

Ali Seyhan Uğurlu

Bioethics and the Patent Eligibility of Human Embryonic Stem Cells-Related Inventions in Europe



Nomos

MIPLC

Munich
**Intellectual
Property**
Law Center

Augsburg
München
Washington DC



MAX-PLANCK-GESELLSCHAFT

UNA
Universität
Augsburg
University

TUM
TECHNISCHE
UNIVERSITÄT
MÜNCHEN

**THE GEORGE
WASHINGTON
UNIVERSITY**
WASHINGTON, DC

MIPLC Studies

Edited by

Prof. Dr. Christoph Ann, LL.M. (Duke Univ.)
Technische Universität München

Prof. Robert Brauneis
The George Washington University Law School

Prof. Dr. Josef Drexler, LL.M. (Berkeley)
Max-Planck-Institut für Innovation und Wettbewerb

Prof. Dr. Michael Kort, University of Augsburg

Prof. Dr. Thomas M.J. Möllers
University of Augsburg

Prof. Dr. Dres. h.c. Joseph Straus,
Max Planck Institute for Intellectual Property and
Competition Law

Volume 8

Ali Seyhan Uğurlu

Bioethics and the Patent Eligibility of Human Embryonic Stem Cells-Related Inventions in Europe



Nomos

MIPLC

Munich
**Intellectual
Property**
Law Center

Augsburg
München
Washington DC

Die **Deutsche Nationalbibliothek** lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data is available in the Internet at <http://dnb.d-nb.de>

a.t.: Munich, Munich Intellectual Property Law Center,
Thesis "Master of Laws in Intellectual Property (LL.M. IP)", 2012

ISBN: HB (Nomos) 978-3-8487-1471-1

British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library.

ISBN: HB (Nomos) 978-3-8487-1471-1

Library of Congress Cataloging-in-Publication Data

Uğurlu, Ali Seyhan
Bioethics and the Patent Eligibility of Human Embryonic Stem
Cells-Related Inventions in Europe
Ali Seyhan Uğurlu
86 p.
Includes bibliographic references.

ISBN 978-3-8487-1471-1 (Nomos)

1. Edition 2014

© Nomos Verlagsgesellschaft, Baden-Baden, Germany 2014. Printed and bound in Germany.

This work is subject to copyright. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, re-cording, or any information storage or retrieval system, without prior permission in writing from the publishers. Under § 54 of the German Copyright Law where copies are made for other than private use a fee is payable to "Verwertungsgesellschaft Wort", Munich.

No responsibility for loss caused to any individual or organization acting on or refraining from action as a result of the material in this publication can be accepted by Nomos, Hart or the author.

Foreword

This work corresponds to the thesis submitted to the Munich Intellectual Property Law Center in partial satisfaction of the requirements for the degree of Master of Laws in Intellectual Property (LL.M. IP) in September 2012.

The patent eligibility of hESC-related inventions creating a tempestuous nexus between patent law and stem cell technology is analyzed in this research with a special focus on the situation in Europe. Achievements in the biotechnology industry related to the stem cell technology are quite important. This is also recognized by the Nobel Prize Committee by awarding the Nobel Prize in Physiology or Medicine 2012 to John B. Gurdon and Shinya Yamanaka for the discovery that mature cells can be reprogrammed to become pluripotent. In line with the pace of development in the stem cell technology, awaited judiciary development at the submission date of the thesis has reached to a result and the update has been done accordingly for the publication purpose as of the situation in November 2013.

It is needless to say that the completion of this research is not the sole achievement of the author. I would like to express my deepest and sincere gratitude to Prof. Dr. Dr. h.c Joseph Straus for his valuable guidance and support for the completion of this thesis. It was an immense pleasure working under his supervision. I am thankful to Dr. Gintarė Surblytė and Seth I. Ericsson for keeping open their door to answer any question during the whole LL.M program. I thank to my tutors, Andrea Hüllmandel and Eugenio Hoss for their mentorship, assistance and encouragement during the coursework. I acknowledge the endless help of the MIPLC team to facilitate our stay at MIPLC. I would like to acknowledge the financial support of the Max Planck Institute for Intellectual Property and Competition Law for the publication of this work. Last but not least, I am thankful to my parents who supported and endorsed me during my stay in Munich. This book is dedicated to my grandmothers.

Munich, November 2013

Ali Seyhan Uğurlu

Table of Contents

Acronyms and Abbreviations	9
I. Introduction	11
II. Background to the Science	13
A. What Are Stem Cells?	13
B. Source of stem cells	13
1. Adult Stem Cells	14
2. ESCs	14
3. iPSCs	15
III. Legal Provisions Applicable to the Patent Eligibility of hESC-Related Inventions	17
A. EPC	17
B. TRIPs	18
C. EC 98/44 Directive	19
IV. Ethics and Stem Cell Related Patents	21
A. Ethics and Patent Law	21
1. Patent Law Isolated from Morality Based Provisions?	
A Look into the Legislative Discretion	22
a) A Closer Look at the EPC	25
b) Specific Examples of Immorality in the Biotech Directive	28
B. Bioethics and Patents for hESC-Related Inventions	29
1. Moral Status of Human Embryos and Its Implications for the hESC Research	30
a) Debate on whether Human Embryo Has Human Dignity	31
b) Double-Edged Sword: A Need of Compromise Considering Different Methods of Obtaining hESCs	32
(1) Research on Embryos Within 14 days After Fertilisation	32

(2) Research with Supernumerous Embryos	33
(3) Research with Embryos from SCNT	34
V. The Panorama in Europe	35
A. Determining the Right Interpretation of the Biotech Directive	35
1. The Patent Eligibility of the Human Embryo	35
2. The Patent Eligibility of hESC-related Inventions	36
a) The Destruction of Human Embryos for hESCs	37
b) The Creation of Human Embryos for hESCs	39
B. Application of the EPC	40
1. Lack of Uniform Moral Standard	40
2. Attempts to Create a Uniform Morality Standard	42
VI. EPO's Web of Precedents	47
A. University of Edinburgh Case	47
B. The WARF Case	49
1. Background	49
2. The Rationale	50
VII. CJEU's Brüstle Judgment	55
A. Background	55
B. The Rationale	57
C. Comparison of WARF and Brüstle Cases	62
D. The Devil is in Details, Unpatentable but Exploitable?	63
E. Implications of the CJEU's Judgment to the Future of hESC-Related Inventions	66
1. Germany	66
2. The U.K.	68
3. The EPO	70
VIII. Conclusion	72
Annex	75
List of Works Cited	81

Acronyms and Abbreviations

AG	Advocate General
Apr.	April
Art.	Article
Aug.	August
BGH	Bundesgerichtshof
Biotech Directive	Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions
BPatG	Bundespatentgericht
CJEU	Court of Justice of European Union
Dec.	December
DNA	Deoxyribonucleic Acid
EBA	Enlarged Board of Appeal
EC	European Council
ECHR	European Court of Human Rights
ECJ	European Court of Justice
EPC	European Patent Convention
EPO	European Patent Organisation
ESC	Embryonic Stem Cell
EU	European Union
Feb.	February
GPA	German Patent Act
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
hESC	Human Embryonic Stem Cell
IIC	International Review of Intellectual Property and Competition Law
iPSCs	Induced Pluripotent Stem Cells
Jan.	January
Mar.	March
Nov.	November
NGO	Non-Governmental Organisation
Oct.	October
OD	Opposition Division

Acronyms and Abbreviations

SCNT	Somatic Cell Nuclear Transfer
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
WTO	World Trade Organisation
para	paragraph
R&D	Research and Development
StZG	Stammzellgesetz (German Stem Cell Act)
TBA	Technical Board of Appeal
TFEU	Treaty on the Functioning of the European Union
U.K.	The United Kingdom
UK IPO	United Kingdom Intellectual Property Office
WARF	Wisconsin Alumni Research Foundation
WTO	World Trade Organisation