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Qinghua Yang

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

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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

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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