kuwayama developed the products," "Discovered that other clinic domestically

and worldwide have excellent results," "Found out that the great results were on academic papers or publications," and "others." [original]

There are two questions for the domestic market in the Customer Survey in November. "Q2" is "Please check the decisive reason from below for the final decision maker to start to purchasing Cryotech products." There are seven answer options. "I felt the simplicity of the procedure through the workshop," "Through the workshop, he was in good condition after thawing of oocytes and blastocysts." "Price," "There is a gentle device for oocytes and blastocysts," "I wasn't satisfied with the products of other companies I was using before." "I felt the possibility of improving my grades through sampling, etc." "I saw that it was stated on our homepage etc. that he could achieve 100% survival rate if he adhered to the protocol." In addition, there are five questions for overseas in the November questionnaire. "Q2" is " How did you know about Cryotech products?" "Q4" is " Please check the decisive reason from below for the final decision maker to start purchase Cryotec product? Please check from the following." The answer options are 15 below. "Function of the products", "Design", "Quality", "Price", "REPROLIFE's homepage", "It was easy to use when you tried the products at the workshop", "It was better than other competitors' products (including customer service)", "Because REPROLIF"s products ", "Introduced by another clinics or labs", "Because Dr Kuwayama developed the products", "Discovered that other clinics domestically and worldwide have excellent results ", "Advertising phrase "100% survival rate", " Achieved 100% survival rate at the workshop", "Found out that the great results were on academic papers or publications", "Others". [original]

(Appellee's Exhibit 74-1, 2, 75-1 to 3, 114~120)

(9) The market share of Plaintiff's and Defendant's products

Most of medical devices for vitrification and thawing oocytes ("the products") sold in Japan are Plaintiff's or Defendant' products.

The market shares of Defendant's and Plaintiff's products are 18%, 64% in India, and 15%, 60% in Russia .

(Appellee's Exhibit 131, 132, Mano Keishi's witness in court)

2. Issues

(1) Whether Defendant's advertisement falls under "Unfair Competition" prescribed at Item 20, Paragraph 1, Article 2 of the Prohibition of Unfair Competition Law)

(1) Issues (1) A. (Target of Defendant's advertisement)

A. The Court finds Defendant's advertisements are promoting the sales of its products. (Appellant's Exhibit 11, 12, 13, 20-1.2, 28, 35-1.2), Defendant's products are devices for fertility treatment, that is, for vitrification of oocytes and embryos as described in 2-2 above, and the patients for fertility are difficult to purchase them by themselves, and Defendant sells its products only to medical fertility facilities described in 1 (3). Thus, the Court concludes its customers are medical fertility facilities.

And such facilities are supposed to take consideration the medical personnel's opinion of the facilities to decide purchasing Defendant's products, but there is no evidence they would take consideration of patients' opinions.

Thus, the Court concludes that the target of Defendant's advertisements is medical fertility facilities and medical personnel of them.

B. As described in 1 (7) above. Medical Park Yokohama's website shows that they are using Defendant's product, and emphasizing that the survival rate after thawing is 100% citing the description on Defendant's website. However, there is no other evidence for another medical fertility facility in Japan to do such advertisement. Thus, the Court conclude a patient is not choosing a medical facility according to whether or not it is using Defendant's products. The "Memorandum of

Understanding on Challenge 100," "Challenge 100" described in 1 (4) B, made between Defendant and medical fertility facilities states that "100% Survival Club facility helps patients to choose facilities as much as possible, we will endeavor to publish the theme of 100% survival in media including institutional magazines and academia." (Appellee's Exhibit 43). Since this memorandum just describes the facilities obligation, thus the Court cannot conclude that a patient chooses a facility in consideration of whether or not it is using Defendant's products. In addition, a patient can view Defendant's advertisement, which does not immediately means a patient chooses a facility in consideration of whether or not it is using Defendant's products. Therefore, the above facts alleged by Appellant does not influence the Court findings described in A.

(2) Issue (1) B. (Meaning of the present descriptions)

A.(A) Defendant's Site 1 (Appellant's Exhibit's 11, 28)

As described in 2-2 above, the Defendant site 1 has the present description 1 to 6, and those described in 1 (2) A.

Since it is common to comply with the instructions when using therapeutic devices at fertility facilities, the Court concludes that medical personnel who view the above description 1 to 6 on Defendant's site 1 recognizes that they can obtain 100% survival rate after thawing the vitrified normal, that is, clinically usable oocytes, embryos and blastocysts (hereinafter referred to as "normal oocytes" and the like) complying with the protocol of the Cryotech method.

(B) Defendant's Site 2 (Appellant's Exhibits 12 and 13)

As described in 2-2 above, Defendant Site 2 has the present description 7 to 12 and those recognized in 1 (2) B. above.

The Court concludes medical personnel who view the above description 7 to 12 of Defendant's site 2 recognizes that they can obtain 100% survival rate after thawing the vitrified

normal oocytes, embryos and blastocysts complying with the protocol of the Cryotech method, as described (A) above.

(C) Defendant's Catalog (Plaintiff's 20-1.2, 35-1.2)

As described in 2-2 above, Defendant's Catalog has the present description 11 to 14 and those recognized in 1 (2) B. above.

The Court concludes medical personnel who vies the above description 7 to 12 of Defendant's catalog recognizes that they can obtain 100% survival rate after thawing the vitrified normal oocytes, embryos and blastocysts complying with the protocol of the Cryotech method.

B. Since there is no description about the method of how decide the survival rate in Defendant's advertisements, the Court concludes the medical personnel who are the consumers generally acknowledge that the survival rate shown in the present description of the 100% survival rate would recognize that it is decided by the method wrote of 1 (5) above.

C. Further, there is no description in Defendant's advertisements about the scope of patient's age who can obtain 100% survival rate (Appellant's Exhibits 11 to 13, 20-1.2, 28, 35-1.2). The Court concludes medical personnel would recognize that there is no age limit for patients to obtain 100% survival rate after thawing.

D. Appellee's allegations

(A) Appellee alleges that medical personnel who vitrify, and thaw with Defendant's products are required to attend Defendant's technical workshop and accurately acquire the correct protocol of the Cryotech method, and be registered for 100% survival rate achievement certification.

However, Defendant's advertisement does not state that special trainings are necessary to comply with the protocol of Cryotech Method (Appellant's Exhibits 11 to 13, 20-1, 2, 28, 35-1.2). "Q & A Frequently Asked Questions" on Defendant's website (Appellee's Exhibit 44) states, "Currently, in principle, our products are limited to sales to medical institutions in 44 overseas countries for which

technical guidance has been completed. If you are at a domestic medical fertility facility, if you are trained on how to use (vitrification method) at the technical workshop held by this center and pass the examination, anyone is free to purchase from the website of Cryotech Japan (credit card accepted). The Cryotech method workshops are held once a month domestically, please contact our domestic division for details." The above is described on a different web page from the present Defendant's advertisement.

Based on the evidence above, the Court concludes that medical personnel who view Defendant's advertisement does not recognize it is necessary that they should participate to Defendant's technical workshop to accurately learn the correct protocol of Cryotech method and obtain a certificate to achieve 100% survival rate.

On the contrary, as described in 1 (2), Defendant Site's 2 states, "It is safer and easier to vitrify and thaw, and to obtain high survival and pregnancy rate," and "With 18 new improvements anyone with or without vitrification experience or basic knowledge can achieve the same good results without human error" are described on Defendant's site 1, and "the most effective, easiest and safest," "the Cryotech method is a highly simplified vitrification procedure. It is easy for anyone." .Thus, the Court concludes the medical personnel who view Defendant sites 1 or 2 recognize that it is extremely easy to comply with the protocol of the Cryotech method.

(B) Appellee alleges that the medical personnel never recognize that 100% survival rate can be achieved for patients over 40 years old, since patients from 20 to 39 years old are defined as general infertility female patients, and patient over 40 years old as elderly infertility patients in fertility medical society.

Defendant's advertisement has no description that the elderly infertile patients over 40 are excluded from the patients' range of age who can achieve 100% survival rate (Appellant's Exhibits 11 to 13, 20-1.2, 28, 35-1.2), and further, there is no evidence that elderly infertility patients over 40

are commonly excluded in such a type of advertisement. Thus, Defendant advertisement descriptions means that the patients who can achieve 100% survival rate include those over 40 years old. The Court conclude Appellee's allegations have no basis.

(3) Issues (1) C. (B) (whether or not 100% survival rate can be achieved)

A. Research Report 2

(A) As described in 1 (6) A above, in Research Report 2, Ms.S et al. tested vitrification and thawing of oocytes with Defendant's products, and 7 out of 13 oocytes were revived. According to the report, the Court finds that the oocyte survival rate after thawing was not 100% when vitrified and thawed with Defendant's products.

Ms.S, one of the authors of Research Report 2, participated in Appellee's technical workshop on Cryotech method, and certified to achieve 100% survival rate after thawing vitrified oocytes. As described in 1(2) above, Defendant sites 1 and 2 states "Anyone with or without vitrification experience and basic knowledge can get the same good results without human error." "It's easy for everyone." The Court finds they states it is easy to comply with the protocol of the Cryotech method. Ms.S et al. publicized in Research Report 2 in a medical journal, it is supposed that there were no problems with its testing procedure, and conducted in compliance with the protocol of the Cryotech method. Research Report 2 states, "there was a drawback that the embryo was difficult to see because I was not accustomed to the operation", but this description does not affect the above recognition. It is unlikely that abnormal oocytes were selected at the test, nor it is unlikely that survival of oocytes was confirmed by the method different from the one wrote in 1(5). Thus, the Court finds survival of oocytes is confirmed by generally approved method in medical practice.

(B) Appellee alleges that the medical fertility facility Ms.S worked for has purchased Defendant's product just twice, so it is unclear how the test was done. As described above, the test method is described in Report 2, thus Appellee's allegations have no basis.

B. Appellant’s Exhibit 91

As described in 1 (6) B. above, when the blastocysts were vitrified and thawed according to Cryotech method, the re-expansion rate of the blastocysts was 98.1% in the group without the zona pellucida, 96.3% in the one with the zona pellucida. Based on Appellant Exhibit 91 the Court finds that the survival rate of blastocysts was not 100% after thawing with Defendants Products.

As described in 1 (6) B. above, its author, Kirienko, belongs to AltraVita medical fertility facility, where Yakovenko, who provided Appellee’s Exhibit 30 (data on which the survival rate of oocytes and embryos after cryopreservation and thawing was 100%) belongs to. AltraVita medical fertility facility is introduced as a Cryotech support center in Defendant's catalog (Appellant’s Exhibit 35-3). Yakovenko is a co-author of Appellant’s Exhibit 91. The Court finds tests were complied with the protocol of the Cryotech method. In addition, it cannot be supposed that abnormal oocytes were selected, the Court finds that normal ones were tested in Appellee’s Exhibit 91. Furthermore, from its description the "re-expansion rate" is understood to mean the survival rate, and the blastocyst is prepared by the method generally used in medical practice (method 1(5) above). Appellee alleges that the "re-expansion rate" described in it means viability, not survival rate, but it has no basis.

C. Alpha International Fertility Centre’s website

(A) As described in 1 (6) C above, AFC’s website describes:

(a) At the 24th Asia-Marine Conference for Obstetrics and Gynecology held in June 2015, it was published that the survival rate after thawing for 65 oocytes vitrified and thawed with Cryotech method was 96.9%.

(b) At the 24th Murray Society of Obstetrics and Gynecology held in June 2016, it was published that the survival rate after thawing for 231 oocytes vitrified and thawed with Cryotech method, was 95.2%.

(c) At the 25th Malaysian Obstetrics and Gynecology Society held in July 2017, it was

published that the survival rate after thawing for 284 oocytes vitrified and thawed with Cryotech method, was 95.8%, and Cryotech method has been adopted by AFC since July 2013, and that 100% survival rate was achieved for embryos, and almost 100% for oocytes.

(d)At AFC, 1491 blastocysts were vitrified and thawed by Cryotech method from July 2013 to May 2017, all blastocysts after thawing were survived.

(e) All the cases are described as clinical cases of fertility treatment for patients.

Based on the above description on the AFC's website, the Court concludes that it has used Defendant's products to vitrify and thaw oocytes and embryos, and has achieved 100% survival rate for embryos after thawing, but not achived100% survival rate for oocytes.

Since AFC is a medical fertility facility introduced as a Cryotech support center in Defendant's catalog, the Court finds that the above clinical cases were performed in compliance with the protocol of the Cryotech method. Furtherer, since they are clinical cases for fertility, the Court finds that the survival rate was confirmed by the method generally used in clinical practice (method 1 (5) above), and also normal oocytes were used.

(B) (a) Appellee alleges AFC is studying on fertility treatment, it dares to vitrify low-quality abnormal oocytes with Cryotech products, thus it fails to achieve 100% survival for low-quality oocytes by submitting Exhibit 72-1. Appellee's Exhibit 72-1 dated on March 10, 2021 with AFC's representative Dr. Collin Lee's signature states, "We have no policy of not vitrifying low- quality oocytes or ones that do not shrink during vitrification process," and that means that we have vitrified low-quality and easy dying abnormal oocytes.) We have vitrified all MII class oocytes regardless of its quality."

However, AFC's website has no description that they have vitrified and thawed abnormal oocytes. Appellee's Exhibit 72-1 does not state that abnormal oocytes were used at the above (a) to (d) publishments. Further, since the above clinical cases are for fertility treatment, it is not rational to

use abnormal oocytes that are not fit for clinical cases. Thus, this evidence has no influence on the Court judgment above. Appellee's Exhibit 125 and 126 has also similar description to Exhibit 72-1, they have no influence the Court judgment above.

(b) Appellee alleges that Appellant's Exhibit 89 states, "the remaining blastocysts were low-quality." However, as described in 1 (6) C. (B) above, Appellant's Exhibit 89 has following description: "220 oocytes were survived and 139 of them were normally fertilized among 231 vitrified and thawed oocytes, and 137 embryos were further cultured, 39 of these 90 blastocysts were poor quality." Appellee just refers these 39 blastocysts, it does not mean that low-quality oocytes were used. Appellee's allegation has no basis. Therefore, Appellee's pointed description has no influence on the Court judgment on it.

D. Appellee alleges that 100% survival rate can be achieved with its products, based on its Exhibit 30 to 32, and its Exhibits 33 to 39 shows 100% survival rate is achieved at its workshop, the fertility facility participated to "Challenge 100" has achieved 100% survival rate, its Exhibit 51, 62 it reproduced the procedure at its technical workshop.

As described in 1(5) above, generally accepted methods in clinical practice for confirming the survival of vitrified oocytes and embryos is confirming with microscope cell volume recovery to the same morphology before vitrified, after cultured for 2 to 4 hours. As described in1(4) above, at Appellee's technical workshop, oocytes are confirmed as survival whether cell volume recovered in 5 minutes after thawed in WS (washing solution). This confirmation of survival is adopted in Appellee's Exhibits 51 and 62 (Appellee's Exhibits 51, 52, 62, 63, Appellee's representative's court witness). The confirmation of survival at Defendant's technical workshop is different from generally accepted methods in clinical practice for confirming the survival of vitrified oocytes at clinical cases.

Further, Appellee's Exhibit 30 [with Sergey Yakovenko's signature of AltraVita, Moscow], Exhibit 31 [with Luis Rubalcaba's signature of Mexico IVF Center], and Exhibit 32 [with Dr. Goral

Ghandi's signature of Rutanda IVF Center, India] describes their outline of tests as follows [in English]:

"(2) Thawing: Insert the Cryotec with the vitrified oocyte/embryo on the sheet into the thawing solution (WS) which was warmed to 37 and wait for 1 minute without moving it. Then, move the oocyte/embryo to the bottom of the dilution solution (DS) and wait for 3 minutes to lower the osmotic pressure. Lastly, move the oocyte/embryo to the bottom of the washing solution and wait for 5 minutes.

(3) Survival judgment: oocytes and embryos as per the conventional method: they were judged as "alive" when they were observed with the microscope as recovering from the shrinking state into the original state by reacting to osmotic change in washing solution (WS). This morphological judgment of recovery in volume was undergone by the microscope at the magnification level of 50 times or higher. The blastocysts were judged as surviving in the washing solution (WS) in the thawing process by confirming the recovery of the blastocoele which had shrunk while exposed to the vitrification solution (VS) in the freezing process. The judgement was performed by the embryologist(s) in charge of the thawing of oocytes and embryos working at each facility in accordance with guidelines of their facility." [original, the Court quoted under lined sentence in English] (Appellee's Exhibit 30-1to3, 31-1to3, 32-1,2).

Based on these descriptions on the exhibits, the Court finds that oocytes are confirmed as survival whether cell volume recovered in 5 minutes after thawed in WS (washing solution), and this is different from generally accepted methods in clinical practice for confirming the survival of vitrified oocytes at clinical cases.

Further, the method for confirming the survival rate in "Challenge 100" is as described in 1 (4) a above, and confirmation of oocyte survival is different from the method generally approved in clinical practice, and the same for blastocysts. The Genesis report (Appellee's Exhibit 47, 48-1~79, 65,

66) is regarding the survival rate of blastocysts in "Challenge 100" based on all arguments and evidence. This report states that survival after vitrified and thawed was confirmed in all 100 cases. On the other hand, the test reports contain descriptions of "Collapsed", "SHRINK", and "not yet expand @ ET". Therefore, the Court cannot find survival rate of 100% was achieved in the test reports.

E. The Court finds that 100% survival rate after thawing cannot be achieved based on Ms.S's response to Lawyer's Inquiry (Appellant's Exhibit's 41-1, 2 and 42-1, 2) and Mr. Yonemoto's statement (that he participated to the Cryotech technical workshop and got certified achieved 100% survival of oocytes after thawing) (Appellant's Exhibit 81-1), when the medical personnel vitrify and thaw normal oocytes and blastocysts using Defendant's products complying with its Cryotech protocol.

F. Appellee alleges that its products are sold only to those who have attended its technical workshop and achieved 100% survival rate there, and so certified by it.

However, as described in (d) above, at its technical workshop course oocytes are confirmed as survival whether cell volume recovered in 5 minutes after thawed in WS (washing solution), and survival confirmation is different from generally accepted methods in clinical practice for confirming the survival of vitrified oocytes at clinical cases, thus a person who participates in its technical workshop and is certified to achieve 100% survival rate with its products, it does not mean that 100% survival can be achieved by generally accepted methods in clinical practice for confirming the survival of vitrified oocytes at clinical cases. Therefore, the Court finds Appellee does not sell its products only to those who achieves 100% survival rate of vitrified and thawed oocytes using its products.

(4) Summary

As described above, the Court finds that the present descriptions on Defendant's advertisement are recognized as having the meaning that medical personnel can achieve 100% survival after thawing vitrified normal oocytes etc. complying with protocol of Cryotec Method and

using Defendant’s products. However, in reality, medical personnel cannot always achieve 100% survival after thawing vitrified normal oocytes etc. complying with protocol of Cryotec Method and using Defendant’s products. Therefore, the Court finds that they are misleading indications of information on quality of goods, and concludes that Appellee's doing such indications on its advertisement descriptions on its advertisement falls under Item 20, Paragraph 1, Article 2 of the Unfair Competition Prohibition Law.

[omitted]

3 Issue 2 (whether Appellant was infringed or likely to be infringed its business)

(1) As described in 2- 2 above, the Court finds Defendant's product and the Plaintiff's ones are competitive since they are the same type of goods. Since Appellant is selling Plaintiff's products that are competitive to Defendant's products, when Defendant's products sales increases, Appellant’s profit is going to be infringed accordingly. And as described in 2 above, the present descriptions on Defendant’s advertisements misleading its quality, etc. falls under unfair competition, thus, the Court concludes Appellant’s profits are infringed by Appellee's unfair competition.

(2) Appellee alleges that Plaintiff’s products are not competitive to Defendant’s since it sells only to medical personnel who participated to Appellee’s technical workshop.

However, Defendant's and Plaintiff's products are competitive, since one of Plaintiff's customers can participate to Defendant’s technical workshop.

The Court concludes that Plaintiff's and Defendant’s products are completive, and Appellee’s allegation has no basis.

4 Issue 3 (Appellee’s intension or negligence)

As described in 2 (3) C., D. Appellee’s allegation on 100% survival is no other than a report on embryos at AFC’s website, thus the Court concludes there is no reason for Appellee to believe the present descriptions on its advertisements are true, and it has negligence to do so.

5. Issue 4 (the damages)

(1) Presumption based on Article 5.2 of the Unfair Competition Prevention Law, and Cancellation of Presumption

Article 5.2 of the Law prescribes that "Where a person whose business interests have been infringed by unfair competition claims damages, which he/she has incurred from such infringement, against the person who has intentionally or negligently infringed his/her business interests and where said person who committed the infringement has received profits through the Law of infringement, the amount of such profits shall be presumed to be the amount of damages incurred by the person whose business interests were infringed." The law prescribes where the infringer has profit from the infringement, the amount of such profits shall be presumed to be the amount of damages incurred by the person whose business interests were infringed. Since both Plaintiff's and Defendant's products are medical-related devices used for vitrification and thawing of oocytes, etc., they can be replaced with each other, thus, Appellant's damages can be presumed based on Article 5.2 of the Law.

The amount of profit obtained by infringing is, in principle, the infringer's total profit. Thus, the presumed amount of profit is the total profits obtained by selling Defendant's products while the present advertisements including the present description are done. Therefore, the presumption based on the article is applicable to Appellee's total profits. Since the above is a presumptive provision, if the infringer proves that there lacks cause and effect relationship between the damage caused by an infringer of the business interest, then the above presumption is cancelled within the range proven.

Appellee alleges that its products are not substitutable with Plaintiff's ones since its customers choose its ones after realizing its excellence in quality at its workshops, etc. However, substitutability between Plaintiff's and Defendant's product cannot be lost under such circumstances. They do not affect the Court's judgment.

(2) Appellee's profit

A. Appellant filed a Request for Submitting Documents Under Article 7 of Unfair Competition Prevention Law on September 7, 2020, requesting Appellee submit the following documents: financial documents including balance sheet, statement of profits and loss, and corporation business summary statement, business report, a copy of tax return (including attached documents), general ledger, sales ledger, purchase ledger between July 26, 2018 [sic] and July 31, 2020, to prove the number of babies born with Defendant's products is 28,333 annually during the above period, the sales price of a set of its products necessary for a baby is 7,733 yen, and, its profit rate is 70% of its sales. On October 9, 2020, the Court ordered Appellee submit the above documents within 14 days from the date of the order serviced, however Appellee did not submit the documents by the deadline.

The Court finds it is extremely difficult for Appellant to prove the facts alleged in its Request for Submitting Documents by other documents.

Thus, the Court finds the facts that the number of babies born with Defendant's products is 28,333 annually during July 26, 2015 and July 31, 2020, the above period, the sales price of a set of its products necessary for a baby is 7,733 yen, and, its profit rate is 70% of its sales are all true under Paragraph 3, Article 224 of the Civil Procedures Law.

As described in 2 to 4 above, Defendant’s advertisements including the present description on its products is an unfair competition Item 20, Paragraph 1, Article 2, of the Unfair Competition Prevention Law, and Appellee is responsible for Appellant’s damages caused by the unfair competition. The documents that r requested a submission order are necessary to calculate its damages. Appellee has not alleged any damages caused by submitting the documents. Thus, the Court finds that Appellee has no reason for refusing to submit them.

(B) Appellee alleges that its customers purchase its products after they use them, they do not purchase by its advertising, they do so because the quality of its products are superior to Plaintiff’s ones, Plaintiffs' sales and profits have not dropped, and that Appellee has gained no profits from its

advertisements.

As described in A. above, the "the amount of profit" in paragraph 2, Article 5 of Unfair Competition Prevention Law does not mean the profit that has cause and effect relationship with the infringement, but the total amount of the profit that the infringer has obtained, and Appellee's total profit during the period when the advertisement including the present descriptions are described. Thus, Appellee's allegation has no basis.

(3) Cancellation of presumption

A. As described 1 (3) above, Appellee's sales activities are mainly door-to-door sales to fertility facilities with its sales representatives. Thus, the role of Appellee's advertisement in its business is small.

If so, the Court finds that fertility facilities start to consider purchasing Defendant's products after viewing its advertisements, and as described in 1 (3) above, they have its embryologist participate to its technical workshop, and thus, the present descriptions in its advertisements can influence the purchase motivation of Defendant's products. The purchase motivation should be deeply influenced by actual impression of use at technical workshops. Thus, the influence of the present descriptions in its advertisements is limited.

Further, Plaintiff's and Defendant's products are sold to medical fertility facilities that already continuously purchased and used their products. Defendant's users they can recognize objectively "survival rate of 100%" can be achieved or not and can relatively easily recognize truth or falsehood of the present description. Thus, Defendant' continuous users would not influence by the present of description "survival rate 100%" etc. in deciding to continue to purchase them.

Under the above circumstances, the contribution of Defendant's advertisement to its sales is considered quite small.

As described in 1 (9), the present products are mostly Plaintiff's or Defendant's in Japan; and

Defendant's share 18%, Plaintiff's 54% in India, and Plaintiff's 15%, Defendant's 60% in Russia, where both parties' products are competing overseas.

Considering the above circumstances, the Court concludes the presumption based on Section 2, Article 5 the Law is partially cancelled, and the ratio cancelled is 95%.

B. Appellee's allegations

(A) Appellee alleges that there is no relation between Defendant's sales increase and 'Plaintiffs sales decrease, since Plaintiffs sales have been steadily increasing after Defendant started the present description in its advertisements.

Plaintiff's sales may have increased further unless Defendant has not described the present description in its advertisement, thus, Appellee's allegation has no basis.

(B) Appellee alleges the questionnaire result and its customer's statement shows that its advertisement does not contribute to customer's purchase motivation to its products.

As described in 1 (8) above, "Q4" of June questionnaire was "... What was the deciding factor when he finally made the decision to purchase a Cryotech product?", and the question of November questionnaire is "... Which was the deciding factor for the final purchase?", "Why did the final decision maker decide to purchase a Cryotech product? Please check from the following." Appellee just asked the deciding factor in the final purchase decision.

As the above questioners have answers, such as, "Our homepage", "I saw the description on our homepage etc. that 100% survival rate can be achieved if complying to the protocol, " "survival rate 100%". Thus, even if none of them were selected (Appellee's Exhibit No. 75-2 to 3, 117, 120), the Court concludes the present description in Defendant's advertisement influence the motivation for purchasing Defendant's product.

Further, the respondent's names and facilities' names are erased in this questionnaire that was submitted to the Court as evidence, and it is impossible to confirm the authenticity of the answer with

the respondent directly. Thus, credibility of the questionnaires is weak. Thus, the Court concludes the present description in Defendant's advertisement influence the motivation for purchasing Defendant's product.

Furthermore, Defendant customer's statements and recorded statements say, that the present description did not trigger the purchase of Defendant's products (Appellee's Exhibits 121-124), and that they chose Defendant's product due to superiority to others' (Appellee's Exhibits 125, 126). The Court concludes the present description in Defendant's advertisement can motivate the purchase of its product.

(C) Appellee alleges that the quality of its products is superior to Plaintiff's or others', which contributes to sales increase.

As described in 1 (1) above, Defendant's products are different from Plaintiff's in the equilibrium treatment process (Defendant's has one step, Plaintiff's has three steps), utilizing natural levitation by specific gravity difference of solutions, shape of wells and shape of vitrifying straw devices, and media.

The Court concludes that these differences does not show superiority of Defendant's to Plaintiff's, since it is not clear what extent these differences effect customer attractiveness by evidence. Further, the Court has not found superiority of Defendant's to Plaintiff's according to the experimental reports on survival rates using pig oocytes with Plaintiff's and Defendant's (Appellee's Exhibits 127, 128).

Research Report 1 (Appellant's Exhibit No. 14 1-3, No. 15 1-2) states that Defendant's products had a better embryogenesis rate than Plaintiff's, that there was no statistically significant difference in survival rate of oocytes. The Court concludes Defendant's products have no higher customer attractiveness in quality than Plaintiff's.

(D) Appellee alleges that there are many competing products. As described in 1 (9) above,

most of the products are Plaintiff's or Defendant's in Japan, and other products are negligible if any. Thus, it cannot cancel the presumption under Article 5.2 of the Law.

Cryotip that Appellee alleges as competing products is Plaintiff's (Appellant's Exhibit No. 138, Appellee's Exhibit No. 82). Other products alleged as competing products (Appellee's Exhibit 83-88, 90-105) are proven their existence, but their quality or sales are unclear on the submitted webpages, thus the Court concludes that these exhibits cannot cancel the presumption under Article 5.2 of the Law.

However, the Court finds that market share in Russia and India where Defendant's and Plaintiff's products are competitive can partially cancel the presumption under Article 5.2 of the Law.

(E) Appellee alleges that Defendant's products are not competitive in the United States, Canada, CE areas (major European countries such as U.K., France, Germany, Italy, Spain, and Netherlands), China, Australia, New Zealand, and Brazil, since it does not sell its products.

In the countries where Defendant's products are not sold, it has not gained its profit, which presumed as Appellant's damages. Thus, Appellee's profits calculated in (2) above do not included the profits in non-competitive countries as described above. Thus, the Court concludes that Appellee's allegation cannot be the basis to cancel the presumption under Article 5.2 of the Law.

(F) Appellee alleges that Plaintiff's customer service is insufficient, and thus this fact can cancel the presumption by the Law. The statement (Appellee's Exhibit 77) is just made and signed by its employee, and does not show the interviewee's name, thus the credibility of the statement is low and cannot prove insufficiency of Plaintiff's customer service, the Court finds no evidence sustained Appellee's allegation.

(G) Appellee alleges that consumers choose Defendant's products because Plaintiff's prices much differs in countries or regions (Appellee's Exhibit 78). If so, the Court cannot conclude that Defendant's customer attractiveness is superior to Plaintiff's. Further, there is no evidence for

significant difference between Defendant's and Plaintiff's prices.

(H) Appellee alleges that the ratio of Appellee's profits derived from its advertisement is unclear, thus presumption under Article 5.2 of the Law is not applied.

The Court concludes that the presumption by the Law is not cancelled when the ratio of cancellation is unclear, since the entity who infringed business interests owes the burden of proof of the existence of facts that cancel the presumption and its ratio.

C. Appellant's allegations

(A) Appellant alleges that the survival rate after thawing of vitrified oocytes or embryos is the most important criterion for medical device for users, and the indication of "survival rate 100%" is the most misleading indication on this criterion.

The Court finds that the survival rate is an important factor in making a choice for users, and as described in A. above, the ratio to which the indication of "survival rate 100%" contributed to Defendant's sales is quite small.

(B) Appellant alleges that Medical Park Yokohama has changed from Plaintiff's to Defendant's products. As described in 1 (7) above, the website of Medical Park Yokohama stated that the vitrification media would be upgraded and quoted Appellee's website that its products can achieve 100% survival rate after thawing vitrification. It does not state that it chose Defendant's products according to its advertisement. Thus, the Court conclude that Medical Park Yokohama has not chosen Defendant's products according to the descriptions on its advertisement.

(4) Summary

A. As described in A (2) above, the number of babies born with Defendant's products is 28,333 annually during July 26, 2015 and July 31, 2020, the above period, the sales price of a set of its products necessary for a baby is 7,733 yen, and, its profit rate is 70% of its sales, and the amount of annual sales of Defendant's products are more than the number of annual baby births, the Court

concludes that Defendant's profits are more than the amount calculated by the above figures.

Therefore, Defendant's annual sales profit should be calculated 153,369,362 yen (28,333 birth cases x 7,733-yen x 0.7 = 153,369,362.3 yen (rounded down 1 yen, the same hereinafter).

Then, Defendant's profit for four years from July 26, 2015, to July 25, 2019, should be calculated 613,477,448 yen (153,369,362-yen x 4 years = 613,470,000 yen). 7448 yen), and its profit for for one year and six days from July 26, 2019, to July 31, 2020, should be calculated 155,890,502 yen (153,369,362 yen + 153,369,362yen x 6 days / 365 days = 155,890, 5 02.19 yen).

The total of them is 769,367,950 yen (613,477,448 yen +155,890,502 yen = 769,367,950 yen).

B. As described in (3) above, the presumption rate under Article 5.2 of the Law in this case should be 95%. The Plaintiff's damages caused by Appellee's unfair competition between July 26, 2015, and July 31, 2020, should be 38,468,397 yen (769,367,950yen x 5% = 38,468,397.5 yen).

The attorney's fees, caused in relation with Appellee's unfair competition, are 1 million yen for injunctions, and 4 million yen for damages, totally 5 million yen.

Thus, Appellant's damages during the above period should be 43,468,397 yen.

Appellant requests late payment charge as follows:

(a) 5% per year for damages occurred from July 26, 2015, to July 25, 2018, and (b) 3% for year for damages occurred from July 26, 2018o the July 21, 2020. The Court admits the attorney's fees for injunction should be included during period (a).

Therefore, the damages incurred during period (a) is 26,397,539 yen (153,369,362 yen x 3 years x 5% + 4 million yen x 3 years / (5 years + 6 days / 365 days) + 1 million yen = 26,397,539 .75 yen), and the damages incurred during the period(b)is 17,070,858 yen (43,468,397 yen 26,397,539 yen = 17,070,858 yen).

Therefore, Appellant has reasonable grounds for damages in the scope of 43,468,397 yen, of which 26,397,539 yen with payment delay charge at 5% per year from July 26, 2018, to the day when would be paid, and 17,070,858 yen with late payment charge at 3% per year from November 11, 2020, to the day when would be paid.

6. Based on the above reasons, the Court judges as the main text of Judgment above.

Intellectual Property High Court the Second Division

Chief Judge Yoshiyuki Mori signature

Judge Shin Sano signature

Judge Tomohiro Nakajima signature

Appendix 1

The list of internet addresses

1. http://reprolife.jp/history/
2. http://reprolife.jp/products/
3. http://cryotech-japan.jp/
4. http://cryotech-japan.jp/about/

Appendix 2

The list of descriptions

1. “Finally we have succeeded in developing “The Cryotec Method” an epoch-making vitrification method achieving 100% survival after thawing!” (yellow marked part ① in attached page1)

2. “In 2012, we have succeeded in developing an epoch-making vitrification method achieving 100% survival after thawing. (yellow marked part ② in attached page1)

3. “Cryotec cryopreservation achieved 100% survival.” (yellow marked part ③ in attached page 2)

4. “Survival 100% after post-warming and improvement of clinical records” (yellow marked part ④ in attached page 2)

5. “Survival rate is 100% for blastocysts, divided embryos and oocytes.” (yellow marked part ⑤ in attached page 2)

6. “You can thaw oocytes and embryos in the same way, and can obtain high 100% survival rate.” (yellow marked part ⑥ in attached page 2)

7. “Cryotech Create sure Happiness by 100% survival vitrification!” (yellow marked part ⑦ in attached page 3)

8. “100% Post-warm Survival” (yellow marked part ⑧ in attached page 3)

9. “Anyone can obtain 100% post-warm survival rates for human oocytes and embryos by strictly keeping Dr. Kuwayama’s original vitrification/warming protocol. It is called "the Cryotec method" (yellow marked part ⑨ in attached page 3)

10. “Only 100% survival proved solutions are provided.” (yellow marked part ⑩ in attached page 3)

11. “WELCOMETO "THE 100% SURVIVAL CLUB"! (yellow marked part ⑪ in attached page 4 and 5)

12. “By strict adherence to specific details of The Cryotec Method, the clinical embryologist is assured of achieving 100%, literally 100%, survival of normal oocytes and embryos.” (yellow marked part ⑫ in attached page 4 and 5)

13. “SUPER-VITRIFICATION Create sure Happiness by100% survival vitrification!” (yellow marked part ⑬ in attached page 5)

14. “CRYOTECH ADVANTAGE; “WHY 100% SURVIVAL?”” (yellow marked part ⑭ in attached page 5)

Ends.

どもを諦めざるを得ない状況だった世界中の多くの人たちが救われるのだ。「ガン治療などの副作用で子どもを産むことができなかったり、また女性だからといって社会の追出を諦めたり、そういった不当な生殖上の差をなくすための、革命を起こしたかった」。男女の生殖上の差にハンディを負い、それによって職業人としての可能性を低めるのではなく、せっかくこの世に生まれて来たのだから、技術の恩恵を、それを望む人世界中のみんなに受けてほしいと強く願う。

Be the first of your friends to like this

リプロライフ

8月23日にヨット部の活動がありました。

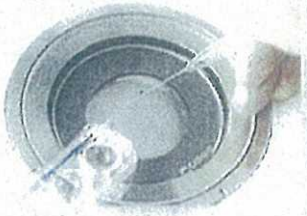
昨年の追水式から3回目。今回は昨年以降入社した職員とその家族を中心に12名が参加し

①

ついに解凍後100%生存の画期的な凍結手法「The Cryotec Method」の開発に成功！

ヒト臨床用に開発し、世界中へ広まって行ったThe Cryotec Methodはそれでもまだ解凍後の生存率や試薬の安全性、プロトコールの困難さにより、多くの卵子や受精卵の命が失われて行き、ヒト不妊治療用の臨床技術として決して満足するものではなかった。またこの凍結製品は患者本意でない販売主義の高価格の為により、意に反して無責任に高値で世界へ転売されて行った。②

世界初の凍結技術をさらに研究、改良を加え 2012年 ついに解凍後100%生存の画期的な凍結手法の開発に成功。



この日本発の、世界で最も効果があり最も安全安心な卵子、受精卵の凍結保存技術を、この技術が必要な世界中の患者様すべてに届くよう、最も安価にそしてかつ、正確な使用法とともに伝えたい。

この画期的な凍結法を「The Cryotec Method」と名付け、開発の凍結製品を安全と信頼の「Cryotecブランド」として、すべての患者様をしあわせにしたいと願い、同じ信念、思想を持つ世界26カ国のパートナー達と共に、昨年より全世界供給を開始しました。

それまで不可能であった赤ちゃんが誕生すると、お母さん、お父さん、そしてそのご両親や兄弟、友人、．．．多くの人達からものすごく感謝され、それが唯一、日々の研究開発のエネルギーになる。

さらにこれから、我々が2007年に世界で初めて成功したヒト卵巣組織の凍結（ガラス化保存）、そして微少精子のガラス化保存、また余受精卵の効率的な体外成熟システムや老化不妊卵子の若返り技術など、生殖上の不平等によって毎日がつらい人、闇の中で苦しんでいる人々の人生に、新生殖医療技術の提供という形で明るい光を灯していきたい。

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ページトップへ

リプロライフ
〒160-0022 東京都新宿区新宿2-5-3 AMビル 9F

REPROLIFE
子供をさずかることの喜びを、より多くの女性へ

トップ　ヒストリー　製品紹介　会社概要　スタッフ募集　お知らせ

PRODUCTS
製品紹介

検索　文字サイズ 小 中 大　お問い合わせ

③
生存率100%を実現、クライオテックの凍結保存

製品一覧へ

Cryoi
Multiple Cooling System

④
クライオテック法はどのステージの卵子・胚でも安全に凍結融解でき、融解後の生存率100%と臨床成績の向上が期待できる最新のガラス化法です。2012年から世界供給を開始し、すでに42カ国で10万症例の、従来法をはるかに上回る臨床実績があります。凍結保存の目的は「命ある大切な卵子や胚を、傷めることなく危険に陥すことなく、その日まで安全、安心にとりおくこと」だと私たちは信じており、これを実現するのがクライオテック法なのです。


品詞を生んだ、なぎちゃんのストーリー

クライオテック製品にはこんな特徴があります。

⑤
- 胚盤胞、分割胚そして卵子の生存率が100%になります。（プロトコールを厳守した場合）
- クライオテックの融解システムは、他のガラス化保存法で凍結した胚や卵子にも利用でき、さらに高い生存率、妊娠率が期待できます。
- より簡単な方法で安全、簡単に凍結融解でき、高生存率、高妊娠率を得ることができます。
- 従来法では凍結が困難であった低グレードな胚や卵子の凍結にも利用できます。

改良された18のポイント

これまでのガラス化法の弱点を徹底的に分析し、問題点を明らかにしました。そしてガラス化経験や基礎知識の有無にかかわらずどなたでも人為的ミスがなく同じ良好成績を得られるように、18ヶ所の改良が新たに加えられました。

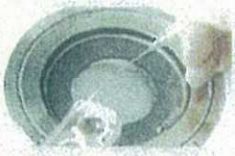
メディウム

- 世界で最もガラス化形成能が高く、細胞への影響が最も低いガラス化液を開発。
- 全培地、無血清、無タンパクのため安全、安心で効果が長く安定しました。(12ヶ月の有効期限)
- エンドトキシンフリーのトレハロースの利用により、安全性を高め、ガラス化形成能をさらに改良させました。
- 浸透圧の変化を極限まで少なくし、卵子や胚への負担を軽減させました。

デバイス

- ガラス化専用のプレートを初めて開発。より正確により簡単にガラス化が可能となりました。
- 凍結容器を専用プレート上に置いて胚のローディングを簡単に行えます。(容器を手で持つ必要がありません)
- 融解専用のプレートも初めて開発。融解作業が全てこれ1枚で正確に実施でき、生存率が向上します。
- 各プレートのウェルは丸底となっており、平底に比べ緩やかな浸漬混合により、より高い生存率が得られます。

プロトコール



- ガラス化法の改良により、卵子と胚で同一のプロトコールで100%の高い生存率が得られます。
- ガラス化平衡の完了が目で容易に正確に判別できます。
- 最強のガラス化形成能を持ったガラス化法を利用しているため、シート上のガラス化ドロップを最小化する必要がなくなりました。

品質管理 (ISO13485 認定工場)

- pH テスト
- 浸透圧テスト
- 卵を用いた生存効果テスト(ブタ卵子を用いて生存率100%の培地のみを提供いたします。)　coming soon
- マウスエンブリオテスト
- エンドトキシンテスト

試験成績

当社関連12施設において4215個の卵子と胚を用いて凍結融解を行った結果、
全てのステージの卵子・胚において生存率100%であった。

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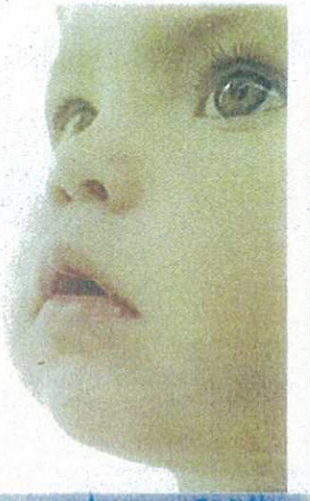
Cryotech

About Cryotech Japan | Contact

SUPER VITRIFICATION



Home | What's Cryotech | Cryotec Method | Products | News | Cryotech Partner | Workshop | TECHMAN News

(7)

Cryotech Create sure Happiness by 100% survival vitrification!

Multiple Cooling System

Our new designed vitrification container, Cryotec and new highest probability Vitrification solution realizes multiple cooling (both open and closed) with same clinical efficiency.

(8)

100% Post-warm Survival

(9)

Anyone can obtain 100% post-warm survival rates for human oocytes and embryos by strictly keeping Dr.Kuwayama's original vitrification/warming protocol. It is called "the Cryotec method".

Most effective, easiest and safety

The Cryotec method is highly simplified vitrification protocol. Easy for anyone.

All the solutions (every batch) have been examined their safety and also effectiveness with repeated chemical and animal experiments.

(10)

Only 100% survival proved solutions are provided.

TOPICS

[illegible] News
COGI 2017 in Vienna, Austria

[illegible] News
ISFP hands-on workshop registration

[illegible] News
promo movie first played at ASRM 2017

[illegible] News
ISFP 2017 in Vienna, Austria on November 16-18, 2017

[illegible] News
Cryotech Method Hands-on Workshop will be in session at ASRM 2017.

INFORMATION

Hands-on Workshop

1 Day Cryotec Vitrification Hands-on Workshop will be held by Dr. Masashige Kuwayama in Tokyo, Japan.

Up coming Tokyo Workshop in 2017.

MARCH 22(Wed), 2017

COMPANY PROFILE

COMPANY NAME 株式会社リプロライフ
LOCATION 東京都新宿区[illegible]2-5-3 MHビル9F
TEL 03-5925-8931

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What's Cryotech

(i)

WELCOME TO "THE 100% SURVIVAL CLUB"!

Vitrification was the third major advance in human ART, after IVF itself and ICSI. Now, the protocol of vitrification has been optimized to preserve oocytes and embryos of any developmental stage. These improvements result in very high functional survival of oocytes, assuring high rates of fertilization after ICSI and high rates of pregnancy after embryo transfer. The optimized method, "The Cryotec Method" has been developed by **Dr. Masashige Kuwayama**, who has introduced major advances in oocyte and embryo cryopreservation.

(2) By strict adherence to specific details of The Cryotec Method, the clinical embryologist is assured of achieving 100%, literally 100%, survival of normal oocytes and embryos.

Dr. Masashige Kuwayama

Dr. Masashige Kuwayama is currently the Head of Reproduction Medical Research Center, [illegible] and providing the new ART including vitrification [illegible] IVF Clinic Group. The center has also International Advanced Fertility Preservation Center. He had been [illegible] director of Kato Ladies Clinic (Japan), the world's largest chain of IVF and [illegible] 25,000 IVF cycles per year. In the ART laboratory, 13 scientists and 36 embryologists were working to develop new ART and for the patients. An author of [illegible] papers and 230 papers in the scientific [illegible]

WHAT'S "THE CRYOTEC METHOD"?

Dr. Masashige Kuwayama is a highly skilled embryologist, with more than twenty years of laboratory and clinical experience with both animal and human oocytes and embryos. He has introduced several novel procedures to vitrify oocytes and embryos, including various dilution methods, as well as the Cryotop method and the Cryotip method.

Over the past twelve years, Dr. Kuwayama has taught his vitrification skills to physicians and embryologists in human clinics located in more than 40 countries. This collaboration has resulted in the births of more than 300,000 babies from vitrified embryos and 40,000 babies from vitrified oocytes fertilized by ICSI.

The Cryotec Method is Dr. Kuwayama's latest and most innovative method of oocyte and embryo vitrification. It is safe, extremely efficient, and designed to enable physicians and embryologists to help their patients achieve their fervent wish for a healthy baby.

All

What's Cryotech INDEX

WELCOME TO "THE 100% SURVIVAL CLUB"!

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SEARCH

Cryotech

Products

Cryotec Products | Dr.Kuwayama's latest investigations for the best vitrification

Cryotec

Dr.Kuwayama's best Vitrification container for human oocyte and embryo.
Multiple Cooling container can be used as "Closed Cooling" after sealing, or "Open Cooling" before sealing.

Cryotec Plates

Vitri-Plate In-focus loading of oocyte and embryo

Warm-Plate Easy warming of vitrified oocyte and embryo

Cryotec Vitrification Solutions

Serum and protein free solution
Best Vitrification capability
With endotoxin-free Trehalose

Vitrification
- ES:Equilibration Solution
- VS:Vitrification Solution

Warming
- TS:Warming Solution
- DS:Diluent Solution
- WS:Washing Solution

Vitrification		Warming	
			
VITRIFICATION KIT 101 For 1 patient (3 times of Vitrification) 4 Cryotecs 3 Vitri- Plates 1 vial of ES (for 3 times vitrification) 2 vials of VS (for 3 times vitrification)	**VITRIFICATION SOLUTION SET 110** For 10 times Vitrification 2 vials of ES 4 vials of VS	**WARMING KIT 102** For one Warming 1 Warm- plate 1 vial of TS 1 vial of DS 1 vial of WS	**WARMING SOLUTION SET 205** For 5 times Warming 5 vials of TS 1 vial of DS 2 vials of WS

Cryotech

Multiple Cooling System

(13)

SUPER-VITRIFICATION

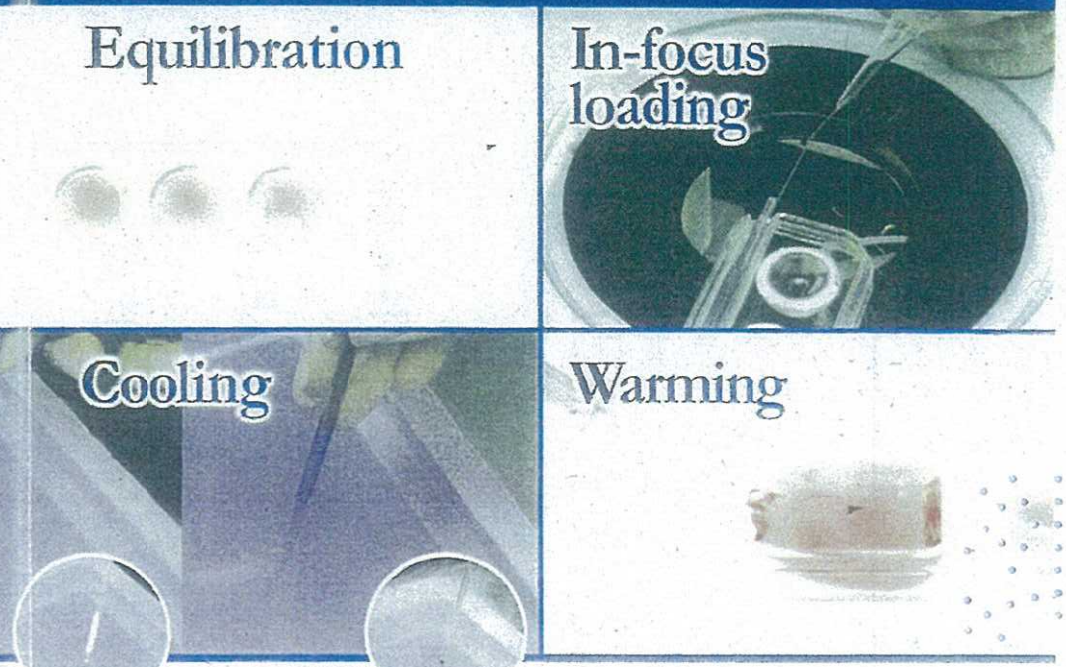
Create sure Happiness by 100% survival vitrification!

Cryotech®

THE CRYOTEC METHOD PERFECT SURVIVAL AND SAFETY

URL:http://cryotech-japan.jp
Order:https://reproisus.com/index.php
Email:contact@cryotech-japan.jp

SUPER-VITRIFICATION



(11)

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(12)

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Over the past twelve years, Dr Kuwayama has taught his vitrification skills to physicians and embryologists in human clinics located in more than 53 countries. This collaboration has resulted in the births of more than 900,000 babies from vitrified embryos and 60,000 babies from vitrified oocytes fertilized by ICSI.

The Cryotec Method is Dr Kuwayama's latest and most innovative method of oocyte and embryo vitrification. It is safe, extremely efficient, and designed to enable physicians and embryologists to help their patients achieve their fervent wish for a healthy baby.

(14)

CRYOTECH ADVANTAGE: "WHY 100% SURVIVAL? "

- **Best Vitrification Solution**
  1. Highest Vitrification Capability by addition of HPC
  2. No Serum or Protein contained in solutions
  3. Endotoxin free Trehalose used instead of Sucrose
- **Best Vitrification Container; Cryotec**
  1. Multiple cooling devises: Closed or Open cooling
  2. Longer and Wider handle and sheet, easy writing and holding samples
  3. Safe and clear material
- **Best exclusive Vitrification and Warm plate**
  1. In-focus vitrification plate
  2. Easy warming plate, no blind well for warming

Dr. Masashige Kuwayama

Dr. Masashige Kuwayama is currently the Head of Repro-support Medical Research Centre, developing and providing the new ARTs including vitrification, PIEZO ICSI and Nuclear Transfer. The center has also International Advanced Fertility Preservation Centre. He was a scientific director at Ikeda Ladies' Clinic Japan), the world's largest human IVF unit performing more than 7,000 IVF cycles per year. In the ART laboratory, 13 scientists and 55 embryologists were working to develop new ARTs for patients. As an editor of RBM Online, he has 105 scientific papers and 240 papers in the scientific conferences.