

## SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the Defense Health Agency (DHA), acting on behalf of the TRICARE Program, through its General Counsel; and the United States Department of Veterans' Affairs ("VA") (collectively the "United States"); Acclarent, Inc. ("Acclarent"); and Melayna Lokosky ("Relator") through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

### RECITALS

A. Acclarent was a Delaware corporation headquartered in Menlo Park, California. In January 2010, Acclarent was acquired by Ethicon, Inc. ("Ethicon") a wholly-owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. At all relevant times herein, Acclarent developed, manufactured, distributed, marketed, and sold medical devices in the United States, including a device under the trade name Relieva Stratus MicroFlow Spacer® ("Stratus"). At all relevant times, the Stratus was cleared by the U.S. Food and Drug Administration (FDA) only for use as a postoperative spacer to maintain an opening to the nasal sinuses within the first 14-28 days following surgery. At no time was the Stratus cleared or approved by the FDA for use as a drug-delivery device or for use with prescription steroids.

B. On July 8, 2011, Melayna Lokosky filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Lokosky v. Acclarent, Inc., et al.* Civ. No. 11-CV-11217-WGY, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action").

C. The United States alleges that Acclarent caused claims for payment for the Stratus to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C §§ 1395-1395kkk-1 ("Medicare"), and to the TRICARE program, 10 U.S.C. §§ 1071-1110b ("TRICARE"), and caused purchases by the VA, 38 U.S.C. §§ 1701- 1743.

D. The United States alleges that it has certain civil claims against Acclarent relating to the following alleged conduct (hereinafter referred to as the "Covered Conduct"):

The United States alleges that Acclarent, prior to its acquisition by Ethicon, designed and engineered the Stratus as a drug delivery device to deliver Kenalog-40, a prescription corticosteroid, to the paranasal sinuses. Kenalog-40 is indicated for use only as an injectable therapy and not for use in the paranasal sinuses or for topical delivery through a sinus spacer. Certain adverse events have been associated with the periocular use of Kenalog 40, such as in the ethmoid sinus.

In an August 2006 regulatory submission, Acclarent represented to the United States Food and Drug Administration ("FDA") that the intended use of the Stratus was as a postoperative spacer to maintain an opening to the ethmoid sinus within the first 14 days following surgery. In connection with the same submission, Acclarent also represented to the FDA that saline could be injected into the Stratus, allowing for moistening. The Stratus had no design specifications to ensure that it would mechanically hold open any particular space, prevent occlusion, or permit drainage. The FDA cleared the Stratus for marketing in September 2006 for use as a spacer; however Acclarent did not intend to market or distribute the Stratus for use as a spacer. In April 2007, Acclarent requested that FDA expand the indications for the Stratus "for use to irrigate the sinus space for diagnostic and therapeutic procedures," but in May 2007, FDA rejected this proposal. Despite the FDA's rejection, beginning in 2008, Acclarent distributed and promoted the Stratus as a drug delivery device at the direction of certain senior managers.

For example, in September 2008, Acclarent's Chief Executive Officer conducted two nationwide conference calls with the Acclarent sales force, during which he discussed marketing the Stratus for drug delivery. Also in September 2008, Acclarent's Chief Executive Officer distributed to a group of physicians on Acclarent's Scientific Advisory Board, as well as to others at Acclarent, a set of presentation slides positioning the Stratus as "simply a way to obtain sustained drug delivery to a targeted sinus or sinus complex. . . ." As part of the effort to distribute the Stratus for the purpose of eluting a steroid, Acclarent employees trained physicians using a video that demonstrated the Stratus being used with Kenalog-40, and also used a white, milky substance resembling Kenalog-40 when demonstrating the Stratus.

In January 2010, Acclarent was acquired and merged into Ethicon. Shortly after the merger, Ethicon instituted a compliance program at Acclarent, which included clear instructions to cease promotion of the Stratus, to report to FDA that the predominant use of the Stratus was for drug-delivery of Kenalog-40, and to add a warning to the Instructions for Use regarding use of active drug substances in the reservoir of the Stratus. Despite the no-promotion directive from Ethicon, certain senior managers at Acclarent directed the sales force to continue promoting the Stratus, including for drug delivery. By May 2013, Ethicon required Acclarent to discontinue all sales of the Stratus, and the company agreed to the withdrawal of all 510(k) clearances for the device.

The United States alleges that as a result of the alleged conduct described above, Acclarent knowingly caused false or fraudulent claims to be submitted to, or caused purchases by, Medicare, TRICARE, and VA at various times during the time period in which the Stratus was commercially distributed, that is, between February 1, 2008 and May 2013.

E. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

F. To settle, compromise, and resolve the claims herein, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. Acclarent shall pay to the United States the sum of \$18,000,000, plus accrued interest at the rate of 2.125% per annum from April 17, 2015, and continuing until and including the day of payment (the "Settlement Amount"). The Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) business days after the Effective Date of this Agreement.

2. Conditioned upon the United States receiving the Settlement Amount from Acclarent and as soon as feasible after receipt, the United States agrees to pay Relator the sum of \$3,510,000, plus a pro rata share of the actual accrued interest paid to the United States by



Acclarent on the amount set forth above in Paragraph 1, above, as Relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d). No other relator payments shall be made by the United States with respect to the matters covered by this Agreement.

3. Acclarent agrees to pay Relator's attorneys' fees and costs, as contemplated by 31 U.S.C. § 3730(d), in accordance with the terms and conditions set forth in a separate agreement entered into between Acclarent and Relator.

4. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon Acclarent's full payment of the Settlement Amount, the United States releases Acclarent, together with its current and former direct and indirect parent corporations and each of their current and former direct and indirect subsidiaries, brother or sister corporations, divisions, and affiliates; and the predecessors, successors, assigns, and transferees of any of them (the "Acclarent Released Parties"), from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual or present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, 0.45(d); or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. OIG-HHS expressly reserves all rights to institute, direct, or maintain any administrative action seeking exclusion against the Acclarent Released Parties or their officers, directors, or employees from Medicare, Medicaid, and all other Federal health care programs (as

defined in 42 U.S.C. § 1320a-7b(f) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

6. Subject to the exceptions in Paragraph 7 below, and conditioned upon Acclarent's full payment of the Settlement Amount, and the amount referred to in Paragraph 3. above, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases the Acclarent Released Parties from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Relator, her heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action; provided, however, that Relator's release of the Acclarent Released Parties does not extend to: (1) any claim by Relator under 31 U.S.C. § 3730(h), or (2) any claims by Relator set forth in *State of California ex rel. Lokosky v. Acclarent, Inc., et al.*, Case No. BC530372 (Cal. Super. Ct. L.A. Cnty.).

7. Notwithstanding the releases given in Paragraphs 4 and 6 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- (a) Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any criminal liability;

- (c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- (e) Any liability based upon obligations created by this Agreement;
- (f) Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- (g) Any liability for failure to deliver goods or services due;
- (h) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- (i) Any liability of individuals.

8. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

9. Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, releases Acclarent, and its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.

10. Acclarent waives and shall not assert any defenses Acclarent may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

11. Acclarent fully and finally releases the United States and its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Acclarent has asserted, could have asserted, or may assert in the future against the United States and its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Acclarent agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

13. Acclarent agrees to the following:

(a) "Unallowable Costs" Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social



Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Acclarent, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Acclarent's investigation, defense, and corrective actions undertaken in response to the United States' audits and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Acclarent makes to the United States pursuant to this Agreement and any payments that Acclarent may make to Relator, including costs and attorneys' fees.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

(b) Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Acclarent, and Acclarent shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Acclarent or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: Acclarent further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or



contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Acclarent or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Acclarent agrees that the United States, at a minimum, shall be entitled to recoup from Acclarent any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Acclarent or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Acclarent or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Acclarent's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. Acclarent agrees to cooperate fully and actively with the United States regarding any matter about which Acclarent has knowledge or information relating to any ongoing investigation, trial, or other proceeding arising out of any ongoing federal investigation

of its current and former officers, agents, and employees on the subject matter discussed in Paragraph D, above. Acclarent's cooperation shall include, but not be limited to, the following:

- (a) Completely and truthfully disclosing all non-privileged information in its possession about which the United States may inquire, including but not limited to all information about activities of Acclarent and present and former officers, directors, employees and agents of Acclarent;
- (b) Providing all non-privileged documents, records, and other evidence in Acclarent's possession, custody, or control as may be requested by the United States;
- (c) Using its reasonable best efforts to make available its present and former officers, directors and employees to provide information and/or testimony as requested by the United States, including testimony before a grand jury, a trial court, other court proceeding, as well as interviews with law enforcement authorities. Cooperation under this Paragraph shall include identification of witnesses who, to Acclarent's knowledge, have material information concerning any criminal prosecution and/or trial, civil trial, or other legal proceedings brought by the United States against any present or former officer, director, or employee of Acclarent;
- (d) Providing testimony or information necessary to identify or establish the original location, authenticity, or other basis for admission into evidence of documents or physical evidence produced by Acclarent in any criminal or other proceeding as requested by the United States; and
- (e) Providing active assistance, including assistance by current counsel (including undersigned counsel) and/or successor counsel, internal or external, in connection with any investigation, criminal prosecution, and/or trial, civil trial, or other legal proceeding

brought by the United States against any present or former officer, director, or employee of Acclarent.

However, notwithstanding any provision of this agreement, Acclarent is not required to: (1) request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its officers, agents, or employees for following their attorney's advice; or (3) waive any claim of privilege or work product protection.

15. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 16 (waiver for beneficiaries paragraph), below.

16. Acclarent agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

17. After payment of the Settlement Amount, the United States and Relator shall file a joint stipulation of dismissal in the Civil Action as follows:

(a) the joint stipulation of dismissal shall be with prejudice as to the United States as to the Covered Conduct and without prejudice to the United States as to all other claims; and

(b) the joint stipulation of dismissal shall be with prejudice as to the Relator as to all claims, except those specifically reserved in paragraph 6 of this Agreement.

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.



19. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

20. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

21. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

22. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

24. This Agreement is binding on Acclarent's successors, transferees, heirs, and assigns.

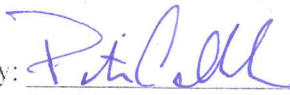
25. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

26. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.


27. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and .pdf versions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

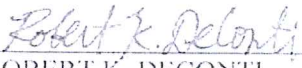
DATED: 3/17/16

By:   
SARA M. BLOOM  
PATRICK M. CALLAHAN  
Assistant U.S. Attorneys  
United States Attorney's Office  
District of Massachusetts

DATED: 3/11/16

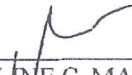
By:   
COLIN M. HUNTLEY  
Senior Trial Counsel  
Commercial Litigation Branch, Civil Division  
United States Department of Justice

DATED: 3/7/16

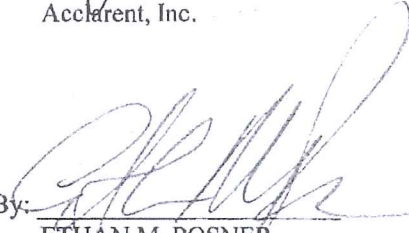
By:   
ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the  
Inspector General  
Office of Inspector General  
United States Department of  
Health and Human Services

ACCLARENT, INC.

DATED: 03/09/16

By:   
CELINE C. MARTIN  
President  
Acclarent, Inc.

DATED: 3/10/16

By:   
ETHAN M. POSNER  
MONA PATEL  
Covington & Burling LLP  
Counsel for Acclarent, Inc.



**RELATOR MELAYNA LOKOSKY**

DATED: 3/4/2016

By: Melayna Lokosky  
MELAYNA LOKOSKY

DATED: \_\_\_\_\_

By: \_\_\_\_\_  
ROYSTON DELANEY  
CHARLES F. KESTER  
ILYAS J. RONA  
Delaney Kester LLP

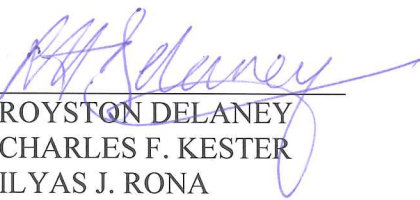
Counsel for Melayna Lokosky

RELATOR MELAYNA LOKOSKY

DATED: \_\_\_\_\_

By: \_\_\_\_\_  
MELAYNA LOKOSKY

DATED: 3/4/16

By:   
ROYSTON DELANEY  
CHARLES F. KESTER  
ILYAS J. RONA  
Delaney Kester LLP

Counsel for Melayna Lokosky