

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

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 Litigation, 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 |

Acronyms and Abbreviations

| | |
|--------------------------|---|
| 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 |