

SPRINGER BRIEFS IN BIOTECH PATENTS

Series Editor: Ulrich Storz

Andreas Hübel

Thilo Schmelcher

Ulrich Storz

Biopatent Law: Patent Strategies and Patent Management



Springer

SpringerBriefs in Biotech Patents

Series Editor

Ulrich Storz, Duesseldorf, Germany

For further volumes:

<http://www.springer.com/series/10239>

Andreas Hübel · Thilo Schmelcher
Ulrich Storz

Biopatent Law: Patent Strategies and Patent Management

 Springer

Dr. Andreas Hübel
Patent Attorneys
Michalski Huettermann
& Partner
Neuer Zollhof 2
40221 Duesseldorf
Germany
e-mail: hl@mhpatent.de

Dr. Ulrich Storz
Patent Attorneys
Michalski Huettermann
& Partner
Neuer Zollhof 2
40221 Duesseldorf
Germany
e-mail: st@mhpatent.de

Dipl.Ing. Thilo Schmelcher
Patent Attorneys
RCD-Patent
Karl-Heinz-Beckurts-Str. 13
D-52428 Juelich
Germany
e-mail: schmelcher@rcd-patent.de

ISSN 2192-9904
ISBN 978-3-642-24845-0
DOI 10.1007/978-3-642-24846-7
Springer Heidelberg Dordrecht London New York

e-ISSN 2192-9912
e-ISBN 978-3-642-24846-7

Library of Congress Control Number: 2011941757

© Ulrich Storz 2012

This work is subject to copyright. All rights are reserved, whether the whole or part of the material is concerned, specifically the rights of translation, reprinting, reuse of illustrations, recitation, broadcasting, reproduction on microfilm or in any other way, and storage in data banks. Duplication of this publication or parts thereof is permitted only under the provisions of the German Copyright Law of September 9, 1965, in its current version, and permission for use must always be obtained from Springer. Violations are liable to prosecution under the German Copyright Law.

The use of general descriptive names, registered names, trademarks, etc. in this publication does not imply, even in the absence of a specific statement, that such names are exempt from the relevant protective laws and regulations and therefore free for general use.

Disclaimer: The information provided herein reflect the personal views and considerations of the authors. They do not represent legal counsel and should not be attributed to the companies or law firms the authors work for.

Printed on acid-free paper

Springer is part of Springer Science+Business Media (www.springer.com)

Preface to the Series

Biotech patents are a different world, even for patent practitioners who have obtained their expertise in neighbouring disciplines, like chemistry. One reason for this phenomenon is that, until about 20 years ago, novel biological embodiments were generally excluded from patentability. Classical breeding methods used for their creation relied on the random distribution of genetic matter, and thus lacked reproducibility and, hence, technicity—a criterion which is, in most patent jurisdictions, considered as a *conditio sine qua non* to qualify for patent protection.

With the rise in biotechnological methods, such as restriction enzymes, PCR, transfection methods and the like, a molecular toolbox is now available for the artisan which guarantees reproducibility with a sufficiently high percentage. Patent applications related to these methods therefore comprise a clear technical teaching. For current methods in biotechnology, technicity is thus no longer denied.

Biotech inventions are, however, facing headwind from another direction, too. Many biotech inventions are under public scrutiny for moral issues, or because they are considered as mere discoveries rather than inventions. Some countries have already established exclusions from patentability with respect to particular fields of biotechnology, or are about to do so. Argentina has, for example, excluded genetically engineered plants,¹ while in the member states of the European Union, human embryonic stem cells are excluded from patent protection in the future.² A recent decision by the U.S. Court of Appeals for the Federal Circuit³ has dispelled fears that gene sequences used for diagnostic purposes or therapeutic proteins isolated from nature would no longer be patentable.

At the same time, biotech inventions often require large investments in R&D, and can develop tremendous commercial potential, thus making patent protection a

¹ Arts. 6 + 7 of the Argentine Patent Act and Argentine Guidelines for Examination of Patent application, Part C, Chapter IV, 2.1.7.

² Decision of the European Court of Justice, case C-34/10, published on the website of the European Court of Justice (<http://curia.europa.eu>).

³ Association for Molecular Pathology, et al. v. USPTO, Myriad Genetics, et al. v. Myriad Genetics, Inc. See No. 2010-1406 (Fed. Cir. July 29, 2011).