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 Judgment 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%, 1iterally 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 with payment delay charge at 5% per year from July 26, 2018, to the day when it would be paid up, and 17,070,858 yen with late payment charge at 3% per year from November 11, 2020, to the day when it would be paid up.

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. The claims requested by the party

1. The Court shall revoke the Tokyo District Court Judgment.

2. The same as paragraphs 2 to 6 of the main text of the Judgment.

3. Appellee shall delete "100% SURVIVAL" out of the indications included in list 11 of annexed sheet of the Tokyo District Court Judgment, delete "achieving 100%, literally 100%, survival" out of the indications included in list 12, delete "100% survival" out of the indications included in list 13, delete "100% SURVIVAL" out of the indications included in list 14, from the advertisements for cryopreserving vitrification straw shaped containers, vitrification and thawing media used together with them.

4. The Court orders Appellee pay Appellant 300 million yen, of which 75,917,834 yen with payment delay charge at 5 % per year from July 26, 2018 to the day when it would be paid, of which 224,082,166 yen with payment delay charge at 3% per year from November 11, 2020 to the day when it would be paid up. (The original request of Appellant at the Tokyo District court was 75,917,834 yen with payment delay charge at 5 % per year from July 26, 2018 to the day when it would be paid up, Appellant expanded its request at this court.)

II. The overview of the case

1. (1) Appellant, who is selling medical equipment for vitrification, warming and thawing of oocytes, etc., filed a lawsuit against Appellee who is selling competing medical equipment requesting the court order Appellee to delete "100% survival after thawing", "Survival rate 100%", "100% high survival rate", "100% survival vitrification!", "100% post-warm survival rates", including those

written in capital letters, and "achieving 100%, literally 100% survival" and the entire display of the present Display 8. (Hereinafter, these are collectively referred to as "the description part of this case") in the present indications 1 to 14 (herein after referred as “the present indication 1” or the like, or collectively “the present indications” on the Appellee’s web site and its catalogues, on the ground Defendant’s indications in its advertisements misleads the quality and content (hereinafter referred to as "quality, etc.") of Defendant’s products, thus the indications on the above website and catalog falls under unfair competition providing by Item 20, Paragraph 1, Article 2 of the Unfair Competition Prohibition Law (hereinafter referred to as the "Law") No. 33 Act of 2018 (Item 14, before revised), and this Unfair Competition infringed its business interests,

and requests the court to order Appellee to delete "the description part of this case" on the above-mentioned website and catalog related to the "straw shaped containers for vitrification, and vitrification or thawing media used together with them" sold by Appellee based on based on Paragraph 1, Article 3 of The Law; also seeking for an injunction against Appellee not use of the words "100% survival after thawing," "100% survival," "100% Post-warm Survival," "achieving100%, literally 100%, survival," and indications to the effect that "100% survival rate can be achieved after thawing vitrified oocytes," in advertisements for the above-mentioned Appellee’s products; and requests the court to order Appellee pay to Appellant 75,917,834 yen including attorney fees with the late payment charge at 5% per year that is prescribed by the Civil Code before the revision by Law No. 44 of 2017, from July 26, 2018 (the day after the day of service of the complaint) to the day when it would be paid based on Article 4 of The Law that occurred from July 26, 2015 to July 25, 2018 under Paragraph 2, Article 5 of The Law, and based on Article 4 of the Law requests the court to order Appellee pay to Appellant 75,917,834 yen to compensate the damages that occurred from July 26, 2015 to July 25, 2018 under Paragraph 2, Article 5 of The Law, including attorney fees, with the late payment charge at 5% per year that is prescribed by the Civil Code before the revision by Law No. 44 of 2017, from July 26,

2018 (the day after the day of service of the complaint) to the day when it would be paid up.

Tokyo District court dismissed Appellant's complaints, then Appellant filed an appeal to Intellectual Property High Court.

(2) (Extension of the claim for damages)

At this Court, Appellant extended the period for calculation its damages from July 26, 2015 to July 31, 2020, and claimed payment of 300 million yen with its delay charge 75,917,834 yen of which at 5% of the year (prescribed under Civil Code before its revision by Act No. 44 in 2017) from July 26, 2018 to the day when it would be paid up, and 224,082,166 yen of which at 3% per year from November 11, 2020 (the day after the date of service of the Request for extension of the claim in this court) from the damages including attorney's fees of 843,531,491 yen under Paragraph 2, Article 5 of The Law that occurred from July 26, 2015 to July 31, 2020. Appellant withdrew the injunction request Appellee not label the present indications on "vitrified cryopreservation straw shaped container and the vitrified and thawing solution."

2. Premised facts (facts without disputes and facts the court found by the evidence below and the whole arguments) are described in "2. Summary of the Case" in the facts and reasons of the Tokyo District judgment. Thus, this Court quotes the same descriptions in it, except following amendments;

(1) This Court amends Line 15, Page 5 of the Tokyo District Court Judgment to " Defendant's site 1, site 2 and Defendant's catalog are collectively called "Defendant's advertisement".

(2) This Court amends Line 2, Page 6 of the Tokyo District Court Judgment adding as follows; "(6) Defendant's products have no indications such as "100% SURVIVAL", "achieving 100%, literally 100%, survival", or"100% survival" on them.

Quoted Tokyo District Court Judgment

1. Premised facts (facts that are easily recognized based on the evidence set forth below and the entire arguments of both parties)

(1) Parties

A. Plaintiff is a stock company established for the purpose of manufacturing and selling pharmaceuticals, medical devices, quasi-drugs, etc. (Appellant's Exhibit 1).

B. Defendant is a stock company established for the purpose of manufacturing and selling medical-related and experimental-related devices, tools, and solutions (Appellant's Exhibit 2).

(2) Sales of medical-related devices used for vitrification, warming, and thawing

A. Plaintiff sells straw shaped containers for vitrification, vitrifying liquids, and thawing liquids (hereinafter, these are collectively referred to as "Plaintiff's Products".) used for vitrification and cryopreservation under the name of "Cryotop." (Appellant's Exhibit 19).

B. Defendant sells straw shaped containers for vitrification, vitrifying liquids, and thawing liquids (hereinafter, these products are collectively referred to as "Defendant's Products".) used for vitrification and cryopreservation under the name of "Cryotec." (Appellee's Exhibit 20-1 and -2).

C. "Vitrification" means a super-quick-freezing method in which a high concentration of a freezing inhibitor is used to remove most part of the intracellular water, and immediately immerse it in liquid nitrogen when freezing oocytes obtained for fertility treatment. With this method it is possible to prevent water, up 90% of the cells, from damaging the cells by forming sharp crystals during the freezing process. "Vitrification" refers to the phenomenon that the water in the cell and the freezing inhibitor become like the glass without forming crystals in the freezing process. (Appellant's Exhibit 3-1)

(3) The indication on website managed by Defendant (URL address "http ://… , the rest is omitted." hereinafter referred to as "Defendant Site 1".)

A. The indications 1 and 2 have been included on the "History" web page of Defendant's Site 1 (URL address "http :// … , the rest is omitted." Appellant's Exhibit 11) since around 2015 (the entire arguments of both parties).

B. The indications 3 to 6 have been included on the web page of "Product Introduction" on Defendant's Site 1 (URL address "http :// . . . , the rest is omitted." Appellant's Exhibit 28) since around 2015 (the entire arguments of both parties).

(4) The indication on website managed by Defendant (URL address "http ://. . . , the rest is omitted." hereinafter referred to as "Defendant Site 2".)

A. The Indications 7 to 10 have been included on the web page of "HOME" on Defendant's Site 2 (the above URL address. Appellee's Exhibit 12) since around 2013 (the entire arguments of both parties). The Japanese translation of each of the above indications is as follows:

(A) The Indication 7: "Cryotech Creates sure Happiness by 100% survival rate vitrification!" [original]

(B) The indication 8: "100% Post-warm Survival" [original]

(C) The indication 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 Cryotech Method". [original]

(D) The indication 10: "Only 100% survival proved solutions are provided." [original]

B. The Indications 11 and 12 have included on the web page of "What's Cryotech" (URL address "http :// and the rest are omitted". Appellant's Exhibit 13) of on Defendant's Site 2 since around 2013 (the entire arguments of both parties). The Japanese translation of each of the above indications is as follows.

(A) Indication 11: WELCOME TO "The 100% Survival Club!" [original]

(B) Indication 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." [original]

(5) The indication on Defendant's catalog SUPER-VITRIFICATION (Hereinafter referred

to as "Defendant catalog".)

The Indications 11 to 14 have been included since around June 2014 as follows: (Appellee's Exhibit 20-1, 35-1~2, the entire arguments of both parties).

A. The Indications 13 is described at the lower part of the front cover page of Defendant's Catalog. The Japanese translation of each of the above indications is as follows:

"SUPER-VITRIFICATION,"

"Create sure Happiness by 100% Survival Vitrification!".

B. The indication 11 is described at the title of the lower left block on the facing left page of Defendant's Catalog.

C. The indication 12 is described at the lower column of the lower left column of the left page of the facing page of Defendant's catalog.

D. The indication 14 is described at the title of the lower left block on the facing right page of Defendant's Catalog. contains the Indication 14. The Japanese translation of it is as follows:

"CRYOTECH ADVANTAGE - "WHY 100% SURVIVAL?" [original]

Unquoted.

3. Issues

(1) Whether the indications in Defendant's advertisement falls under Item 20, Paragraph 1, Article 2 of the Unfair competition Prohibition Law?

A. To whom did Defendant's advertisement target?

B. What is the meaning of the present indications?

(a) Are there any prerequisites for achieving 100% survival rate?

(b) Are there any limitation of the age of patient?

C. Can Defendant's products be recognized to not be able to achieve 100% survival of oocytes and embryos?

(a) How is the method for confirmation of survival?

(b) Is Defendant's products can achieve 100% survival or not?

D. How did Appellee sell Defendant's products?

(2) Is Appellant's profit possibly infringed, or will be possibly infringed by Appellee?

(3) Are there Appellee's willful misconduct or negligence?

(4) How much is Appellant's damages to be compensated?

4. Allegations by parties on the Issues

(1) Issues (1) A. (To whom did Defendant's advertisement target?)

(Appellant's allegations)

The information from Defendant's advertisement will eventually reach the patients for medical treatment, and they will bear the price for Defendant's products believing in Defendant's indication, if it is directly to medical personnel and academic researchers who have sufficient specialized knowledge.

Alpha International Fertility Center (hereinafter referred to as "AFC") and Genesis IVF and Women's Specialist Center (hereinafter referred to as "Genesis ") in Malaysia has announced that they have adopted Cryotech method (Appellant's Exhibit 88-90, 92, 93), and the medical corporation Tokyo-kai Medical Park Yokohama (hereinafter referred to as "Medical Park Yokohama") has announced "survival rate of 100%" to its patients in its website (Appellant's Exhibit No. 94, 95) by quoting Defendant's website (Appellant's Exhibit No. 96, 97).

The patients are supposed to directly browse Defendant's sites 1 and 2 and may choose Defendant's cryopreservation technique for oocytes and the like. In this sense, patients for fertility treatment are the dealers who come into contact with the indications on Defendant's sites 1 and 2.

The "Memorandum on Challenge 100" (Appellee's Exhibit 43) states, "In order to help patients choose medical facilities, the facilities that joined to 100% Survival Club should contribute

articles related to 100% survival to the media including journals and academic societies." Thus, the indications of "survival rate 100%" in Defendant's advertisements are to patients as well, and are intended to "help patients choose medical facilities". It is clear that the indications are for attracting customers, that is, patients.

(Appellee's allegations)

A. Defendant's products are used for cryopreservation of oocytes and blastocysts in artificial human reproduction. In Japan and overseas Doctors or academic researchers who have specialized knowledge have taken out oocytes from the human body (mother), and fertilized with sperm to produce blastocysts. An ordinary people without specialized knowledge cannot do so. In addition, as described in (6) below, Appellee sells its products only to those who have been certified as having achieved 100% survival rate of vitrified and thawed oocytes. Appellee does not sell its products to an ordinary consumer. Therefore, the dealers of Defendant's products are not ordinary consumers, but limited to medical personnel or academic researchers who have sufficient specialized knowledge. Thus, the information in Defendant's advertisement is aimed to medical personnel or academic researchers who have sufficient specialized knowledge, and not to anyone else.

B. Appellant alleges that Medical Park Yokohama advertises using Defendant's product on its website. However, the article Appellant pointed was posted on the website on January 28, 2020, and there described Appellee representative's name but not its company name.

(2) Issues (1) B. (What is the meaning of the present indications?) (a) Are there any prerequisites for achieving 100% survival rate?

(Appellant's allegations)

The prerequisites that "the correct usage is correctly educated to professional personnel or doctors," "the medical personnel who are certified by Appellee, with sufficient specialized knowledge, and participating to its technical workshop," or "degenerated or abnormal oocytes that has no tolerance

with IVF are excluded because they cannot be cryopreserved and thawed," are not described neither in Defendant's advertisements. On the contrary, Defendant Site 1 (Appellant's Exhibit No. 28) states, "You can vitrify and thaw safely and easily in a simpler way, and obtain high survival rate and high pregnancy rate.", "18 new improvements have been made so that anyone with or without experience or basic knowledge can obtain the same good results without human errors," and Defendant Site 2 (Appellant's Exhibit No. 12) states., "It is the most effective, easiest and safest.", "The cryotech method is a highly simplified vitrification cryopreservation procedure.", "It is easy for everyone."

(Appellee's allegations)

A. A medical personnel cannot obtain 100% survival rate with Defendant's products unconditionally. (1) Selecting normal oocytes and embryos, use the correct devices, and (2) accurately acquired the correct protocol., (3) strictly adhering to the protocol, and (4) accurately reproduce the protocol, are necessary.

B. Appellee's representative has held free technical workshops on the Cryotech method all over the world, and accurately transfer the technique to medical personnel or doctors in the clinical field instructing its protocol. It is necessary that the participants can achieve 100% survival rate using the Cryotech method in the technical workshop, to correctly transfer the techniques. When a participant achieved, Appellee gives him a certificate of it. Appellee just sells its products only to the medical institutions certified to have achieved 100% survival rate using the Cryotech method.

The target of providing information on Defendant's advertisements are all medical personnel who have sufficient specialized knowledge, and the target persons of a survival rate of 100% are those medical personnel who have sufficient specialized knowledge, and who participated to Appellee's technical workshop and got the certificate (a person who achieved a survival rate of 100% at Appellee's workshop) strictly observing the protocol. A survival rate of 100% can only be achieved when normal oocytes are vitrified and thawed using Defendant's products strictly observing the

Cryotech method. Therefore, even a medical person who participated to Appellee's workshop and obtained a certificate cannot achieve survival rate of 100% if not strictly observing its protocol.

(3) Issues (1) B. (What is the meaning of the present indications?) (b) Are there any limitation of the age of patient?

(Appellant's allegation)

A. Defendant Site 1 (Appellant's Exhibit No. 28) only states that "the survival rate of blastocysts, split embryos, and oocytes will be 100% (when the protocol is strictly observed)", and there is no mention of age restrictions for the patients.

B. On May 2, 2013, the Ministry of Health, Labor and Welfare announced the "The Current Situation of Infertility Treatment" (Appellant's Exhibit No. 68) at the "1st Study Group on the Ideal Way of Specific Treatment Support Projects for Those Suffering from Infertility" (Appellant's Exhibit No. 67). The literature states that the percentage of those aged 40 and over in the specific infertility treatment subsidy project has reached 30.1%, and the patients over the age of 40 in fertility treatment cannot be negligible.

C. "Embryo development of fresh 'versus' vitrified metaphase II oocytes after ICSI: a prospective randomized sibling-oocyte study (Appellant's Exhibit No. 73) announced in "Human Reproduction" on October 27, 2009, states that "The average age of patients is 36.5 years ± (standard deviation) 4.8 years (range 26-42 years)," As seen thereof patients aged 42 years over 39 years old are the subject of research the in "infertility medical society."

The paper (Appellant's Exhibit No. 91-1; hereinafter referred to as "Appellant's Exhibit No. 91 Documents") written by Konstantin Kirienko (hereinafter referred to as "Kirienko"), a senior embryologist at Altravita IVF Clinic (hereinafter referred to as "Altravita") in Russia, and wo-written with Sergei Yakovenko (hereinafter referred to as "Yakovenko") who wrote Appellee's Exhibit 30-1 (hereinafter referred to as "Appellee's Exhibit 30 Report") states that patients over 39 years old up to

44 years old are targeted for clinical research, and the AFC research report (Appellee's Exhibit No. 50-1) also reports infertility treatment for patients over 39 years old.

In addition, the table of patients aged 40 years or older are described in the "ART (Assisted Reproductive Technology) Pregnancy Rate, Production Rate, Miscarriage Rate in 2016" (Appellant's Exhibit No. 75-1) announced by Japan Society of Obstetrics and Gynecology (Appellant's Exhibit No. 75-3) .

D. Therefore, infertility treatment is not limited to those younger than 39 years old.

(Appellee's allegations)

Infertility patients aged 20 to 39 years are defined as general infertility female patients in the infertility medical society, and infertility patients aged 40 years or older are defined as elderly infertility patients. Oocyte's fertilization ability, developing ability after fertilization, vitrifying ability, implanting ability after transplantation, bearing baby ability, the rate of neonatal abnormalities, etc. are significantly different due to patient's aging. Thus, various data analyses become difficult, it is natural for professional medical personnel to clearly distinguish elderly infertile patients from general infertility patients. Therefore, even if Defendant's advertisements do not mention the age of patients, it cannot be misunderstood for professional medical personnel who see them.

(4) Issues (1) C. Can Defendant's products be recognized to not be able to achieve 100% survival of oocytes and embryos? (a) How is the method for confirmation of survival?

(Appellant's allegations)

A. It needs 2 hours to confirm survival after thawing for oocytes, and 1 to 4 hours after thawing for blastocysts. This is shown as follows:

(1) De Munck and others' "Survival and warming in vitro competence of human oocytes after high security closed system vitrification" (January 25, 2013) (Appellant's Exhibit No. 69, hereinafter referred to as "De Munck paper"),

(2) Professor S's written opinion (Appellant's Exhibit No. 65-1; hereinafter referred to as "S's written opinion"),

(3) Kasai Magosaburo et al. "Morphological appearance of the cryopreserved mouse blastocyst as a tool to identify the type of cryoinjury" Human Reproduction Vol. 17, No. 7, pp. 1863-1874 (2002) (Appellant's Exhibit No. 102-1; hereinafter "Kasai Paper ".),

(4) Documents prepared by Embryotools (Appellant's Exhibit No. 63-1) and papers by PMA Research Institute Director Lodovico Parmegiani et al. (Appellee's Exhibit 40-1). According to the said De Munck Paper states that all oocytes are in a state of dysfunction immediately after thawing and cannot be confirmed their survival, and after a lapse of time from thawing can be confirmed survival by observing their functional recoveries. The said Kasai paper reports thawing cases that the embryos that look like normal immediately after thawing died during one hour culturing.

B. Defendant's method for confirming survival are "the oocyte and the split-stage embryo have recovered to their original volumes," and "the blastocyst has been observed to have re-dilation of the blastocoel". The cell volume recovery is derived from "osmotic pressure," that is, the semipermeable membrane's function in which the solvent moves to the higher concentration when contacted with solutions of different concentrations with the semipermeable membrane as a boundary. Defendant's confirmation method merely observes only the function of the osmotic pressure of the cell membrane, and does not observe the cytoplasm, which is the essence of the cell. Since an oocyte may die from collapse of cell membrane after its volume is restored, "observation of volume recovery by osmotic pressure and re-expansion of the blastocoel" is not sufficient to confirm survival of an oocyte. Therefore, Defendant's method of confirmation cannot confirm the survival of an oocyte or blastocyst.

(Appellee's allegations)

A. Oocytes and embryos have no great motility unlike sperms, so we depend on its

morphological observation under a microscope. In the past, "evidence of death" was the standard to determine the death of an oocyte based on morphological observation of cell under a microscope . When a clear form of "death" such as rupture or cracking of oocyte's cell membrane, or atrophy of the cell are observed, they are confirmed as "dead". Such morphological observations can only provide the cells that have shown signs of complete death, and when the degree of discoloration is light or the contraction is slack, it was difficult to determine whether dead or alive. That is, even under a microscope level, dead cells that has no change in appearance could be determined alive, and cells pretending dead could be erroneously determined dead even if they were alive. In order to overcome these problems Appellee's representative applied the theory of bio-membrane function, in addition to conventional morphological observations, and established a method for confirmation of survival of oocytes and blastocysts by the "evidence of survival" of cells, that is, restoring normal cell volume and reforming the blastocyst cavity, and has spread it to the world.

B. The method for confirmation survival 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 recovery culturing for 3 hours.

The blastocoel remodeling is morphologically observed with an inverted microscope (generally 200 to 400 magnifications depending on the facility) before transplantation of blastocysts according to the

clinical guidelines of each institution.

(C) The method of confirmation survival at Appellee's work shop for technology transfer in order to confirm vitrifying and thawing techniques, is confirming survival of oocytes that contracted cell volume are restored by vitrifying (that is, those in which the cell morphology is being restored) are determined to alive by using abnormal oocytes (provided by a medical institution, and not for clinical use due to its weak resistance) after thawing an oocyte, observe with a stereomicroscope of 50 times or more magnification during treating with WS (washing solution) for 5 minutes. At technical workshop Appellee has to use abnormal oocytes with weak resistance and easy to die, instead of normal oocytes with high vitality, and culture conditions after thawing are completely different, and in vitro fertilization is not performed, it confirms survival by recovery of the volume during 5 minutes of treatment. As described above, the method of confirming survival at Appellee's technical workshop where vitrifying and thawing techniques transfer by manipulation is different from those of determining survival of the clinical data as (a) and (b) above.

(D) During the two to three years from 2012 to 2014, Appellee's representative asked doctors and researchers who are world-class experts in the fields of assisted reproductive technology and reproductive technology to verify the effectiveness and safety of Cryotech method, "Evaluation of Post-thaw Survival rate of Your Patient's Oocyte and Embryos vitrified and thawed with Cryotech method." The method for confirming survival in the study is as follows.

"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 stare 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 vitrifying process. The judgment 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 in Appellee's Exhibit 30-2]

C. De Munck paper

The purpose of the De Munck paper states, "To compare two vitrification methods and two warming methods for human oocyte vitrification using a high security closed device in terms of survival, fertilization and embryo development. Thus, it is clearly states that the paper is not only about survival rate but also about survival issues such as fertilization rate and embryonic development rate. According to the paper, regarding the evaluation of survival, it state, "Warmed oocyte were considered 'morphologically surviving' if there was no dark/ degenerated or contracted ooplasm and has no cracked zona pellucida." This is not a stricter standard than Defendant's method for survival confirmation mentioned above for clinical data. Thus, even if this standard is adopted, the survival rate by Defendant's Cryotech method will not be altered.

In addition, in De Munck Paper states that they analyzed reproduction of the mitotic spindle by boroscope (polarizing microscope), but they just studied "fertilization and embryo quality". It is a matter of "survivability" and has nothing to do with "survival rate".

D. S's written opinion

S's written opinion states, "a condition of survival that is functionally equivalent to that before freezing," "Frozen-thawed oocytes are required to have at least the same fertilization rate and embryogenesis rate as non-freeze-thawed oocytes." But this is not a "survival rate" but a "survivability" issue. Thus, S's written opinion confuses the discussion of survival and viability and is unreliable.

E. Kasai paper

Defendant's method for confirming survival of a blastocyst is to confirm survival when observing the remodeling of the blastocyst that has shrunk or disappeared when vitrified with a

microscope during the recovery culture for 3 hours after thawing, and not to confirm survival immediately after thawing. Kasai paper's essence is that "The damages that cells receiving during each process of vitrifying and thawing differs depending on each process. Thus, improvements of vitrifying can be supposed by analyzing the cell damages after vitrifying and thawing." Kasai paper's essence is consistent with Defendant's method of confirming survival, and it supports Appellee's allegations.

Appellant alleges that a lapse of time from thawing is necessary to confirm survival by observing their functional recoveries. However, Kasai's paper does not contain such description, thus, it cannot support Appellant's allegations.

(5) Issues (1) C. Is Defendant's products can be recognized to not be able to achieve 100% survival of oocytes and embryos? (b) Is Defendant's products can achieve 100% survival or not?

(Appellant's allegations)

A. According to the following papers, it is proved not possible to achieve 100% survival rate with Cryotech method procedures even if strictly observed when vitrifying and thawing oocytes and embryos using Defendant's products.

(A) "A comparison of two different vitrification methods for cryopreservation of mature human oocytes (1 and 2 of Appellant's Exhibits A14 and 15; hereinafter referred to as" Research Report 1") is published at annual meeting of the European Society for Reproductive Medicine held in July 2013.

a. Research Report 1 was published by the personnel of Rotunda CHR (Center of Human Reproduction), etc. in India. It states that the survival rate for cases vitrified and thawed by Cryotech method was 97.1%. Appellee's representative is one its co-authors, and he must have involved in the management of the protocol. The research report was officially published at the annual meeting of the European Society for Reproductive Medicine, thus, the reliability of the contents should be high. Therefore, it shows Cryotech method cannot achieve 100% survival rate.

b. (a) Dr. Goral Gandhi's (hereinafter "Gandhi") letter (hereinafter "Gandhi's Letter", 1 and 2 of Appellee's Exhibit 12) state that the poor survival rate suggested the causative factor to be poor oocyte handling by the embryologist who joined the team. Based on "Gandhi's Letter" the district court stated that it could not find that 100% survival cannot be achieved by strictly observing the procedure. However, "Gandhi's Letter" does not include a date of preparation, and her title as author is Director of Laboratory at the Rotunda Human Reproduction Center, which was already closed.

The doctors at Rotunda CHR has been charged with fatal accidental death against the oocyte donor (Appellant's Exhibit No. 51, and 53-1. 53-2). Gandhi's office was subjected to domiciliary search on suspicion of smuggling human embryos (Appellant's Exhibit No. 52). These facts show Gandhi's low awareness of abiding laws. Moreover, Gandhi has co-authored with Appellee's representative (Appellant's Exhibit No.26-2). She participated at international conferences wearing a T-shirt with "Cryotech" logo (Appellant's Exhibit No. 54, 55). This shows she is not a neutral third party because she has deeply involved Appellee's business. Therefore, Gandhi's Letter is not reliable.

(b) The district court judgment states that the cases performed may have included those before the completion of Cryotech method. If so, "what was done before its completion" is not Cryotech method. Research Report 1 (comparison of two different vitrification methods for cryopreservation of human oocytes) compares Cryotop method with Cryotech method, and therefore it cannot include the cases before completion of Cryotech method. If Cryotech method is not completed, it cannot be compared with Cryotop method.

(c) Defendant Site 1 (Appellant's Exhibit No. 28) states, "In a simpler way, you can vitrify and thaw safer and easier, and sure to get higher survival and pregnancy rates.", "New 18 improvements have could anyone with or without vitrification experience and basic knowledge achieve the same good results without human errors."

Defendant Site 2 (Appellant's Exhibit No. 12) states, "The most effective, easiest and safest.",

"Cryotech method is a highly simplified vitrification procedures.", "It is easy for everyone."

According to the above and Cryotech method manual (Appellant's Exhibit No.44), the procedures for cryopreserving vitrification and thawing oocytes, etc. by Cryotech method does not require any special techniques or skills, and even an inexperienced person has no difficulties to do so. Therefore, even if an embryologist's skill in charge is not mature, it does not mean its protocol has not been observed.

(B) A research report entitled "Study of vitrifying of unfertilized human oocytes - Experience with Cryotop and Cryotech" published in "Journal of the Japan Society for Reproductive Medicine" published on July 1, 2014 (Appellant's Exhibit No.16 1-3. Hereinafter, "Research Report 2")

a. Research Report 2 states that the survival rate with Appellant's products was 70.0% and Defendant's products was 53.9%. From this description, this means that the survival rate of 100% cannot be achieved with Defendant's products, that is, Cryotech method.

b. the Tokyo District Court Judgments states regarding Research Report 2 that it found the cases using Defendant's products might have conclude those that the doctors and medical personnel in charge might not have observe the protocol, based on the description that they were not accustomed to the procedures and the embryos were difficult to see. However, there is no relation with "difficult to see the embryos" to "observing the protocol," therefore the said finding in District Court Judgment is erroneous. The co-writer of Research Report 2, Ms. Q (hereinafter Q) answered in a Lawyer's inquiry that she participated Defendant's workshop and complied with Defendant's protocol (Appellant's Exhibit No.42). As described in (a) b (c) above, Cryotech method does not need require any special technique or skills to cryopreserving, and even an inexperienced person is not difficult. "It was hard to see" does not mean that the procedure was not followed.

(C) Lecture at the "South African Society of Assisted Reproductive Technology and Gynecologic Endoscopy" held on October 30, 2015 and November 1, 2015.

Research report entitled "Oocyte and blastocyst survival rates following implementation of the Cryotech vitrification method" (Appellant's Exhibit No. 17-5; hereinafter referred to as "Research Report 3")

a. Research Report 3 states that the average survival rates for blastocysts and oocytes were 87.8% and 83.8%, respectively, according to Cryotech method. It has been shown that 100% survival has not been achieved.

b. The original judgment stated that "Study Report 3 has significantly higher survival rates in the more recent months than in the previous months, suggesting that the experience of engineers using this technique is beneficial. The survival rate had reached 100% by the last month of the above period at the latest by the engineer in charge repeatedly using Defendant's product and following the procedure. According to Research Report 3, it cannot be determined that 100% survival rate cannot be achieved even if the oocytes are cryopreserved and thawed using Defendant's product in strict adherence to the procedure." However, the "procedure" does not have the requirement of "accumulating experience of use", and the fact that "the engineer in charge accumulates experience of using Defendant's product" has nothing to do with "observing the procedure". It means that 100% survival rate could not be achieved even if the procedure was strictly adhered to, unless 100% survival rate could be achieved only by observing the procedure regardless of the experience of use.

Research Report 3 states that "Purpose: To study the survival rate of oocytes and blastocysts using the Cryotech method." And "The study was conducted to determine the reliability of Cryotech technology." That is, since the purpose is to study the survival rate of Cryotech method, it is a natural premise that the procedure was followed.

Further, as described in (a) b (c) above, the procedures for cryopreserving vitrification and

thawing oocytes, etc. by Cryotech method does not require any special techniques or skills, and even an inexperienced person has no difficulties to do so. Therefore, the fact that the medical personnel in charge of using Defendant's products has lack experience cannot be the reason that he/she does not observe the protocol.

(E) "Our Experience with Oocyte Vitrification" in "3 Vitrification of Oocytes: General Considerations" of "Vitrification in Assisted Reproduction" (Appellant's Exhibit No. 26-1-6; hereinafter as "Research Report 4")

Research Report 4 co-written by Gandhi et al. states that the survival rate of vitrified and thawed oocytes by Cryotech method is 94.5%. The description shows that Cryotech method could not achieve 100% survival. They cannot be supposed having not complied Defendant's protocol in it.

(F) "Cryotech method: A new strategy that can achieve 100% survival" published at the 34th Annual Meeting of Japanese Fertilization and Implantation Society held in September 2016 (Appellant's Exhibit No. 33-1 and 2, hereinafter as "Research Report 5")

a. Research report 5 is Appellee's representative's publication, and states "This vitrification method is extremely effective in obtaining a survival rate of almost 100% after thawing not only for embryos of general patients but also for immature oocytes, mature oocytes, low-grade oocytes of cancer patients or elderly patients. I have accomplished as extremely safe and non-invasive vitrification method (Cryotech method: 2012)." This description shows that people in this field believes "100% survival of thawed oocytes or embryos" cannot be achieved, and also Appellee's representative himself is aware that he cannot achieve "100% survival."

b. The Tokyo District Court Judgment states that Research Report 5 does not show enough that 100% survival cannot be achieved after thawing vitrified oocytes with Defendant's product by strictly observing its protocol, since it is not clear the report is limited to the cases that strictly observing its protocol. However, it cannot happen that Appellee Representative does not strictly observe his

protocol, and not observing its protocol is no longer Cryotech method, therefore the said finding in the Tokyo District Court Judgment is erroneous.

(F) Altravita's website (Appellant's Exhibit 59)

Altravita's website which Yakovenko who wrote Appellee's Exhibit 30 belongs states, "Our techniques for vitrification have generally demonstrated an average of 98% survival at thaw." [original] It admits that 100% survival after thawing cannot been achieved.

(G) Appellant's Exhibit No. 91

a. The paper (Appellant's Exhibit No. 91) states, "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.", "The re-expansion rate of the zona-free group (98.1%) was comparable with that of the intact group (96.3%), suggestion that blastocyst viability was not affected by zona removal procedure." [original] It states that survival rate of 100% has not been achieved after vitrifying and thawing using Cryotech method.

b. Appellee alleges that Appellant's Exhibit No. 91 paper shows viability, not survival rate. However, "Fertilization rate after in vitro fertilization (1 day later)", "the incidence rate to division (2 to 3 days later) or blastocyst (4 to 6 days later)" is called "development ability (or developmental competence)". These concepts are different from "Viability" of vitrified oocytes.

(H) AFC's website (Appellant's Exhibits 88-90)

AFC's website includes "Outcome of Vitrified-thawed oocytes at Alpha International Fertility Centre (AFC) in 2015 (Appellant's Exhibit No. 88), "Clinical outcome of Vitrified-thawed oocytes at Alpha International Fertility Centre (AFC) in 2016" (Appellant's Exhibit No. 89), "Clinical outcome of blastocysts derived from vitrified donor oocytes versus fresh donor oocytes in fresh blastocyst

transfer cycles in 2017" (Appellant's Exhibit No. 90). Appellant's Exhibit No 88 states, "Result: A total of 65 oocytes were thawed. 63 oocytes survived (Post-thaw Survival Rate :96.9%) and had ICSI," Appellant's Exhibit No 89 states, "Result: A total of 231 oocytes were thawed. 220 oocytes survived (Post-thaw Survival rate: 95.2%), and had Piezo-ICSI. Appellant's Exhibit No 90 states, "Results: In Group A, a total of 284 oocytes were thawed. 272 oocytes survived (Post-warmed Survival Rate: 95.8%)."

These description shows that survival rate100% has not been achieved.

(C) Den'entoshi Ladies Clinic's website (Appellant's Exhibit No. 57)

a. Den'entoshi Ladies Clinic's website (Appellee's Exhibit 33), of which personnel were trained with Appellee's oocyte vitrification and thawing techniques, states that "embryos may not return after vitrifying and thawing." (Appellant's Exhibit No. 57) Since "embryo does not return" means that embryo's decease, it shows that survival rate 100% has not been achieved.

b. Appellee alleges that the meaning of "embryos may not return" is unclear.

"Embryos may not return after vitrifying and thawing" describes the state of the embryo. An embryo cannot spontaneously return to its mother's uterus, but returns there by medical treatment, thus, there is no room for interpretation as "the embryo does not return to the mother's uterus."

c. Appellee alleges that only Muramatu Hirotaka (hereinafter referred to as "Muramatu") has trained at Appellee's technical workshop and obtained its certificate, and that other personnel at Denentoshi Ladies Clinic than him just states that "embryos may not return after vitrifying and thawing." If so, personnel of Appellee's customer might use Defendant's product without its Certificate.

(D) Answers from medical facilities, etc.

Appellant received following answers regarding the survival rates of vitrified and thawed oocytes and embryos using Defendant's products.

a. Dr. W, the chief gynecologist and director of the Reproductive Medicine Center, Yancheng

Maternal and Child Health Hospital, Yancheng City, Jiangsu Province, China, answered that the survival rate was 80% or less strictly observing the protocol. (Appellant's Exhibit 45)

b. Embryologist Z at Reproductive Medicine Center of Huaian Maternal and Child Health Hospital in Jiangsu Province, China, answered that the survival rate was 80% or less strictly observing the protocol. (Appellant's Exhibit No. 47)

c. Senior expert Qi at the developmental department of Clinical Assisted Reproductive Technology Center of Jiangsu People's Clinic in China, answered that the survival rate was 80% or less strictly observing the protocol. (Appellant's Exhibit No. 49)

d. Dr. K. M. at Assisted Reproductive Technology Center of St. Luke's International Hospital answered to Bar Association's Inquiry, that 100% survival rate after thawing oocytes and embryos could not achieved strictly observing the protocol. (Appellant's Exhibit No. 38).

e. Embryologist S at Tawara IVF Center answered to Bar Association's Inquiry, that 100% survival rate after thawing oocytes and embryos could not achieved strictly observing the protocol. (Appellant's Exhibit No. 40)

f. Ms. Q answered to Bar Association's Inquiry, that survival rate after thawing oocytes and embryos was 80% or less strictly observing the protocol. (Appellant's Exhibit No. 42).

Embryologist Y (hereinafter Y), who had a Certificate after training Appellee's workshop, cannot achieve survival 100%. (Appellant's Exhibit 8).

B. Appellee's Exhibit 30, Exhibit 31-1 (hereinafter referred as "Appellee's Exhibit 31 Report") and Appellee's Exhibit 32-1 (hereinafter as "Appellee's Exhibit 32 Report")

(A) About the authenticity of the establishment

Appellee's Exhibit No. 30-1 has a signature of "e f", but "Sergey Yakovenko," the signer, and its Russian letters has no notation of "e f". Appellee's Exhibit 31-1 has no description of the facility name, and the name is unreadable. Appellee's Exhibit 32 has no description of the facility name, thus,

Appellee argues authenticity of these papers.

(B) About credibility

a. the method of confirmation of survival

Appellee's Exhibit No. 30 to 32 Reports states, "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." [original]

Appellee's Exhibit No. 30 to 32 shows the method to confirm survival is "volume recovery from the contracted state" as a result of "responding normally to the difference of osmotic pressure." Since osmotic pressure is also generated in cellophane, which is not a living thing, the above method just confirms that the cell membrane responds to osmotic pressure, that is, the cell membrane is not destroyed but not confirms an oocyte or an embryo survives. If the cell membrane is destroyed, an oocyte or an embryo cannot survive. However, we cannot confirm survival of them when the cell membrane is just not destroyed.

"Cryotec Method Manual" (Appellant's Exhibit No. 44) states, in paragraph of "WS dilution (5 minutes)", "Sucking an oocyte/embryo in DS, … insert the tip of the pipette into the center of the bottom of WS1 ... Slowly drain DS and create a layer of DS on the bottom. Next, gently place the oocyte/embryo on the bottom of the DS layer. Memorize the morphology of the oocyte/embryo, turn off the light of the stereomicroscope, and wait for 5 minutes ... After 5 minutes, then compare them with the morphology of the memorized oocyte/embryo. If the contracted oocyte/embryo is recovered,

its survival is confirmed."

In the second Appellee's Brief, "judgment method for survival" is described as "While the oocytes and embryos in the splitting stage were allowed to stand in the washing solution, the oocytes and embryos that recovered from the contracted state to the original volume in response to changes in the osmotic pressure of the solution were considered to be alive. The morphological observation of the recovery state of the cell volume was performed using a stereomicroscope at a magnification of 50 times or more. Blastocoels that have shrunk or disappeared due to exposure to the vitrification solution have re-expanded during washing or recovery culture in an incubator are living embryos."

That shows that Appellee has confirmed survival when an oocyte/embryo recovers its shrunken volume responding to cell membrane osmotic washing solution.

An oocyte stays dysfunction immediately after thawing, and its survival can be confirmed by observing its functional recovery after a time lapse. Such Appellee's error in confirmation of survival has come from that its Representative who developed Cryotech method has no medical experience and has never known medical field.

b. Situational guarantee for credibility

(a) Yakovenko, the writer of Appellee's Exhibit No. 30 Report, With Luis Ruvalcaba (hereinafter as "Ruvalcaba"), the writer of Appellee's Exhibit 31 Report and Appellee Representative are listed as members of international support of the Mexican Assisted Reproductive Technology Center (Appellant's Exhibit No. 60), and this shows these people's close relationship. Thus, these reports have no situational guarantee of credibility.

(b) As described above Ms. Gandhi, the writer of Appellee's Exhibit 32, has close relationship with Appellee, and not in a neutral third-party. Thus, her report has no situational guarantee of credibility.

c. Additionally, Appellee's Exhibit No. 30 to 32 reports has many doubtful questions and have

no credibility.

(C) Misrepresentation regarding patient's age

As mentioned above, Defendant's advertisement has no indication that the targeted patients who can achieve 100% survival rate is a general infertile female patient aged 20 to 39 years old. "Survival 100%" in Defendant's advertisements is based on Appellee's Exhibit No. 30 to 32 Reports, which limited for general infertile female patients aged 20 to 39 years old. Thus, Defendant's indications in its advertisement are misrepresentation that misleads the quality of its products.

C. Appellee's Exhibits 33-39 (documents describing the survival rate of oocytes after thawing at Appellee's workshop)

(a) Appellee's Exhibits 33-39 have no description whether (1) human or bovine oocytes were used, (2) how many oocytes were vitrified and thawed, and how many survived, (3) who was the instructor of the workshop, or what were the contents of the workshop, and there is a discrepancy between the title and the text. These documents merely state the slogan of "100% survival rate", and none of them is credible.

(B) Appellee's article (Appellant's Exhibit No. 30) on its website of the 14th ART Lifelong Training Course held by Japan Fertilization and Implantation Society, states that bovine oocytes were used in the practical training of Cryotech method. Ms. R writing (Appellant's Exhibit No. 66-1) states that bovine and pig oocytes were used in the in-house practical training course.

Thus, it is clear that bovine or pig oocytes were used in the practical training at Appellee's workshop for technology transfer.

D. Appellee's Exhibit 51 and 62

Appellee's Exhibit 51 and 62 are evidence filmed the verification process to confirm survival in the vitrifying and thawing procedure at its workshops. Since they confirm survival immediately after thawing at Appellee' workshop for technology transfer, the data of workshops cannot be the basis

for survival of oocytes as clinical data. Therefore, Appellee's Exhibit 51 and 62 cannot be the basis that oocytes survival rate is 100%.

E. "Challenge 100" and aggregated data of Genesis (Appellee's Exhibit 47, 48-1 to -79, 65, 66)

The details of "REPROLIFE Challenge 100 Trial Agreement" by Appellee are as follows:

(1) "Reward for 100% success rate" (Article 4.1),

(2) "Promote REPROLIFE's mission", make at least one academic publication regarding the 100% Survival rate within one year after the admittance to the 100% Survival Club." (Article 5.1) etc. (Appellee's Exhibit 42-2). In these ways Appellee requests to its member making academic publications by using medical data with "survival rate of 100%" under the incentives of reward to "promote REPROLIFE's mission." Thus, the aggregated data of Appellee's Exhibit 47 (Appellee's Exhibit 65) and Appellee's Exhibit 48-1 to 48-79 (Appellee's Exhibit 66) made under the premise of reward lacks credibility, since such cases that oocytes died after vitrifying and thawing may have been intentionally excluded from the report.

Since the vitrifying and thawing date are not continuous, and the original data includes descriptions such as "Collapsed", "SHRINK", "not yet expand", and "not yet expand @ ET," etc., survival rate 100% has not been achieved after vitrifying and thawing.

(Appellee's allegations)

A. Appellee's Exhibits 30 to 32 Report

(A) The data from Appellee's Exhibit No. 30 to 32, which are shown on "Product Introduction" web page of Defendant Site 1 (Appellant's Exhibit No. 28) are prepared by Yakovenko, Ruvalcaba, and Gandhi, the authorities of oocytes cryopreservation in each country. The method of confirming survival of oocytes and blastocysts were performed in clinical data, not by the method of confirming survival at Appellee's workshop.

(B) Yakovenko, Ruvalcaba, and Gandhi would not make false reports intentionally just because they have a connection with the Appellee's Representative. The points that the appellee asserts about Gandhi are as described in F. (A) a below.

(C) There are no doubts about the contents of Appellee's Exhibit No. 30-32 Reports, and they are credible.

B. Appellee's Exhibit 33-39

(A) Appellee has held Cryotech method technical training workshop around the world. Many medical personnel have received technical lessons and achieved survival rate of 100% with Cryotech method (Appellee's Exhibit 33-39).

(B) The Appellant alleges that there is no description of whether human oocytes or bovine oocytes were used for Appellee's Exhibit 33 to 39. Since it is a technical training course for cryopreserving human oocytes, human oocytes were used, and there is no reason to dare to use bovine oocytes. Currently, it is possible to obtain discarded human oocytes, and there is no reason to use bovine oocytes. If bovine oocytes were used, it should be stated so, because it is unusual. However, there is no such statements, this means bovine oocytes could not be used.

In the past, due to consideration for ethical issues, bovine oocytes were used on a trial basis at training stage mainly in Japan. The data of Appellee's "survival rate 100%" does not include bovine oocytes, Appellee's Exhibit 33 to 39 were performed with human oocytes. The practical trainings of Cryotech method in the ART lifelong training course are hosted by Japan Fertilization and Implantation Society, not held by Appellee. Bovine oocytes were used there prepared by the Society. The contents of the technical training course are always the same for accreditation of certificates, and it is not necessary to describe its contents every time.

C (A) Appellee has started a program called "Challenge 100" from around April 2019. This is to confirm whether survival rate of 100% can be continuously achieved at the facility to which the

medical personnel who have participated in the technical training and have been certified and registered. The Appellee has agreed with multiple medical institutions to do so and has signed a memorandum of understanding (Appellee's Exhibit No. 42-1, 2, 43).

The program plan under the name of "Challenge 100" is as follows:

Three certified and registered technicians will be selected from each facility, aiming for 100% survival in 100 consecutive thawing cycles at any one stage of the vitrifying cycle of oocytes, split embryos or blastocysts. Currently, reports of 100% survival rate are being collected one after another from the facilities that participated in "Challenge 100." Appellee's Exhibit 47 (or Appellee's Exhibit 65) is a report prepared by Chen Shu-in, the director of the Genesis lab, and Appellee's Exhibit 48 1-79 (or Appellee's Exhibit 66) are the original data. These evidences show survival rate of 100% has been achieved.

(B) Appellant alleges that the blastocysts after thawing are described as "collapsed", "SHRINK", etc. in Appellee's Exhibit 48 1-79 (Appellee's Exhibit 66), and the blastocysts are not alive. The descriptions pointed out by Appellant are all expressions of shrinkage and disappearance of the blastocoel of the blastocyst. Both are normal phenomena of the living blastocyst. The blastocyst breaks through the zona pellucida and hatches while repeating contraction and expansion, and any of the above expressions shows only one process of a normal phenomenon. Therefore, Appellant's allegation has no basis.

D. (A) AFC has released a research report on Cryotech method, in which it is reported that all of 1491 have survived, and survival rate of 100% has been achieved (Appellee's Exhibit No. 50-1). The AFC paper in August 2017 (Appellee's Exhibit 68-1), the survival rate after thawing for 1011 cases of vitrified blastocyst transplantation and 1491 blastocysts was 100%. "By using Cryotech method, we show that we have consistently achieved 100% post-thaw survival in blastocysts." Furthermore, in June 2016 paper of AFC (Appellee's Exhibit 69-1), it was confirmed that the survival

rate after thawing of 62 split embryos was 100%.

(B) Since AFC is also conducting research on infertility treatment as its mission, thus, not only normal oocytes but also low-quality abnormal oocytes are used to perform cryopreservation technology by Cryotech method (Appellee's Exhibit 72-1). Therefore, in its 2015 report, the survival rate was only 96.9% (Appellant's Exhibit No. 88), and in its 2016 paper, the survival rate was only 95.2% (Appellant's Exhibit No. 89). There is a description in Exhibit No. 89 that "the remaining blastocysts were of poor quality." That indicates that poor quality oocytes were used.

E. Appellee's Exhibit 51 and 62

Appellee's Exhibit 51 and 62 are recorded videos of the reproductions of vitrifying and thawing techniques at Appellee's workshop. These videos shows that survival rate will be 100% if performed by correctly observing the protocol.

At the workshops, abnormal oocytes with weak resistance are used instead of normal oocytes with high vitality, and they are often reused many times, and the culture conditions are different from those at clinical practice. Thus, strictly speaking, the indications of survival rate in Defendant's advertisements do not presuppose these. Oocytes do not extinguish receiving damages from vitrification and thawing by observing the protocol of Cryotech method with using Defendant's products, it is exactly the same as the clinical data, in which oocytes do not extinguish. Thus this evidence proves that survival rate of 100% for oocytes in clinical data.

F. Appellant's evidence

(A) Based on the research reports 1 to 5, they cannot prove that survival rate of 100% cannot be achieved by Cryotech method, as the Tokyo District Court Judgment states.

a. Research Report 1

Appellant alleges that Gandhi may be blunted in legal norms because of alleged smuggling of human embryos into India. However, Appellant's allegation has no basis due to the following reasons. In

India, importation of human embryos is prohibited except with the permission for research use, and importing without permission violates the Indian Customs Law. A Malaysian agency asked Gandhi's clinic, which has a good reputation for its technology, whether it can send human embryos. The clinic answered that they could not receive them without Permission for research use. In March 2019, an employee of the above Malaysian agency was arrested at Indian Customs for trying to import human embryos. Then Ms. Gandhi was involved in the incident due to the employee's confession. According to its lawyers, Ms. Gandhi has nothing to do with the case and there is no evidence other than the employee's confession above. Ms. Gandhi has not been arrested yet and is unlikely to be prosecuted. (Appellee's Exhibit 27 and 28-1).

b. Research Report 2

(a) Ms. Q attended Appellee's technical workshop and passed its examination. According to its sales record of Defendant's product, she purchased only twice in September 2015. Other than that, there is no purchase record. It is unclear what kind of verification were done with only two purchases.

(b) Appellant argues that it is erroneous to find that "may include those that did not observe the protocol" in the Tokyo District Court Judgment from the description of that "the embryos were difficult to see." The Tokyo District Court Judgment states that they were not accustomed to the procedures of Defendant's product and the embryos were difficult to see. Thus, Appellant's allegation is misunderstanding the Tokyo District Court Judgment.

c. Research Report 3

The exhibit shows that just a small percentage of many medical professionals and researchers around the world have the same opinion as Appellant's. Even on the premise of Research Report 3, the Tokyo District Court Judgment that the survival rate seems to have reached 100% by accumulating experience and observing the protocol. Thus, Appellants' allegation has no basis.

(B) Description on Altravita's website (Appellant's Exhibit No. 59)

a. It is not clear whether the test of Appellant's Exhibit 59 was conducted by Yakovenko.

b. Appellant alleges that it states that the description on the website state "generally demonstrated an average of 98% survival after thawing." Appellant' translation to Japanese intentionally omits the word "generally". From that expression of "generally," it implies that they are trying other methods than Cryotech method.

Moreover, the expression "have generally demonstrated" means the entire period from the past to the present, so it should be interpreted as including the method before Cryotech method. At Altravita facility, Cryotop method was introduced in 2007, and the improved version of Cryotech method was introduced around 2012. Prior to the introduction, oocytes and embryos were vitrified by Cryotop method, of which the survival rate was lower. With the former Cryotop method, the survival rate is about 90% on average, so it is highly possible that even a facility with a high technical level did not reach 100% at that time.

Therefore, there is no contradiction with the survival rate 100% reported in Appellee's Exhibit No. 30. Rather, it can be read it support that 100% can be reached with Cryotech method, if it would be the average value including the results with Cryotop method which the survival rate is low.

(C) Appellant's Exhibit 91 paper

Appellant's Exhibit 91 paper states, "The re-expansion rate of the zona-free group (98.1%) was comparable with that of the intact group (96.3%), suggestion that blastocyst viability was not affected by zona removal procedure." [original] What is not 100% is not survival rate, but survivability.

(E) The description on Den'entoshi Ladies Clinic website (Appellant's Exhibit No. 57)

The meaning of the sentence "embryos may not return" on the clinic's website is unclear. "It does not return to the state before vitrifying" or "it returns to the state before vitrifying, but the embryo does not return to the mother's uterus for some reason."

If it means the latter sense, it is a story after confirmed survival. Thus, it is a matter of viability, not survival rate. Even if "embryos may not return." means "does not return to the state before vitrifying," it is not described whether the description is based on by Muramatsu, Director of Culturing at Futako Tamagawa" Branch of the clinic. There are 3 branches of Den'entoshi Ladies Clinics, and the certificate (Appellee's Exhibit 33) was issued to Mr. Muramatsu, Director of Culturing at Futako Tamagawa Branch of the clinic. There must be other embryologists than him, and they would possibly state "embryos may not return."

a. Appellant's Exhibits 45, 47, 49

Dr. W, Embryologist Z and Qi are not certified nor and certified and registered after receiving technical training at Appellee's workshop. There is no record of selling Defendant's products to any of the Yancheng Maternal and Child Insurance Medical Hospital in Yancheng City, Jiangsu Province, Huaian Maternal and Child Health Clinic in Jiangsu Province, and People's Hospital in Jiangsu Province. Therefore, these answers are not credible.

b. Appellant's Exhibits 38 and 40

There are many sales records of Defendant's products to the Assisted Reproductive Technology Center of St. Luke's International Hospital and Tawara IVF Clinic.

The following matters are not objectively confirmed, under what environment survival were confirmed, whether the protocol was correctly observed, only normal oocytes were used, in which meaning the word of survival were used.

c. Appellant's Exhibit 81-1

Ms. Q has participated to a technical workshop and obtained a Certificate, but according to the sales record of Defendant's product to K Clinic purchased only twice in September 2015. Other than that, there is no purchase record, and it is not clear what kind of verification were done with only two purchases.

In addition, P (hereinafter referred P) does not actually understand the contents of Cryotech method at all, even though he supervised the laboratory and grasped all the work, as described later (F). Thus, L, who was operating under P's instructions, has not been doubtful to observe the protocol, and it is clear that there was a considerable problem with the management system, including at least protocol observance.

(F) P's witness in this court and his written statement (Appellant's Exhibit No. 43, 101)

a. P alleged that the number of infertility treatments per year is 8,000 cycles, and that the total number of fertility cases is 20,000. According to the article based on the questionnaire to fertility medical facility of the weekly magazine Diamond, the number of fertility cases at the K clinic managed by P is 1514 cycles from January 2017 to December 2017, and total number of the cases is 7619 cycles cumulatively.

b. P witnessed in this court that he was qualified as a managed embryologist and actually performed his job as an embryologist as the chief supervisor of the lab and knew most of that work. In fact, he witnessed that he observed to the protocol of Cryotech method without understanding what is Cryotech method at all.

c. P's written statement (Appellant's Exhibit No. 43) says that the indication of 100% survival rate in Defendant's advertisements are against "Prohibiting Unjustifiable Premiums and Misleading Representations Law" However, he witnessed in the court that he has never read the law. From this, P could just have signed his statement prepared by Appellant's attorney as instructed to do so.

d. [omitted due to defamation on false facts]

e. From the above, credibility of P's witness in this court and written statement is low.

(G) Appellant representative's witness in this court and his written statements (Appellant's Exhibit No. 64, 103)

Since oocytes will extinguish if stained with color, it is not possible to confirm survival of

oocytes in clinical practice by "observation of the nucleus with a fluorescence microscope after staining with color." Appellant's representative's witness and written statements saying so are unreasonable, and thus, not reliable.

In addition, his witness and written statements are inconsistent with them in his own paper (Appellee's Exhibit 41).

(6) Issues (1) D. How did Appellee sell Defendant's products?

(Appellee's allegations)

Appellee has never sell its product to other than personnel who have attended its technical workshop, and there have achieved survival rate 100%, certified and registered as so. This is proven by the following points.

A. Appellee started selling its products to medical facilities in 44 overseas countries, antecedently to domestic sales. Appellee only have sold to medical facilities that had "completed technical coaching," that is, those that had attended a technical workshop on Cryotech method and were certified and registered. Appellee only have sold to medical facilities in Japan in the case that they attended a technical workshop on Cryotech method and were registered for certification as is the case overseas. (Appellee's Exhibit 44).

B. Appellee is using two systems in side, a sales database (Appellee's Exhibit 45, the customer management system) and the "order and deliver system (called as Techro)" (Attachment 2 of Appellee's Exhibit 60), and with these system selling its products only when a customer has been certified and registered by attending its technical workshop on Cryotech method.

(A) Appellee has made a data by each medical facility with the sales database. When the technical briefing was held there and passed the examination, the items of "STONE training completed" in the sales database is checked, and set a flag of completion, and input workshop implementation date in the field of "the date of workshop implementation," etc. Thus, the completion

of workshop was reported to its sales manager. Finally, at this stage the facility is certified and registered.

(B) After a customer is certified and registered, it will be registered in the " order and deliver system " for instructing its manufacturing department to deliver products. If it is not registered in it, products will not be delivered due to Appellee's internal management. Additionally, the " order and deliver system" and daily business report have recorded the entire process of how much was sold to whom and how much was actually delivered, so the process can be checked afterwards.

(C) After certified and registered, Appellee's domestic sales department is always following up customers. At the fertility facility that has been certified and registered, the techniques will be inherited between the embryologists, but if the embryologist who attended the technical workshop retires, Appellee sometimes proposes the second or third time technical workshops, and confirms the status of technology inheritance by follow-up etc. to existing customers.

C. Appellee has concluded sales agency agreements with local sales distributors in each country (Appellee's Exhibit 46-1), and manages overseas certified and registered medical facilities through these distributors.

D. Appellant submits Appellant's Exhibits 82, 83, 85, and 86 (recorded statement of each medical facility).

These appellant's Exhibits 82, 83, 85, and 86 were created by Appellant's employees voluntarily, and it is doubtful whether the intentions of each talkers were accurately reflected (Appellee's Exhibit 54-58, Mr. Mano's witness in this court). Thus, they are not credible.

(Appellant's allegations)

Based on appellant's Exhibit No. 82, 83, 85, and 86 (statement records of each medical facility), Defendant's products cannot have been sold to personnel other than those who have been certified and registered.

(7) Issue (2) Is Appellant's profit infringed, or will be possibly infringed by Appellee?

Since both parties' allegations on this point are as described from the beginning of line 10 on page 9 to the end of line 6 on page 10 in the Tokyo District Court Judgment. Thus, this Court quotes the same descriptions in it.

Quoted Tokyo District Court Judgment

Plaintiff's allegations

A. Both of Plaintiff's and Defendant's products are straw shaped containers for vitrification, vitrifying liquids, and thawing liquids, and they are competing each other.

Defendant alleges that Plaintiff's products cannot be replaced by Defendant's products. However, in the reports by academic societies, etc. include comparing results with Plaintiff's and Defendant's products. This shows Plaintiff's products can be replaced by Defendant's.

B. The survival rate after thawing vitrified oocytes is the most important criterion of the quality, etc. for medical devices cryopreserving oocytes. And, also it is the most important criterion for users to choose products, a misleading indication that misleads to recognize achieving 100% survival after thawing vitrified oocytes is a serious impact on Plaintiff's business to sell its products that competes with Defendant's and inflict Plaintiff's business interests. [Unquoted.]

(8) Issue (3) Are there Appellee's willful misconduct or negligence?

Since both parties' allegations on this point are as described from the beginning of line 8 on page 10 to the end of line 15 on page 10 in the Tokyo District Court Judgment. Thus, this Court quotes the same descriptions in it.

Quoted Tokyo District Court Judgment

(3) Are there Appellee's willful misconduct or negligence? (Issue 3)

Plaintiff's allegations

Defendant's representative admitted in his lecture at the conference that 100% survival rate

could not be achieved after thawing vitrified oocytes with Defendant's products. Thus, Defendant's willful misconduct or negligence can be determined to infringe Plaintiff's business interests by the present indications on Defendant's products quality, etc.

Defendant's allegations

Defendant does not admit Plaintiff's allegations.

The presentation on the lecture just shows that Defendant's representative states that 100% survival rate could be achieved when Cryotech method protocol is strictly observed at his lecture.

[Unquoted.]

(9) Issue (4) How much is Appellant's damages to be compensated?

(Appellant's allegations)

A. The amount of damages suffered by Appellant is as follows:

From July 26, 2015, to July 31, 2020, Appellee continually displayed the present description in its advertisement, and the total sales of products during that period was 1,095,495,445 yen. Since Appellee's profit ratio selling Defendant's product is 70%, the profit that Appellant obtained from its advertisement that displayed the present description during the above period is 766,846,810 yen. Therefore, according to Section 2 of Article 5 of the Unfair Competition Prohibition Law, the damages suffered by Appellant due to Appellee's present advertisement that posted the present description during the above period is 766,846,810 yen. In addition, since the amount equivalent to attorney's fee is 76,684,681 yen, which is 10% of the above amount, the damages suffered by Appellant is 843,531,491 yen in total.

As a part of the above damages, Appellant requests 300 million yen, of which 75,917,834 yen with payment delay charge at 5% per year from July 26, 2018 to the day when would be paid up, and 224,082,164 yen with late payment charge at 3% per year from November 11, 2020 to the day when would be paid up.

B. The premise facts of Presumption based on Paragraph 2, Article 5 of the Unfair Competition Prohibition Law

(A) Appellee alleges that in this case, the premise facts of the presumption of Paragraph 2, Article 5 of the Law does not exist.

The survival rate after thawing of cryopreserved oocytes / embryos is the most important criterion for patients to choose medical devices because the purpose of cryopreservation cannot be achieved if the cryopreserved oocytes / embryos extinguish. The indication of "survival rate 100%" is a misleading indication of the maximum criterion for choice of products, and the misleading indication will surely to induces demand for Defendant's products and also its benefits.

Medical Park Yokohama's website (Appellant's Exhibit No. 96, 97) states that they switched from Plaintiff's products to Defendant's, citing Defendant's website.

(B) Questionnaires, etc.

The questionnaires conducted by Appellee (Appellee's Exhibit No. 75 1-3) lack neutrality as a third party, objectivity, or situational guarantee of credibility, since the answers name or its facility names are disclosed, there is no credibility.

In addition, the questionnaires of Appellee's Exhibit 114 and 115 do not disclose the name of answerers, the date of answering, and lack neutrality as a third party, objectivity, or situational guarantee of credibility, there is no credibility Appellee submitted statements from just four medical facilities (Appellee's Exhibit 121-124). The number of medical institutions that Appellee obtain the statements was just about 2.5% of the number that Appellee conducted questionnaires. This means that the remaining medical facilities did not accept to submit such a statement.

(C) There is no particular difference in the quality of Defendant's products and Plaintiff's.

a. Research Report 1 that Appellee's representative has involved, states "this study showed a higher survival rate in Cryotech, although there was no significant difference." This shows that there

is "no significant difference" in the survival rates between vitrified and thawed oocytes by Cryotop method and Cryotec method.

b. The18 points of improvement alleged by Appellee

(a) Appellant’s allegations against Appellee's are as follows.

(1) Improvements (1) (Optimization of HPC concentration)

Appellee's representative has stated that he has never changed the composition of the vitrified solution and thawed solution since the start of sales. Appellee's allegation of improvement (1) is not credible.

(2) Improvements (2) (composition change to trehalose)

Appellee's representative has stated that he has never changed the composition of the vitrified solution and thawed solution since the start of sales. Appellee's allegation of improvement (2) is not credible. In addition, there is no significant difference statistically between trehalose and sucrose in the solutions used for vitrification and thawing (Appellant’s Exhibit No. 106).

(3) Improvements (3) (decrease of ethylene glycol and DMSO concentrations)

The decrease of ethylene glycol and DMSO in the concentration means changes the composition of the solution. Appellee's representative has stated that he has never changed the composition of the vitrified solution and thawed solution since the start of sales. Appellee's allegation of improvement (3) is not credible.

(4) Improvements (4) (Introduction of static grooves)

Appellee has not proved Improvement point (4).

(5) Improvements (5) (Introduction of disposal grooves)

Plaintiff's products have disposal grooves for discarding unnecessary cleaning solutions from the start of sales.

(6) Improvements (6) (making marks with indicator)

Appellee's product is equipped with an indicator on its lid, but the volume of solutions cannot be measured during working, thus there is no use of it. On the other hand, since Plaintiff's products were equipped with the diameter of the circle on the bottom of the conical well has the function of an indicator since the start of sales, and when observing an oocytes or embryos, the solution volume can be recognized easily and that enables adjustment the volume of dilution media.

(7) Improvements (7) (Development of a dedicated well built-in the integrated plate)

The melting volume of Plaintiff's product is 4 ml, and Defendant's product is 1.8 ml. Too small thawing media causes difficulty to keep the temperature during melting, which may reduce the survival rate. When a vitrification straw shaped containers is put into thawing media, it is easier if the volume of thawing media is much. Thus, it cannot be concluded that "a well with a sloped bottom" is excellent in quality and performance.

(8) Improvements (8) (Development of a square well with few blind spots)

Appellee does not admit that the "square well" has "less blind spots under a microscope".

(9) Improvements (9) (Development of a curved well to reduce blind spots)

Appellee does not admit that the plate of Plaintiff's product had a blind spot in the field of view and that the oocytes were often lost.

(10) Improvements (10) (Development of a well with a spherical bottom)

Appellant alleges that osmotic pressure cannot be affected by whether the bottom shape of a well is "round bottom," "spherical bottom" or "curved."

(11) Improvements (11) (Change in shape of the tip of the vitrified container sheet)

Appellee has not proved Improvement point (11).

(12) Improvements (12) (Change in handle of vitrified container)

Plaintiff's and Defendant's cryopreserving vitrification straw shaped containers are almost the same overall length. Thus, if the length of the handle is longer, the cap part becomes shorter, and the

easier it may come off. It will increase the risk of the container being damaged. In addition, at medical facilities where patient information is affixed with stickers as barcodes, such a function of handwriting is not an advantage of quality and performance.

(13) Improvements (13) (Improvement of transparency of the handle part of the vitrified container)

Even if the transparency of the handle is improved, it is difficult to understand when writing patient information by hand or attaching a sticker. When liquid nitrogen is put into, it becomes difficult to see, so it cannot be excellent in quality and performance.

(14) Improvements (14) (Optimization of tip sheet width and thickness)

There is no comparative data that can be used as a basis for optimization for changes in "tip sheet width and thickness". If the width of the tip sheet is widened, the amount of liquid nitrogen brought into the melt increases and the generation of bubbles is not suppressed, so that the quality and performance are not excellent.

(15) Improvements (15) (Improvement of a cover cap)

Since the cover cap of Plaintiff's product is long, the cover cap can be safely taken out above the media surface while the sample is placed in liquid nitrogen, it is easy to do so. On the other hand, since the cover cap of Defendant's product is short, it is difficult to handle because it is necessary to be operated with tweezers in liquid nitrogen. Thus, a short cover cap does not mean that it is superior in quality and performance.

(16) Improvements (16) (three-dimensional engraving)

Plaintiff's product has a one-sided logo engraved in three dimensions from the beginning of sale, and the front and back can be distinguished by touch. In addition, the patient information cannot be written by hand, and a sticker is easily peeled off when it is attached, thus three-dimensional engraving does not mean that it is superior in quality and performance.

(17) Improvements (17) (Simplification of equilibrium processing process)

An oocyte is physically damaged by a sudden change in osmotic pressure, it is necessary to raise the osmotic pressure slowly. The simplified protocol with Defendant's products increase the risk of damaging an oocyte due to rapid osmolality changes.

(18) Improvements (18) (Development of vitrification method using natural levitation)

The method of waiting for "spontaneous ascent due to the difference in the specific gravity of the solution" increases the time that an oocyte is exposed to the chemical substance which is a vitrify-protecting substance, compared with Plaintiff's method of mixing the solution. Such method of waiting for spontaneous ascent increases the risk of damaging an oocyte, and it does not mean it is superior in quality and performance.

(b) Since the above allegations regarding improvements are behind time allegations, and they should be dismissed under Paragraph 1, Article 157 of the Civil Procedure Code.

(E) Paragraph 2, Article 5 of the Law is a stipulated provision that, regardless of Appellant's sales and the existence of profit, if Appellee has a profit due to unfair competition, the amount of the profit is presumed as Appellant's damages. The correlation between the increase in sales of Defendant's products and the decrease in sales of Plaintiff's products is not a requirement.

C. Presumption of Paragraph 2, Article 5 of the Law

Appellee alleges that the presumption based on Paragraph 2, Article 5 of the Law is not overturned according to following reasons.

(A) Existence of alternatives and absence of competing products

a. Appellant has patent rights for "oocytes vitrifying storage equipment", "oocytes vitrifying equipment and ordinary parts holding equipment". (Appellant’s Exhibit 9 and 10) Since Appellant has never licensed these patent rights to anyone other than Appellee, only Appellant and Appellee has manufactured and sold their products for which the above patented inventions have been implemented.

b. According to Mr. Keishi Mano's witness at this court, it is clear that the market is divided by Plaintiff's and Defendant's products.

c. Rebutting Appellee's allegations

Cryotip is manufactured and sold by Appellant, and the sales is a part of Appellant's sales. Appellee's Exhibit No. 84-2, and 3 are "free sample products" and just indicate that "1 piece" has been imported. Thus, these evidences do not prove that Japanese medical facilities can place orders or receive them as business use. Thus, Cryoleaf has not proved having been sold in Japan, nor around the world. Neither, Appellee has not proved sales of Cryolock, or Cryo Bio System in Japan or around the world with evidence.

(B) Appellees allege that Plaintiff's products have different selling prices depending on a country or a region. It is commonly experienced that products famous overseas brands products are priced more expensive in Japan than the selling prices at there origins.

(C) Defendant alleges that it does not sell Defendant's products in many major European countries, the United States, China, Oceania and Brazil. However, Appellee's list of sales agents and support centers shows it has them in many countries all over the world such as European countries, the United States, China, and South American countries. (Appellant's Exhibits No. 20-3, -4, No. 35-3, -4, No. 131-1, -2, No.132-1, -2, No. 133-1 to 3, No. 134, 1 to 3, No.135-1 to 3, No. 136, 1-3, No. 137).

In addition, Defendant's website states as follows. "In 2012, we finally succeeded in developing an epoch-making vitrifying method that survives 100% after thawing." "We named this epoch-making vitrifying method "The Cryotech Method." … Together with our partners in 26 countries around the world, we have started worldwide supply." (Appellant's Exhibit No. 11) As shown the above, Appellee has declared on its website that it started to supply its products over the world.

(Appellee’s allegations)

A. Absence of the premise facts of Paragraph 2, Article 5 of The Law (Appellee receives a certain amount of profit from Defendant's advertisements)

(A) Questionnaire results, etc.

a. Appellee conducted a couple of questionnaires to domestic and overseas customers (fertility treatment facilities) from June to July and November 2020 (hereinafter referred to as "Questionnaire held in June," that was conducted from June to July of the same year, and "Questionnaire held in November" that was conducted in November of the same year. "Questionnaire held in June" and "Questionnaire held in November" are collectively called as "the Questionnaires." The result of the Questionnaire shows no customer purchased Defendant’s products after looking at Defendant's advertisements (Appellee’s Exhibit No. 75-1 to 3, No.114 to 120).

b. Appellee's customer, "Komachi Ladies Clinic," states, "The protocol is certainly simpler than before, and the confirmation of equilibrium completion by the floating stop type is leveled that does not rely solely on an embryologist observing power. I felt this point was a benefit to our clinic.” (Appellee’s Exhibit 121). He states that these are the reasons for the purchase, and he does not decide to purchase Defendant's products by looking its advertisement.

As well, "Omiya Ladies Clinic" states, "we used actual products, and implemented sampling test them with our techniques, and decided to adopt them because we thought that they were superior to other companies' products in function and quality than those we had been used until then." Thus, the above is the reason to choose Defendant’s products. On the other hand, it states, "the expression of 100% survival ... is not a motivation for consideration to choose." Thus, it clearly denied that the indication of Defendant’s website etc. is not the reason to choose Defendant products. (Appellee’s Exhibit 122)

The Advanced Fertility Center Cancun states, “The reason for choosing Defendant’s products

were that "all the embryologists who attended the workshop confirmed survival of blastocysts after thawing," and on the other hand, "The indication of 100% survival is not a motivation for choosing Defendant's products." (Appellee's Exhibit 123)

Mumbai Fertility Clinic & IVF Center states, "Simple protocol, high reproducibility, excellent results after vitrifying and thawing" is the reason for choosing Defendant's products, and on the other hand, 100% survival, which is the advertising phrase, is not the reason for choosing. (Appellee's Exhibit 124).

c. Appellee interviewed Sin Yee, an embryologist of AFC, one of the most advanced fertility treatment facilities in Asia through web conference system (Appellee's Exhibit 125, 126). Sin Yee clearly states that he chose Cryotech method because of the superior results compared to other companies' products.

d. As mentioned above, the embryologists who actually uses Defendant's products does not decide to purchase them without trying the assisted reproductive technology instruments or medias, which are related to the safety of patient's life or body. After trying to use it at Appellee's workshop, etc., they chose and purchase them after confirming their quality and performance. Even if there may be misrepresentative indications of quality in Defendant's advertisements, they do not cause Appellee's profit.

(B) Defendant's products' superiority in quality to Plaintiff's.

a. Cryotech method has the following 18 changes to the prior Cryotop method. The method is an improved technique of cryopreservation, which has improved survival rate when its protocol is strictly observed. It has not only improved the performance and quality of products, but also highly devised technique for accurate operation. Thus, no doubt, Defendant's products is superior to Plaintiff's in its quality and performance.

(1) Appellee has optimized HPC concentration.

(2) Appellee has removed sucrose from the solution and replaced with trehalose, which is safe for cells due to concerns about endotoxin toxicity.

(3) Appellee has reduced the concentrations of ethylene glycol and DMSO, which are vitrify-protective substances, thus improved to reduce chemical and physical toxicity from these substances.

(4) Appellee has introduced static grooves, which makes a vitrified container to stand still on the plate, and makes easy and accurate oocyte loading with the same focus. (Appellant has also introduce static grooves since 2019.)

(5) Appellee has added disposal grooves to the plate to discard the Pasteur cleaning solution.

(6) Appellee has developed a dedicated culture plate and engraved an indicator on it. This made it possible to measure the amount of solution in the Pasteur accurately.

(7) Appellee has developed a dedicated well built-in the integrated plate (a well with a sloped bottom). This made it possible to introduce thaw solution accurately into a vitrified container.

(8) Appellee has developed a square well with few blind spots under a microscope that makes it easy to find oocytes after thawing.

(9) Appellant's plate has blind spots in the field of view; thus, oocytes were often lost on it. Thus, Appellee has developed a curved well that significantly reduces the blind spot in the field of view of the plate.

(10) Appellee has developed a well with a spherical bottom that can reduce the osmotic pressure from thawing media to diluting media, and from diluting media to washing solution. The round bottom well became optimal for slow osmotic decompression after the above improvement.

(11) Appellant's tip of the vitrified container sheet is rectangular, Appellee changed its shape to a triangular acute angle so that the tip of the vitrified container sheet could be easily inserted into the cap. At the same time, by making the acute angle an isosceles triangle, it could possible to distinguish the front and back (the side on which an oocyte is placed when thawed). (Since around 2017,

Appellant started to adopt the same vitrified container sheet with Plaintiff's products.)

(12) Appellee changed its products with the handle of the vitrified container longer and wider, made it easy to hold with and operate with, further made it easy to write patient information on it.

(13) Appellee increased the transparency of the handle part of the vitrified container and make it clearer, made it easy to find scratches or stains, and improved the container to be cleaner and more beautiful.

(14) Appellee optimized the width and thickness of the tip sheet in order to suppress the generation of air bubbles during thawing, and to eliminate the loss of oocytes and the damage caused by long-term exposure.

(15) Appellee improved the cover cap shorter in order to make it easy to operate with.

(16) Appellee engraved three-dimensionally to make it possible to distinguish the front and back of the container sheet not only visually but also tactilely.

(17) Plaintiff's products have three steps at equilibration process for an oocyte in equilibrium solution, Appellee simplified the steps to only one step in equilibration process with Defendant's products

(18) Appellee developed a vitrification method using spontaneous ascent due to the difference in the specific gravity of the solution, and established a simple and accurate equilibrium method. This made it possible to operate no relation to embryologist's technique.

b. Defendant' products are clearly superior to Plaintiff's according to the questionnaires alleged above (A) Questionnaire results, the written statements prepared by Appellee's customers, and the interview with Sin Yee.

c. On November 27, 2020, in the presence of Appellee's attorney, we asked a veteran embryologist to conduct an experiment to compare the survival rates with Plaintiff's product and Defendant's product using 50 pig oocytes each. 48 out of 50 survived and the survival rate was 96%

with Plaintiff's products, 50 out of 50 survived and the survival rate was 100% and with Defendant's products. (Appellee's Exhibit 127, 128) This experimental result also confirms that Defendant's products are superior to Plaintiff's.

d. Appellant alleges that Research Report 1 states that there is "no significant difference" in survival. The report confirmed Appellee's allegations, stating that "it is believed to have cumulatively increased the higher survival and incidence of oocytes when vitrified using Cryotech system."

(C) Appellant's sales and profits have not decreased.

There is no correlation between the increase in sales of Defendant's products and the decrease in sales of Plaintiff's products. Appellant's Exhibit No. 118 shows that the sales of Plaintiff's products ranged from 1,021,615,722 yen, 1,034.844,412 yen, and 1,163,686,938 yen in Japan for the three years from March 1, 2017 to March 31, 2020.

The sales in India ranged from 74,899,000 yen to 92,691,800 yen, and 15,681,700 yen. The sales ranged from 62,500,0300 yen to 73,643,500 yen, and 92,315,400 yen In Russia. In all countries Appellee's sales are steadily increasing. Therefore, it is clear that Appellant has not suffered any damages due to the present indications in Defendant advertisings.

Appellant's Exhibit No. 118 is not credible because there is suspicion that Appellee may have tried to show a relatively larger proportion of Japan by making sales outside Japan lower as alleged below. For example, Appellee asked its local distributors in India and Russia. Appellant's share was 54% in India (Appellee's Exhibit 131), and its share was 60% in Russia. (Appellee's Exhibit 132) Appellant's sales are estimated 578.34 million yen in India, and 433.303,280 yen in Russia by calculating the above Appellant's share in each county with the estimated total sales in India and Russia. The sales amount in India in Appellant's Exhibit118 was 74,849,000 yen (from April 1, 2017 to March 31, 2018), and the sales amount in Russia was 6.250.300 yen (from April 1, 2017 March 21, 2018). These figures are significantly lower than estimated sales derived from the above calculation.

B. Overturn of the presumption of Paragraph 2, Article 5 of the Law

Even if the provision of Paragraph 2, Article 5 of the Law may applied, the Appellee's profit is the result of a combination of various factors, and the presumption of the provision shall be overturned by following reasons.

(A) There is no substitutability

As alleged in A. above, Appellee's customers decide to purchase Defendant's products after they realizes that the quality and performance of Defendant's products are excellent through actually using them at Appellee's workshop, etc. In this meaning, there is no substitutability between Defendant's products and Plaintiff's.

(B) The ratio of Appellee's profit amount derived from Defendant's advertisement to the total amount of its profit is zero or unknown.

Considering the following reasons, the ratio of Appellee's profit amount derived from Defendant's advertisement to the total amount of Appellee's profit is zero or unknown. In such a case, the provision of Paragraph 2, Article 5 of the Law cannot be applied for estimating the amount of damages, so the provision does not apply in this case.

a. Motivation to purchase Defendant's products

Consumers of Defendant's products are limited to medical personnel or academic researchers, and Appellee does not sell its products to general consumers. Fertility treatment facilities purchased its products after confirming the excellent functions and performance of cryopreservation products such as oocytes. Appellee's customers decided to buy them after experienced its quality and performance. And Defendant's representative's high reputation in the industry also contributes to its sales. Therefore, the present indications does not contribute to the increase of profit or sales of Defendant's products.

b. Quality and performance of Defendant's products

As mentioned above, the quality and performance of Defendant's products are superior to

Plaintiff's or other companies', and as a result, the sales of Defendant's products have been increasing. The present indications do not contribute to the increase of profit or sales of Defendant's products.

c. Existence of competing products

Defendant's products and Plaintiff's include, for example, Cryotip (Appellee's Exhibit No. 80-1 and 2, No. 81-1 to 6, No. 82), Cryoleaf (Appellee's Exhibit No. 83-85 [including branch numbers]), Cryolock (Appellee's Exhibit No. 86, 87 [including branch numbers]), Cryo Bio System (Appellee's Exhibit No. 88-1 and 2), Vita Vitro Biotech products (Appellee's Exhibit No. 94-1 and 2), ARSCI products (Appellee's Exhibit No. 95-1 and 2),Fujifilm products (Appellee's Exhibit No.91, No. 101-1 and 2, 102), Cooper Surgical's products (Appellee's Exhibit No. 92, No. 100-1and 2). There are many competing products such as these, and these competing products can also be purchased in Japan (Appellee's Exhibit 90, 103-105).

d. Problems in Plaintiff's products and its sales behaviors

If there are cases in which a customer switched to use Plaintiff's products to Defendant's, it is due to the problems in Plaintiff's products and its sales behaviors, and not relevant to the present indications in Defendant's advertisements. There are various complaints against Plaintiff and its products (Appellee's Exhibit 77). These shows Appellant's customer behaviors seem to be poor, and as a result, Appellant has just lost its business opportunities.

e. Pricing of Plaintiff's products

The selling price of Plaintiff's products vary significantly from a country or a region to another one (Appellee's Exhibit 78). Consumer purchases Defendant's products, which have normal prices. The selling prices of Defendant's and Plaintiff's products are different, and thus, they are not in competitive relationship. [stet]

f. Sales decrease of Defendant's products

The sales of Defendant's products have decreased compared to before and after its website

was opened.

(C) Defendant's products are not sold in Europe, the United States, China, Oceania, etc.

Appellees do not sell its products in the United States, Canada, CE areas (major European countries such as Britain, France, Germany, Italy, Spain, and Netherland), China, Australia, New Zealand, nor Brazil. In these countries Defendant's products are not competing with Plaintiff's. Defendant's products and Plaintiff's competes just in Japan, India and Russia. Appellant's Exhibit No. 118 shows, Appellant's sales between April 1, 2017 and July 31, 2020 in Japan, India and Russia is 49%, in the United States, Canada, CE area (major European countries such as Britain, France, Germany, Italy, Spain, and Netherland), China, Australia, New Zealand, etc. is 51%. Thus, 51% of Plaintiff's products do not compete with Defendant's products.

C. Medical Park Yokohama

The questionnaire (Appellee's Exhibit 75-1) shows, no fertility treatment facility has purchased Defendant's products on the reason of having seen Defendant's advertisements. Medical Park Yokohama did not admit that they purchased Defendant's products on the reason of having seen the present indications in Defendant's advertisements. Medical Park Yokohama blog (Appellant's Exhibit No. 95) states, "The developer Dr. Kuwayama, is a very authoritative person and supported as a 'Specialist in the field of vitrification and thawing," "The director of this clinic, Dr. Kikuchi, and Dr. Kuwayama worked together at oocyte vitrification and, ovarian vitrification," "Currently, at our clinic an oocyte does not perish after thawing."

According to these descriptions above Medical Park Yokohama evaluated the authority and reputation of Appellee's representative as an expert, and after the director of Medical Park Yokohama himself and its embryologists actually used Defendant's products and evaluated its good results they purchased them. Thus, Medical Park Yokohama has not switched to Defendant's products according to seeing the present indications in its advertisements.

III. The Court's Judgment

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 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 3,15-1 to 2, 18, 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), 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 thawing 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 verification 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 strictly observed 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%, 54% 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. (To whom did Defendant's advertisement target?)

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. (What is the meaning of the present indications?)

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

As described in 2-2 above, Defendant's website 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 website 1is recognized 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) observing with the protocol of the Cryotech method.

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

As described in II. 2 above, Defendant Website 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 Website 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 II. 2 above, Defendant's Catalog has the present description 11 to 14 and those recognized in above (A).

The Court concludes medical personnel who views the above description 11 to 14 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 be recognized 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 work 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 is not recognized 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) (Can Defendant's products achieve100% survival rate?)

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 was 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-Oceania Society of 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 Malaysia 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:

"(2) Thawing: Insert the Cryotec with the vitrified oocyte/embryo on the sheet into the thawing solution 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 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. 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 in the thawing process by confirming the recovery of the blastocoele which had shrunk while exposed to the vitrification solution in the freezing process. The judgment 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 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. Y's statement (who participated to Cryotech technical workshop and got certified achieved 100% survival of oocytes after thawing) (Appellant's Exhibit 81-1) (both parties admitted), when a 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 participated its technical workshop, and achieved 100% survival rate and so certified there by itself.

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 II. 2 above, the Court finds Defendant's products and Plaintiff's products 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 (Are there Appellee's willful misconduct 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 (How much is Appellant's damages to be compensated?)

(1) Presumption based on Paragraph 2, Article 5 of the Unfair Competition Prevention Law, and Cancellation of Presumption

Paragraph 2, Article 5 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 Paragraph 2, Article 5 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, in order to

prove that the number of babies born with Defendant's products is 28,333 annually during the above period, that the sales price of a set of its products necessary for a baby is 7,733 yen, and, that 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 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) Overturn 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 activities is small.

Even 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.

Appellant’s sales may have increased further, if Appelee 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, one step for the equilibrium treatment (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, in Japan most of the present products are Plaintiff's or Defendant's, and other products are negligible if any. Thus, it cannot cancel the presumption under Paragraph 2, Article 5 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 Paragraph 2, Article 5 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 Paragraph 2, Article 5 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 is not presumed as Appellant's damages. In short, Appellee's profits calculated in (2) above did not include 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 Paragraph 2, Article 5 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). Even 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 Paragraph 2, Article 5 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.

Although the survival rate is an important factor in making a choice for users, the Court finds that 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 it would be upgraded vitrification media quoting 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 = 613,477,448 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 overturned rate for the presumption under Paragraph 2, Article 5 of the Law in this case should be 95%. 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 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 up, of which 17,070,858 yen with late payment charge at 3% per year from November 11, 2020, to the day when would be paid up.

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 observing 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進出を諦めたり、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きたのだから、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。

昨年の進水式から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

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高額生殖の患者達の手により、意に反して無責任に高値で世界へ転売されて行った。

世界初の凍結技術をさらに研究、改良を続け 2013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、間違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、また未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、間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。

リプロライフ
〒160-0022 東京都新宿区新宿7-5-3 AMビル 9F

別紙2

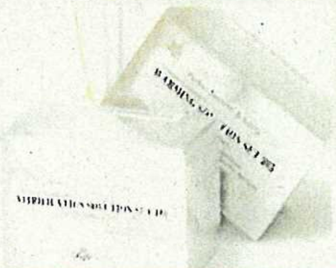
甲第28号証

REPROLIFE
子供をさずかることの喜びを、よりおおくの女性へ

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

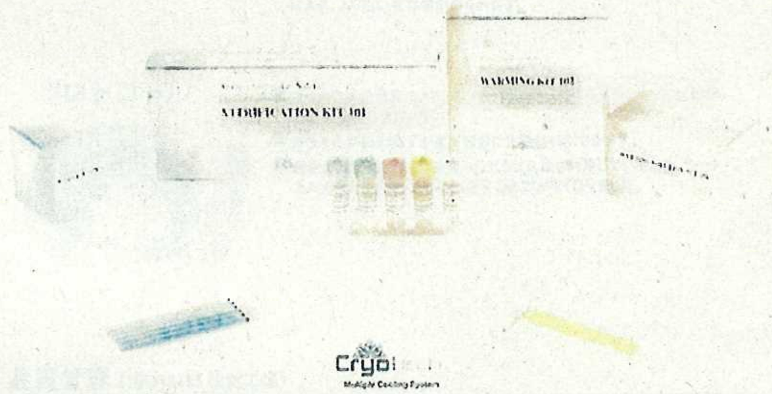


文字サイズ 小 中 大 お問い合わせ

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



News & Topix | トピックス一覧へ

最近の投稿

2018年5月8日 [illegible]センター OPEN

2018年4月24日 新人歓迎会

2018年4月3日 入社式

2018年3月29日 お花見会

2018年3月13日 第14回ART生殖補助コースにてクライオテック法の実技研修実施

2018年1月16日 第7回日本臨床エンブリオロジスト学会

2017年12月19日 2017大忘年会！！

④

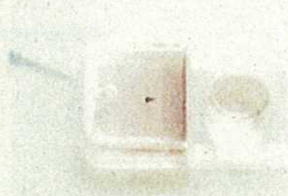
クライオテック法はどのステージの卵子・胚でも安全に凍結融解でき、融解後の生存率100%と臨床成績の向上が期待できる最新のガラス化法です。2012年から世界供給を開始し、すでに42カ国で10万症例の、従来法をはるかに上回る臨床実績があります。凍結保存の目的は「命ある大切な卵子や胚を、傷めることなく危険に晒すことなく、その日まで安全、安心にとりおくこと」だと私たちは信じており、これを実現するのがクライオテック法なのです。

奇跡を生んだ、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

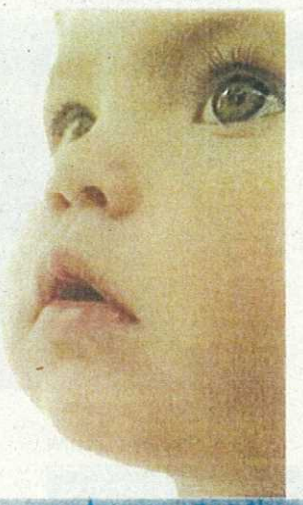
試験成績

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。

12

甲第 13 号証

SUPER VITRIFICATION



(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

[redacted]
COGI 2017 in Vienna, Austria

[redacted]
ISFP hands-on workshop registration

[redacted]
promo movie first played at ASRM 2017

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

[redacted]
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 東京都新宿区新宿2-5-3 AMビル9F

TEL 03-5925-8931

甲第 ~~14~~ 13 号証

Cryotech

About Cryotech Japan | Contact

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

What's Cryotech

(11)

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.

(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.

Dr. Masashige Kuwayama

Dr. Masashige Kuwayama is currently the Head of Repro-support Medical Research Centre, developing and providing the new ARTs including vitrification, HF20 ICSI and Nuclear Transfer. The center has also International Advanced Fertility Preservation Centre. He had been scientific director of Kato Ladies' Clinic (Japan), the world's largest human IVF unit performing >25,000 IVF cycles per year. In the ART laboratory, 13 scientists and 55 embryologists were working to develop new ARTs and for the patients. An editor of RBM Online, he has 98 scientific papers and 230 papers in the scientific conferences.

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.

What's Cryotech INDEX

WELCOME TO "THE 100% SURVIVAL CLUB"!

TOPICS

[illegible] News
COGI 2017 in Vienna, Austria

2017.11.11 [illegible] News
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[illegible] News
promo movie first played at ASRM 2017

2017 [illegible] News
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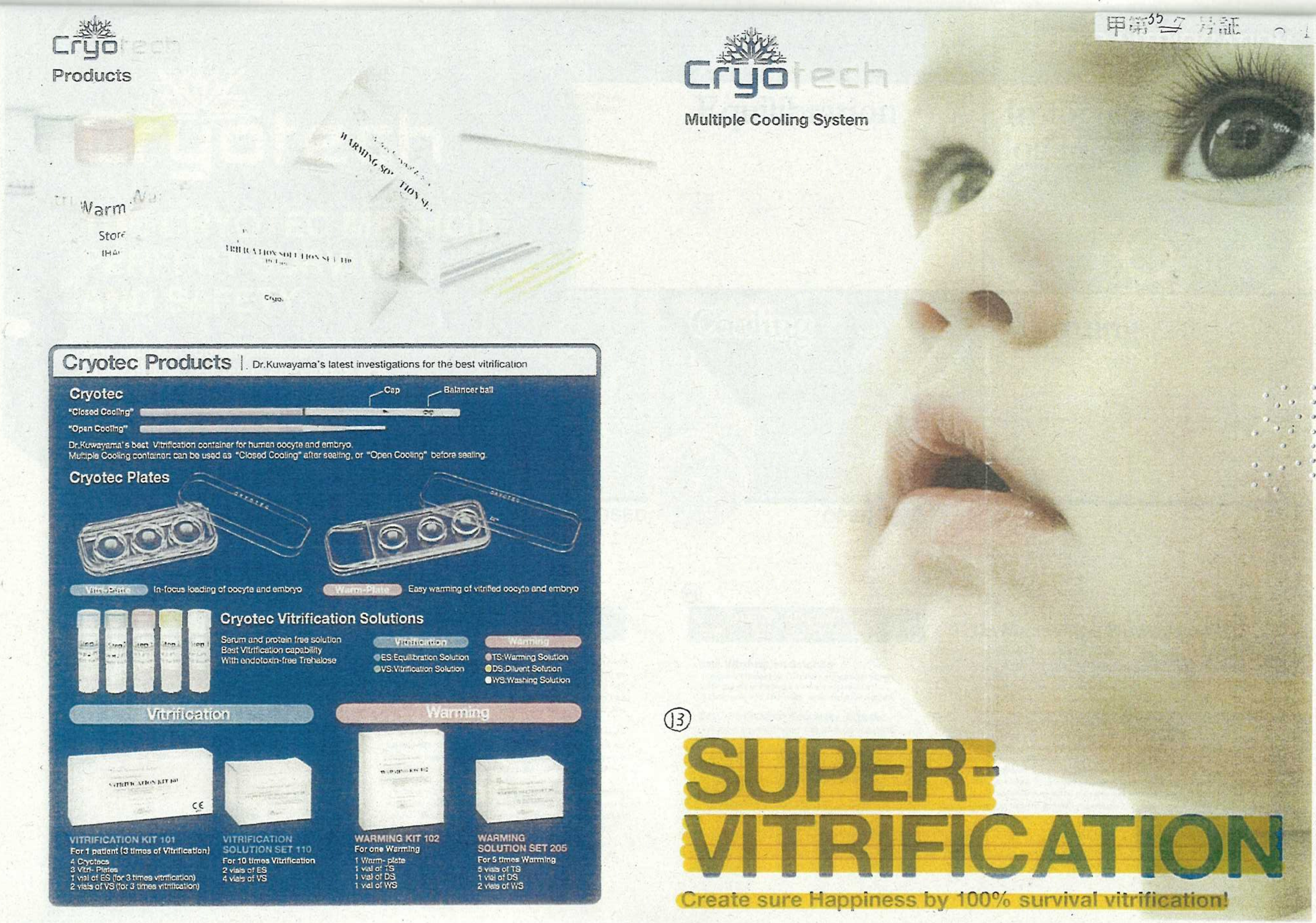
All

SEARCH

別紙5



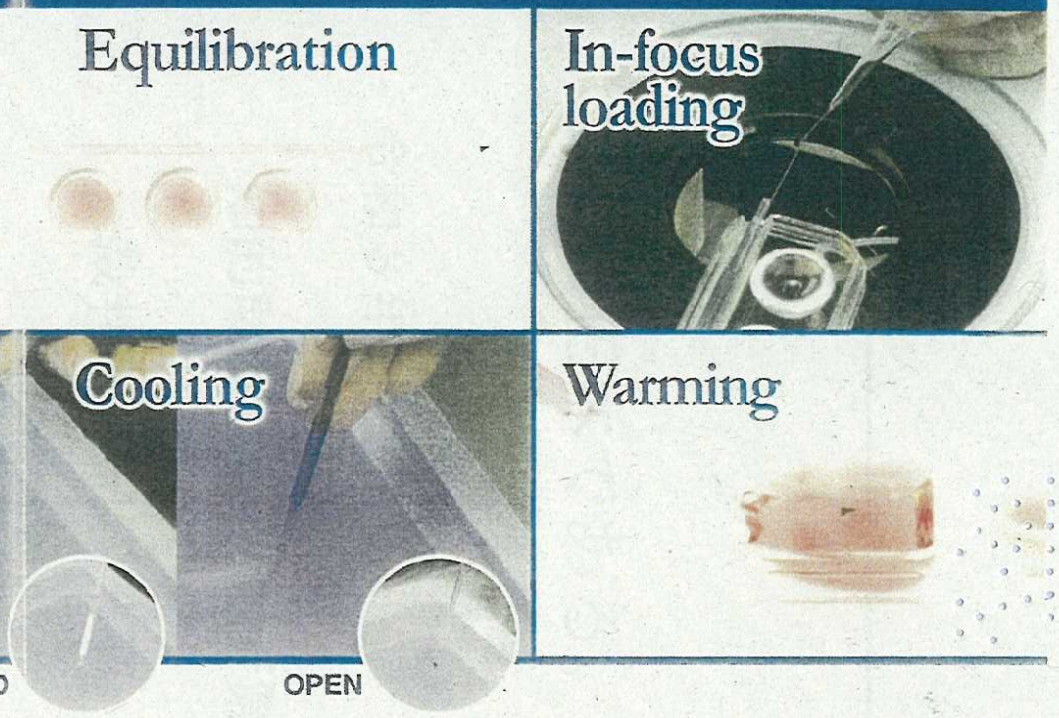
甲第35号証
Cryotech
Products
Cryotech
Multiple Cooling System
Cryotec Products | Dr.Kuwayama's latest investigations for the best vitrification
Cryotec
"Closed Cooling"
"Open Cooling"
Cap
Balancer ball
Dr.Kuwayama's best Vitrification container for human oocyte and embryo.
Multiple Cooling container: can 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
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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(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 devices: Closed or Open cooling
2. Longer and Wider handle and sheet; easy writing and loading 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

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