V. Novozymes Mingles Sufficient Disclosure and Support

A. Sufficient Disclosure and Support Have Different "Prior Art"

The current interpretation on homology claims not only rooted in an insufficient understanding of the technology, but also came from the failure to distinguish the support requirement from sufficient disclosure. In the patent law, sufficient disclosure and support are two separate requirements. The former is reflected in Article 26.3 of the Patent Law:

> *The written description shall contain a clear and comprehensive description of the invention or utility model so that a technician in the field of the relevant technology can carry it out; when necessary, pictures shall be attached to it. The abstract shall contain a brief introduction to the main technical points of the invention or utility model.*[134]

The latter is stated in Article 26.4 of the Patent Law:

> *The written claim shall, based on the written description, contain a clear and concise definition of the proposed scope of patent protection.*[135]

These two requirements constitute both the grounds for refusal and revocation, in accordance with Article 53.2 and Article 65.2 *Rules for Implementation of the Patent Law*[136]. The two requirements are closely connected. When the breadth of the claim exceeds the technical contributions of an inventor, and some ways within the claimed scope owes nothing to the patent or application to achieve the desired result, both grounds can be invoked for an invalidity challenge. This scenario is usually mentioned as

134 The Patent Law (n 27). This article coincides with Article 83 EPC, usually referred as the requirement of sufficient disclosure.

135 The Patent Law (n 27). This article coincides with Article 84 EPC, usually referred as the requirement of support.

136 Rules for Implementation of the Patent Law of the People's Republic of China (2001, 2010 Ed.). An English version is available at <http://www.wipo.int/wipolex/zh/text.jsp?file_id=182267> accessed 12 September 2017. Note, the support requirement is not a ground for revocation under Article 138 EPC.

Biogen insufficiency,[137] and can also be exemplified in the PRB Decision No. 23542.[138]

Nevertheless, they are different. The fundamental difference can be read from the wordings of each provision. Article 26.3 describes the standard for "written description" being sufficiently clear to enable others; while, Article 26.4 states that the "claims" are drafted based on the written description. Apparently, before drafting or reading the claims, the teaching of an invention is already laid down in the written description. The skilled addressees when informed of the asserted protection will firstly bear the teaching of the written description in mind. Therefore, the desired results are not merely a matter starting from the prior art of that patent or application, but must be considered in combination with the teachings already disclosed in the written description. As a consequence, whether not directly disclosed matters are protectable may not have the same assessment with sufficient disclosure.

B. Novozymes Tests Support Using the Standard of Sufficient Disclosure

To be sufficient, the written description teaches a person, from the beginning, how to work the invention. This requirement corresponds to the fact that being inventive this patent should advance beyond the reach of persons skilled in the art on the filing date. However, when the skilled persons have been enabled to work this invention in the disclosed way(s), any other ways to work the invention should be able to refer to the disclosed one(s).

In view of such difference, it is important to understand the relationship between the first sequence that qualifies the sufficient disclosure and those other sequences homologous to the first one. To this point, Robert Hodges argued that "the key event is the cloning of the first gene in a family of corresponding genes. Once a researcher accomplishes this very difficult task, the researcher can typically obtain other members of the gene family

137 See *Biogen v Medeva* [1997] RPC 1 HL. Note, according to Article 138 EPC, support is not a ground for revocation. Therefore, a challenge for this reason should employ the ground of insufficiency.

138 PRB Decision No. 23542 (23 July 2014) < http://app.sipo-reexam.gov.cn/reexam_out/searchdoc/decidedetail.jsp?jdh=23542&lx=wx> accessed 11 September 2017.

with much less effort."[139] This idea has been adequately reflected in the assessment of inventive step. But in the support requirement, it seems to have been ignored. Following Hodges' logic, when the first sequence and its function is disclosed, the search for other functional homologous sequences "is conducted on the basis of what is known, that is, the function, rather than on the basis of what is unknown - the precise structure" said Burk and Lemley.[140]

The first sequence provides the very initial but fundamental idea that "a particular sequence can do a certain kind of job". Subsequently, looking for the other variants having the same function, no matter whether naturally existing or arbitrarily modified ones, will be significantly easier. This fact reveals that, the major technical contribution originates from the identification of a particular sequence-function correlation. Although detailed information may be lacking as on what basis or to what extent the sequence is tolerant to alteration, it only amounts to a minor concern in comparison to the contribution. Particularly, the vast majority of variants encompassed in a given homology range are arbitrarily modified; and considering the top-down nature of the knowledge in biotechnology, they are impossible to be reached without referring to the disclosed sequence. As long as the distance in homology is reasonably close, even without detailed knowledge, persons skilled in the art will have no problem in predicting the similar function of a variant.

Skilled persons in sufficient disclosure and support may need to answer the same question when the claim contains parallel methods or products which are not fully described and which do not share the same fundamental technical principle. But it is simply not the case for sequence-related inventions. For a sequence-related invention, the first sequence-function

---

139 Robert A Hodges, 'Black Box Biotech Inventions: When a "Mere Wish or Plan" Should Be Considered an Adequate Description of the Invention' (2001) 17 Georgia State University Law Review <http://readingroom.law.gsu.edu/gsulr> accessed 10 September 2017. See also John M Lucas, 'The Doctrine of Simultaneous Conception and Reduction to Practice in Biotechnology: A Double Standard for the Double Helix' (1998) 26 AIPLA Quarterly Journal <http://heinonline.org/HOL/Page?handle=hein.journals/aiplaqj26&id=389&div=16&collection=journals> accessed 10 September 2017.

140 Dan L Burk and Mark A Lemley, 'Is Patent Law Technology-Specific?' (2002) 17 Berkeley Technology Law Journal 1155 <https://login.e.bibl.liu.se/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=aph&AN=9133378&site=eds-live&scope=site> accessed 10 September 2017.

correlation forms the singularity. Whatever population the rest of the sequences may be, they only amount to a tiny fraction compared to the technical contribution.

These two persons thus face very different questions. The person in sufficient disclosure is about to read the written description. He may want to know how to obtain the said molecule from available sources, what is the identity of this molecule – the sequence, what is the specific utility, and if not available in the prior art yet – verification methods and technical parameters of its function. The person in support will examine that, given an arbitrarily drafted homology range, whether within this distance of homology a variant is still believed to perform a similar function. The first person needs comprehensive and credible information, whereas the second person does not have to answer the question as right or wrong, but an answer as more likely than not.

Therefore, the question to the person in the support requirement should be like a "likelihood of success" in assessing the inventive step. The role of a high homology can be exemplified into two scenarios: 1) if Seq A is known, Seq B is highly homologous to A, there will be a good estimate that Seq B has the same function with Seq A; and 2) if Seq A is known, and someone wishes to modify Seq A within a reasonable homology range, she will experience only limited trials to reach a certain Seq B which maintains Seq A's function. These two scenarios are rooted in the same level of confidence if the value of homology is set. The only difference is whether Seq B is given or to be found. The accuracy of estimation in scenario 1) thus negatively corresponds to the difficulty of finding a Seq B the scenario 2). When 1) is clearly held obvious, it indicates that 2) is not an undue burden.

Having discussed all the above, let us review the reasoning given by the PRB and endorsed by the courts: "without adequate experimental data in the written description, those skilled in the art cannot determine which variants within the claimed homology range, other than the disclosed, would work the invention."[141] Apparently, the PRB wants a concrete answer, which assumes that the skilled person is still so naïve that she needs further teaching to be enabled. But the fact is that the singularity is already reached in the written description, and she is anyway enabled in the first place. The person in support now should, in turn, assess within what dis-

141 PRB Decision No. 17956 (n 12) 16.

tance the variants cannot escape the gravity of the technical contribution of the first enablement.

C. An Example Test Given by the EWHC

Having found that the PRB asked an inappropriate question to the person in the support requirement, a correct question needs to be exemplified for future direction.

In *GlaxoSmithKline v Wyeth*[142], GlaxoSmithKline (GSK) wished to clear the way for its vaccine Bexsero, and sought to challenge the validity of Wyeth's UK part of European patent EP2343308 [143] on multiple grounds. And Wyeth counterclaimed for infringement of the patent. The Claim 1 is as follow:

> *A composition containing at least one protein comprising an amino acid sequence* ***having sequence identity greater than 95% to the amino acid sequence*** *of any one of SEQ ID NOs: 212, 214 and 216, wherein the composition additionally comprises at least one PorA protein.*[144]

As one of those grounds, GSK challenged the threshold figure of 95% homology.[145] GSK argued that this homology threshold did not arise from any of the data in the specification (written description) of the patent, and the figure was arbitrary. Henry Carr J. disagreed GSK's argument, and sided with the technical expert Prof Ala'Aldeen's opinion that "the skilled person would understand from the data [that specified] protein was a useful antigen that elicits antibodies which are cross-bactericidal, and would expect that effect to be related to the degree of amino acid homology."[146] The expert further viewed that "a claim to utility based on 95% homology would be entirely credible and well above the level of homology which would cause the skilled person to question it".[147]

---

142 *GlaxoSmithKline UK Ltd v. Wyeth Holdings LLC* [2016] EWHC 1045 (Ch).

143 GW Zlotnick and others, 'Novel Immunogenic Compositions for the Prevention and Treatment of Meningococcal Disease' <https://www.google.com/patents/EP2343308B1?cl=en> accessed 10 September 2017.

144 *GlaxoSmithKline v Wyeth* (n 138) [68].

145 According to Article 138 of the European Patent Convention, support is not a ground for revocation, instead GSK challenged on the ground of insufficiency, which in its essence is a challenge of support.

146 *GlaxoSmithKline v Wyeth* (n 138) [104].

147 Ibid.

The reasoning held by Henry Carr J. only dealt with the credibility under the given homology range, and did not touch upon the absolute question: which one works? Moreover, this credibility was built upon the known factor that the disclosed sequence was confirmed to be functional in the first place. This approach corresponds with the author's opinion that homology claims stand for a level of confidence, not an abrupt inclusion of the huge amount of variants. The huge amount of variants can only be interpreted from its native context, the perspective from the skilled persons. The skilled person appreciates no technological advance or plurality over the number of variants, but the remarkable significance of the first sequence-function correlation. Though needs may arise to find working variants, they never seek to make it exhaustive. Thus, the support requirement ought to be assessed individually rather than on the whole, *i.e.* can the person skilled in the art, inspired by the disclosed sequence, reach at one working variant without undue burden? – If yes, the claimed range is supported. By posing the appropriate question to the skilled person in the support requirement, the unclaimable gap will be effectively constrained.

D. On Non-Working Variants – How to Avoid a "Negative Gap"?

Having addressed the working variants, it is still important to analyse the non-working variants within an asserted homology range. Non-working in this context does not necessarily mean that a variant has no functionality, but only indicates that it does not perform the function as mentioned in the claims.

The author's discussion on the appropriate questions is mainly to address the implicated unclaimable gap. However, there could be a reverse scenario where the accepted homology range by the support requirement exceeds a plausible inventive step, *e.g.* a minor mutation resulted in a new and irrelevant technical effect, for which an inventive step may subsist. Should this happen, the two requirements may face a crossover in their respective homology values. This in turn appears to create a negative gap. When the homology claim relates to an absolute product protection, *i.e.* the product *per se*, a clash in homology values may translate into a prejudice over the later inventive mutation, as the later invention already escapes from the technical contribution documented in the first patent.

This "negative gap" exists because of a breach of the preconditions that the author sets forth in Section IV.A. One-dimensional alignment of sup-

port and inventive step only occurs under the condition of relating to the same technical effect. However, the "negative gap" takes place when the support and the inventive step are regarding different technical effects. Thus, it is important to limit the corresponding protein or polypeptide of the disclosed sequence to a particular technical effect before homology should be employed.

The SIPO Guidelines explicitly addressed that a protein claim could be drafted in such a way:

> *A protein of (a) or (b) as follows:*
> *(a) a protein whose amino acid sequence is represented by Met-Tyr-…-Cys-Leu,*
> *(b) a protein derived from the protein of (a) by substitution, deletion or addition of one or several amino acids in the amino acid sequence in (a) and having the activity of enzyme A.* [148]
> …

Paragraph (b) includes the homology concept "substitution, deletion or addition" and a value "one or several amino acids". Meanwhile, this claim also includes "having the activity of enzyme A" as a functional limitation. This example suggests that homology only works in combination with a given function. Thus, a homology claim in its entirety includes "homology plus function". The homology language is not meant to work alone. In Section III.C, it is already discussed that homology, in essence, represents a level of confidence, but more importantly a confidence on what? This confidence is about the achievability of a certain goal — in this case, a certain function that the homologous sequences perform.[149] Otherwise, a simple homology description does not generate any technical meaning. Hence, in the alignment of the support and inventive step requirements, the coordinate axis of homology is conditioned by the same function of different sequences. Only under the condition of having the same function, homology values can be coordinated and analysed on along the same dimension. A homologous sequence asserting another technical effect may well find its way in filing an independent patent, without being threatened

148 The SIPO Guidelines (n 85) 357.

149 See Sangar and others (n 94). See also UK Biotech Guidelines (n 2) 49, "Claims should be limited by reference to the activity of the reference sequence where there is doubt about the identity of a homologue in relation to the reference sequence".

by the earlier claimed scope of protection. For this reason, the "negative gap" does not exist from the beginning.

In *Novozymes*[150], the enzymatic activity in the claimed homology range, without a further limitation by species of origin, was assigned as a burden for the patentee. This decision, in its effect, conceded that the functional limitation of enzymatic activity has little value in asserting the scope of protection. From the discussion of the preceding paragraphs, it is clear that homology claims must include both elements: homology and functionality. Thus, the current practice broke the homology claim apart, and attenuated the validity of the homology language used in the claims. This practice is neither supported by the SIPO Guidelines,[151] nor by the technical understanding of homology in biotechnology. Therefore, to assess the requirement of support, functional limitation within a homology claim should never be put aside.

150 *Novozymes* (n 4).
151 The SIPO Guidelines (n 85) 357