IV. Novozymes may Create an Unclaimable Gap

A. Inventive Step and Support are One-Dimensionally Aligned by Homology

The Patent Law defines the inventive step as involving two separate requirements: prominent substantive features and notable progress.[108] An invention has prominent substantive features when it is not obvious to the person skilled in the art.[109] This non-obviousness is assessed against the technical motivation of the person skilled in the art to apply the different features on the closest prior art.[110] The other requirement, the notable progress, is to mean the advantageous technical effects.[111] The SIPO Guidelines enumerates four criteria to fulfil this requirement, in which No. 2 recognises that a different inventive concept to achieve substantially the same technical effect in the prior art qualifies notable progress.[112] An invention like in the '338 patent has its inventive concept as providing a new type of enzyme that performs prior art functions. In other words, this kind of invention finds a different way to produce a technical effect in the prior art. The requirement of notable progress is thus fulfilled in such scenario. In the following discussion, the inventive step will be identical with non-obviousness.

The inventive step confers upon a patented invention a distance beyond the reach of persons skilled in the arts, and the support requirement tunes the claimable scope of protection. For sequence-related inventions targeting the same technical effect, an independent patentable invention in assessing its inventive step must supersede the claimed scope of protection of the prior art patent and its extent of obviousness. The relationship between a later independent patent (B) and the prior art patent (A) will be as expressed below:

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108 The Patent law (n 27) Article 22.3. Note that the Patent Law employs "creativity" for this concept.
109 The SIPO Guidelines (n 85) 195.
110 Ibid 196, Section 3.2.1.1 (3).
111 Ibid 200, Section 3.2.2.
112 Ibid.

Inventive Step B (p2) > Claimed Scope A (p1) + Obviousness (p2) (7)

In this inequation, the left side represents the later invention, whereas the right side stands for prior art patent. The numerals accompanying each term refer to different persons skilled in the art. To determine the claimed scope of the prior art patent (A), the relevant date for those skilled is the filing date (p1). As for the inventive step of a later patent (B), those skilled in the art have the relevant date of filing that patent (p2). The obviousness of the prior art patent (A) is thus assessed on the same date (p2).

Thereafter, if the Claimed Scope A is to the best extent a patentee can claim, it equals Claimable Scope A. It means that there is no such fault of the patentee that she gives up any scope if she can satisfy the support requirement. In the situation of homology claims, as discussed in Section III.B, the patentee faces tremendous variants and has no effective way to counter an argument like which one works. There is nothing that the patentee is intending to give up, as coined by the concept of the doctrine of dedication.[113] The inequation transforms to:

Inventive Step B (p2) > Claimable Scope A (p1) + Obviousness (p2) (8)

Now we assume that the scientific knowledge of the sequence in the prior art patent (A) has not evolved, and the mutagenesis techniques have no evolutionary progress against large scale experimentation. Under this assumption, the common and general knowledge of the persons skilled in the art are stable for p1 and p2. The only difference between the two will be that p2 and p1 may have different dates to determine prior arts. This assumption can be tested against the history of prosecution and invalidation proceedings of Patent B. If no other prior art relevant to the sequence or technical argumentation is raised, this case falls into the hypothetical scenario. In such a scenario, Obviousness A effectively approaches zero, as long as Patent B and Patent A deals with the same technical effects. Because, person p2, without any new knowledge and better skills, cannot add anything more when the earlier patentee has claimed to the best extent - Claimable Scope A.

113 The Supreme People's Court, O*n Several Issues concerning the Application of Law in the Trial of Patent Infringement Dispute Cases* (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), Fa Shi [2009] 21 Article 5.

Now the inequation becomes:

Inventive Step B (p2) > Claimable Scope A (p1) (9)

p2 has its relevant date on the filing date of Patent B, and p1 has the date of filing Patent A. But what exactly is the difference between p2 and p1? The assumption leading to (9) already dictates that no new knowledge and better skills are relevant. And certainly she (p2) knows the prior art patent (A). What does p1 know? Given the statutory language "based on the written description"[114], it is apparent that she should have known the teachings of Patent A, otherwise she has nothing to base upon when drafting claims. The only difference is that p2 reads the claims that p1 has written, thus p2=p1. Taken that they are persons with the same knowledge and the same skills, they should be able to reach an acceptable consensus to delineate the claimable and free-to-operate spaces. To this point, the inequation has been simplified to the following:

Inventive Step B > Claimable Scope A (10)

From the above reasoning, we know that Claimable Scope A is governed by the support requirement. If the patentee did the best she could to safeguard her interest, the Claimable Scope is then solely a matter of discretion of the support requirement. This discretion, in the context of this thesis, is the attitude on homology. Given that Patent B performes the same technical effect as Patent A does, the only aspect to establish an inventive step is how the way of doing so is different. For a biological sequence, the sole criterion is how far is deemed to be a safe distance to separate two sequences as different inventions. Again, this is a decision on homology. So far as homology is concerned, the requirements of inventive step and support are now aligned one-dimensionally.

B. Disparity in Views on Homology Creates an Unclaimable Gap

In the preceding discussion, some preconditions are set forth to reveal the interrelation of inventive step and support requirements. They are: 1) the inventive concept only covers the identification of a particular sequence of

114 The Patent Law (n 27) Article 26.4.

a new kind, and does not extend to a new technical effect; 2) no further knowledge relating to the prior art sequence enters the public domain; and 3) there is no revolutionary technological progress in dealing with a large scale experimentation. Condition 1 and 2 can be found by examining the prior art documents produced in a proceeding when assessing the inventive step; Condition 3 is by default given, in view that the question "which one works" and the scale of experimentation makes a very high burden. In this section, another PRB case is analysed to examine the PRB's position on homology for the requirement of inventive step.

The patent application CN 201080053990 by Novozymes disclosed polypeptides having xylanase activity and their coding polynucleotides, isolated from *Penicillium pinophilum*. The priority date was 29 Sep 2009. One piece of prior art, dated in 2005, disclosed a xylanase from *Penicillium funiculosum*, with both the amino acid sequence and the coding sequence.[115] Through sequence alignment, one of the claimed amino acid sequence SEQ ID No:2 shares 96.56% homology with the prior art sequence.[116] The examination division rejected relevant claims for lack of inventive step. The examination division reasoned that in light of high homology, the finding of another xylanase within the same genus was obvious.[117] In the appeal, the PRB maintained the decision and added more detailed technical reasonings: persons skilled in the art could clone the highly homologous sequence, using primers designed from the prior art sequence. The test of enzymatic activity was known, and the prior art sequence provided enough motivation to find a functional enzyme in a species within the same genus. In conclusion, the application was rejected for lack of inventive step.[118]

This decision suffers from some flaws in its reasoning. As the author found, the genome sequence of *P. pinophilum* was only made available be-

115 Caroline SM Furniss, Gary Williamson and Paul A Kroon, 'The Substrate Specificity and Susceptibility to Wheat Inhibitor Proteins of *Penicillium funiculosum* Xylanases from a Commercial Enzyme Preparation' (2005) 85 Journal of the Science of Food and Agriculture 574.

116 The nucleic acid sequence has a homology of 92.79% compared to the prior art. But the homology value of nucleic sequence and amino acid sequence cannot be judged using the same standard. Because, codon degeneracy allows certain level of changes to the nucleic sequence without troubling the person skilled in the art.

117 The actual finding work usually bases on the homologous nucleic acid sequence.

118 PRB Decision No. 120691 (n 66).

tween 2016 and 2017, [119] the "high homology" between the claimed sequence and the sequence in the cited prior art was unlikely to be known by the inventor before hand. It is only after the claimed sequence had been successfully identified by the inventor that 96.56% homology became relevant. Before the invention was created, the existence of a high homology itself remained a hypothesis. Therefore, the argument based on a later-identified high homology is not an appropriate reasoning,[120] though the same decision may be reached in other ways. Despite all this, the decision sends out a clear signal that homology is such a prominent factor that the examiners and the Board largely rely upon it. Furthermore, in evaluating the inventive step, the functionality of a sequence did not attract much attention; the PRB explained that as long as the assumption of functionality was there, to test the functionality with known methods would be a routine task.

As an anecdote, it is interesting to know that during the review, the homology range of the claimed sequence was amended from 99% to 100%. It means that only the disclosed sequence is sought for protection, and no real homology claim is involved. A species of origin limitation is already included in the original version. The complete abandonment of homology claim took place during the proceedings of Novozymes' glucoamylase patent, after the Beijing High Court's ruling and before the decision of the Supreme Court. It is apparent that the invalidation decision from the first two instances affected the applicant's confidence on such kind of claims. Since this xylanase patent application is also from Novozymes, the same applicant centred around in this thesis, it makes the xylanase patent a

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119 Cheng-Xi Li and others, 'Genome Sequencing and Analysis of *Talaromyces pinophilus* Provide Insights into Biotechnological Applications' (2017) 7 Scientific Reports 490 <http://www.nature.com/articles/s41598-017-00567-0> accessed 10 September 2017. Note that the species name was changed: *Talaromyces pinophilus* = *Penicillium pinophilum* <http://www.mycobank.org/BioloMICS.aspx?TableKey=14682616000000067&Rec=480573&Fields=All> accessed 10 September 2017.

120 The SIPO Guidelines (n 85) 209, Section 6.2: "when evaluating the inventive step of an invention, the examiner is apt to underestimate the inventive step of the invention since he has already known the contents of the invention, and hence a mistake of *ex post facto* analysis is likely to be made. Therefore, the examiner shall always bear in mind that, in order to reduce and avoid the influence of subjectivity, the evaluation shall be presumed to be made by a person skilled in the art on the basis of comparison between the invention and the prior art before the filing date thereof".

quintessence to demonstrate a plight as such: a patent applicantion cannot support its homology claims, even in a very narrow range of ≥99%, unless species of origin is further limited; but a lower homology like 96.56% has no problem penetrating the boundaries of species classification, and rendering an invention obvious.

Adding to the discussion on species of origin limitation, we now see that species of origin can help to reduce the doubt of support about homology, but cannot prevent the influence of confidence by homology. This phenomenon makes the species of origin only a passive choice of an applicant, but should not be a justifiable and universal method to further limit a homology claim.

Although the xylanase patent received an inventive step rejection based on a 96.56% homology, it is still not clear how low a homology should be to escape such rejection. In examples provided by the Japanese Patent Office (JPO),[121] Case 6 shows a scenario where the claimed sequence shares 80% homology with a prior art sequence, and it is held lack of an inventive step, unless the difficulty to obtain the claimed sequence can be otherwise provided. The earlier mentioned EPO case T 0111/00 showed that 78% homologous to the prior art sequence made the claimed sequence obvious. But the obviousness was partially based upon secondary considerations.[122] Considering other patent offices' practice, it is thus reasonable to believe that in China the actual threshold of homology to establish an inventive step can be much lower than the exemplified value. In view of the JPO's example and the EPO's case law, the threshold in China has no reason to be above 90%.

When incorporating the homology values into Inequation (10), we see that to establish inventive step, the homology is supposed to be much lower than 96.56% - possibly the requirement will not be any easier than 90%; and 99% cannot get supported without species of origin, which effectively puts the current value of support in fact at 100%. As a consequence, a large gap appears between the homology thresholds of support and inventive step requirements. A problem then arises - what is the nature of the unclaimable gap?

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121 Japan Patent Office, *Examples of examinations on the inventions related to genes* <http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/dnas.htm?url=/tetuzuki_e/t_tokkyo_e/dnas.htm> accessed 11 September 2017.

122 T 0111/00 (n 66).

C. The Unclaimable Gap May Constitute a Discrimination

The unclaimable gap may find its justification based on the fact that the person skilled in the art usually searches for new inventions among sequences in their wild-type form; but to support a homology claim, the patentee has to consider all other possible mutations.

In the review of the xylanase patent, the PRB correctly pointed out that the person skilled in the art can use primers to probe the possible homologous sequences in species within a certain taxonomic classification. Although the author argued that the existence of such homologues and their homology are all in hindsight, it does not change the fact that the skilled persons have a relatively small pool to conduct their searching. Therefore, the belief on possible homology can effectively lead the person to a claimed sequence. Meanwhile, in the support requirement, the PRB and the courts wished to apply a similar argument of the pool size. They reasoned that in light of the large population of variants and the lack of sequence-function knowledge, a skilled person could not predict which variant works. Should this argument be justifiable, the unclaimable gap might find its grounds. But under scrutiny, this is unlikely to be the case.

The searching in the wild-type has its root in reality. It is survival of the life in their natural environments that gives rise to the different sequences and their functions. The knowledge of any particular sequence having any useful function owes largely to the naturally existing. Even in the era of synthetic biology, when the skilled have the power to edit these sequences to work in an entirely different way, this correlation is still unbreakable. Unlike the situation where a person can apply the laws of nature in an arbitrary technical embodiment, in the sequence-related invention man gets the idea from a sequence and embodies an invention as such, or a new idea into another sequence. This makes a man-made sequence in any matter a mimic or an alteration of the natural ones. Therefore, for any existing function already achieved by prior art sequences, the searching for a new type, albeit a homologous one, is always conducted among the natural sequences. This is a confidence beyond the sequence-function correlation; it even extends to the existence of such sequences. But considering that

there is a limited number of natural ones to test, this confidence justifies an attempt.[123]

The situation in supporting a claim is quite different. The purpose of claims is to prevent misappropriation. The primary goal of the claimed homology is to defend against arbitrary modifications.[124] In such a case, a homology claim has to face a tremendous amount of variants due to the combinations exemplified in Section III.B. If the same argument for inventive step is applied here, there is no chance to discharge the requirement. However, the seemingly numerous variants are the perspective from the applicant. While the purpose of the claim is to defend against other parties, the standing point should not be of the applicant but a person who wishes to achieve the same technical effect starting from the disclosed sequence, especially a wild-type one. From this person's perspective, the aim is to find one working variant, not to test every single variant in the claimed range. In light of the confidence based on high homology, this person expects to experience only a few trials before she reaches one that works perfectly to achieve the same technical effect.[125] In this scenario, the experimentation burden for this person cannot be deemed high.

The knowledge of a sequence is predominantly a matter of top-down discovery, not a bottom-up design of an inventor. An inventor can only contribute to combining and altering certain functions, but the building blocks remain as a gift of nature. Therefore, there is little chance for the person skilled in the art to reach a similar sequence without knowing the one in prior art. In other words, a variant is not an independent creation,

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123 Following the Court's in argument *Novozymes* (n 4) that there is usually one or several sequences among individuals of the same species, the inventor only need to try representative strains of one species, and the amount to examine is largely dependent on the availability of sample species.

124 T 2101/09, Human Delta3 Notch/MILLENNIUM, EPO Technical Board of Appeal, 26 Feb 2013. "It is common practice in the field of biotechnology that claims […] are not required to be limited to a very specific sequence but may also embrace molecules having a certain degree of homology and/or identity to this specific sequence. […] This practice allows patentees/applicants **to protect their inventions against arbitrary modifications of the specific sequences**".

125 Conversations with two biotechnology researchers provided the expected number of trials as follows: a technician in AppTec (a global research outsourcing provider in Wuxi, China) projected less than 10 possible trials before reaching a working variant, based on "99% homologous to a 591 AA sequence"; a postdoctoral researcher in Singapore Agency for Science, Technology and Research (A*STAR) predicted 20 possible trials at most.

but a derivative. Hence, a change made to the claimed sequence without targeting any other technical effects can never contribute to technology. This effort could never be deemed inventive, and should not be encouraged. However, if the change is done to generate other functions, it will automatically fall outside the claimed scope of protection, in light of the further functional limitation in a homology claim.

A certain level of homology has conferred upon the skilled persons a confidence both to conduct searching and to make working variants. As discussed in the preceding paragraphs, the huge amount of variants is only a fact from an omniscient perspective, not the perspective of the skilled persons. From the skilled person's perspective, the claimed homology range is not a "laundry list"[126] which seeks an extension of protection to those not tested, but a boundary which prevents non-inventive and non-meaningful efforts in modifying the claimed sequence. Thus, it is not appropriate to impose an unreasonable burden upon an applicant claiming a homology range. The unclaimable gap in Chinese patent law practice seems ungrounded.

Admittedly, the support requirement need not always match the standard of inventive step. There is always a possibility that further knowledge and techniques infiltrate into the public domain, and push the inventive step further. But it is not the case discussed in this thesis. Analysis of the relevant knowledge and techniques has already ruled out the contribution from other sources. This thesis enjoys a privilege to align only the support and inventive step requirements in a single dimension so that a significant mismatch is conspicuously exposed.

Protection in exchange for disclosure forms a fundamental principle of the patent law.[127] Under this principle, the system of patent law works in such way as to grant a term of monopoly on the economic aspects of an invention, making the technological contributions eventually fall into the public domain. The unclaimable gap, however, paves another way to directly put an inventor's contributions into the public domain without any compensation measures. The unclaimable gap, in its nature, is a direct de-

126 See, *e.g. Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) "a 'laundry list' disclosure of every possible moiety does not necessarily constitute a written description of every species in a genus because it would not 'reasonably lead' those skilled in the art to any particular species".

127 T 1452/06, Serine protease/BAYER, EPO Technical Board of Appeal, 10 May 2007 para 23. See also, *Pfaff v. Wells Electronics, Inc.* 525 U.S. 55 (1998) 63.

privation of the technical contributions made by an inventor. There are many ways that the public domain can benefit from additional technological progress without delaying, by publication of books and articles, the obviousness in light of prior art combinations, the doctrine of dedication and the abandonment of patent rights. But expropriation of protection from a patentable invention should never be one of them. Such conduct will undermine the purpose of the patent law. By creating a gap, this practice prevents an inventor either from claiming a reasonable scope of protection, or from establishing an inventive step with the matching standard. As a result, technical contributions within such a gap directly fall into the public domain.

This phenomenon in the patent practice is nothing but a *de facto* discrimination to biotechnology, which is not tolerated by the TRIPS Agreement. As required by Article 27.1 of this Agreement:

> *...[P]atents shall be available and patent rights enjoyable without discrimination as to ... the field of technology...*[128]

Unlike the common form of discrimination, which prevents patentability of inventions from certain technological fields,[129] the discrimination in homology claims does not refuse protection but sets up unfriendly double-standards that expropriates some technical contributions of applications and patents. In view of the ambition to build up a strong IP environment, this inappropriate practice should be corrected.

D. Downregulating Inventive Step is Not a Feasible Option

The unclaimable gap, without a plausible cause from the growth of prior art and common and general knowledge, is a result of decoupling persons skilled in the art. For this reason, either side needs to be examined against their proper capability. To restrict the unclaimable gap, two options can be made. One is to lower the bar for inventive step, and the other is to relax the support requirement.

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128 TRIPS Agreement (n 78).

129 Stefania Fusco, 'TRIPS Non-Discrimination Principle: Are Alice and Bilski Really the End of NPEs?' <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2653463> accessed 10 September 2017.

But, to lower the bar for inventive step may not be an feasible option. Firstly, being a substantive requirement of patentability, the requirement of inventive step has been explicitly included in Article 27.1 of the TRIPS Agreement.[130] On the other hand, the requirement of support lacks grounds in international treaties. A treaty-level requirement is supposed to perform a role in international patent law harmonisation. It influences proper functions of international filing cooperations. The requirement of support is dealing with the drafting of claims which thus enjoys more flexibility with regards to amendment, compared with written descriptions. In light of the exemplified views from JPO and EPO, it is unlikely that the practice in China will change. Secondly, lowering the bar for inventive step may lead to the tragedy of anticommons.[131] This option inevitably avails more patents surrounding the first known sequence-function correlation. In its appearance, it looks as if an implementer has multiple choices. However, with the expansion of relevant knowledge and techniques, these closely situated patents may grow in their equivalent powers.[132] Possibly, significant merger of scope will occur among multiple patents. At that moment, one particular functional sequence may face multiple right owners. The exploitation in turn becomes extremely difficult. This is exactly an unfavourable situation typified by the tragedy of anticommons. Lastly, even if the significant merger might not occur, a lower inventive step would still be unfavourable, as it finally affirms the narrow scope of protection, disincentivising innovation as no one is likely to receive enough economic reward to recoup their costs or to support further research and development.[133]

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130 TRIPS Agreement (n 78) Article 27.1: "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, **involve an inventive step** and are capable of industrial application".

131 MA Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Science 698 <http://www.sciencemag.org/cgi/doi/10.1126/science.280.5364.698>.

132 The relevant date for the doctrine of equivalents is the date of infringing activity. See The Beijing High Court, *Guidelines for Patent Infringement Determination* (2013) Article 44.

133 See Kenneth G Chahine, 'Enabling DNA and Protein Composition Claims: Why Claiming Biological Equivalents Encourages Innovation' (1997) 25 AIPLA QJ 333.

The author thus seeks to address a plausible solution to the unclaimable gap on the support's side.