Standing Committee on

Subcommittee Biotechnology

2017

International Association for the Protection of Intellectual Property
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Date: 12th October 2017

REPORT
Standing Committee on

Subcommittee Biotechnology

Chair: Jürgen MEIER
Responsible Reporter: Ralph Nack

1) Report on the activities of your Standing Committee during the reporting period

Please provide a general overview of the activities of your Standing Committee over the last 12 months, including at least:

a) Internal meetings of the Standing Committee during the reporting period (whether by telephone, video conference or in person);

The last personal meeting of the members of the Biotechnology Subcommittee took place during last years conference in Milano (September 18, 2016). It was held as a joint meeting with the Pharma Committee. Major discussion points were our "Gene Patenting Position Paper" and a corresponding "Resolution" as well as novel issues and concerns on the deposits of biological materials as well as the corresponding release practice of certain depositories. This prompted a new project for the Biotechnology Subcommittee, namely a new position paper on "Deposits" which is currently under discussion between the members of the Biotech Subcommittee.

Further telephone discussions between members of the Biotechnology Subcommittee took place on March 15/16, 2017 and on June 15/16, 2017 during which our "Gene Patent Position Paper" was reviewed and the "Gene Patent Resolution Draft" for Sydney was discussed. Further information on deposits of biological material and/or microorganisms was exchanged.

Individual members of the Biotech Subcommittee also joined a telephone conference of the Pharma Committee on September 5th, 2017. It is intended that the Pharma Committee and Biotech Subcommittee will work on a joint project relating to antibody patenting.

Since on April 1st, 2017 Claire Baldock resigned as chair from the Biotech Committee and Jürgen Meier took over. Several phone conferences and a personal meeting between Claire and Jürgen took place in oder to garantee a smooth transition. The Biotech Subcommittee is extremely pleased that Claire will remain a member of the Commitee. Claire has not only been a very successful and dedicated chairperson of the Commitee. Her advise and help is still highly appreciated and she has again proven to be an extremely active and supportive member of the Commitee.

Besides the above mentioned phone conferences and meetings, several individual phone discussions and e-mail exchanges took place in particular in order to co-ordinate our "Gene Patenting Resolution" and the position paper on "Deposits".

b) any external representation on behalf of AIPPI by any member of your Standing Committee;

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none

c) any contribution by your Standing Committee to any external consultations; and

none

d) any studies or analyses undertaken or position papers prepared by your Standing Committee, with a brief summary of the outcome(s).

The Committee has discussed various studies during this year and has in particular finalized the "Gene Patenting" Position Paper and the corresponding Resolution draft (to be presented in Sydney). Furthermore, a first draft of a Position Paper on "Deposits of Biological Material" was prepared but is still discussed within the Committee and between the members.

a) Gene Patenting Position Paper and Resolution (draft) for Sydney

The last draft for AIPPI Position Paper on Gene Patenting was approved by 18 out of 18 members of the Biotech Subcommittee in June 2017. The corresponding final draft for the Gene Patenting Resolution was also agreed on and provided to the Reporter General Team end of July 2017.

Both documents (Position Paper and Resolution-Draft) were approved by the AIPPI Bureau in August 2017 and were send to the National and Regional Groups as well as to Delegates of Independent Members with an invitation to provide written comments on the resolution.

The Gene Patenting Resolution (draft) as well as comments thereon will be further debated during the Plenary Session at the Sydney Congress (Sunday, October 15th, 11.00 to 12.30 am).

The Gene Patenting Position Paper and the corresponding Resolution concern the patenting of genetic materials, whether in a form isolated from nature by a technical process or artificially synthesized by man. The Biotech Subcommittee takes the position that genetic material should not be regarded as subject-matter excluded from patentability by virtue of TRIPS Art. 27(2)/(3), in particular, should not be regarded as inventions contrary to *ordre public* or *morality.*

Accordingly, the Position Paper as well as the Resolution (draft) take the position that (isolated) genetic material, whether or not identical to that which occurs in nature, should be treated for patent purposes as a chemical compound. The position is taken that genetic material when isolated from nature or artificially synthesized, which is novel, inventive and capable of industrial application should constitute patentable subject-matter.

All Committee members have been very active in the discussion and preparation of the position paper and the Resolution (draft). Committee members who contributed to the drafting of the position paper as well as the draft Resolution include Claire Baldock of the United Kingdom (main author), Graeme Boocock of Canada, Takashi Fujita of Japan and Jürgen Meier of Germany.

b) Deposits of Biological Material and Harmonisation of Practice under the Budapest Treaty on the International Recognition of Deposits for the purpose of Patent Procedure

Prompted by a couple of recent (international) litigation proceedings and also enablement discussions before certain Patent Offices, the Biotech Subcommittee has decided initiating an international study to determine how deposits of biological material and/or microorganisms are treated during the prosecution of patent applications before national and regional Patent Offices. Furthermore, it is elucidated what formal requirements are to be met for such deposited materials in order to be accepted for patent purposes. A further aspect of this study concerns the release of such deposited material to third parties.

The issues to be considered in this international survey are, *inter alia*: (i) at what point in the patenting procedure should a microorganism deposit be made for the purpose of sufficiency of disclosure, (ii) when should information about the deposit (name of International Depository Authroity, IDA, and accession no) appear in the patent specification, (iii) to whom should a third party make a request for a sample of the deposit, the national or regional Patent Office or the IDA, and

when, (iv) to whom may the deposit be released and (v) what obligations does the requester have to meet in order for a sample of hte deposit to be released to them.

The Committee received detailed and important input on the questions from several European practioneers (U.K.,Sweden, Italy, Germany), but also from the U.S., Canada, Brazil, Australia, Japan, China, Korea, the Philippines and Israel.

The Committee still discusses certain issues of this study, in particular the date from which deposited material may be released to third parties and the right of the applicant/patentee to object to the release of samples to third parties.

This "Deposit" paper is to be discussed during the Subcommittee's personal meeting in Sydney and in a joint meeting with the Pharma Committee. It is intended to provide the AIPPI Bureau with a finalized version of this position paper by the end of 2017/beginning of 2018.

2) Key issues/developments during the reporting period

Please include any significant case law, legislative or regulatory developments, or policy initiatives, including their relevance and/or any implications for the work of your Standing Committee or for AIPPI more generally.

Committee members have reported on developments in their corresponding jurisdictions in Brazil, Canada, China Europe, Japan and Korea (in alphabetical order) as occured in the last year.

(A) Brazil

Gabriel Di Blasi provides the following updates on legislation and regulatory approaches related to Biotechnology in Brazil:

1. Current Legal Framework:

1.1 Law no. 9.279/96: Brazilian Industrial Property Law (BIPL)

Regarding biotech patents, articles 10 and 18 determine that:

Art. 10: The following are not considered to be inventions or utility models:

IX. all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.

Art. 18: The following are not patentable:

II. all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability—novelty, inventive step and industrial application—provided for in Article 8 and which are not mere discoveries.

Sole Paragraph. For the purposes of this Law, transgenic microorganisms are organisms, except for all or part of plants or animals, that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions

Those articles are complemented by BPTO's Resolution n° 144/2015, which determines that when an invention involves biological sequences, the patent application must describe its practical use; that is, industrial application can only be achieved when the patent application reveals a utility for the referred biological sequence.

1.2 Law no. 13.123/2015: Brazilian Biodiversity Law

Before Law no. 13.123, the use and exploitation of the Brazilian Biodiversity was governed by a poorly written Provisional Measure that, created in 2011 as a fast executive response for the Convention for the Biological Diversity. The Provisional Measure would present number of rules that would make the access to the Brazilian Biodiversity difficult, such as excessive bureaucracy, extremely complex to share the benefits and stipulating overly excessive penalties for non-compliance, which ultimately would make companies give up on exploiting ring the rich biodiversity in Brazil.

That being said, in 2015 the government approved a most-awaited law determining the access to Genetic Resources (GR) and Associated Traditional Knowledge (ATK) and its requirements.

The law establishes that the Board of Management of Genetic Heritage – CGen will perform the public management required in this area and regulate the registration of private companies and institutions that wish to have access to GR and ATK .

The Biodiversity Law focused on three main points (I) decreasing the bureaucratization of the process to access the biodiversity; (II) assuring that the sharing of benefits is fair and; (III) promoting biodiversity with focus on R&D.

Therefore, Law no. 13.123 had important victories such as implementing and improving key concepts, avoiding dubious interpretation, implementing a simple registration process to the companies that wish to explore GR and ATK.

It is up to CGen to establish and manage the access to GR and ATK, and regulate the Benefits Sharing Agreement, which consists of an agreement in which companies must sign to explore Brazilian biodiversity. This agreement a form to repay society and, most importantly, the providers of GR and ATK who granted the access and conduction of R&D to Brazilian biodiversity. In sum, the benefits sharing agreement can be provided either on a monetary or non-monetary basis, with the monetary form of compensation being limited to up to 1% of the company's net revenue obtained with the exploitation of the product or up to 0,1% if CGen signs an agreement with representatives of a segment to reduce the maximum percentage of the benefits sharing agreement. It's important to note that, in accordance with the Biodiversity Law, the Benefits Sharing Agreement is due to the final product of the R&D. Some companies are exempted to take up such agreement, such as small businesses and intermediary companies. A National Fund for the Sharing of Benefits (FNRB) was created to promote value to the Brazilian biodiversity.

Although this law was considered a breakthrough in the history of access to biodiversity, it still could not be applied for its entirety as it demanded a deeper regulation, which had to be discussed with specific segments of the civil society, namely the native communities. After intense debates, a decree was issued in May 2016 in this regard.

1.3 Decree no. 8722/2016: Regulates the Biodiversity Law

This decree was responsible for enabling the implementation of the Brazilian Biodiversity Law.

It further establishes CGen's responsibilities and attributions, which will be carried out by an executive board. CGen's executive board will operate an online system named National System of Management of Genetic Heritage – SISGEN, a platform through which interested parties shall request access to GH and ATK, submit Benefits Sharing Agreements and request other provisions regulated by the Biodiversity Law.

Other important aspect of the Decree is establishing the conducts characterized as infringement to GH and ATK, such as financially exploiting a final product based on the Brazilian Biodiversity without notifying CGen and requesting an IP right in Brazil or abroad that derives from access to GH and ATK without previously registering on CGen.

1.4 Decree no. 9085/2017: creates CGen's acting executive board

This decree creates a supporting department for CGen, which will act as its executive board. This will allow SISGen to operate in full capability very soon – considering that it is, so far, running a test version.

2. Biodiversity Law and Biotech Patents

The Biodiversity Law and its regulatory Decree contain a few dispositions related to the request of Biotech Patents that were made possible by accessing GT and ATK before the BPTO.

The Biodiversity Law states, in article 47, that the granting of an IP right obtained through the access of GR or ATK is conditioned to the registration at CGen for the access to the biological material, whereas article 12 (second paragraph) of the same law states that the registration must be prior to the IP right application.

Furthermore, article 109 of the decree no. 9722/16, which regulates the Biodiversity Law, reiterates that the applicant must inform the BPTO if there was access to GR or ATK, as well as if there a registration was performed before CGen.

In view of the importance of the discussion, the majority of IP practitioners in Brazil understands that CGen's registration should be mandatory just for the granting of the Patent that is based on GR or ATK and not in the moment of filing its application.

Therefore, the BPTO should not condition the beginning of the prosecution of a patent application to any document proving registration or authorization to access GR or ATK.

3. Most Important Bills that propose changes in the mentioned legal framework

3.1 PL 4961/2005

In 2005, a Bill was presented in the Federal Legislative Branch to modify articles 10 and 18 of the BIPL, proposing the following changes:

Current wording	Proposed wording
Art. 10: The following are not considered to be inventions or utility models: IX. all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.	Art. 10: The following are not considered to be inventions or utility models: IX. all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, **except substances or materials extracted from them, obtained or isolated therefrom, which present the requirements for patentability in article 8 and are not mere discoveries**

Art. 18: The following are not patentable: II. all or part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability—novelty, inventive step and industrial application—provided for in Article 8 and which are not mere discoveries.	Art. 18: The following are not patentable: II. all or part of living beings, except transgenic microorganisms **and the substances and materials detailed in article 10, IX**, that satisfy the three requirements of patentability—novelty, inventive step and industrial application—provided for in Article 8 and which are not mere discoveries.

The change proposed should be highly supported by national and international organizations related to IP, once it will take Brazil to a next level in Biotech Patents, considering that the limitations on articles 10 and 18, as they are currently worded, prevent the country to fully grasp its biodiversity.

Also, the TRIPS agreement does not present any barriers to the patentability of genetically modified microorganisms. In fact, most of the countries consider it patentable. Brazil could gain much with the proposed change in the legislation. That is also the position of ABPI.

(B) Canada

Graeme Boocock comments on recent developments in Canada as follows:

1. In its much anticipated June 2017 decision in AstraZeneca Canada Inc. v. Apotex Inc. (2017 SCC 36[https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/16713/index.do]), the Supreme Court of Canada struck down the problematic Promise Doctrine, stating that it was “not good law”. Under the Doctrine, Canadian courts had looked to the description for statements promising certain utilities, and had assessed patent claims against those elevated promises, as opposed to the longstanding “mere scintilla” threshold. In some cases, claims to highly successful pharmaceuticals had been invalidated for lack of utility under the Promise Doctrine. In its decision, the Supreme Court found that the Promise Doctrine has no basis in the Patent Act. It further found that the doctrine was antagonistic to the patent bargain, in that it would discourage patentees from disclosing fully. The Court articulate a two-part test for utility as follows: “First, courts must identify the subject-matter of the invention as claimed in the patent. Second, courts must ask whether that subject-matter is useful — is it capable of a practical purpose (i.e. an actual result)?” Notably, the Supreme Court did not venture into the Doctrine of Sound Prediction: a further aspect of Canada utility law that can pose challenges during examination and litigation.

2. Significant challenges persist for patent applications in the areas of diagnostic and personalized medicine under a 2015 examination Practice Notice published by the Canadian Intellectual Property Office (CIPO), which had been criticized both for lacking a basis in Canadian law and for being contrary to the Supreme Court’s pronouncements on claims construction. In a March 2017 training presentation[https://ipflyonthewall.files.wordpress.com/2016/10/a-2016-01398.pdf#page=12] , CIPO instructed its examiners to disregard the Supreme Court. Material obtained through access to information[https://ipflyonthewall.wordpress.com/access-to-information-request/select-excerpts/#2013] indicates that the policy was developed amidst internal opposition.

3. CIPO has enshrined new examination practices for antibodies into Chapter 17[https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr01611.html] of its Manual of Patent Office Practice (MOPOP). These changes relax a heretofore very strict approach to sufficiency requirements for certain antibody sub-types, including humanized and fully human antibodies. These changes were prompted by a 2015 decision of the Patent Appeal Board pertaining to humanized antibodies.

4. In July 2017, proposed amendments to Canada's linkage regime under the Patented Medicines (Notice of Compliance) (PM(NOC)) Regulations were published with an unusually short, 15-day consultation period. These amendments are made to comply with Canada's obligations under the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA). Proposed change include:

- The introduction of Certificates of Supplementary Protection (CSPs) allowing up to a two-year restoration of patent term for regulatory delays.
- The replacement of former summary proceedings with full actions.
- The introduction of a right of appeal.
- The end of dual litigation.

5. In August 2017, CIPO published for consultation proposed amendments[http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr04277.html] Patent Rules to enact earlier amendments to the Patent Act made to comply with the requirements of the Patent Law Treaty. The revised Patent Rules, once finalized, are expected to be enacted in early 2019.

The proposals include significant changes for well-known aspects of Canadian practice, such as:

- A shortened term of 30 months for national phase entry (NPE) for PCT applications. NPE would be possible at 42 months, but only if a declaration is submitting indicating that the failure to enter Canada in a timely manner was unintentional, and provided that the Commissioner of Patents accepts that this was so.
- The introduction of a standard of "due care" for reinstatement in some circumstances.

Of high relevance in life sciences cases is the proposed amendment that electronic sequence listings be excluded from excess page fee calculations

(C) China

Gesheng Huang from China reports the following legislative activities and gives an overview of relevant cases in the life science field:

1.1 Beijing Higher People's Court issued *Guidelines for Patent Infringement Determination (2017)*

On April 20, 2017, Beijing Higher People's Court issued Guidelines for Patent Infringement Determination (2017; thereafter referred as "Guidelines"). The Guidelines contains 153 articles, specifying requirements on the following issues in the patent-relating trial:

(1) Determination of Protection Scope of the Patent for invention or utility model;

(2) Determination of infringement on the patent for invention and utility model;

(3) Determination of Protection Scope of Patent for Design;

(4) Determination of Infringement of Patent for Design;

(5) Determination of Acts of Patent Infringement;

(6) Defense of Patent Infringement.

1.2 SIPO decided to amend *Guidelines for Examination*

On February 28, 2017, SIPO issued *Decisions on amending Guidelines for Examination*, which has taken effect on April 1, 2017. The amendments relate to 13 aspects, wherein in Part II, Chapter 10, Section 3.4 "Specific Mode for Carrying Out the Invention" , the following amendments relating to supplementary experimental data were made:

For the determination of sufficient disclosure of description, the original second part of Section 3.4 stipulating "any embodiment and experimental data submitted after the date of filing shall not be taken into consideration" was deleted. It was replaced with a new Section 3.5 which reads "Examiner should examine experimental data filed after the application date. The technical effects proved by the supplementary experimental data should be obtainable by the skilled person in the art from the disclosure of patent application".

Accordingly, supplementary data should have a connection to the content of the original application.

2.1 Administrative case relating to invalidation dispute over patent named "Thermostable Glucoamylase"; (2016) Zuigaofa Xing Zai No.85

Patent Re-Examination Board's (PRB) Invalidation Decision declaring ZL98813338.5 titled "Thermostable Glucoamylase"partially valid and partially invalid, was maintained upon retrial by the Supreme People's Court (SPC), although said PRB decision was previously overturned by courts of both 1st instance and 2nd instance.

The Patent in dispute:

The patentee of the patent in dispute entitled "Thermostable Glucoamylase" is Novozymes.

The claims in dispute read as follows:

> Claim 6: An isolated enzyme having activity of glucoamylase, which have at least 99% homology with the whole sequence of SEQ ID NO:7, and have an isoelectric point below 3.5 which is determined by isoelectric focusing.
>
> Claim 10: Isolated enzyme according to claims 6 to 9, wherein said enzyme is derived from filamentous fungus Talaromyces, wherein the filamentous fungus is T. emersonii strain.
>
> Claim 11: An enzyme of lcaim 10, wherein the filamentous fungus is T. emersonii CBS793.97.
>
> Claim 12: A cloned DNA sequence, wherein said DNA sequence codes an enzyme exhibiting glucoamylase activity, and said DNA sequence comprises (a)…(b)…
>
> Claim 13: The DNA sequence of claim 12, wherein said DNA sequence is derived from filamentous fungus Talaromyces, wherein the filamentous fungus is T. emersonii strain.
>
> Claim 14: The DNA sequence of claim 12, wherein the filamentous fungus is T. emersonii CBS793.97.

Facts (prior proceedings):

1. The PRB held in invalidation proceeding initiated by Shandong Longda Bio-products Co Ltd (hereinafter referred as Longda) and Jiangsu Boli Bio-products Co Ltd (hereinafter referred as Boli) that the claims in dispute are valid. Specifically, PRB held that "Since the specification has shown that the enzyme derived from T. emersonii CBS793.97 has the activity of glucoamylase, a person skilled in the art can predict that the polypeptide derived from T. emersonii strain and having at least 99% homology with SEQ ID NO:7 can also have the activity of glucoamylase".Claims 11 and 12 as well as claims 13 and 14 are supported by the description.
2. The court of 1st instance revoked the PRB's decision decided that "although the claims have defined the source of the sequence of the specific strain, the definition by homology and in an open-ended way

render the claimed amino acid sequences and DNA sequences to cover various sequence variants. Since the specification did not provide enough experimental data, the generalization of the claims went beyond the disclosure of the specification".

3. The court of 2nd instance maintained the ruling made by the court of 1st instance.
4. The PRB and patentee applied the retrial before the Supreme People's Court.

Rule

Article 26(4) of the Patent Law stipulates that the claims shall be supported by the description and shall define the extent of the patent protection sought for in clear and concise manner.

Legal issue

Did the courts of 1st instance and 2nd instance err in holding the claims in dispute as finding no support in the description since the homology and open-ended claim format cover variants going beyond the scope of description?

Reasoning

Upon retrial, the Supreme People's Court held that,

1. species is the basic unity of biological classification and thus individuals in one species have high similarity with each other on some basic features;
2. the gene sequence of one enzyme in one species or one strain is usually definite, occasionally there may be very few variant sequences with extremely high homology, and correspondingly the enzymes encoded by said genes are also definite or very few;
3. although the sequences having more than 99% homology with SEQ ID NO:7 still have about 5 or 6 amino acids variation, claims 10 and 11 further limit the enzyme source as specific species T. emersonni and specific strain T. emersonii CBS793.97;
4. the double definition by at least 99% homology and the species or strain source have restricted the protection scope of claims 10 and 11 to very few enzymes;
5. claims 10 and 11 also have some other functional definitions derived from claim 6;
6. the working examples 1-4 have proved SEQ ID NO:7 have the activity of glucoamylase;
7. the protection scope of claims 10 and 11 as well as claims 13-14 can be supported by the specification.

Ruling

The ruling of both 1st instance and 2nd instance were reversed and PRB's decision was maintained. Claims of biological sequences defined by homology, source and function can find support in description.

Discussion

The Supreme People's Court set out the rules for the examination whether claims of biological sequences defined by homology, source and function are supported by the description. The ruling provides a valuable guidance on the drafting and examination of patent applications relating to protein and genes. It is beneficial to innovation and the development of biological technique and industry.

2.2 Patent infringement case relating to patent entitled "Compounds and Methods for Immunotherapy and Diagnosis of Tuberculosis"; (2016) Yue Min Zhong No.1093

Plaintiff: State Serum Institute

Defendant: Beijing Wantai Biological Pharmacy Enterprise CO., LTD. (hereinafter referred as "Wantai")

Facts

1. State Serum Institute is the exclusive licensee of the patent named "Compounds and Methods for Immunotherapy and Diagnosis of Tuberculosis".
2. State Serum Institute sued Wantai for infringing its patent rights by producing and selling the alleged infringing products.
3. The court of 1st instance determined the technical feature of the alleged infringing products based on its drug registration documents in CFDA (China Food and Drug Administration), entrusted an institution for appraisal and admitted the conclusion of the appraisal institution that Wantai infringed the patent right of State Serum Institute.
4. Wantai appealed to the court of 2nd instance (the Higher People's Court of Guangdong).

Legal issue

Did the court of 1st instance err in admitting the appraisal opinion to ascertain the infringement conclusion?

Reasoning

1. The court of 2nd instance summoned the appraiser to the court for inquiry.
2. The court further ascertained that the alleged infringing products had passed their expiry date and Wantai failed to provide valid alleged infringing product for appraisal.
3. It has factual and legal basis for the court of 1st instance to ascertain infringement based on registration documents and appraisal opinion.

Ruling

The appraisal opinions should be admitted and the ruling of the court of 1st instance was affirmed.

Discussion

This case is Guangdong's first patent infringement dispute relating to the biological engineering field and involving DNA sequence. The court of 2nd instance, according to the specificity of the alleged infringement product and the specific circumstance of the case, specified the admittance rule on appraisal opinions for cases involving genetic drugs.

2.3 Infringement case relating to New Varieties of Plants "Beauty elm"; (2014) Lu Min Zai Zi No. 13

Plaintiff: Hebei institute of Forestry Science and Shijiazhuang Lvyuanda Garden Engineering Co., Ltd

Defendant: Jiutai Landscaping Management Office

Facts

1. Plaintiff is the owner of new plant variety "Beauty elm".
2. Defendant planted large quantities of Beauty elm in the greenbelt of streets without authorization.
3. Plaintiff sued Defendant infringement of its right of new plant variety by planting Beauty elm without its authorization, requested Defendant to stop the acts of infringement and claimed royalty of exploitation.
4. The court of 1st instance (The Intermediate People's court of Changchun, Jilin) and 2nd instance (The Higher People's court of Jilin) rejected Plaintiff's claim.
5. Plaintiff filed a retrial application to SPC and SPC then designated the Higher People's Court of Shandong to retrial the case.

Rules

1. Article 6 of Regulations of the Peoples Republic of China on the Protection of New Varieties of Plants sets out the exclusive right of variety rights holder "……*Except otherwise provided in these*

Regulations, no other entity or person shall, without the consent of the holder of the variety rights, produce or sell for commercial purposes the propagating material of the said protected variety, or use for commercial purposes the propagating material of the protected variety in a repeated manner in the production of the propagating material of another variety".

2. Article 10 of Regulations of the Peoples Republic of China on the Protection of New Varieties of Plants sets out the exceptions for non-infringement as "*Without prejudice to other rights of the variety right owner under these Regulations, the exploitation of the protected variety may not require authorization from, or payment of royalties to, the variety right owner for the following purposesï¼□(a) exploitation of the protected variety for breeding and other scientific research activitiesï¼□(b) the use by farmers for propagating purposes, on their own holdings, of the propagating material of the protected variety which they have obtained by planting on their own holdings*".

Legal issues

1. Whether Defendant's planting activity falls within the scope of propagating material of the said protected variety?
2. Whether Defendant's planting activity are for commercial purposes? Or Whether

Reasoning

Upon retrial, the Higher People's Court of Shandong held that:

1. Beauty elm is an asexually propagated plant, and thus is propagating material. Therefore, the planting behavior of the Defendant belongs to a behavior to produce propagating material of the protected varieties;
2. Although Defendant is a legal entity of government with functions of building urban public green landscape, to determine whether the behaviors of Defendant are for commercial purpose should not be merely based on its nature, but should also be based on its specific behaviorsï¼□
3. The propagation and exploitation of Beauty elm by Defendant implied commercial interests and thus can be deemed for commercial purpose;
4. Defendant planted a large number of Beauty elms for street planting, but failed to prove its legal source of the planted Beauty elm; Defendant did not purchase the Beauty elm from the variety owner and planted it without authorization from the owner;
5. Defendant and its behaviors do not belong to the exceptions that can use the protected variety without authorization and with no need to pay exploitation fee;

(6) The behavior of Defendant has infringed the rights of variety rights holder.

Holding

The rulings of 1st and 2nd instances were reversed. Defendant (Jiutai Landscaping Management Office) was found as infringing the variety rights and being ordered to pay suitable exploitation fees to Plaintiff.

Discussion

This case is significant for the determination whether government agencies' action of producing propagating materials of protected plant varieties when performing their functions constitute an infringement. It is typical and a guidance for identification of whether a behavior belong to the production of propagating materials of protected plant varieties and whether the behavior is for commercial purposes.

(D) Europe

Claire Baldock, Olga Caspasso and Jürgen Meier report that there is a certain tendency before national patent offices in Europe, but also before the EPO to restrict or even exclude products obtained by "essential biological processes" from patentability.

In this respect, it is worthwhile to note that also the Administrative Council (AC) of the EPO changed.

The following assessment of the situation before the EPO was generated with Olaf Malek, representative of patentee in G 2/12, who kindly provided his time and expertise.

With effect of July 1, 2017, the Administrative Council (AC) of the EPO amended the Implementing Regulations so as to exclude plants obtained by essentially biological processes from patenting. In particular, Rule 27 EPC which relates to "Patentable inventions" and stipulates that "[b]iotechnological inventions shall also be patentable if they concern [...] plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety" was amended by including the caveat "without prejudice to Rule 28, paragraph 2". And Rule 28 EPC which specifies "Exceptions to patentability" was amended by including the new subsection:

> "(2) Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process."

According to the AC, this law change was made "in order to ensure very swiftly as much harmonisation and legal certainty as possible" (OJ EPO 2017, A54). However, whether this goal will be reached has to be questioned. The wording of new Rule 28(2) EPC directly contradicts the Enlarged Board of Appeal (EBA)'s interpretation in its decisions G 2/12 and G 2/13 of March 25, 2015 where it was held that, from the relevant provisions (in particular Article 53(b) EPC and the EU Biotech Directive EC/98/44), it cannot be derived that the exclusion of essentially biological processes for the production of plants provided for in Article 53(b) EPC also extends to the plants obtained thereby. The contradiction between the new Rule 28(2) EPC and the EBA's interpretation of Article 53(b) EPC may lead to a new period of legal uncertainty – running counter the intention phrased by the AC to achieve the opposite. The situation caused by the law change is reminiscent of the tension between Article 53(b) EPC (excluding "essentially biological processes") and Rule 26(5) EPC (defining the excluded processes as "consisting entirely of natural phenomena such as crossing and selection") that led to the first broccoli referral (T 83/05 of 22 May 2007 followed by EBA decision G 2/07). In that case, the EBA resolved the tension between Article and Rule by completely ignoring the Rule due to its "self-contradictory wording." New Rule 28(2) EPC could suffer the same fate should it once be scrutinized by the EBA. The essential logic behind the new Rule was, according to the law makers, that Article 4 of the Biotech Directive has to be interpreted as foreseeing an extension of the process exclusion to the products obtained thereby. In this sense, the Rule change was called a mere "clarification". Whether this is a sound interpretation of Article 4, however, can be doubted since its sub-sections (1) and (2) are very clear in that they leave no loophole for "clarification", i.e. excluding anything else in terms of plant-related products but plant varieties; see:

> 1. The following shall not be patentable:
>
> (a) plant and animal varieties;
>
> (b) essentially biological processes for the production of plants or animals.
>
> 2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

To read into this provision an exclusion of plants obtained by essentially biological processes was made for the first time in 2013 (during pendency of the G 2/12 proceedings!) when the German legislator introduced an exclusion clause to "plants and animals exclusively obtained by such processes" into Section 2a of the German Patent Act. This interpretation was then picked up in a Resolution of the European Parliament of December 2015, a Notice of the EU Commission issued on November 3, 2016 and, finally, in the EPO President's opinion CA/PL 4/17 based on which the AC adopted new Rule 28(2) EPC. Given its thorough analysis of the pertinent law including Article 4 of the Biotech Directive in G 2/12 and G 2/13, it is difficult to see how the EBA could anyhow depart therefrom and accept the "clarification".

As a further point, it needs to be considered that the exclusion of plants produced by essentially biological processes also creates legal uncertainty because such plants can nowadays no longer be

clearly distinguished from plants produced by new technologies of homologous recombination, also known as “gene-editing”, such as CRISPR-Cas. An Expert Group actually asked by the EU Commission to evaluate the questions at stake pointed to this problem in their Report[[EU Commission: Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (http://ec.europa.eu/growth/industry/intellectual-property/patents/biotechnologica--inventions/index_en.htm[http://ec.europa.eu/growth/industry/intellectua--property/patents/biotechnological-inventions/index_en.htm]), pages 37 and 38]].

However, this voice was not heard.

(E) Japan

Takashi Fujita from Japan provides the following information:

As already reported last year, before the revision of Examination Guideline in April 2016 the Japanese Patent Office (JPO) routinely decided that an invention directed to a new use of a known food or beverage lacks novelty. Some Japanese foods and/or drink manufacturers claimed foods or beverages by defining said products through (a) parameter(s) or through mathematical formulae to distinguish the claimed products from the prior art.

Such patent applications (relating to food/beverage products defined by parameters/mathematical formulae) have consequently been filed in Japan.

Yet, patent practioners have found that the prior art search or patent examination for parameter-defined foods/beverages can be difficult, last but not least because “the prior art” for these products is often a “prior use”.

In the meantime, some of granted patents claiming foods/beverages defined by parameters have been challenged in invalidation trials before the Board of Appeals.

In IP High Court decision 2016 (Gyo-ku) 10147 of June 8th, 2017 the court revoked a BoA's decision for Invalidation trial NO 2015-800008, rejecting the invalidation request for JP Patent NO: 5189667 (patent application filed on April 20, 2011).

> Corrected Claim 1 of the disputed patent reads:
>
> “Tomato-containing drink characterized in that sugar degree ranges 9.4 to 10.0, a ratio of sugar to acid ranges 19.0 to 30.0, and a total amount of glutamic acid and aspartic acid range 0.36 to 0.42 weight %.”

The description of the patent under dispute discloses 3 Examples (corresponding to 3 specific juice products) with data including brix (sugar content of an aqueous solution), acidity, a ratio of sugar to acid, acidity and a total content of glutamic acid and aspartic acid.

In a previous IP High Court Grand Panel Decision 2005 (gyo-ke) 10042, it was held that support requirements for a parameter-limited invention are met if the description discloses examples with which a person in the art, taking general common knowledge into consideration, recognizes that the effects are achieved when the claimed parameter are met. Support requirements are also met when the description explains to the person skilled in the art the relation between the the (claimed) range of the parameter and effects (performance) achieved even without illustrating examples.

Common General Knowledge at the filing date indicates that flavor of foods/drinks are associated with salty, bitterness, umami, pungency, astringency and other tastes, in addition to sweetness and sourness,

and the flavor can also be influenced by physically susceptible sensation such as viscosity.

In the case under dispute, the description discloses that tomato juice with rich flavor, reduced acidity and sweetness similar to the tomato fruit can be obtained by defining the sugar degree and the sugar to acid ratio. However, the description of the case under dispute lacks details of the mechanism how such effects may be achieved. The description also discloses that the sourness of a tomato-comprising drink may be suppressed (and inherent sweetness of tomato become enhanced) without deterioration of the richness when the content of glutamic acid etc. is defined. Yet, the description does not disclose that only sugar degree, the sugar to acid ratio and content of glutamic acid, etc. influence the sweetness, sourness and richness of the product.

Accordingly, in IP high Court decision 2016(Gyo-ke) 10147 it was held that the ingredients and physical properties of the Examples were not made in line with Comparative Examples and Reference Examples. It was disclosed what other various ingredients or various physical properties could influence sweetness, sourness or richness.

Thus, for a person skilled in the art it is not sufficient to specify the sugar degree, the sugar/acid ratio and the amount of glutamic acid etc., in order to obtain tomato juice with rich flavor, suppressed acidity, and sweetness similar to fruit tomato. The person skilled in the art does not understand the technical meaning of the relationship between sugar degree, the sugar to acid ratio and amount of glutamic acid and aspartic acid, and the effects of the invention.

Hence, the claims were considered as not being supported by the description.

(F) Korea

Yoon Suk Shin from Korea provides the following information on extended patent term in a pharma case. This case is also applicable to biologics:

Although the Korean Patent Act has provided a provision for patent term extension for drug products which an approval from the regulatory authority (Ministry of Food and Drug Safety) is necessary for marketing since 1987, there has been no case law regarding the protection scope of claims during the extended patent term. Korean Patent Court recently rendered a decision regarding the scope of the extended patent term in Case No. 2016 Na 1929.

The patent claim in the suit relates to quinuclidine derivatives which can include solifenacine succinate, solifenacine fumarate, etc, and the patent term of the claim has been extended based on a marketing approval of the drug product that contains a specific compound, i.e., solifenacine succinate as an API. During the extended patent term, the patentee claimed that alleged infringer's product containing solifenacine fumarate infringes on the patent claim. In the case, the Patent Court ruled that the protection scope of the claim the term of which is extended is limited to the specific salt on which the marketing approval is based, solifenacine succinate in this case, and does not extend to other salts such as solifenacine fumarate literally or under the doctrine of equivalents. The Korean Patent Court limitedly interpreted the scope of claims during the extended term since the patent term extension is an exceptional compensation for the period which the patented invention cannot be practiced due to regulatory requirements.

3) Any recommendations for AIPPI involvement/action for the next 12 months

This need not be limited to recommendations for your Standing Committee but can be recommendations for AIPPI more broadly. For example, please include:

In each case, please explain why such involvement/action is recommended, by whom it should be undertaken and any relevant time frames.

a) any recommendations for involvement/action in relation to any upcoming or foreshadowed case law, legislative or regulatory developments, or policy initiatives;

Since the Brexit negotiations are still ongoing, AIPPI and its Committees should follow this process very closely.

b) any other recommendations for AIPPI involvement/action;

none

c) any recommendations for the work programme of your Study Committee.

The current situation of products obtained by essential biological processes should be evaluated and assessed in light of recent case law and legal amendments in Europe.

Plant breeder's rights should be further reviewed and a potential new survey could be started.

Novel biological/biochemical/recombinant methologies, like CRisPR-cas should be evaluated and corresponding consequences for the IP world should be discussed. Such topics will be reviewed during the Sydney meeting of the Biotech Subcommittee.

4) Outline of the work programme of your Standing Committee for the next 12 months

Please set out specific activities and priorities having regard to the matters in 1) - 3) above, including any relevant time frames.

As in previous years, the Committee envisages at least two international phone conferences to be held in February/March and June/July. If need be or if important life science/biotechnology cases become public, additional ad hoc phone conferences will be scheduled in order to co-ordinate a fast response and/or input on these issues from the Committee for the general public and the AIPPI community. Accordingly, the members of the Biotech Subcommittee will actively screen and monitor for important developments in the life science field.

The above discussed position paper or deposits of biological material/microorganisms will be finalized during Winter 2017/2018 and presented to the Bureau.

In addition, the Biotech Subcommittee will start working with our mother Committee (Pharma and Biotechnology) on the new project on antibody patenting. In particular, the requirements for claiming antibodies in the different jurisdictions will be assessed and sufficieny requirements will be compared. Furthermore, it is intended to review the patentability requirements for medical and diagnostic uses/methods of antibodies as well as for antibody development, modification and/or manufacturing.

A further project currently initiated and under discussion is the international review of potential patent infringement of gene modification patents and methology patents, in particualr when gentic material is introduced and/or modified *in situ*.

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