MIPLC Studies 32

Qinghua Yang

Aegis or Achilles Heel: The Dilemma of Homology in Biopatents in the Wake of Novozymes

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

MIPLC Studies
Edited by

Prof. Dr. Christoph Ann, LL.M. (Duke Univ.)
TUM School of Management

Prof. Robert Brauneis
The George Washington University Law School

Prof. Dr. Josef Drexl, LL.M. (Berkeley)
Max Planck Institute for Innovation and Competition

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 Innovation and Competition

Volume 32

Qinghua Yang, Ph.D.

Aegis or Achilles Heel: The Dilemma of Homology in Biopatents in the Wake of Novozymes

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available on the Internet at http://dnb.d-nb.de

a.t.: Munich, Master Thesis Munich Intellectual Property Law Center, 2017

ISBN 978-3-8487-5021-4 (Print)
978-3-8452-9271-7 (ePDF)

British Library Cataloguing-in-Publication Data
A catalogue record for this book is available from the British Library.

ISBN 978-3-8487-5021-4 (Print)
978-3-8452-9271-7 (ePDF)

Library of Congress Cataloging-in-Publication Data
Yang, Qinghua
Aegis or Achilles Heel: The Dilemma of Homology in Biopatents in the Wake of Novozymes
Qinghua Yang
72 p.
Includes bibliographic references.

ISBN 978-3-8487-5021-4 (Print)
978-3-8452-9271-7 (ePDF)

1st Edition 2018

Acknowledgements

In the past a couple of months, I have been working on the *support* requirement for homology claims. In this thesis, it is *support* that salvaged Novozymes' patent. Outside the thesis, it is also *support* that accompanied me throughout this rewarding journey at MIPLC.

The *support* came from my thesis advisor Prof. Joseph Straus. It is his wisdom and insights that enlightened my interest in the patent law issues in biotechnology. It is his carefulness and patience that guided me through the mist of thesis writing.

The *support* came from Mrinalini and Seth who did their best to take good care of the students, coordinate this programme, and facilitate the teaching and learning.

The *support* came from Yuan who oriented me in Munich, provided me the first-hand experience, and tolerated most of my nonsense. The *support* came from Lan who shared this journey and worked together with me, nine to nine, in the library.

The *support* came from Nadiya who helped me in finalising the last publication of my earlier research. The *support* came from my besties Bahar and Carolina who shared the hobby with me and dispersed my loneliness. The *support* also came from the other colleagues of Class 2016/17 whom I could not enumerate here.

The *support* came from Takeshi and Jingdong who furnished me valuable knowledge and skills from their patent examination practices.

Lastly and most importantly, the *support* came from my family who were always at the back of me, and gave me the faith to explore my life.

At the final moment of this LL.M. programme, I would like to express my sincere gratitude to my thesis advisor, friends and colleagues. You made my journey at MIPLC fruitful. And you made the programme at MIPLC memorable. Thank you.

Table of Contents

Abstract

Biological inventions frequently involve polypeptides, proteins and nucleic acids. Sequences of these molecules are disclosed for patent application. To obtain a broader scope of protection, an applicant employs homology language to formulate the claims and create a homology range surrounding the disclosed sequence. This homology range encompasses sequences that are expected to perform similar functions as the disclosed one does. However, the homology claims face a hurdle that they may not be supported by the written description. In a recent case, *Novozymes*, the Supreme Court of China ruled that homology claims lack support, but a further limitation by species of origin could satisfy this requirement. In this thesis, it is found that species of origin is not an effective limitation. Homology, as the essence of the dispute in *Novozymes*, should have been adequately addressed by the courts. Homology dictates the skilled person's confidence on the functionality of unknown sequences, and is involved in multiple patentability requirements. Therefore, the assessment of support concerning homology shall not be isolated from other patentability requirements. An empirical study shows that the current views on homology are different in the requirements of inventive step and support, thus creating an unclaimable gap along homology values. This gap may constitute a discrimination to biotechnology. This thesis shows that the disparity in views on homology is caused by intermingling the requirements of sufficient disclosure and support. To fix this problem, an appropriate test is furnished for assessing the support requirement concerning homology claims. It may help to narrow the unclaimable gap, meanwhile avoiding prejudice to other inventions. A more reasonable scope of protection is expected to be conferred to sequence-related biological inventions in the future.

Acronyms and Abbreviations

AA	Amino Acid
the Court	the Supreme People's Court of the People's Republic of China
DNA	Deoxyribonucleic Acid
EPC	European Patent Convention
EPO	European Patent Office
EWHC	the High Court of Justice of England and Wales
HFCS	High Fructose Corn Syrup
HL	House of Lords
JPO	Japan Patent Office
Paris Convention	Paris Convention for the Protection of Industrial Property
the Patent Law	Patent Law of the People's Republic of China
PRB	Patent Reexamination Board
RNA	Ribonucleic Acid
SIPO	State Intellectual Property Office of the People's Republic of China
TBA	Technical Board of Appeal
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UKIPO	Intellectual Property Office of the United Kingdom

Chinese Document Nomenclature

Note: Chinese document identifiers are searchable as cited.
A brief translation of the Romanised Chinese characters is provided below:

Er Zhong Min San Chu Zi	First Instance Case, Civil Ligation, by the Third Chamber of the [place] Second Intermediate People's Court
Fa Shi	Judicial Interpretation Document issued by the Supreme People's Court
Gao Xing (Zhi) Zhong Zi	Final Instance Case, Administrative Litigation on Intellectual Property Law Matters, by the [place] High People's Court

Guo Fa	Official Document issued by the State Council
Jin Gao Min San Zhong Zi	Final Instance Case, Civil Litigation, by the Third Chamber of the Tianjin High People's Court
Yi Zhong Zhi Xing Chu Zi	First Instance Case, Administrative Litigation on Intellectual Property Law Matters, by the [place] First Intermediate People's Court
Zui Gao Fa Xing Zai	Retrial Case of Administrative Litigation by the Supreme People's Court