TWN Info Service on Intellectual Property Issues (May13/12)
28 May 2013
Third World Network
www.twn.my

Dear friends and colleagues,

An investigation conducted by Edward Hammond, consultant researcher of Third World Network, has revealed that a leading medical centre in The Netherlands is using a material transfer agreement (MTA) that claims proprietary rights over the Middle Eastern Respiratory Syndrome (MERS) virus, contrary to their public denial of placing restrictions on the virus.

The Erasmus Medical Centre issued a press statement on 24 May in response to public criticism by the World Health Organization's Director General, Dr. Margaret Chan, on 23 May of the Erasmus MTA.

A copy of the MTA was obtained by Third World Network some weeks ago under the public records law of the North Carolina, the United States, as part of our ongoing research into potential biopiracy of the MERS virus, triggered by a media report of criticism by Saudi Arabia's Deputy Minister of Health of Erasmus on this matter.

Due to the growing controversy and widespread public interest, Third World Network is now distributing the MTA, which is a public record. Below is a research note with more details and attached is the MTA.

For more details please contact: Edward Hammond at eh@pricklyresearch.com <mailto:eh@pricklyresearch.com>

With best wishes,

Third World Network

TWN Research Note
28 May 2013

The Material Transfer Agreement underlying the controversy over patent rights and the Middle Eastern Respiratory Syndrome (MERS) virus

At the World Health Assembly in Geneva on 23 May 2013, Dr. Margaret Chan, the World Health Organization (WHO) Director-General, criticized The Netherland's Erasmus Medical Centre for the conditions it has placed on study of the Middle Eastern Respiratory Syndrome (MERS) virus through a material transfer agreement (MTA) asserting proprietary rights.

Intellectual property assertions on MERS virus can be a problem for public health, the Director-General said, "Making deals between scientists because they want to take IP (intellectual property), because they want to be the world's first to publish in scientific journals, these are issues we need to address... No IP will stand in the way of public health actions."

The controversy over the restrictive agreement has been simmering since December of last year, when the Saudi Deputy Minister of Health criticized the fact that the then-unidentified virus had been sent to Erasmus without the Saudi government's permission and that Erasmus had subsequently asserted rights over the virus.

On 24 May, Erasmus Medical Center released a statement responding to the criticism, and claiming that "Virologists of the Viroscience Department of Erasmus MC are sending MERS coronavirus free of charge and without restrictions to all research institutions that work to benefit public health."

This and other claims made by Erasmus in defense of its MTA, however, are not correct. This is demonstrated by the MTA itself. A copy of the MTA, obtained by Third World Network some weeks ago under the public records law of the US state of North Carolina, is released with this note.

Third World Network requested the MTA because it has a long standing interest in issues of access and benefit sharing for biodiversity, recently working with governments to help develop the Nagoya Protocol to the Convention on Biological Diversity, and for the WHO Pandemic Influenza Preparedness Framework, an agreement adopted last year that set terms for sharing of potentially pandemic influenza viruses between labs.

Numerous provisions of the Erasmus MTA are designed to support intellectual property claims, and Erasmus has a track record of taking an aggressive intellectual property stance. Erasmus attempted to take out patents over the SARS virus in the early 2000s, and has broad patents on use of human metapneumovirus, a respiratory virus that often infects children. Erasmus licenses rights

to several companies to manufacture diagnostic tests for this virus, earning royalties when the assay is performed. It is also developing vaccines for that virus, and may wish to take a similar intellectual property strategy with MERS virus.

(As of 27 May, no international patent applications over MERS or its use by Erasmus have been published. This does not indicate Erasmus - or others - have not filed for patents, however, because there is a lag of six months or more from the time of filing of a patent application until its publication. It is thus too early to expect to see published applications on this recently-identified virus.)

Proprietary provisions in the Erasmus MTA for MERS virus include paragraph 2.2, which states that Erasmus retains ownership over the virus, and that if the recipient makes any inventions that include the virus or modifications to it, that these inventions will belong to Erasmus, and not to the institution where any invention was made.

Paragraph 2.4 prohibits recipients of the virus from sending it to anyone else without Erasmus' permission. Paragraph 1.3 prohibits recipients "to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization."

The MTA defines the material of the agreement to be not only the actual virus it sends, but also all of the virus' constituent pieces and the proteins its genes encode in any form: "any progeny and

unmodified derivative, clones, subunits and/or products expressed by the MATERIAL or fractions thereof."

The Erasmus MTA and the surrounding controversy clearly show negative impacts on public health of the extension of intellectual property to viruses and their use in treatments. Claims by Erasmus that it is distributing the virus "without restrictions" are also clearly false, as the MTA demonstrates.

Media discussion has understated the Erasmus MTA's chilling effect, a major reason why the agreement has become so controversial. Erasmus has a track record of making wide patent claims over newly-discovered respiratory viruses, and was the first to isolate the MERS virus. Because of this, and because Erasmus is using an MTA designed to protect its own potential patent claims, a discouraging effect on other institutions is created. Other labs might be able access the virus, from Erasmus or others, but don't want to, for fear that any work they do on the virus may later be alleged to be infringement of patent claims yet to be published.

Third World Network is now distributing the MTA, which is a public record, due to the widespread public interest. The situation with access to and intellectual property over the MERS virus, and other pathogens, will be addressed in future publications.

THE UNIVERSITY
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April 12, 2013

Edward Hammond
3103 Powell Circle
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VIA ELECTRONIC MAIL

Dear Mr. Hammond:

I write in response to your request for public records received January 25, 2013 (sent to Ralph Baric & Regina Stabile via electronic mail). Specifically, you requested "[a] complete copy of each incoming material transfer agreement for novel human coronavirus isolates and/or human medical specimens containing such viruses received by UNC Chapel Hill from 1 June 2012 to the present…[including] but…not limited to all MTAs for isolates or specimens of novel coronaviruses that were originally obtained or isolated in the UK, Netherlands, Qatar, Jordan, or Saudi Arabia, whether obtained directly from cooperators in those countries or through intermediate entities…[and] [a]ll the incoming MTAs for 'Saudi SARS,' hCoV-EMC, 'novel betacoronavirus' etc."

The enclosed documents are being provided to you in accordance with the North Carolina Public Records Act. If you have another public records request, you may reach me through the contact information provided in the letterhead above or via electronic mail sent to orth@email.unc.edu.

Sincerely,

Zach J. Orth, J.D.
Public Records Specialist

ZJO/dqa

Enclosure

cc: Regina Stabile, Public Records Officer

MATERIAL TRANSFER AGREEMENT

Effective Date: 03/October/2012

PARTIES:

1. **The University of North Carolina at Chapel Hill,** with registered offices at 222 East Cameron Ave, 308 Bynum Hall, CB#4105, Chapel Hill, NC 27599-4105, hereby lawfully represented by the Associate University Counsel in his/her capacity of authorized signatory (hereinafter referred to as: "**RECIPIENT**");

and

2. **Erasmus *University* Medical Center Rotterdam**, an institution organized in accordance with public law of the Netherlands (article 1.13,2 WHW), with principal place of business at 's-Gravendijkwal 230, 3015 CE Rotterdam, The Netherlands, acting exclusively for and on behalf of its Department of Viroscience Lab, hereinafter referred to as "**PROVIDER**", lawfully represented by the Head of the Department of Viroscience Lab,

HAVE AGREED AS FOLLOWS

1. Definitions

1.1 **MATERIAL**: One ampule New human coronavirus isolate Human betacoronavirus 2c EMC/2012, including any progeny and unmodified derivative, clones, subunits and/or products expressed by the MATERIAL or fractions thereof.

1.2 **MODIFICATIONS**: Substances created by the RECIPIENT which contain/incorporate the MATERIAL.

1.3 **COMMERCIAL PURPOSES**: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

2. Terms and Conditions of this AGREEMENT

2.1 The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested by the PROVIDER, the amount will be indicated here: NA. However, RECIPIENT shall provider a courier account to arrange for shipping and charges thereof and shall arrange all necessary permits to receive the MATERIAL at its sole expenses].

2.2 The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS and any inventions made by RECIPIENT that ***directly*** relate to the MATERIAL. In the event an invention made by the RECIPIENT ***directly*** related to the MATERIAL, while ownership vest in PROVIDER, RECIPIENT retains the right to use such inventions for internal non-commercial research and teaching purposes only..

2.3 The RECIPIENT retains ownership of any other invention made through the use of the MATERIAL:

2.4 The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:

a) is to be used solely for non-commercial research purposes as set out in Annex I (Research), attached to this AGREEMENT;

b) will not be used in human subjects or for diagnostic purposes involving human subjects without first obtaining all necessary approvals by the relevant authorities.

c) is to be used only at the RECIPIENT organization and only in the RECIPIENT scientist's laboratory under the direction of the RECIPIENT scientist or others working under his/her direct supervision; and

d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER.

2.5 The RECIPIENT and the RECIPIENT scientist agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT scientist's direct supervision. To the extent supplies are available; the PROVIDER agrees to make the MATERIAL available, under a separate agreement having terms consistent with the terms of this AGREEMENT, to other scientists at non-commercial entities for non-commercial research purposes; provided that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL.

2.6 The RECIPIENT and/or the RECIPIENT scientist shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not MODIFICATIONS.

2.7 Under a separate agreement at least as protective of the PROVIDER's rights in this AGREEMENT, the RECIPIENT may distribute MODIFICATIONS to other non-commercial entities for non-commercial research and/or teaching purposes only.

2.8 Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT scientist may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights under 2.3 of this Agreement.

2.9 The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this AGREEMENT, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER, including any altered forms of the MATERIAL made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.

2.10 If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others.

2.11 The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS.

2.12 Any MATERIAL delivered pursuant to this AGREEMENT is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

2.13 RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.

2.14 This AGREEMENT shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees:

a) to provide appropriate acknowledgment of the use of and the source of the MATERIAL in all publications;

b) to promptly communicate in writing all results, data and developments resulting from the use of the MATERIAL by RECIPIENT (**"RESULTS"**) to PROVIDER while preparing a prospective publication. PROVIDER may request delay in publication for a reasonable period (not exceeding ninety (90) days in any case) in order to protect intellectual property affecting the MATERIAL. Upon publication, PROVIDER shall be free to use these RESULTS for its own academic research, including further publications provided that no disclosure shall be made of any confidential information of RECIPIENT to any third party

2.15 Paragraphs 2.2, 2.9, 2.12, 2.14, 3.13 and 2.18 shall survive termination.

2.16 The term of this AGREEMENT is as of the EFFECTIVE DATE and until Research has been completed or RECIPIENT's scientist is no longer at the RECIPIENT institution. At the end of such Research, this AGREEMENT shall automatically terminate and RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL.

2.17 This AGREEMENT shall be construed and governed in accordance with the laws of the Netherlands. Any and all disputes arising from or in connection with this AGREEMENT that can not be settled amicably by and between the parties hereto, shall be subject to the exclusive jurisdiction of the courts having competence in any such matter at Rotterdam, the Netherlands..

2.18 This AGREEMENT is the entire agreement of the Parties relating to the use of the MATERIAL and may not be modified, assigned or transferred (in whole or in part) by RECIPIENT without the written consent of an authorized representative of PROVIDER. The Parties agree that exchanged signatures by PDF document shall be deemed as original

The University of North Carolina at Chapel Hill

Signature:

Wm. Fletcher Fairey
Associate University Counsel

Erasmus *University* Medical Center Rotterdam,
Department of ViroScience Lab

Signature:

Erasmus MC
University Medical Center Rotterdam

Name:		Name:	
Function:	OFFICE OF TECHNOLOGY DEVELOPMENT	Function:	Head of the Viroscience LabDepartment
Place:	Campus Box #4105, 308 Bynum Hall The University of North Carolina at Chapel Hill	Place:	Rotterdam
Date:	Chapel Hill, North Carolina 27599-4105 10/16/12	Date:	

For acknowledgement of the investigators/scientists (not a signatory to this AGREEMENT):

Signature:		Signature:	N/A
Name:		Name:	
Function:	RECIPIENT SCIENTIST	Function:	PROVIDER SCIENTIST
Place:	UNC-Chapel Hill	Place:	Rotterdam
Date:	10/3/2012	Date:	

ANNEX I: DESCRIPTION RESEARCH/PROTOCOL

Please insert a description that is more specific and that can be defined expecting completion within reasonable period of time (4 to 5 year max.).Note that the term of the agreement has been link to this description, as such the project as proposed is too general to allow definition.

We seek to understand the viral determinants of this novel coronavirus that cause disease, We plan to study virus pathogenic outcomes in young and aged mouse models, various knockout mice and perhaps in the Collaborative Cross Mouse Resource.