II. Novozymes – a Long and Hard Journey to Patent Validity

The *Novozymes* decision was delivered by the Supreme Court of China on 31 Dec 2016. It dealt with the patent validity dispute dating back to 2011, when a parallel patent infringement case was on trial.[6] This section will describe the patent and related proceedings in detail, followed by the author's analysis of the merits of this final decision.

A. The Glucoamylase

Glucoamylase is one of the widely used bio-catalysts in the food industry. It has traditionally been produced by employing filamentous fungi, like *Aspergillus niger* and *Aspergillus awamori*. Glucoamylase is an exo-acting amylase catalysing the release of D-glucose from the non-reducing ends of starch and related oligo- or polysaccharide molecules (see Figure 1).[7] D-glucose is an essential substrate for a number of fermentation processes and for a range of food and beverage industries.[8]

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6 *Novyzymes v Longda*, The Tianjin Second Intermediate People's Court (2011) Er Zhong Min San Chu Zi No. 81; *Novozymes v Boli*, The Tianjin Second Intermediate People's Court (2011) E Zhong Min San Chu Zi No. 82; *Longda v Novozymes*, The Tianjin High People's Court (2012) Jin Gao Min San Zhong Zi No.41; *Boli v Novozymes*, The Tianjin High People's Court (2012) Jin Gao Min San Zhong Zi No.42.

7 See Julia Marín-Navarro and Julio Polaina, 'Glucoamylases: Structural and Biotechnological Aspects' (2011) 89 Applied Microbiology and Biotechnology 1267.

8 Pardeep Kumar and T Satyanarayana, 'Microbial Glucoamylases: Characteristics and Applications' (2009) 29 Critical Reviews in Biotechnology 225 <http://www.tandfonline.com/doi/full/10.1080/07388550903136076> accessed 10 September 2017.

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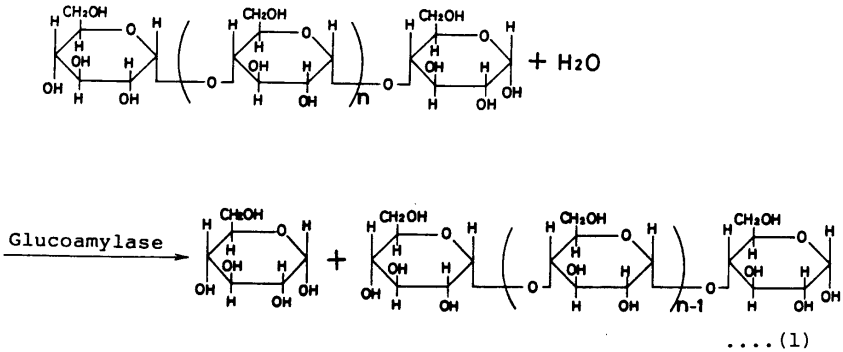

Figure 1. Glucoamylase-catalysed hydrolysis of terminal (1->4)-linked alpha-D-glucose residues successively from non-reducing ends of the chains with release of beta-D- glucose.[9]

An important application of glucoamylase is in the production of the commonly-used high fructose corn syrup (HFCS). Glucoamylase is employed to convert partially-hydrolysed corn starch by α-amylase to glucose, which is further converted by glucose isomerase to a mixture composed of glucose and fructose. This type of mixture, often further enriched with fructose, is commercialised as HFCS in worldwide trades. The HFCS is the largest tonnage product produced by an enzymatic process, making glucoamylase one of the most important industrial enzymes only second to protease. [10]

Ideally, it is economically advantageous if the three enzymes in the catalytic process share the same working conditions. In such way, the enzymatic reactions can proceed without changing vessels and ambient parameters to adapt each enzymatic process. However, the *Aspergillus* glucoamylase has certain limitations, such as moderate thermostability and acidic pH conditions, which increase the cost of the catalytic process. Accordingly, the search for new glucoamylases of optimal pH and temperature have been major goals of research over the years.

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9 Source: A Kariyone, Y Hashizume and R Hayashi, 'Enzyme Electrode for Measuring Malto-Oligosaccharide and Measuring Apparatus Using the Same' <http://www.google.com/patents/EP0335167A1?cl=en> accessed 10 September 2017.

10 Vimal S Prajapati, Ujjval B Trivedi and Kamlesh C Patel, 'Kinetic and Thermodynamic Characterization of Glucoamylase from *Colletotrichum* sp. KCP1' (2014) 54 Indian Journal of Microbiology 87.

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B. The Patent

The Danish Pharmaceutical Company Novo Nordisk filed a PCT application PCT/DK1998/000520 titled "Thermostable Glucoamylase", claiming the priority date of 26 Nov 1997. Its corresponding Chinese patent was granted as CN98813338 (hereafter referred to as the '338 patent).[11] In 2001, the proprietary was transferred to its subsidiary Novozymes, which is the world's largest provider of industrial enzymes and microorganisms.

The '338 patent disclosed a new type of glucoamylase isolated from a strain of *Talaromyces emersonii*. This isolated glucoamylase exhibits an increased thermostability compared to prior art glucoamylases, such as the *Aspergillus niger* glucoamylase. It is worth noting that the enzyme in this invention is not the first glucoamylase that shows thermostability, but a newly identified one. At 70°C (pH 4.5), the T½ (half-life) was determined to be over 100 minutes. The specification of this patent disclosed the full sequence of the thermostable glucoamylase in SEQ ID NO: 7. The relevant claims are as follows:[12]

> *Claim 1: An isolated enzyme with glucoamylase activity, wherein the enzyme* ***comprises*** *the full sequence shown in SEQ ID NO:7.*
> *Claim 6: An isolated enzyme with glucoamylase activity, wherein the enzyme* ***exhibits a degree of at least 99% identity*** *with the amino acid sequence shown in SEQ ID NO:7, and has a PI*[13] *below 3.5 determined by isoelectric focusing.*
> *Claim 10: The isolated enzyme according to claim 6-9 which* ***is derived from*** *a filamentous fungus of the genus Talaromyces, wherein the filamentous fungus is* ***Talaromyces emmersonii****.*
> *Claim 11: The isolated enzyme according to claim 10, wherein the Talaromyces emmersonii is Talaromyces emmersonii CBS 793.97.*

Claim 1 is to mean that the claimed enzyme has, in its primary structure, at least the full sequence shown in SEQ ID NO:7. Additional amino acid residues may exist before or after the reference sequence, which as a consequence extends the scope beyond the disclosed sequence.

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11 Also granted as a European Patent EP19980958217. See BR Nielsen, RI Nielsen and J Lehmbeck, 'Thermostable Glucoamylase' <https://encrypted.google.com/patents/EP1032654B1?cl=nl> accessed 10 September 2017.

12 Amended version used in the PRB review, translated by the author. See PRB Decision No. 17956 (31 Dec 2011), <http://app.sipo-reexam.gov.cn/reexam_out/searchdoc/decidedetail.jsp?jdh=17956&lx=wx> accessed 10 September 2017.

13 Isoelectric Point (PI): The pH at which the net charge on the protein is zero.

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Claim 6 enlarges the scope beyond the reference sequence from a different aspect.[14] It asserts a group of sequences that exhibit "a degree of at least 99% identity" with the reference sequence. "Identity" in this context has a close meaning to similarity or homology. For proteins, it refers to a one-to-one match of the corresponding amino acid residues of the query sequence with those of the reference sequence. A percentage is calculated with a predetermined algorism that defines the penalty scores when there are mismatches or gaps. For example, 100% means two sequences are exactly matching with each other, while 20% shows they are quite different. "Similarity" further concerns residues with similar physicochemical properties, *e.g.* leucine and isoleucine.[15] Hence, for the same set of protein sequences, the degree of similarity can be higher than that of identity. As a keyword of this study, "homology" has its original meaning defined as having shared ancestry in the evolutionary history of life. Strictly speaking, sequence identity/similarity is an observation of two or more given sequences; and homology is the likely conclusion based on a high degree of that. To be scientifically correct, drafters frequently use "identity" or "similarity" instead of "homology". However, unlike "identity" and "similarity", "homology" bears fewer lexicon meanings. The concept is less ambiguous than that of the other two terms when appearing in general contexts. For a clear and concise delivery, "homology" is used in this thesis for a broader meaning embracing both "identity" and "similarity".[16]

Claims 10 and 11 further limit the enzyme mentioned in Claim 6 to be from a particular source. It is derived from the thermophilic fungus *Talaromyces emmersonii,* in particular, from the strain CBS 793.97. Claim 10's limitation narrows down the source of such enzyme to the lowest taxonomic classification, a species. Claim 11 further defines the enzyme from a particular strain stock which is accessible via microbial culture collection centres. A strain is a representative of its corresponding species that

14 For the purpose of this thesis, the additional limitation defined by PI is not discussed.

15 Substitution occurred between these amino acid residues are termed conservative substitution, which is generally predicted to have a minimal impact on the tertiary structure of a protein and which thus usually maintains the functionality of this protein. See Simon French and Barry Robson, 'What Is a Conservative Substitution?' (1983) 19 Journal of Molecular Evolution 171.

16 Homology is also used in the field of chemistry, referring to similar functional groups, *e.g.* $-CH_3$ is homologous to $-CH_2CH_3$.

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has been collected and preserved or even characterised by the scientific community.

C. The Proceedings on Patent Infringement

Shandong Longda Biology Engineering Co., Ltd. (hereafter, refered to as Longda) and Jiangsu Boli Bioproducts Co., Ltd. (hereafter, referred to as Boli) are major industrial enzyme suppliers in mainland China, both offering thermostable glucoamylase for sale.

In 2011, Novozymes sued Longda and Boli for infringing its patent before the Tianjin Second Intermediate Court (the First Instance Court).[17] In the July of 2011, the two alleged infringer companies filed a Request for Invalidation of the '338 patent to the Patent Reexamination Board (PRB, the Board).[18] In its Decision No. 17956 on 31 Dec 2011, the PRB invalidated some of the claims including Claim 1 and Claim 6, while maintaining the other including Claims 10 and 11.[19]

The Tianjin Second Intermediate Court tried this case based on Claim 10.[20] Novozymes submitted an appraisal conclusion, indicating that the alleged infringing product has the same technical features as Claim 10 in respect of protein sequence and isoelectric point.[21] Novozymes further submitted a search report by the Patent Searching and Consulting Center of the SIPO, indicating that the alleged infringing enzyme cannot originate from organisms other than *T. emersonii*.[22] The alleged infringers failed to prove that the alleged infringing enzyme originated from strains of another species. In its decision, the Tianjin Second Intermediate Court held that Longda and Boli infringed the '338 patent, and awarded Novozymes damages and other fees amounting to CNY 2.2 million (~EUR 270,000 as in

17 *Novozymes v Longda*; *Novyzymes v Boli* (n 6).

18 The PRB is the reviewing arm of the State Intellectual Property Office of the Peoples' Republic of China (SIPO). For more procedural requirements for this request, see Yang Zhimin, *New insights on Interlectual Property Law – Detailed Analysis of the Theories and Practice* (知识产权法新解-详析知识产权法的理论与实务) (Sichuan University Press, 2009) 360.

19 PRB Decision No. 17956 (n 12).

20 *Novozymes v Boli*; *Novozymes v Longda* (n 6).

21 Ibid.

22 Ibid.

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2012).[23] Longda and Boli appealed. The Tianjin High Court dismissed the appeal and affirmed the decision of the first instance.[24]

Patent invalidity is not an admissible counter-claim in patent infringement proceedings in China's judicial practice. Longda and Boli, thus, had to challenge the patent validity in a separate proceeding. According to Article 11 of *Rules on the Application of Laws in Patent Dispute Proceedings*[25] issued by the Supreme Court, the infringement court may not stay proceedings when the invalidity claim is filed during the defence period. Therefore, in this dispute the infringement was established before the the final decision on the validity of the '338 patent.

D. The Proceedings on Patent Validity

1. The Patent Reexamination Board

The patent litigation in China is bifurcated.[26] The PRB has sole jurisdiction over patent validity issues.[27] In a patent infringement proceeding, the invalidity request must be submitted to the PRB for a review in a parallel proceeding. The '338 patent, which formed the basis of the infringement allegation, was reviewed and held partially invalid by the PRB in its Decision No. 17956.[28] The ground for revocation was Article 26.4 of the Patent Law, which reads as follows:

> *The written claim shall, based on the written description, contain a clear and concise definition of the proposed scope of patent protection.*[29]

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23 Ibid.

24 *Boli v Novozymes*; *Longda v Novozymes* (n 6).

25 The Supreme People's Court of the People's Republic of China, *Rules on the Application of Laws in the Trial of Patent Dispute Cases* (最高人民法院关于审理专利纠纷案件适用法律问题的若干规定) (19 Jun 2001).

26 Katrin Cremers and others, 'Invalid but Infringed? An Analysis of the Bifurcated Patent Litigation System' (2016) 131 Journal of Economic Behavior and Organization 218. See also Yang Zhimin, *A Study on the Scope of Patent Protection* (Sichuan University Press, 2013) 360 paragraph 1.

27 Patent Law of the People's Republic of China (1984, 2008 Ed.)(the Patent Law) An English version is available at <http://www.wipo.int/wipolex/en/details.jsp?id=5484> accessed 10 September 2017. Article 45.

28 PRB Decision No. 17956 (n 12).

29 The Patent Law (n 27) Article 26.4.

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This clause coincides with Article 84 of EPC and Section 112 of U.S. Code Title 35, which is commonly referred to as the *support* requirement in the EU or the *written description* requirement in the USA. In this thesis, *support* will be used in the following text concerning this legal concept.

Claim 1 employs an open-ended transitional phrase "comprise", which encompasses variants that have additional residues before or after the reference sequence.[30] The Board opined that the person skilled in the art would not foresee that adding residues to either end of the reference sequence, by any number and with any type of amino acids, will result in a protein that possesses glucoamylase activity.[31] The Board further gave the following reasons. Firstly, this addition could change the tertiary structure of the protein.[32] Secondly, when this addition results in a much longer sequence than the reference, the reference sequence may be folded inward the protein's tertiary structure, and in such senario the protein loses its original functions.[33] Thirdly, additional residues may interact with those in the protein domains of the reference sequence by forming ionic bonds, hydrogen bonds or disulphide bonds, which as a consequence changes or sabotages the protein domains, or leads to loss-of-function.[34] The Board concluded that open-ended Claim 1 was not supported by the description.[35]

Claim 6 relates to a technical solution defined by the combination of homology and function of a protein or polypeptide. However, only two polypeptides, one with the sequence disclosed in SEQ ID NO:7 and one variant shown in SEQ ID NO:34, were verified to possess glucoamylase activity.[36] The PRB opined that a person skilled in the art could not determine that all variants have the alleged function and can achieve the purpose of this invention.[37] The PRB explained that the basis of a protein's functionality is determined by its tertiary structure, which is subject to change by editing the primary structure, *i.e.* the sequence; substitution made to critical residues would significantly alter the tertiary structure and

30 PRB Decision No. 17956 (n 12) 15.
31 Ibid.
32 Ibid.
33 Ibid.
34 Ibid.
35 Ibid 16.
36 Ibid.
37 Ibid.

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thus the functionality.[38] Without adequate experimental data in the description, those skilled in the art cannot determine which variants within the claimed homology range would work the invention.[39] Novozymes' submission that the common and general knowledge of conservative substitution would enable those skilled in the art to understand the claim, and that the variant SEQ ID NO:34 which is about 99% homologous to SEQ ID NO:7 demonstrated that the claimed homology range was credible.[40] However, the Board rejected this argument. The Board reasoned that SEQ ID NO:34, as confessed by Novozymes during the oral proceeding, was most probably generated from the infidelity of polymerase chain reaction (PCR). It indicated that SEQ ID NO:34 could have originated from the same source.[41] Nevertheless, SEQ ID NO:34 shares above 99% homology with SEQ ID NO:7, not having reached the bottom line of 99%.[42] Moreover, neither did the written description disclose the conserved domains nor was Claim 6 limited only to conserved substitution.[43] Therefore, Novozymes' argument was not accepted. The Board concluded that Claim 6's technical solution relating to homology was not supported by the description.[44]

Claims 10 and 11 define the origin of the enzyme as *Talaromyces emmersonii,* in particular the strain CBS 793.97. In light of the knowledge that organisms in the same species exhibit high similarity in some fundamental features, the PRB held that an active gene with a specific function would normally have only one sequence in organisms of the same species, and its wild-type sequences with very high homology would have the same function.[45] Given that the glucoamylase activity of the enzyme derived from *Talaromyces emersonii CBS 793.97* had been verified in the description, those skilled in the art would foresee that polypeptides derived from *T. emersonii* and exhibiting at least 99% homology are most

38 Ibid.
39 Ibid.
40 Ibid.
41 Ibid. Note that being generated by PCR infidelity does not disqualify SEQ ID NO:34 as a different sequence. This argument seems to have no impact.
42 Ibid.
43 Ibid.
44 Ibid.
45 Ibid 17.

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likely to have glucoamylase activity.[46] Therefore, the Board concluded that Claims 10 and 11 were supported by the description.[47]

Claims relating to DNA sequences are not discussed in this thesis, as they are technically connected to protein claims. It is worth noting that nucleic acids and proteins or polypeptides may share some similar arguments, but they do have differences.

2. The Courts of First Instance and Second Instance

Given the infringement decision in the first place, Longda and Boli had to invalidate the patent in its entirety. According to Article 46.2 of the Patent Law[48], they may take legal action against the PRB's decision before a court, more precisely the Beijing First Intermediate Court[49]. On the other hand, although the infringement decision could rely on Claim 10, Novozymes nevertheless wished to recover its patent right related to Claim 6. Consequently, all the three companies filed administrative proceedings against the PRB regarding its Decision No. 17956[50].

The Beijing First Intermediate Court upheld the PRB's decision on the invalidity of Claim 6,[51] and further invalidated Claim 10, Claim 11 and other claims.[52] With regards to Claims 10 and 11, the Beijing First Intermediate Court did not acknowledge the effect of limitation by the species of origin. In the court's opinion, the species of origin limitation did not overcome the defect of allowing random mutagenesis within the defined

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46 Ibid.

47 Ibid.

48 The Patent Law (n 27), Article 46.2: "A person that is dissatisfied with the patent review board's decision on declaring a patent right invalid or its decision on affirming the patent right may take legal action before a people's court, within three months from the date of receipt of the notification. The people's court shall notify the opposite party in the invalidation procedure to participate in the litigation as a third party."

49 The Beijing Intellectual Property Court took over the first instance from Nov 2014 onwards.

50 PRB Decision No. 17956 (n 12).

51 *Novozymes v PRB,* The Beijing First Intermediate People's Court (2012) Yi Zhong Zhi Xing Chu Zi No. 2596.

52 *Boli v PRB*, The Beijing First Intermediate People's Court (2012) Yi Zhong Zhi Xing Chu Zi No. 2721; *Longda v PRB* The Beijing First Intermediate People's Court (2012) Yi Zhong Zhi Xing Chu Zi No. 2722.

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homology range. Thus, the claims still encompassed a huge number of variants, of which the functionality was unpredictable. In conclusion, Claims 10 and 11 lacked support from the written description.[53]

Unsatisfied with either result, Novozymes appealed to the Beijing High Court. The Beijing High Court affirmed all the decisions of the lower court.[54] Regarding the species of origin limitation, the Beijing High Court ruled that "originated from a certain species" did not effectively limit the number of sequences from any organisms within this particular species. Thus such limitation could not cure the defect of a homology claim.[55]

As per the Administrative Procedure Law, this was the in-principle final instance.[56]

3. The Supreme Court

By Article 92.2 of the Administrative Procedure Law, the Supreme Court has the power to hear further appeals and retry cases "where the application of laws and regulations in the original judgment or ruling was truly incorrect".[57] Novozymes thus appealed to the Supreme Court as a last resort on Claim 10, Claim 11 and related claims.

The Supreme Court reasoned in its *Novozymes* decision that: a *species* is a basic unit of biological classification and a taxonomic rank, individuals of which exhibit a high level of similarity in certain fundamental features. The genetic sequence of an enzyme from the same fungal or bacterial species is usually definite, though a very limited number of variants with high homology may exist. Accordingly, the corresponding enzyme is also definite or has only very few variants. The Supreme Court finally held that the double limitations of "at least 99% homology" and species of origin ensured a rather narrow scope of protection, and *a fortiori* Claims 10 and 11 had limitations of enzymatic activity and the isoelectric point

53 Ibid.

54 *Novozymes v PRB* (n 51); *PRB v Boli* (n 52); *PRB v Longda* (n 52).

55 *PRB v Boli* (n 5); *PRB v Longda* (n 5).

56 The Administrative Procedure Law of the People's Republic of China (1990, 2015 Ed.) Article 6: "In handling administrative cases, the people's courts shall, as prescribed by law, apply the systems of collegial panel, withdrawal of judicial personnel and public trial and a system whereby the second instance is the final instance."

57 Ibid Article 91.4

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followed from Claim 6.[58] Hence, the Supreme Court concluded that Claim 10 and Claim 11 were supported by the description.[59]

Eventually, the Supreme Court upheld the PRB's Decision No. 17956[60] and put an end to the five-year-long dispute on the validity of the '338 patent. In a nutshell, a "homology plus function" claim does not enjoy an easy support from the written description; further experimental data may be demanded; Additional limitation by species of origin will overcome the *support* problem, due to the limited variants and similar functions within a defined species. Now it is known as the function-homology-source rule in the patent law practice in China.

E. Comments – a Good Will, but also a "Chicken Rib"

By recognising the limitation of species of origin, the Supreme Court overcomes the argument that the homology claim encompasses too many unpredictable variants. Given the clear-cut infringement decision delivered in the first place, invalidation of Claims 10 and 11 would have helped the two domestic companies escape from liability if the Supreme Court had not reversed it.

This decision of the Supreme Court may partly reflect China's determination to advance its IP systems and stature. As explicitly expressed by the Premier of the State Council: "The Chinese government sees the fruits of innovation equally; be it by foreign or domestic entities, we provide the same level of protection. The government is dedicated to enhancing the IP protection and strives to build a transparent, fair and just legal and market environment."[61] This ambition has been documented in *Opinion on Accelerating the Building of IP Power under New Conditions*[62], emphasising

58 *Novozymes* (n 4) 41.
59 Ibid 42.
60 PRB Decision No. 17956 (n 12).
61 Situ Yuqian, "Premier Li Keqiang Meets WIPO's Director General Gurry" (李克强会见世界知识产权组织总干事高锐) (Beijing, 11 July 2014) <http://www.gov.cn/guowuyuan/2014-07/11/content_2716177.htm> accessed 10 September 2017.
62 State Council of the People's Republic of China, *Opinion on Accelerating the Building of IP Power under New Conditions* (国务院关于新形势下加快知识产权强国建设的若干意见) Guo Fa [2015] 71 <http://www.mof.gov.cn/zhengwuxinxi/zhengcefabu/201512/t20151223_1626379.htm> accessed 10 September 2017.

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the importance of IP rights as a means to incentivise innovation and promote economic growth.

This policy concern was also acknowledged by the patentee. "The Supreme Court's decision is of important significance. It shows that China highly values IP protection, which serves as a flag leading the direction of encouraging technological innovation. We believe that the respect towards IP rights will encourage investments in R&D, which is conducive to social development and progress" said Mikkel Viltoft, the general counsel of Novozymes.[63]

This case for the first time clarified the admissible claim styles for patents involving biological sequences, as well as the scope of protection.[64] It provided useful guidance on future drafting and examination practices. For the above reasons, *Novozymes* was enlisted in *TOP10 IP Cases decided by Chinese courts in 2016* and *Typical Cases in Administrative Litigations*.

Be great as it may, the author opines that the significance of this case is limited. As an essential characteristic of biological sequences, the homology issue has not been adequately addressed in *Novozymes*. The concept of homology is almost inevitable in many bio-patents, sometimes it is the sole effective way to describe an invention. Homology not only matters to the support requirement but also serves as a critical factor in other patentability aspects. Novelty, as a substantive requirement of patentability, requires a new biological sequence to be searched against the database. If it is novel and the claimed function is hypothetical, the requirement of industrial application will be assessed with known functions of homologous sequences;[65] or, if it is novel and the claimed function is experimental, the inventive step requirement will be assessed with homologous se-

63 Zhu Wenming, 'After the Twists and Turns, Novozymes' Protein Patent Is Finally Maintained'(历经曲折, 诺维信蛋白质专利终被维持) *China Intellectual Property News* (15 March 2017) <http://sipo-reexam.gov.cn/pub/wwzwcsz/alzx/dxalbd/20764.htm> accessed 10 September 2017.

64 Wu Wenying, 'effective limitation by microbial species of orgin in patent claims' (微生物来源限定的权利要求的合理概括) *China Intellectual Property News* (3 May 2017)

65 See T 1452/06, Serine protease/BAYER, EPO Technical Board of Appeal, 10 May 2007.

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quences having the same function.[66] High homology increases the possibility of fulfilling industrial application requirement but endangers this molecule regarding the requirement of inventive step, and *vice versa*. Similarly, the inventive step also has something to do with the support requirement. They together delineate the boundaries between prior art and a new invention, as well as between this new invention and a future one. Therefore, the requirements of inventive step and support must coordinate with each other. Without a thorough clarification of homology in the patent law, several problems may arise or continue in future practices.

Firstly, the species of origin is not an effective limitation in the infringement analysis. In the first infringement proceeding, the court admitted the proof that the alleged infringing product was falling within Claim 10 in respect of protein sequence and isoelectric point. Moreover, another piece of evidence indicated that the alleged infringing product could not originate from any other species. It is noted that the court, in order to assure the additional limitation - species of origin, required the alleged infringers to show that the product originated from other sources. Although they failed to prove so, it would be interesting to make a thought experiment for a further discussion: what if the alleged infringers had successfully proved that the product was from another source? This could be a scenario where the two enzymes are identical in any other material features than the species of origin.[67] Would the court have held the case differently? If a counterproof is meaningful in this scenario, it will render the claim useless in the case of sequences that are highly conserved across species. Alternatively, one can argue that since the enzymes are identical in their material features and the species of origin only makes a difference conceptually, the court would still find infringement.[68] If so, why did the court seek evi-

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66 See PRB Decision No. 120691 (2 Mar 2017) <http://app.sipo-reexam.gov.cn/reexam_out/searchdoc/decidedetail.jsp?jdh=120691&lx=fs> accessed 10 September 2017. See also T 0111/00, Monokine/FARBER, EPO Technical Board of Appeal, 14 Feb 2002.

67 See Annex I, adapted from Arthur N. Strahler, *Science and Earth History: The Evolution/creation Controversy* (Prometheus Books 1987) *e.g.* Cytochrome c in pig, cow and sheep are identical.

68 Possibly the infringement can be found though the doctrine of equivalents. Note that the doctrine of equivalents is recognised by the Supreme Court. See The Supreme People's Court, O*n Several Issues concerning the Application of Law in the Trial of Patent Infringement Dispute Cases II* (最高人民法院关于审理侵犯专利权纠纷案件应用法律若干问题的解释 (二)), Fa Shi [2016] 1 Article 8.

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dence from the alleged infringers in the first place? To make things more complicated, one should bear in mind that an infringing product is usually different from the exact form of the patented invention. It is also probable that the product differs from any known sequences within the defined species. Does it mean that this variant is out of the scope of protection automatically? Or, does it mean that the plaintiff can attribute such variant to that species on certain scientific grounds? If yes, what are those grounds? The only answer is by sequence comparison and homology analysis. In conclusion, the species of origin limitation seems only useful to uphold the validity of a claim, and will not have meanings in the infringement analysis.

Secondly, this case may create an unclaimable gap in biotechnology under the patent law. In *Novozymes*, the '338 patent seems to be limited to a very narrow scope. Although the Supreme Court was only obliged to interpret the law in relation to Claims 10 and 11, it did not make any further comments on homology issues even as *obiter dicta*. It leaves the understanding of homology in the patent law as it was. Unlike the common law jurisdictions, there is no jurisprudence in the Chinese judicial system. Albeit true, it should be noted that this case is an administrative litigation and the PRB was one party in the litigation, meaning that the decision will have a direct influence on the practice of the PRB, and in turn the Patent Office[69]. Therefore, this case, in fact, has a precedence effect on general patent law practices in China. Being important confers this case an exemplary effect on patent drafting and examination, which almost ensures a narrow scope of homology claims in the future. However, the scope of protection is not an isolated concept in patent law; it may interact with the inventive step. An inventive step enables a new invention to escape from the reach of persons skilled in the art. It certainly surpasses the scope of protection of any patents. But what would happen, if the gap between the scope of protection and the inventive step is significantly large? If the scope of protection is narrow, will the bar for of inventive step be lowered accordingly, or will it maintain the status quo? Will there be any problem? In view of these questions, we see that the homology issue is not a problem stirring only the support requirement. It may be intertwined with other legal requirements, which makes the understanding of homology a com-

69 State Intellectual Property Office of the Peoples' Republic of China (SIPO).

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plex task. From the Supreme Court's decision, no corresponding concerns were reflected.

Thirdly, this case mingles the sufficient disclosure and support requirements. A patent is drafted to enable persons skilled in the art to implement the invention, and to deter the potential infringers who want to circumvent the invention with little meaningful efforts. Consequently, on the one hand, it is at the core of the *quid pro quo* of the patent system to ensure the claimed inventions are workable, and it is also important to draw a fence to repel free-riding attempts, on the other. This ideology indicates that the purposes of the above two are distinct. These two purposes are safeguarded by the sufficient disclosure requirement and the support requirement, respectively.[70] The author's view is that there is an inacceptable merger of the tests on these two requirements during the invalidity proceedings. The support requirement seems to have been tested in the same way as required by the sufficient disclosure requirement. As can be seen from the reasoning of the above proceedings, the large population of variants and poor predictability formed the focus of the debate. From the PRB to the courts, none managed to escape from this topic. Each of them seemed to always have in their mind one simple question – which sequence works? Eventually, by reasoning the limited number of variants within a given species and a high likelihood of similar functionality among them, the Supreme Court was able to confirm the validity of Claims 10 and 11. Considering the prior literal infringement judgement, as long as the Court finds a way to uphold the '338 patent, its policy objective can be achieved. From the perspective of providing general guidance, however, this practice is of limited value when the reasoning was as simple as being written in the decision. The intermingling of the sufficient disclosure and support requirements may continue.

To sum up, *Novozymes* shows a good will of the Chinese judicial system in building a healthy and strong IP environment. However, under scrutiny, it appears to be a "chicken rib"[71] in the real sense – flavourous but fleshless.

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70 Moreover, another mechanism the doctrine of equivalents also supplements the support requirement for the latter purpose. For the doctrine of equivalents, see note (n 68).

71 See Luo Guanzhong, *Romance of the Three Kingdoms* (XinXii-GD Publishing 2016) Chapter 72; See also the biography of Yang Xiu, available at <http://kongming.net/novel/sgyy/yangxiu.php> accessed 10 September 2017.

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