UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA *Plaintiff*, v. EDWARDS LIFESCIENCES CORP. and GENESIS MEDTECH GROUP LIMITED *Defendants*.	Civil Action No.

[PROPOSED] FINAL JUDGMENT

WHEREAS the United States of America filed its Complaint on July 13, 2026, alleging that Defendant Edwards Lifesciences Corp. ("Edwards") and Defendant Genesis Medtech Group Limited ("Genesis") violated Section 7A of the Clayton Act (15 U.S.C. § 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act"));

AND WHEREAS the United States and Defendants have consented to the entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party regarding any issue of fact or law;

AND WHEREAS the entry of this Final Judgment does not constitute an admission or finding of wrongdoing or liability by any Defendant, and Defendants deny any wrongdoing or violation of law;

NOW, THEREFORE, it is ORDERED, ADJUDGED, AND DECREED:

I. JURISDICTION

The Court has jurisdiction over the subject matter of this action and each of the parties to this action. The Complaint states a claim upon which relief can be granted against Defendants under Section 7A of the Clayton Act, 15 U.S.C. § 18a.

II. DEFINITIONS

A. "Edwards" means Edwards Lifesciences Corp., a corporation organized, existing, and doing business under the laws of the state of Delaware, with its executive offices and principal place of business located at One Edwards Way, Irvine, California 92614, including its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

B. "Genesis" means Genesis Medtech Group Limited, a corporation organized, existing, and doing business under the laws of Singapore, with its executive offices and principal place of business located at 16 Science Park Dr., #04-03 DNV Technology Centre, Singapore 118227, including its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. "Defendants" means Edwards and Genesis, individually and collectively.

D. "Antitrust Laws" means the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 et seq., the Sherman Act, 15 U.S.C. § 1 et seq., the Clayton Act, 15 U.S.C. § 12 et seq., and the Hart-Scott-Rodino Act, 15 U.S.C. § 18a.

E. "AR valve replacement system" means a system for treating aortic regurgitation through the replacement of the aortic valve.

F. "Including" means including, but not limited to.

G. "TAVR-AR device" means a transcatheter aortic valve replacement device for the treatment of aortic regurgitation as described in the Memorandum Opinion Granting Plaintiff's Petition for a Preliminary Injunction issued by the District Court for the District of Columbia in *Federal Trade Commission v. Edwards Lifesciences Corp, et al.*, Civil Action No. 25-2569 (Jan. 9, 2026), 2026 U.S. Dist. LEXIS 19409.

H. "TAVR-AR valve replacement system" means a transcatheter system for treating aortic regurgitation through the replacement of the aortic valve.

III. APPLICABILITY

This Final Judgment applies to Defendants, as defined above, and all other persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise.

IV. CIVIL PENALTY

A. Judgment is hereby entered in this matter in favor of the United States and against Defendant Edwards, and, pursuant to Section 7A(g)(1) of the Clayton Act, 15 U.S.C. § 18a(g)(1), the Debt Collection Improvement Act of 1996, Pub. L. 104-134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461), the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114-74 § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 90 Fed. Reg. 5580 (January 17, 2025). Defendant Edwards is hereby ordered to pay a civil penalty in the amount of ten million dollars ($10,000,000). Payment of the civil penalty ordered hereby must be made by wire transfer of funds. Prior to making the wire transfer, Defendant Edwards will contact ATR.CivilJudgment@atr.usdoj.gov for instructions.

B. Judgment is hereby entered in this matter in favor of the United States and against Defendant Genesis, and, pursuant to Section 7A(g)(1) of the Clayton Act, 15 U.S.C. § 18a(g)(1), the Debt Collection Improvement Act of 1996, Pub. L. 104134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461), the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. 114-74 § 701 (further amending the Federal Civil Penalties Inflation Adjustment Act of 1990), and Federal Trade Commission Rule 1.98, 16 C.F.R. § 1.98, 90 Fed. Reg. 5580 (January 17, 2025). Defendant Genesis is hereby ordered to pay a civil penalty in the amount of two million dollars ($2,000,000). Payment of the civil penalty ordered hereby must be made by wire transfer of funds. Prior to making the wire transfer, Defendant Genesis will contact ATR.CivilJudgment@atr.usdoj.gov for instructions.

C. Each Defendant must pay the full amount of its civil penalty within thirty (30) days of entry of this Final Judgment. In the event of a default or delay in payment, interest at the rate of eighteen percent (18%) per annum will accrue thereon from the date of the default or delay to the date of payment.

V. COSTS

Each party will bear its own costs of this action, except as otherwise provided in Paragraph IX.C.

VI. PRIOR NOTIFICATION

A. Prior to the expiration of the Final Judgment, Defendant Edwards shall not, without providing advance written notification to the Federal Trade Commission

("Notification"), acquire, directly or indirectly, through subsidiaries or otherwise, any ownership interest, in whole or in part, in any firm that commercially sells a TAVR-AR device in the United States, is engaged in clinical trials in the United States for a TAVR-AR device, or has received an Investigational Device Exemption from the U.S. Food and Drug Administration to conduct clinical trials on a TAVR-AR device in the United States. *Provided however,* that prior written Notification to the Federal Trade Commission under this provision shall not be required for an acquisition of any ownership in a firm that produces only (a) component parts of an AR valve replacement system or (b) devices that are not a TAVR-AR valve replacement system.

B. The Notification required by Paragraph VI(A) shall be provided on the Notification and Report Form (the "Form") set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended, and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification; Notification shall be filed with the Secretary of the Federal Trade Commission ("Commission"); Notification need not be made to the United States Department of Justice; and Notification is required only of Defendant Edwards and not of any other party to the transaction.

C. Defendant Edwards shall provide the Notification required under Paragraph VI(A) to the Commission at least thirty (30) days prior to consummating the transaction (hereinafter referred to as the "First Waiting Period"). Further, if, within the First Waiting Period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Defendant Edwards shall not consummate the transaction until 30 days after submitting such additional information or documentary material. Early termination of the waiting periods in this Section VI may be requested and, where appropriate, granted by letter from the Bureau of Competition. *Provided, however*, that prior written Notification shall not be required by this Section VI for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

VII. COMPLIANCE

A. Defendant Edwards shall design, maintain, and operate an antitrust compliance program to ensure compliance with this Final Judgment and the Antitrust Laws, and as part of such program shall:

1. within thirty (30) days of entry of the Stipulation and Order, Defendant Edwards must designate an internal antitrust compliance officer ("Antitrust Compliance Officer"), to supervise the design, maintenance, and operation of the program, and shall authorize the Antitrust Compliance Officer to perform all tasks necessary to fulfill these obligations. Defendant Edwards may replace the Antitrust Compliance Officer with another qualified person at any time;
2. within forty-five (45) days of signing the Stipulation, distribute a copy of this Final Judgment to each current officer and director, and each employee, agent, or other person who has responsibility or authority over business development, strategic planning, or mergers and acquisitions;
3. distribute a copy of this Final Judgment to any person who takes a position described in Paragraph VII(A)(2) within thirty (30) days of the date the person takes such position;

4. provide in-person or online training concerning Defendant Edwards' obligations under this Final Judgment and the Antitrust Laws as they apply to Defendant Edwards' activities, to each person designated in Paragraphs VII(A)(2) or (3):
    a. no later than forty-five (45) days after signing the Stipulation is entered;
    b. no later than thirty (30) days after a person first takes a position described in Paragraph VII(A)(2); and
    c. at least annually.

    Provided, however, that as to any person on extended leave (*e.g.*, parental, family, or disability leave), the training for such person under the above schedule shall be completed within thirty (30) days of the date the person returns to work; and
5. obtain within sixty (60) days from signing the Stipulation, and annually thereafter, and retain for the duration of this Final Judgment, a written certification from each person designated in Paragraphs VII(A)(2) & (3) that the person: (a) has received, read, understands, and agrees to abide by the terms of this Final Judgment; (b) understands that failure to comply with this Final Judgment may result in conviction for criminal contempt of court; and (c) is not aware of any violation of the Final Judgment.

B. Within sixty (60) days of signing the Stipulation, Defendant Edwards shall certify to Plaintiff that it has (1) designed, established, and is maintaining an antitrust compliance program; (2) designated an Antitrust Compliance Officer, specifying their name, business address, and telephone number; (3) distributed this Final Judgment as required in Paragraph VII(A)(2); and (4) provided training as required in Paragraph VII(A)(4).

C. For the term of this Final Judgment, on or before its anniversary date, Defendant Edwards shall file with Plaintiff an annual statement verifying that it is complying with the requirements of this Final Judgment and describing in detail the manner of its compliance with the provisions of Sections VI and VII.

D. If any of Defendant Edwards' directors or officers, or the Antitrust Compliance Officer, learns of any violation of this Final Judgment, Defendant Edwards shall within three (3) business days take appropriate action to assure continued compliance with this Final Judgment, and shall notify the Plaintiff in writing of the violation within ten (10) business days of learning of the violation.

VIII. COMPLIANCE INSPECTION

A. For the purposes of determining or securing compliance with this Final Judgment or of related orders such as the Stipulation and Order, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time authorized representatives of the United States, including agents and consultants retained by the United States, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to Defendant Edwards, be permitted:

1. access during Defendant Edwards' business hours to inspect and copy, or at the option of the United States, to require Defendant Edwards to provide electronic copies of all books, ledgers, accounts, records, data, and documents, wherever located, in the possession, custody, or control of Defendant Edwards, relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendant Edwards' officers, employees, or agents, wherever located, who may have their individual counsel present, regarding any matters contained in this Final Judgment. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendant Edwards.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendant Edwards shall submit written reports or responses to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained pursuant to any provision of this Final Judgment may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party, including grand jury proceedings, for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. In the event of a request by a third party, pursuant to the Freedom of Information Act, 5 U.S.C. § 552, for disclosure of information obtained pursuant to any provision of this Final Judgment, the United States will act in accordance with that statute and the Department of Justice regulations at 28 C.F.R. part 16, including the provision on confidential commercial information at 28 C.F.R. § 16.7. If submitting information to the United States, Defendant should designate the confidential commercial information portions of all applicable documents and information under 28 C.F.R. § 16.7. Designations of confidentiality expire 10 years after submission, "unless the submitter requests and provides justification for a longer designation period." See 28 C.F.R. § 16.7(b).

E. If at the time that Defendant Edwards furnishes information or documents to the United States pursuant to any provision of this Final Judgment, Defendant Edwards represents and identifies in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendant Edwards marks each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure," the United States must give Defendant Edwards 10 calendar days' notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

IX. ENFORCEMENT OF FINAL JUDGMENT

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendants agree that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of any remedy therefore by a preponderance of the evidence, and Defendants waive any argument that a different standard of proof should apply.

B. The Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws, including Section 7A of the Clayton Act and Regulations promulgated thereunder. Each Defendant agrees that it may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In any enforcement proceeding in which the Court finds that a Defendant has violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment as to that Defendant, together with such other relief as may be appropriate. In connection with any successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved prior to litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as any other costs including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

D. For a period of four (4) years after the expiration of this Final Judgment pursuant to Section XI, if the United States has evidence that a Defendant violated this Final Judgment before it expired, the United States may file an action against that Defendant in this Court requesting that the Court order (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four years following the filing of the enforcement action under this Section IX, (2) any appropriate contempt remedies, (3) any additional relief needed to ensure Defendant complies with the terms of the Final Judgment, and (4) fees or expenses as called for in Paragraph IX(C).

X. RETENTION OF JURISDICTION

This Court retains jurisdiction to enable any of the parties to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XI. EXPIRATION OF FINAL JUDGMENT

Unless this Court grants an extension, this Final Judgment shall expire, as to Defendant Edwards, five (5) years from the date of its entry if Defendant Edwards has paid the civil penalty in full. Unless this Court grants an extension, this Final Judgment shall expire as to Defendant Genesis upon payment of the civil penalty in full.

XII. RESERVATION OF RIGHTS

This Final Judgment terminates only the claims stated in the Complaint against Defendants and does not affect other charges or claims the United States may file.

XIII. PUBLIC INTEREST DETERMINATION

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' response to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Dated: ________________

[Court approval subject to the procedures of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16]

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United States District Judge