foiapa

From:

Mark Edwards < medwards@biosciadvisors.com>

Sent:

Friday, February 02, 2018 5:58 PM

To:

foiapa

Subject:

**FOIA Request** 

RECEIVED

FEB 05 2018

mic∈nt Lia Service

I would like to request access to Exhibit 10.66 to the Form 8-K, as amended, filed by IsoRay, Inc. on 8/19/2011. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to \$61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397



# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

#### Office of FOIA Services

February 9, 2018

Mr. Mark G. Edwards Bioscience Advisors 2855 Mitchell Dr., Suite 103 Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552

Request No. 18-02317-E

Dear Mr. Edwards:

This letter is in response to your request, dated February 2, 2018 and received in this office on February 5, 2018, for access to Exhibit 10.66 to the Form 8-K, as amended, filed by IsoRay, Inc., on August 19, 2011.

The search for responsive records has resulted in the retrieval of 21 pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed for the processing of this request. If you have any questions, please contact me at <a href="mailto:churchmant@sec.gov">churchmant@sec.gov</a> or 202-551-8330. You may also contact me at <a href="mailto:foiapa@sec.gov">foiapa@sec.gov</a> or (202) 551-7900. You also have the right to seek assistance from Dave Henshall as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Tina Churchman

Tina Churchman FOIA Research Specialist

Enclosure

CONFIDENTIAL TREATMENT

# LICENSE AGREEMENT

THIS AGREEMENT (hereinafter referred to as this Agreement) is made as of this 1<sup>st</sup> day of the month of June, 2011 (Effective Date) by and between

**DR. REDDY'S LABORATORIES (EU) LTD.**, having a place of business at Riverview Road, Beverley, East Yorkshire, HU17 0LD, UK (hereinafter referred to as "LICENSOR" or "Dr. Reddy's" which expression shall unless contrary to the meaning and context thereof mean and include its successors, representatives and permitted assigns) of the One Part.

And

**ISORAY MEDICAL INC.**, having its registered office at 350 Hills St, Suit106, Richland WA 99354, USA, (hereinafter referred to as "LICENSEE" or "IsoRay" which expression shall unless contrary to the meaning and context thereof mean and include its successors, representatives and permitted assigns) of Other Part;

Within this Agreement the LICENSOR and the LICENSEE shall be collectively referred to as the Parties and the term Party shall refer to either of them as the context permits.

#### Recitals

#### WHEREAS

- A) Dr. Reddy's is a pharmaceutical company engaged in the business of manufacture, distribution and sale of pharmaceutical products and has obtained from The Dow Chemical Company by virtue of the acquisition, certain research and development projects involving certain radiopharmaceutical chelating agents and organic compounds for various pharmaceutical applications, including application for use of agents as *in vivo* therapeutic and/or diagnostic agents; and
- B) Dr. Reddy's has obtained proprietary rights in technology relating to said agents, including: patent rights, know-how, health registration files and registration applications and drug master files, and other

industrial property rights from DOW Chemical Company by a deed of Assignment dated May 1, 2008.

- C) IsoRay desires to undertake the further development and commercial exploitation of said agents;
- D) IsoRay desires to obtain an exclusive license in the Licensed Field (defined below) from Dr. Reddy's Technology relating to said agents; and
- E) Dr. Reddy's is willing to grant an exclusive license to IsoRay of the Technology in relation to the Licensed Field.

NOW, THEREFORE, Dr. Reddy's and IsoRay in consideration of the mutual covenants contained herein, agree as follows:

#### **ARTICLE 1 - DEFINITIONS**

When used in this Agreement, the following terms shall have the meanings set out below. The singular shall be interpreted as including the plural and vice versa, unless the context clearly indicates otherwise.

- 1.1 "Affiliate" means a corporation or any other entity that at any time during the term of this Agreement directly or indirectly through one or more intermediaries is Controlled by the designated Party, but only for so long as the relationship exists. A corporation or other entity shall no longer be an Affiliate when through loss, divestment, dilution or other reduction of a Party's ownership, the Party loses Control of such corporation or other entity.
- 1.2 "Approval" means final clearance by the FDA of a Premarket Notification, [510(k)] in the United States, for commercial marketing of Licensed Product including approval of final labeling.
- 1.3 "Calendar Year" means each twelve consecutive month period within the Royalty Term.
- 1.4 "Confidential Information" means any information of either Party regarding Technology, Patents, any samples or financial terms of this Agreement, and business development plans and does not include information excluded under Article 6.3.
- 1.5 "Control" or "Controlled" shall mean in the case of a corporation, ownership or control directly or indirectly, of more than fifty percent (50%) of the shares of stock entitled to vote for the election of

directors and, in the case of an entity other than a corporation, ownership or control, directly or indirectly, of more than 50% of the assets or the ability to direct the management and affairs of such entity.

- 1.6 "Effective Date" shall mean the date set forth above in the preamble of this Agreement.
- 1.7 "FDA" means the United States Food and Drug Administration or any successor U.S. governmental agency performing similar functions.
- 1.8 "Licensed Field" means in the field of any and all forms of brain cancer.
- 1.9 "Net Sales" shall mean the amount invoiced on sales of Licensed Product in the Licensed Field by IsoRay and its Affiliates and sublicensees to a Third Party, less the following deductions to the extent included in the amounts invoiced:
  - (i) trade, cash or quantity discounts actually allowed, granted from the invoiced amount and taken; and
  - (ii) amounts repaid or credited by reason of rejections, defects or returns or because of retroactive price reductions; and
  - (iii) insurance, shipping and handling; and
  - (iv) rebates paid pursuant to government regulations; and
  - (v) taxes or governmental charges for export/import feed in the Territory on sales of Licensed Product to a Third Party, whether denominated as value added taxes, sales taxes, or excise taxes, to the extent included in said invoiced amount.
- 1.10 "Patents" means all patent applications and patents, together with any continuations, continuations-in-part, divisions, reissues, extensions, and reexamination applications of the foregoing which cover the process or manufacture, use or sale of Licensed Product in the Licensed Field in the Territory which are owned, licensed or controlled by Dr. Reddy's or which become owned, licensed or controlled by Dr. Reddy's during the life of this Agreement.
- 1.11 "Licensed Product" means a radiotherapy solution, source, composition or formulation, the manufacture, use or offer for sale of which, but for the license granted herein, would in whole or part infringe a Valid Claim.
- 1.12 "Patent Rights means": (i) U.S. Patents No. US 6,315,979, US 6,506,363, and US 6,861,044; (ii) any patents issuing from divisional, continuations, or continuations-in-part of any patents from which any of

the foregoing patent applications claims priority, throughout the world; and (iii) patents that are foreign counter parts, reissues, reexaminations or extensions of the foregoing (i) and (ii).

- 1.13 "Royalty Term" means from the date of the first sale of the Product to a Third Party till the expiration of the last Patent.
- 1.14 "Technology" means all intellectual property which is not a Patent, but is utilized for the manufacture of the Licensed Product.
- 1.15 "Territory" means worldwide.
- 1.16 "Third Party" means anyone, other than a Party and its Affiliates, contractors and sublicensees. Thus Third Party includes, without limitation, physicians, hospitals, clinics, hospice facilities, patients, distributors, formularies, and radiopharmacies.
- 1.17 "Valid Claim" means any claim set forth in a pending patent application or issued patent included in the Patent Rights which: (i) has not expired, been revoked or cancelled, been declared invalid, unpatentable or unenforceable by a final decision of a court or other government agency of competent jurisdiction, from which decision no further appeal or other legal course is possible, and (ii) has not been withdrawn, disclaimed, denied, admitted by the owner or its successors or assigns to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.
- 1.18 "Intellectual Property Rights" means the Patents and the Technology.

## **ARTICLE 2 - GRANT OF LICENSE**

- 2.1 Grant of License Dr. Reddy's hereby grants to IsoRay and IsoRay hereby accepts:
- (a) An exclusive, non-transferable but sub-licensable, limited license to use the Patents and Technology to make, have made, use, sell and have sold in the Territory the Licensed Product in the Licensed Field. The license shall be fully exclusive, to the exclusion of Dr. Reddy's and its Affiliates.
- 2.2 Sublicensing -The exclusive license under Article 2.1(a) to Licensee includes the right to sublicense to Third Parties, as well as Affiliates of Licensee, under the terms and conditions of this Agreement. Licensee shall notify Licensor of each sublicense in writing at least five days prior to commencing the sublicense. Licensee will make and be responsible for all payments to Dr. Reddy's for all sales of

Licensed Product in the Territory including sales made pursuant to the sublicenses. Licensee hereby irrevocably agrees that it shall be solely and primarily responsible for payment of all royalties payable under this agreement irrespective of whether Licensee receives the consideration from the sub-licensee or not. Licensee will also be responsible for the observance of all covenants and conditions contained herein by all sublicensees of the Technology and Patents, and will use its best efforts to cause all sublicensees to observe the covenants in this Agreement regarding confidentiality, maintenance of records, and exchanges of information. All such sublicenses shall be in writing,

Any sublicense granted by Licensee shall provide that the sublicensee shall not assign or transfer the sublicense nor any of its rights or obligations thereunder, in any manner (including by operation of law) without the prior written consent of Licensor, which Licensor may withhold in its sole discretion; provided however, that such sublicensee may assign or transfer such sublicense as part of a sale or merger of such sublicensee or a sale by such sublicensee of all or substantially all of the assets to which the sublicense relates if, and only if, prior thereto, the assignee delivers to Licensee and Licensor (i) a written agreement of such assignee to assume all of the assigning sublicensee's obligations under such sublicense and (ii) evidence reasonably satisfactory to Licensor of such assignee's ability to perform such obligations (which evidence shall be deemed satisfactory unless Licensee or Licensor delivers reasonable and reasonably detailed written objection to such assignment within thirty (30) days following receipt of such evidence).

Licensee's sublicensee shall only have the right to grant further sublicenses upon the approval of Licensor (which approval shall not be unreasonably withheld or delayed) and only in the event that such sub sublicense both (i) covers all the rights of the sublicensee to the Licensed Product that is the subject of such sublicense, and (ii) includes the grant to the sub sublicensee of substantial intellectual property rights owned or controlled by such sublicensee.

- 2.3 Other Licenses Dr. Reddy's reserves the right to proceed, solely at its option and expense, to research, develop, make, have made, use, sell, have sold and license, the Patents and Technology in the Territory solely outside the Licensed Field.
- 2.4 Ownership of Inventions The Parties agree that any invention or intellectual property derived by the Licensee from the exercise of its rights hereunder shall be the sole property of the Licensee. However, the Parties agree to negotiate in good faith for the terms, including payment of royalties by Licensor, of the grant of a license to the Licensor by the Licensee for any such invention upon request by Licensor.

- 2.5. As between Licensee and Licensor all the Intellectual Property Rights in and over the Licensed Product and the derivatives of the Patents that hereafter may be conceived or made by Licensor shall vest solely with Licensor. Except as expressly provided in this Agreement, Licensor shall have unrestricted, exclusive rights to exploit the same in perpetuity throughout the world. Further, Licensor shall at its own costs have the worldwide right to register and control the drafting, filing, prosecution and maintenance of any patents for inventions which Licensor owns, including decisions about the countries in which to file patent applications and the costs associated with the patent activities.
- 2.6. Except to the extent of the rights granted under this Agreement, Licensee hereby represents that it has no right, interest or otherwise in the Intellectual Property Rights owned by the Licensor and it will not, during the term of this Agreement or at any time thereafter, either directly or indirectly assert or claim any right, interest or make any claim against the Licensor's Intellectual Property Rights nor will do any acts or omissions nor make any statements that would negatively affect the Intellectual Property Rights owned by the Licensor.

## **ARTICLE 3 - PAYMENTS & ROYALTY**

- 3.1 Initial Consideration- As initial consideration, Licensee shall pay to Dr. Reddy's an upfront payment of US\$10,000 in cash within thirty (30) days of the execution of this Agreement and this payment shall not be credited against future royalty payments or any other payments made under this Agreement and shall be nonrefundable.
- 3.2 Royalties The royalty payable to Dr. Reddy's shall be 2.75% of the Net Sales in each Calendar Year. Further, if in any case the annual payment of royalties falls below the amounts specified below, then the Licensee shall make a payment to reach the amounts in the time period specified below. Royalty payments shall be paid quarterly, however if in the fourth quarter the minimum amount payable is not reached for the Calendar Year then the amount necessary to reach the payment specified below shall be made within 60 days after the end of the fourth quarter.

1st Calendar Year minimum	US \$5,000
2nd Calendar Year minimum	US \$10,000
3rd Calendar Year minimum	US \$20,000
4th Calendar Year minimum	US \$25,000
5th Calendar Year and beyond minimum	US \$30,000

- 3.3 Taxes If any taxes, withholding or otherwise, are levied by any taxing authority in connection with the receipt by Dr. Reddy's of any royalties payable under this Agreement, IsoRay shall have the right to pay such taxes to the local tax authorities on behalf of Dr. Reddy's and the payment to Dr. Reddy's of the net amount due after reduction by the amount of such taxes, together with evidence of payment of such taxes, shall comply with IsoRay's royalty reporting obligations under this Agreement.
- 3.4 Quarterly Royalty Reports and Payments Within sixty (60) days after the close of each quarter of a Calendar Year as defined in Article 1, IsoRay shall submit a report on the Net Sales in the Licensed Field for the Territory in sufficient detail to enable a calculation of the royalty due in accord with Article 3 and payment of the royalty (if any) due.
- 3.5 Books of Account IsoRay shall maintain true and complete books of account containing an accurate record of all data necessary for the proper computation of royalty payments due from it or on behalf of any Affiliate or sublicensee.
- 3.6 Audit Right-Throughout the term of this Agreement, Dr. Reddy's shall have the right, either through a certified public accountant employed by Dr. Reddy's or through a firm of independent public accountants to whom IsoRay has no reasonable objection, to examine the books of account of IsoRay at reasonable times but not more than once in each Calendar Year for the purpose of verifying the correctness of any report concerning diligence or payment of royalties under this Article 3. Such examination shall be made during normal business hours at the place of business of IsoRay. The information furnished as a result of any such examination shall be maintained in confidence on the terms specified in Article 6. The fees and expenses of such an audit shall be borne by Dr. Reddy's. If any such audit shows any underpayment or overcharge, a correcting payment or refund shall be made within thirty (30) days of IsoRay's receipt of the auditors' statement. If such error is greater than a ten percent (10%) underpayment by IsoRay, IsoRay shall be subject to a penalty as if the payment were deemed late in accord with Article 3.8. Should IsoRay fail to make any correcting payment within sixty (60) days from receipt of the auditors' statement, then Dr. Reddy's shall have the right to terminate this Agreement under Article 12.4.
- 3.7 Arms Length Sale: IsoRay and its Affiliates should not sell the Licensed Product on a non-arms length basis. IsoRay and its Affiliates agree (i) that in calculating Net Sales it shall not include in the deductions from Net Sales any special discounts, rebates, volume reimbursements or other incentives for the Licensed Product that are given as an inducement for the purchase of other IsoRay products; (ii) that any discounts, rebates or volume reimbursements offered by IsoRay and its Affiliates on the basis of

multiple product purchases which include Licensed Product shall be allocated to the Licensed Product on a no greater than proportionally equal basis on the respective average invoiced price of each such product; (iii) that IsoRay shall not sell the Licensed Product as a loss or otherwise cause its sales of some other product to benefit at the expense of the Licensed Product.

3.8 Late Payments - If royalties are not remitted to Dr. Reddy's by the due date then IsoRay shall be liable for the interest at the current prime rate plus 2% established by a leading New York bank, such as CitiBank. Should IsoRay fail to make the payment within sixty (60) days from its due date, then Dr. Reddy's shall have the right to terminate this Agreement under Article 12.4.

## **ARTICLE 4 - REPRESENTATIONS AND WARRANTIES**

4.1 Organization; Good Standing - Each Party hereby represents to the other Party on the Effective Date that it (i) is a corporation duly organized, validly existing, (ii) is in good standing under the laws of the jurisdiction of its incorporation, (iii) is qualified to do business and in good standing in each jurisdiction in which the performance of its obligations hereunder requires such qualification, and (iv) has all requisite power and authority, corporate or otherwise, and the legal right to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform under this Agreement.

4.2 Binding Obligation; Due Authorization; No Conflict - Each Party hereby represents to the other Party on the Effective Date that this Agreement is a legal and valid obligation binding upon its execution and enforceable in accordance with its terms and conditions. The execution, delivery and performance of this Agreement by each Party have been duly authorized by all necessary corporate action, and the person executing this Agreement on behalf of each Party has been duly authorized to do so by all requisite corporate actions and does not and will not (a) require any consent or approval of its stockholders or any Third Party or (b) conflict with, or constitute a material breach or violation of, any agreement, instrument, understanding, oral or written, to which it is a party or by which it may be bound, and any judgment of any court or governmental body applicable to such a Party or (c) violate any law, decree, order, rule or regulation of any court, governmental body or administrative or other agency having authority over it.

4.3 No Suit- Each Party hereby represents to the other Party on the Effective Date that it is aware of no action, suit or inquiry or investigation contemplated or instituted by any Third Party that questions or threatens the validity of this Agreement or asserts that the use of the subject matter of the licenses granted to IsoRay and/or actually or potentially granted to Dr. Reddy's under this Agreement (as applicable) or the

manufacture, use, sale, offer for sale or import of embodiments thereof infringes upon or misappropriates the intellectual property of any Third Party.

- 4.4 Title to Intellectual Property Rights Each Party hereby represents to the other Party that it has sufficient legal and beneficial title to its intellectual property rights necessary for the purposes contemplated under this Agreement and to grant the licenses contained in this Agreement.
- 4.5 No Violations of Third Party Intellectual Property Rights Each Party hereby represents to the other Party as of the Effective Date, to the best of its knowledge, IsoRay's commercialization of the Licensed Product in the Licensed Field will not violate any of the intellectual property rights of any Third Party or Affiliate of a Party.
- 4.6 Licensor Limitations on Representations Except as set forth in Sections 4.3, 4.4 and 4.5, Licensor makes no representation or warranty with respect to the Licensed Products or the infringement by the same of any proprietary rights, or any representation or warranty with respect to the absence of any defect in the Licensed Products or Patent Rights.
- 4.7 Licensee Review Licensee has had the opportunity to review or has reviewed the Patent Rights to verify the sustainability of the Patent Rights for Licensee's intended purpose and is not relying on any statements of Licensor with respect to such verification, except for representations and warranties set forth in Sections 4.3, 4.4, or 4.5.
- 4.8. Registration & Approvals: Licensee will at its own cost register/obtain and maintain all the necessary approvals (including renewals) that may be required under any law or regulatory authority to permit Licensee's activities hereunder, from time to time, and at all times keep such approvals in full force in the respective portions of the Territory in which the Licensee manufactures, produces, distributes, sells and markets the Licensed Product and shall fully adhere to the applicable laws, rules and statutory orders of such authorities that may be required to permit Licensee's activities hereunder. Further Licensee hereby agrees and undertakes that it shall be solely responsible for all the costs that may arise from registration or default in adhering to the said laws, rules and statutory guidelines,
- 4.9. No Conflict: Each Party hereby represents to the other Party that it will not do any act, omission or enter into any agreement that would adversely affect or be detrimental to the business interest proposed under this Agreement.

## **ARTICLE 5 - INDEMNIFICATION**

5.1 By IsoRay - IsoRay shall indemnify, defend, and hold harmless Dr. Reddy's and its Affiliates and their directors, officers, employees and agents and their respective successors, heirs and assigns (collectively, "Dr. Reddy's Indemnified Parties"), against any liability, damage, loss or expense incurred by or imposed upon such persons or any one of them in connection with any claims, settlements, suits, actions, or demands by any Third Party, whether under any theory of product liability, or actions in the form of tort, warranty, strict liability, or otherwise, arising out of or relating to (1) the performance by IsoRay or the sub licensees of its activities hereunder, (2) IsoRay's or the sub licensees negligence, reckless misconduct or intentional misconduct in the manufacture, and use of the Licensed Product by IsoRay or offer for sale, sale, or import of any pharmaceutical product incorporating a pharmaceutical intermediate made through use of the Licensed Patents that is developed, made, used, or sold by IsoRay, its Affiliates or the sub licensees hereunder or pursuant to any right or license granted under this Agreement, and/or (3) the breach by IsoRay of its obligations, representations or warranties hereunder; provided, however, that such indemnification right shall not apply to any liability, damage, loss or expense to the extent directly attributable to the breach of any obligations, representations or warranties in this Agreement, or negligence, reckless misconduct or intentional misconduct of any Dr. Reddy's Indemnified Party. No Dr. Reddy's Indemnified Party shall be entitled to indemnification for the settlement of any claim pursuant to this Agreement unless it obtains the prior written consent of IsoRay to such settlement. Dr. Reddy's shall not be entitled to settle any such claim unless it obtains the prior written consent of IsoRay provided, however, that such consent shall not be required where IsoRay is fully released from any liability for such claim and where no restrictions are otherwise imposed on IsoRay by such settlement.

5.2 By Dr. Reddy's - Dr. Reddy's shall indemnify, defend, and hold harmless IsoRay and its Affiliates and their directors, officers, employees, and agents and their respective successors, heirs and assigns (collectively, "IsoRay's Indemnified Parties"), against any liability, damage, loss, or expense incurred by or imposed upon such persons or any one of them in connection with any claims, settlements, suits, actions, or demands, by any Third Party, whether under any theory of product liability, or actions in the form of tort, warranty, or strict liability, or otherwise, arising out of or relating to the performance by Dr. Reddy's of its activities hereunder and/or the breach by Dr. Reddy's of its obligations, representations or warranties hereunder; *provided*, *however*, that such indemnification right shall not apply to any liability, damage, loss, or expense to the extent directly attributable to the breach of any obligations, representations or warranties in this Agreement, or negligence, reckless misconduct or intentional misconduct of an IsoRay Indemnified Party. No IsoRay Indemnified Party shall be entitled to

indemnification for the settlement of any claim pursuant to this Agreement unless it obtains the prior written consent of IsoRay to such settlement. IsoRay shall not be entitled to settle any such claim under this Section 5.2 unless it obtains the prior written consent of Dr. Reddy's; *provided*, *however*, that such consent shall not be required where Dr. Reddy's is fully released from any liability for such claim and where no restrictions are otherwise imposed on Dr. Reddy's by such settlement.

#### ARTICLE 6 - CONFIDENTIAL INFORMATION

6.1 Definition of Confidential Information - "Confidential Information" shall mean any scientific, technical, or business information furnished by the disclosing Party to the receiving Party in connection with this Agreement, whether orally, in writing or in electronic form, and whether exchanged before the Effective Date of thereafter. Such Confidential Information shall include, without limitation, the existence and terms of this Agreement, information disclosed by one Party to the other Party relating to the structure of a license, the use and manufacture of the Licensed Product, Dr. Reddy's Technology, royalty reports, trade secrets, know-how, inventions, technical data or specifications, testing methods, business or financial information, research and development activities, product and marketing plans, and customer and supplier information, including, but not limited to, such information that becomes or became known to a Party during visits to the facilities of the other Party.

6.2 Obligations- The Receiving Party agrees that from the Effective Date, during the Royalty Term and for a period of ten (10) years thereafter, it shall:

Maintain all Confidential Information in strict confidence, except that the receiving Party may disclose or permit the disclosure of any Confidential Information to its, and its Affiliates' and sublicensees' directors, officers, employees, consultants and advisors who are obligated to maintain the confidential nature of such Confidential Information and who need to know such Confidential Information for the purposes of performing their obligations under this Agreement;

Use all Confidential Information solely for the purposes set forth in, or as permitted by, and otherwise as necessary in connection with, this Agreement.

Allow its Affiliates, sublicensees, directors, officers, employees, consultants and advisors to reproduce the Confidential Information only to the extent necessary to effect the purposes set forth in this Agreement, with all such reproductions being considered Confidential Information; and 6.3 Exceptions - The obligations of the receiving Party under Section 6.2 above shall not apply to any specific Confidential Information to the extent that the receiving Party can demonstrate by competent written proof that such Confidential Information:

Was generally known to the public or otherwise part of the public domain prior to the time of its disclosure under this Agreement;

Entered the public domain after the time of its disclosure under this Agreement through means other than an unauthorized disclosure resulting from an act or omission by the receiving Party's or its Affiliates' directors, officers, employees, consultants, advisors or agents;

Was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party; or

Is or was disclosed to the Receiving Party at any time, whether prior to or after the time of its disclosure under this Agreement, by a Third Party having no fiduciary relationship with the disclosing Party and having no obligation of confidentiality to the disclosing Party with respect to such Confidential Information or was independently developed.

6.4 Permitted Disclosure - Each Party shall be permitted to disclose Confidential Information in the event that, and only to the extent that, such information is required to be disclosed to comply with applicable laws or regulations (such as disclosure to the FDA, United States Securities and Exchange Commission, the United States Environmental Protection Agency, the United States Department of Energy, or the United States Patent and Trademark Office, or to their foreign equivalents), or to comply with a court or administrative order, provided that the disclosing Party receives reasonable prior written notice of such disclosure and that the receiving Party takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, if possible, to minimize the extent of such disclosure. In addition, each Party may disclose the terms of this Agreement to lenders, investment bankers, and similar financial institutions solely for purposes of financing the business operations of such Party either upon the written consent of the other Party or if the disclosing Party obtains a signed confidentiality agreement with such financial institution with respect to such information, upon terms substantially similar to those contained in this Article 6.

## **ARTICLE 7 - FORCE MAJEURE**

7.1 Event of Force Majeure - In the event that performance under this Agreement, or any obligation hereunder, is hindered, delayed or prevented by reason of act of God, strikes, lockouts, labor troubles,

intervention of any governmental authority, fire, riots, insurrections, invasions, war or other reasons of similar nature beyond the reasonable control of the Party and are not due to such Party's fault or negligence, then performance of that act shall be excused for the period of the delay and the period for the performance of that act shall be extended for an equivalent period, provided that if any payment of royalties is delayed by such force majeure event, such overdue amount shall be subject to payment of interest at the prime rate as established by a leading bank at New York such as CitiBank during such period of delay.

7.2 Notification- Upon occurrence of an event of force majeure, the affected Party shall promptly notify the other Party in writing, setting forth the nature of the occurrence, its expected duration and how that Party's performance is affected. The affected Party shall resume the performance of its obligations as soon as practicable after the force majeure event ceases.

## ARTICLE 8 - THIRD PARTY INFRINGEMENT CLAIMS

8.1 Defense of Third Party Patent Claims - If a claim is brought by a third party that manufacture, use or the sale of Licensed Product in all or in any portion of the Territory infringes a patent of such Third Party, IsoRay will give prompt written notice to Dr. Reddy's of such claim when IsoRay becomes aware of it. Dr. Reddy's shall have the sole discretion and right to seek to dispose of said claim or to conduct the defense of any suit resulting from such claim if it concerns a Patent or Technology. IsoRay at its option and expense may participate with Dr. Reddy's in any suit resulting from such claim that directly affects its market in the Territory, and shall be entitled to retain its pro rata share of any recovery obtained from such litigation, settlement or compromise thereof, in the proportion that of its expense spent on such litigation, settlement or compromise thereof bears to the overall expense spent by IsoRay and Dr. Reddy's on such litigation, settlement or compromise thereof. IsoRay's cost of such litigation (as approved by Dr. Reddy's) in any quarter after the said decree may be credited against one hundred percent (100%) of the royalties due to Dr. Reddy's under Article 3 in the following quarter until such time as all costs have been credited for the defense of the alleged infringement in the Territory. At IsoRay's request and expense, Dr. Reddy's shall cooperate with IsoRay in such litigation, including joining in said litigation. Dr. Reddy's shall also cooperate, at IsoRay's expense, by way of providing access to evidence and witnesses available to Dr. Reddy's. However, the expenses incurred by IsoRay that solely relate to Dr. Reddy's cooperation shall not be allowed to set off from the royalties payable to Dr. Reddy's Dr. Reddy's shall advise IsoRay in writing, within ninety (90) days after IsoRay's notice, whether it intends to defend such suit or claim at Dr. Reddy's expense. During said ninety (90) day period, IsoRay may, in consultation with Dr. Reddy's

take such action as it deems necessary to defend against such suit or claim.

## **ARTICLE 9 - PATENT ENFORCEMENT LITIGATION**

9.1 Prosecution by Dr. Reddy's - Dr. Reddy's at its sole discretion, may take action on its own behalf and expense to institute any action or proceeding by reason of infringement of any of the Patents. If either Party learns of any infringement of a Patent or misappropriation of trade secrets by a third party, it shall promptly notify the other Party. Dr. Reddy's shall have the first right, at its own expense, to prosecute all litigation against a third party infringer who may be infringing a Patent. IsoRay shall provide all reasonable cooperation at Dr. Reddy's expense, including any necessary use of its name, required to prosecute such litigation. IsoRay shall be consulted concerning the litigation. Dr. Reddy's will bear the costs and shall be entitled to any recovery obtained from such litigation, settlement or compromise thereof.

9.2 Prosecution by IsoRay, Royalty Offset - If Dr. Reddy's does not prosecute such infringer or otherwise abate such infringement (which must be of commercial significance to IsoRay under this Agreement in Dr. Reddy's reasonable business opinion) within ninety (90) days after giving or receiving notification of such infringement in the Territory, unless an extension of the term is mutually agreed upon in writing by the Parties, then, if said Patent infringement relates solely to the Licensed Field under this Agreement, IsoRay shall have the right to prosecute such infringer, at its own expense, and shall be entitled to retain any recovery obtained from such litigation, settlement or compromise thereof. IsoRay's cost of such litigation in any quarter may be credited against one hundred percent (100%) of the royalties due to Dr. Reddy's under Article 3 in the following quarter until such time as all costs have been credited for the infringement in the Territory. At IsoRay's request and expense, Dr. Reddy's shall cooperate with IsoRay in such litigation, including joining in said litigation. Dr. Reddy's shall also cooperate, at IsoRay's expense, by way of providing access to evidence and witnesses available to Dr. Reddy's. If any such Patent covers subject matter outside the Licensed Field outside this Agreement and the infringing acts include acts outside the Licensed Field or outside this Agreement, then IsoRay must have Dr. Reddy's prior written consent to enforce said Patent, which consent will not be unreasonably withheld. However, IsoRay is aware that other licensees for other end uses of Patents are likely to exist such that consent may not be possible and that the risks presented to such other Dr. Reddy's licensees shall be deemed by IsoRay as a reasonable basis by Dr. Reddy's to withhold its consent.

9.3 Invalidity - In the event that, whether by virtue of a third party infringement claim under Article 8 or

patent enforcement litigation under Article 9, or by any other means, a Patent in all or any portion of the Territory is finally declared invalid or unenforceable in a judicial or administrative proceeding from which no appeal is or can be taken, Dr. Reddy's shall have three (3) months in which to obtain a license or other rights for IsoRay to the intellectual property underlying the invalid or unenforceable Patent to the extent necessary to permit IsoRay to fully exercise the license granted by Section 2.1, and until such rights are successfully obtained, no royalties shall be paid by IsoRay on the basis of that Patent-, provided, however, that royalties due for other Patents not so held invalid or unenforceable or royalties for use of Technology shall not be affected. If Dr. Reddy's is unsuccessful in obtaining such rights for IsoRay within the three (3) month period, IsoRay may, in its sole discretion, immediately terminate this Agreement without providing a cure period.

9.4 Settlement - Any settlement of an infringement suit whether brought by Dr. Reddy's or by IsoRay, shall be subject to the consent of both Parties, which consent shall not be unreasonably withheld.

#### ARTICLE 10 - COOPERATION IN PATENT LITIGATION

10.1 Cooperation - Each Party shall cooperate with the other Party to the extent reasonably requested in any legal action brought by a third party against one Party or against both of them or taken against a third party by either Party regarding Patents in the Licensed Field in all or any portion of the Territory, and each Party shall have the right to participate in any defense, compromise or settlement to the extent that, in its judgment, it may be prejudiced thereby. In addition IsoRay shall not settle any claim or suit in any manner that shall adversely affect any Patents, require any payment by Dr. Reddy's or reduce the royalty due to Dr. Reddy's hereunder, without the prior written consent of Dr. Reddy's.

## ARTICLE 11 - WARRANTY, DISCLAIMER, INSURANCE

11.1 Belief of Accuracy - Dr. Reddy's represents that the licensed Patents and other Confidential Information transferred or provided to IsoRay hereunder are believed to be accurate and complete as of their transfer to IsoRay and that Dr. Reddy's interpretations and conclusions drawn there from were made in good faith and in the exercise of Dr. Reddy's' scientific judgment as of the dates of the documents contained therein, and that to the best of Dr. Reddy's' knowledge, data subject to regulations regarding Good Laboratory Practices, Good Clinical Practices, Good Manufacturing Practices, and other FDA regulations, as well as the corresponding foreign regulations, is in compliance with such regulations.

However, Dr. Reddy's does not warrant or represent that such information is or will be sufficient to obtain Approval to market a Licensed Product or to commercially produce or to commercialize a Licensed Product. IsoRay represents that it is solely relying on its own evaluation of the licensed Patents and the other Confidential Information transferred or provided to it hereunder and on its own medical and scientific expertise in using the same in its development and commercialization of Licensed Product.

- 11.2 Limitation of Liability In no event shall Licensor be liable for any incidental, consequential or punitive damages, including, but not limited to, any lost profits or opportunities, arising out of, relating to, or in connection with the subject matter of this Agreement, even if Licensor has been advised of the possibility of such damages.
- 11.3 Insurance IsoRay agrees to carry such liability insurance as would reasonably be expected of a company of IsoRay's net worth operating in the pharmaceutical.

## **ARTICLE 12 - TERM AND TERMINATION**

- 12.1 Term This Agreement shall commence on the Effective Date and, unless terminated pursuant to this Article 12, this License shall continue in effect until the expiration of the last of the Patents listed in Annexure-A.
- 12.2 Mutual Consent This Agreement may be terminated early or extended at any time by mutual written agreement of the Parties with ninety (90) days written notice in advance.
- 12.3 Default Notice of Default In the event any material representation or warranty made hereunder by either Party shall be untrue ("Representation Default") or upon any breach or default of a material obligation of this Agreement by a Party ("Performance Default"), the Party not in default ("Non-Defaulting Party") must first give the other Party ("Defaulting Party") written notice thereof ("Notice of Default"), which notice must state the nature of the untruthfulness, breach or default in reasonable detail and request the Defaulting Party cure such default within thirty (30) days.
- 12.4 Termination for Default The Non-Defaulting Party may, in addition to any other remedies which may be available to such non-defaulting Party at law or equity, terminate this Agreement in the event of a Representation Default or Performance Default by the Defaulting Party that has not been cured within thirty (30) days after receipt of a Notice of Default or is not curable; provided, however, in the case of a Performance Default that is curable but cannot be cured within such 30-day period, the Non-Defaulting Party may terminate this Agreement following such 30-day period only if the Defaulting Party shall have

failed to do any of the following – (i) commence substantial remedial actions within such 30-day period, (ii) diligently pursue the same thereafter and (iii) cure such default within sixty (60) days after receipt of Notice of Default.

12.5 Bankruptcy - All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party that is a licensee of such rights under this Agreement shall retain and may fully exercise its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the Party hereto which is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate, to make complete duplicates of) any such intellectual property and all embodiments of such intellectual property, and same, if not already in their possession, shall be, within ten (10) days of the commencement of such proceeding, delivered to them (v) upon any such commencement of a bankruptcy proceeding upon their written request therefore, unless the Party subject to such proceeding (or a trustee on behalf of the subject Party) elects to continue to perform all of their obligations under this Agreement or (vi) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefore by the non-subject Party.

12.6 Disposition of Confidential Information - Except as provided under any future agreement(s) between the Parties, in the event of termination or expiration of this Agreement, each of the Parties shall return or destroy all forms of Confidential Information for which it is a Receiving Party under this Agreement, within sixty (60) days after such termination or expiration, provided, however, that each Party may retain one copy of such Confidential Information for the sole purpose of use in any litigation resulting from this Agreement or the activities undertaken pursuant to this Agreement.

12.7 Effect of Termination or Expiration- Termination or expiration of this Agreement shall not relieve the Parties of any obligation accruing prior to such termination or expiration. In addition, the obligations of confidentiality set forth in Article 6 shall survive for the time stated therein and the indemnification obligations set forth in Article 5 shall also survive as to all claims or actions arising from events which occurred before termination and shall not limit any other available rights and remedies of the Parties. Upon termination of this Agreement, Licensee and any sublicensees shall immediately cease to import, make, offer to sell, sell or use Licensed Products. Within thirty (30) days after termination, Licensee shall pay to Licensor all royalties due under this Agreement that accrued prior to termination.

**ARTICLE 13 - CONSENTS** 

13.1 Commitments - Dr. Reddy's agrees to take reasonable efforts to maintain in full force and effect the

agreements or written commitments which Dr. Reddy's has made prior to the Effective Date in the

Licensed Field.

13.2 Agreements - Dr. Reddy's expects to enter into other agreements for licensees outside the Licensed

Field. After the Effective Date, IsoRay consents to let Dr. Reddy's disclose to such Dr. Reddy's licensees

that IsoRay is Dr. Reddy's licensee for the Territory in the Licensed Field.

**ARTICLE 14 -NOTICES** 

14.1 Official - Any notice, request or communication specifically provided for or permitted to be given

under this Agreement must be in writing and may be delivered by hand delivery, mail, courier service, or

electronic transmission such as telex, facsimile, telegram or electronic mail, and shall be deemed effective

as of the time of actual delivery thereof to the addressee. For purposes of notice the addresses of the

Parties shall be as follows:

a) If to Dr. Reddy's

Name: Mark Pearson

Title: Director Business Development

Address:

Unit 162 Cambridge Science Park

Milton Road, Cambridge

CB4 0GH, UK

Mail: mpearson2@drreddys.com

Fax: +44 (0)1223 506701

b) If to IsoRay

Name:

Dwight Babcock

Title:

**CEO** 

Address:

350 Hills Street

Richland, WA 99354-5411

Mail:

dbabcock@isoray.com

Fax:

509-375-3473

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Each Party may change its address and its representative for notice by the giving of notice thereof in the manner hereinabove provided.

#### **ARTICLE 15 - DISPUTE RESOLUTION**

15.1 The Parties agree to attempt initially to seek to resolve any dispute, claim or controversy arising under, out of, or in connection with this Agreement (a "Dispute") by conducting good faith negotiations between the parties. Any Dispute which cannot be resolved by good faith negotiation within twenty (20) days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer, or authorized representative designated by the Chief Executive Officer, of each Party. Such Chief Executive Officers (or their respective designees) shall negotiate in good faith to resolve such Dispute through discussions promptly following such written notice, and in any event within fifteen (15) days thereafter. If the Chief Executive Officers of the Parties (or their respective designees) are unable to resolve the Dispute within thirty (30) days after the date of the notice referring such Dispute to the Chief Executive Officers for resolution, either Party may, by written notice to the other Party, invoke the provisions of Section 15.2.

15.2 All Disputes, that cannot be settled amicably in accord with Section 15.1, shall be referred to arbitration, which shall be governed by the rules of London Court of International Arbitration. The place of arbitration shall be London.

15.3 Pending the selection of the arbitrator or pending the arbitrator's determination of the merits of any Dispute, either Party may seek appropriate interim or provisional relief from any court of competent jurisdiction as necessary to protect the rights or property of that Party.

15.4 This Agreement shall be governed by and construed in accordance with the Laws of England.

## **ARTICLE 16 - ASSIGNMENT**

16.1 Assignment - Neither Party to this Agreement shall assign any rights hereunder without the prior written consent of the other Party, such consent not to be unreasonably withheld.

16.2 Effect on Successors and Assignees - This Agreement shall inure to the benefit of and be binding upon each Party's successors and permitted assignees.

#### ARTICLE 17 - MISCELLANEOUS PROVISIONS

17.1 Amendments - This Agreement may be amended only in writing executed by both Parties.

17.2 Entirety of Agreement - This Agreement sets forth the entire Agreement and understanding between the Parties hereto with respect to license of the Patents for their commercialization in the Territory and the Licensed Field. The Confidentiality Agreement dated October 1, 2010 (a copy of the agreement is provided in Annexure B) shall remain in effect only with respect to provisions not herein contained. If there is any conflict between the terms and conditions of this Confidentiality Agreement and this Agreement, the terms and conditions of this Agreement will control.

17.3 Severability - If any term or provision under this Agreement is deemed invalid under the laws of a particular state, country or jurisdiction, the invalidity shall not invalidate the whole Agreement but it shall be construed as if not containing that particular term or provision and the rights and obligations of the Parties shall be construed and enforced accordingly. The Parties shall negotiate in good faith a substitute provision in compliance with the law to as nearly as possible retain the Parties' intent in legally valid language.

17.4 Waivers; Cumulative Remedies - A waiver by either Party of any term or condition of this Agreement in any one instance shall not be deemed construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

17.5 Advertising and Publicity - Except as required by law, neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other Party and not until on or after the Effective Date. In the event of a legally required public announcement, the Party making such announcement shall provide the other Party with a copy of the proposed text, subject to such other Party's reasonable comments, prior to such announcement. Neither Party may use the name, logos, trademarks or service marks of the other Party in any manner whatsoever without the prior written consent of the other Party.

17.6 Relationship of the Parties - The Parties hereto are independent contractors with respect to one

another and not at any time agents of one another.

17.7 Headings - Headings in this Agreement are included herein for ease of reference and shall not affect the meaning of the provisions of this Agreement, nor shall they have any other legal effect.

17.8 Other Documents - Each Party agrees to execute such additional papers or documents in customary legal form and to make such governmental filings or applications as may be necessary or desirable to affect the purposes of this Agreement and carry out its provisions.

IN WITNESS WHEREOF, each Party has caused this Agreement to be signed by its duly authorized representatives and made effective as of the Effective Date.

For DR.REDDY'S (EU) LIMITED

For IsoRay, Inc.

/s/ J. P. Kilham

/s/ Dwight Babcock

Name: J. P. Kilham

Name: Dwight Babcock

Title: Country Manager

Title: CEO

Date 16 May 2011

Date: 6/1/2011