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Analysis of the Legal and Competitive Market Environment for Intellectual Property Operation in the Seed Industry

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Abstract

For the seed industry to gain a foothold in the fierce market competition and achieve breakthroughs in technology, products and markets, the most important thing is to bring into play the unique value of intellectual property. The use of IPR search and analysis can be effectively informed of the real competitive environment, understand the development of technology, layout, gap vulnerability and other information, providing legal risk analysis, technological innovation guidance, cooperation ecological construction, M&A financing assistance and other aspects of value for domestic seeds to achieve leapfrog development. The operation of intellectual property rights in the seed industry requires, on the basis of grasping the special characteristics of the industry, and on the premise of making a good tracking judgment of the legal environment and market environment, designing specific intellectual property management and operation strategies that fit the actual situation according to the company's overall business plan, development stage, technical strength and other factors, and making comprehensive use of various types of intellectual property rights such as new variety rights, patent rights, trademark rights and trade secrets. IPR operation in the seed industry has both the general functions of general IPR operation and the special features of the seed industry such as strong regulation and object restrictions, etc. A complete operation system and value play requires an organic combination of these two.

Keywords

Seed Industry, IPR Operation, Domestic Substitution, Bending the Curve, Plant Patents, New Plant Varieties, Seed Law, Trade Secrets, Trademarks, Gene Editing, Breeding 4.0

1. Formulation of the Problem

For the seed industry to gain a foothold in the fierce market competition and achieve breakthroughs in technology, products and markets, the most important thing is to bring into play the unique value of intellectual property. Intellectual property rights, as the core assets of the seed industry, play a role in stimulating innovation and guaranteeing returns and maintaining orderly competition externally, and play a role in preventing infringement risks, guiding R&D directions and motivating researchers internally. In recent years, the state has attached great importance to the protection of intellectual property rights in the seed industry, and the Central Economic Work Conference and the Central Rural Work Conference have repeatedly proposed to vigorously promote independent innovation, protect intellectual property rights and fight a good turnaround in the seed industry. A representative and significant measure is the fourth amendment to the Seed Law, which came into effect on March 1, 2022, and has increased the protection of intellectual property rights in the seed industry by expanding the scope of protection of new plant variety rights, extending the protection link, establishing a substantial derivative variety system, and strengthening the liability for damages for infringement. Therefore, IPR operation in the seed industry is responsible for general IPR operation duties such as layout cultivation, value assessment, transfer and transformation, investment and financing, strategic use and patent navigation, etc., and also needs to undertake the special operation needs of the biological breeding industry, and moreover, it has to use a combination of plant variety protection, patents, trade secrets and trademarks to achieve operation goals. The differences between IPR operations in the seed industry and other industries are mainly reflected in the legal environment and the competitive dynamics of the industry. In addition to the industry-specific issues such as high patent quality and low quantity, genetic resource protection and variety suitability brought by biotechnology itself, IPR protection in the seed industry also involves complex issues such as public health, food and environmental safety and protection of farmers' interests, thus leading to a more complex and diverse legal environment for the corresponding operation. At present, the international seed industry has entered a period of opportunity to seize strategic heights and economic growth points, showing the development trend of high-tech, integration and oligarchization; developed agricultural countries have entered the breeding 4.0 era characterized by "biotechnology + artificial intelligence + big data". At the same time, mergers and reorganizations of seed companies have been intensifying worldwide, with the emergence of a seed oligarchy that integrates modern biotechnology, bioagriculture and digital agriculture. In this situation, if China's seed industry wants to fight a turnaround battle, it is crucial to do a good job in IPR operation, which requires top-level design and tactical preparation based on a full analysis of the legal and market environment at home and abroad, combined with long-term planning for industrial development. Under such circumstances, China's seed industry should

strengthen its research on IPR operation, and make top-level design and tactical preparation based on a full analysis of the domestic and international legal and market environment, combined with long-term planning for industrial development.

2. Analysis of the Legal Environment of Seed Industry Intellectual Property

As a proposed intangible asset, the value and operation of seed industry IP is highly dependent on the completeness of the legal environment and the intensity of enforcement. Technical innovation in the field of plant breeding has very unique innovation characteristics: it can be either an overall innovation of plant varieties with specificity, stability and consistency, or a local innovation of plant genes, gene sequences, methods of producing transgenic plants, etc. In line with this, the seed industry innovations are mainly protected by two legal pillars, namely, new varieties and patents, supplemented by trade secrets and trademarks, which together constitute the legal protection system of intellectual property rights in the seed industry.

Although China has fully converged with the world in terms of intellectual property protection based on the requirements of the TRIPS Agreement after its accession to the World Trade Organization, the relevant international treaties have left ample room for countries to make adjustments in the protection of new plant varieties due to the special nature of the seed industry in the public interest[1]. This has objectively formed a legal environment for IPR in the seed industry with three different levels of protection, represented by China, the US and Europe. At the same time, the different attitudes of countries on the safety of genetically modified plants have also led to the formation of administrative barriers to biotechnology innovation in the seed industry market access, which also affects the full play of IPR value from another perspective. Therefore, the first task of IPR operations in the seed industry is to fully understand the legal environment of the markets in which they operate, and to understand the strategic impact of the level of IPR protection in different countries on operations from a comparative law perspective.

2.1. Analysis of the Evolution of the International Seed Industry IPR Legal System and the Protection Environment

2.1.1. The International Seed Industry IPR Legal System Is Driven by Technological Innovation to Evolve

In general, the evolution of the IPR regime of the seed industry at the international level is driven by technological innovation. So far, technological innovation in the seed industry has gone through four stages: natural breeding, hybrid

[1]Article 27(3)(b) of the TRIPS Agreement "Plants and animals, other than micro-organisms, and the principal biological methods of producing plants and animals, other than non-biological and micro-organisms." This is one of the objects for which members of the TRIPS Agreement may refuse to grant patent rights. Article 25 of the Patent Law of China clearly stipulates that patents shall not be granted for "animal and plant varieties".

breeding, molecular breeding and intelligent breeding (biotechnology + information technology + artificial intelligence).

In the natural breeding stage (breeding 1.0 era), natural variant plants are mainly selected based on experience and observation, and then domesticated artificially over a long period of time to obtain varieties with superior traits. The new plant varieties formed by natural selection breeding are mainly "natural products", not the results of intellectual activities formed by people's intervention in the breeding process. The breeding technology theory at that time could not provide scientific judgment for the intellectual activities of breeders condensed in new plant varieties, and therefore there was no need to create a corresponding intellectual property system to protect them.

The hybrid breeding stage (breeding 2.0 era) is mainly based on the three laws of genetics, through artificial crosses to achieve plant height, yield, quality, resistance and other excellent trait improvement, breeding new biological varieties. Among the innovations at this stage, if the hybrid variety can maintain high quality traits for only one season and cannot be maintained as a pure species by asexual reproduction, the parents can be protected as trade secrets, for example, hybrid corn is a typical representative of this. However, if asexual reproduction can maintain the purity of the crop, a special protection system needs to be created. The U.S. Plant Patent Act of 1930 was the first legislation in the world to grant plant breeders a plant patent, formally recognizing in law that breeders' breeding innovations can receive the same specialized protection as inventions in industry. The U.S. Plant Patent Act, however, provides plant patent protection only to "persons who invent or discover and propagate in an asexual manner any remarkable and novel variety of plant, including the cultivation of buds, variants, hybrids, and newly discovered seedlings, but excluding plants cultivated in stem blocks and plants found in an uncultivated state. Another major legislation in the breeding 2.0 era is the International Convention for the Protection of New Varieties of Plants (UPOV Convention) created in 1961[2]. Since then, countries have created or improved their own legal systems for the protection of new varieties of plants, providing protection of variety certificates for new varieties of plants propagated sexually or by stems and blocks. The 1978 version of the UPOV Convention (hereinafter referred to as UPOV 1978) systematically improved the basic contents of the system for the protection of new plant varieties (Li, 2020), such as clarifying the use of plant phenotypic characteristics as a factor for judging whether an applied variety possesses specificity, consistency and stability, establishing the fundamental status of the DUS test in the protection of new plant varieties, and deleting the institutional arrangement between the UPOV Convention and the Paris Convention, so that UPOV became an independent international organization and became "the basis of the existing UPOV system for the protection of new plant varieties" with global influence. It should be noted that the new plant variety protection system established by UPOV 1978

[2]One of the more representative ones is the enactment of the U.S. Plant Variety Protection Act (PVPA) that came into effect in 1970.

was based on the scientific understanding of breeding technology and breeding results (varieties) at that time, and the judgment of new plant varieties was based on the phenotypic characteristics of plants and did not go deeper into the molecular level of genes. UPOV 1978 mainly targeted the uniform market within a country, rather than the large market with an eye on global trade.

The molecular breeding stage (breeding 3.0 era) mainly involves the use of molecular marker technology and recombinant DNA technology to transfer functional genes for disease resistance, insect resistance, stress resistance, yield improvement, etc. into recipient organisms to obtain stable inherited superior traits and breed new varieties in combination with conventional breeding. The main institutional arrangement corresponding to this phase is the 1991 text of the UPOV Convention (hereinafter referred to as UPOV 1991). Compared with UPOV 1978, UPOV 1991 focused on the global trade of agricultural products and strengthened protection in response to the development of molecular breeding technology. The main measures include: 1) abolishing the list of plant variety protection, requiring members to provide protection for all plant species or genera, avoiding different protection lists among countries, reducing transnational variety rights infringement and other acts, and expanding the scope of global protection of new plant varieties; 2) clarifying the meaning of the object of variety rights protection from the genetic perspective and the association between plant phenotypic characteristics and specific genotypes or genotype combinations, emphasizing that the specificity, stability and consistency that plant varieties should possess are based on the characteristics expressed by specific genotypes or genotype combinations, which lays a technical foundation for the introduction of the substantial derived variety system and reflects the development and application of biotechnology on the new plant variety protection system; 3) breaking the principle of independence of variety rights established by UPOV 1978 and establishing the substantial derived variety protection system to prevent free-riding behavior of the original varieties through modified breeding, so as to effectively stimulate innovation of the original breeding; 4) extending the protection period of breeders' rights from 15 years to 20 years (for trees and vines, from 18 years to 25 years); 5) Allowing a dual-track protection system of special variety protection rights or patent rights for new plant varieties; 6) Weakening the protection of farmers' rights to keep seeds. UPOV1991, which strengthens the protection of variety rights, has greatly enhanced the protection of molecular breeding innovations represented by molecular marker technology and recombinant DNA, in conjunction with the patent system for the confirmation of gene technology protection.

Intelligent breeding stage (breeding 4.0 era), mainly by the use of cutting-edge science and technology led by the "biotechnology + information technology + artificial intelligence" intelligent, efficient and accurate breeding of new varieties. The most important technological innovation in this phase is the application of gene editing technology and big data and artificial intelligence in the field of breeding. Although both transgenic technology and gene editing technology can

alter the genome of an organism to obtain inheritable superior traits, there are significant differences between them. Genetic modification introduces exogenous gene sequences outside the original gene pool of the target species, and produces superior varieties with new traits by "addition". Gene editing can also theoretically introduce exogenous genes, but currently it is more often applied by "subtraction", i.e., by specific breakage at specific sites in the genome, so that the target gene loci are precisely knocked out or precisely modified. Since no exogenous genes are introduced, it is widely believed that gene edited organisms are safer than GMOs, and thus there is a tendency for countries to relax their safety regulatory policies on new gene editing breeding technologies.[3]

2.1.2. The International Seed Industry Intellectual Property Protection Environment Is Becoming Increasingly Adequate

For the protection of intellectual property rights in the seed industry, the construction of a sound legal system is only one part of the process, but what is more important is the protection rules clarified in actual judicial cases, among which the typical cases include: 1) the Diamond v. Chakrabarty case in 1980[4], in which the U.S. Supreme Court confirmed that living organisms could be granted patent rights; 2) the Ciba-Geigy case in 1983 and the Lubrizol case in 1988, in which the European Patent Office established that propagating material and hybrid plants could receive patent protection; 3) the USPTO case in 1985[5], which confirmed that plant varieties, including seeds, could be patented, and granted 17 patents on the relevant corn seeds in 1986; 4) the J.E.M. Ag Supply, Inc. v. Pioneer Hi--Bred International, Inc.[6] in 2001, the U.S. Supreme Court confirmed that plant varieties, including seeds, are the subject of patent protection and clarified that patent law and the Plant Variety Protection Act (PVPA) can overlap to protect new plant varieties; 5) In the Monsanto V. Cefetra case in 2010 (Li, 2016), the Court of Justice of the European Union (CJEU) held that plant varie-

[3]More and more countries are now implementing easier and faster regulatory approval processes for gene edited plant product shows, such as the United States, Chile, Canada, Brazil, Argentina, Japan, and Israel, which do not regulate gene edited organisms as GMOs without the introduction of foreign DNA. However, there are some countries that adopt the same level of regulation for gene editing technology as for GMO technology, such as the EU. For gene-edited organisms, in 2018 the Court of Justice of the European Union ruled that organisms obtained through gene editing are GMOs and should be subject to the regulatory provisions related to GMOs. The Union of European Academies for Agricultural Applications (UEAA) issued a statement that as scientific knowledge advances and technologies such as genome editing develop, the EU should adjust GMO-related regulations to accommodate scientific advances. The EU's Chief Scientific Advisory Panel (CSA) recommended that legislation be based on the characteristics of the end product rather than the method of production, and it stressed the need to take into account "current knowledge and scientific evidence, in particular gene editing and other known GM technologies" to create a regulatory environment conducive to innovation so that "society can benefit from new technologies." In January 2022, China's Ministry of Agriculture and Rural Affairs issued the Guidelines for Safety Evaluation of Gene Edited Plants for Agricultural Use (for Trial Implementation), which focuses on gene edited plants without the introduction of exogenous genes, while gene edited plants with the introduction of exogenous genes must still be declared for safety evaluation in accordance with the requirements of the Guidelines for Safety Evaluation of Genetically Modified Plants.

[4]447 U.S. 303 (1980).

[5]Ex parte Hibbard, 227 USPQ (BNA) 443 (Bd.Pat.App. & Int. 1985).

[6]J.E.M. Ag Supply, Inc. v. Pioneer Hi--Bred International, Inc. (2001). 534 U.S. 124 (2001).

ties, including seeds, are the subject of patent protection. Cefetra case in 2010, the Court of Justice of the European Union held that if the relevant genes contained in the genetically modified product could not perform the gene functions described in its patent application documents at the time of the alleged infringement, it would not constitute an infringement of the gene patent. This interpretation unified the different understandings of EU members on the scope of gene patent protection and had an important impact on the global strategic layout of intellectual property rights of multinational biotechnology companies.

The increasingly perfect legal system of intellectual property rights coupled with an increasingly strict judicial protection environment has resulted in adequate protection of intellectual property rights in the seed industry at the international level, especially in developed countries such as the US, Japan and Europe. This has greatly incentivized private capital to fully enter the seed industry and dominate the R&D, industrialization, technology transfer and licensing of breeding technologies, which has led to the intensification of mergers and reorganization of seed companies worldwide and the emergence of seed oligarchs that integrate modern biotechnology, bioagriculture and digital agriculture.

2.2. Analysis of the Legal Environment of Intellectual Property Rights in China's Seed Industry

2.2.1. The Legal System of Intellectual Property Rights in China's Seed Industry Is Becoming More and More Perfect

Although China is late in legislating intellectual property rights in the seed industry, it is developing rapidly. The Regulations of the People's Republic of China on the Protection of New Plant Varieties promulgated in 1997 officially established the system of new plant variety rights, and the Measures for Administrative Law Enforcement on the Protection of New Varieties of Plants in Forestry in 2014, and other departmental regulations; in the judicial field, the Supreme People's Court issued the Interpretation on Several Issues Concerning the Trial of Disputes on New Varieties of Plants (Fa Shi [2001] No. 5), the Notice on the Trial of Disputes over New Plant Varieties (Fa [2001] No. 18), Several Provisions of the Supreme People's Court on the Specific Application of Law in the Trial of Disputes over Infringement of New Plant Variety Rights (Fa Shi [2007] No. 1) and Several Provisions on the Specific Application of Law in the Trial of Disputes over Infringement of New Plant Variety Rights (II) (Fa Shi [2021] No. 14). No. 14), etc. By the end of 2022, the competent departments of agriculture, rural areas, forestry and grassland under the State Council had issued a total of eleven lists of protected agricultural plant varieties and eight lists of protected new forestry plant varieties. In order to meet the new requirements of intellectual property protection in the seed industry, a new chapter of "New Variety Protection" was added in the third revision of the Seed Law in 2015, upgrading the legal status of new plant variety protection in China, and the Civil Code of the People's Republic of China promulgated in 2020 explicitly included new plant variety rights as a category of intellectual property rights.

It is noteworthy that in order to strengthen the protection of new plant varieties, the fourth amendment of the Seed Law, which will take effect in March 2022, has leaned towards the UPOV 1991 text, and the amendment mainly includes four aspects: 1) expanding the scope of protection and protection links of new plant variety rights, extending the scope of protection from the propagation materials of authorized varieties to the harvest materials, and extending the protection links from production, propagation and sale to production; 2) establishing the system of substantial derivative varieties and implementing extended protection, clarifying the definition of substantial derivative varieties, and stipulating that when a substantial derivative variety is used for commercial purposes, the consent of the owner of the new plant variety right of the original variety shall be obtained; 3) improving the compensation for infringement penalties and administrative penalties, improve the system of punitive damages and administrative penalties, raise the upper limit of punitive damages from three times to five times, raise the upper limit of statutory damages from RMB 3 million to RMB 5 million, and increase the administrative penalties for the production and operation of fake and inferior seeds; 4) clarify the benefit-sharing ways of the owners of new plant varieties, and the owners of new plant varieties may license the new plant varieties to others for implementation and collect the license royalties in accordance with the contractual agreement, and the license The license fee can be charged in the form of a fixed price or a percentage of the promotion proceeds. It should be noted that the new seed law still retains the original provisions on the privilege of farmers to keep seeds. On the one hand, farmers who reproduce and use the propagation materials of authorized varieties for themselves may not pay royalties to the owner of the new plant variety rights without permission; on the other hand, farmers who have surplus conventional seeds for their own reproduction and use may sell them in the local market without the need to apply for a seed production and operation license.

2.2.2. The Practice of Intellectual Property Protection in China's Seed Industry Is Relatively Small, and It Is Relatively Difficult to Defend Rights

As mentioned above, a relatively complete legal protection system for intellectual property rights in the seed industry has been formed in China, with the seed law, patent law, regulations on the protection of new plant varieties and other laws and regulations as the main body, supplemented by relevant judicial interpretations. The new plant variety rights are protected through special legislation such as seed law and regulations on the protection of new plant varieties; the production methods, relevant functional genes, encoded proteins and carriers of plant varieties are protected through patent law; breeding technology secrets and business secrets are protected through anti-unfair competition law; the source of seeds and commercial reputation are protected through trademarks and geographical indications of trademark law; the crimes of producing and selling counterfeit and substandard seeds, the crime of The crime of production and

sale of counterfeit and substandard products, illegal operation, infringement of registered trademarks and other crimes, to sanction counterfeit and substandard seeds and other agricultural production and sale of counterfeit crime. In the protection practice, it is not difficult to find by searching the cases published by the court that the current seed industry intellectual property rights are mainly through new plant variety rights, and less through patents and trade secrets[7]. In the protection of new plant variety rights, there are three main categories of common infringements: 1) production and sale of propagation materials of authorized varieties without the consent of the right holder; 2) impersonation of authorized varieties with non-authorized varieties, i.e. counterfeiting new plant variety rights; 3) impersonation of authorized varieties of the right holder with other authorized varieties, i.e. sleeve infringement, which mainly refers to printing the names of others' varieties on the packaging and actually selling their own seeds, "hanging sheep's head to sell dog meat" to sell their own varieties by the excellent traits of others' varieties to obtain illegal benefits. By analyzing the judicial cases of infringement of new plant variety rights, we can easily find that before the fourth revision of the seed law, the protection scope of variety rights is too narrow and incomplete protection links, so that the right holder is often caught in the unfavorable situation of difficult to obtain evidence, difficult to defend rights, low compensation, etc. Many infringements are difficult to be investigated, which not only discourages the innovation of new varieties, but also discourages the enthusiasm of intellectual property rights operation.

In terms of patent protection, the Chinese Patent Law explicitly excludes new plant varieties from the protection object, and the examination guidelines have expanded the understanding of new plant varieties, but biotechnology inventions such as relevant functional genes, encoded proteins and vectors discovered in the process of breeding innovation can obtain patent protection. Therefore, if the innovation of transgenic plants or gene edited plants lies in the transfer or editing of relevant functional genes and the patent right of the gene fragment is obtained, the protection scope can be extended to the plant itself with the gene fragment through the infringement lawsuit of gene patent.

This view has been indirectly confirmed by the court in the case of Genesis Seed Co., Ltd. v. Shandong Shengfeng Seed Technology Co.[8] The court held that the transgenic sequence of the allegedly infringing cotton seeds "Shan Nong Sheng Cotton No. 1" was different from the Bacillus thuringiensis insecticidal protein gene protected by the patent in question in eight places, and did not have the cowpea trypsin inhibitor gene sequence protected by the patent in question, thus ruling that it did not constitute patent infringement. Based on this decision, we can infer that if the insecticidal protein gene of Bacillus thuringiensis contained in the allegedly infringing cotton seeds is identical to the gene se-

[7]As of December 2022, 175 first instance cases of infringement of new plant varieties, 2 first instance cases of infringement of plant seed-related invention patents and 3 first instance cases of plant seed-related trade secrets were retrieved.

[8](2012) Ji Min San Chu Zi No. 144.

quence in the plaintiff's patent claims, the defendant's cotton seeds will infringe the plaintiff's gene patent. Therefore, in this sense, in practice, the protection can be extended to the plant itself with the gene fragment through the infringement lawsuit of the gene patent. It has been argued that patenting strategies for manufacturing methods to extend protection to products can also be used to protect new varieties of plants by breeding for transgenes or gene editing. However, in practice the strategy is difficult to work[9], the right holder is often unable to prove the alleged infringer's planting or breeding method, and cannot compare it with the claims of the patent method at issue, thus making it difficult to defend the right. Although the Patent Law stipulates that if a patent infringement dispute involves a patent for an invention of a new product manufacturing method, the unit or individual manufacturing the same product shall provide proof that its product manufacturing method is different from the patented method. However, the difficulty of proving that a plant variety is a new variety, thus realizing the reversal of the burden of proof for patent infringement of new product manufacturing method, is equally difficult for the right holder.

In terms of trade secret protection, breeding materials with commercial value obtained through breeding innovation activities, under the conditions of secrecy, value and confidentiality, can be protected by law as trade secrets. For example, in 2022, the Supreme People's Court held in the case of Huasui Seed Company v. Baosheng Seed Company infringement of technical secrets[10], crop breeding process formed in the breeding of intermediate materials, self-compatible parents, etc., different from the plant material found in nature, which is the intellectual results of the breeder's creative labor, bearing the breeder to the natural plant material selection and domestication or selection of traits of existing varieties The breeding material has the characteristics of both technical information and physical carrier, thus the breeding material belongs to the object of trade secret protection, and the formulation of a confidentiality system, the signing of confidentiality agreements, the prohibition of external proliferation, and the propagation of the material to the generation of the name, etc., in specific cases can constitute reasonable confidentiality measures. The court emphasized in the judgment that there are differences between the two systems of new plant varieties and trade secrets in terms of the way of rights generation, protection conditions and protection scope, and the right holders can choose different protection methods according to the actual situation. The protection of breeding innovation results that have not obtained the protection of new plant varieties is given to stop unfair competition under the condition of trade secrets, which is the inevitable requirement to encourage breeding innovation and the proper intention to strengthen intellectual property protection. The conditions and protection path of breeding material trade secret protection clarified in the case will help further increase the protection of legitimate rights and interests of breeding in-

[9]Ltd. and Chengdu Jinghu Agricultural Development Co., Ltd. for infringement of patent rights, (2012) Chuan Min Final No. 137.

[10](2022) Supreme Court Zhi Min Final No. 147.

novation subjects, stimulate breeding innovation and promote the revitalization of seed industry.

2.2.3. Analysis of the Regulatory Policy Environment of Bio-Breeding Technology and Its Products

Considering that GM seeds may cause damage in terms of food safety and environmental safety, the current seed law in China stipulates that GM seeds need to go through two stages of applying for safety certificates and variety approval for marketing before they can officially enter the market. It is because innovative breeding technologies also need to go through the administrative threshold of safety review before they can enter the market, and thus the regulatory policy of biological breeding technologies and their products is an important factor affecting the R&D of biological breeding technologies and their industrialization in a country, and IPR operations need to consider the influencing factors of regulatory policy. With regard to the regulatory attitude, the international community is mainly divided into two camps: 1) the lax school represented by the United States, which implements a product-oriented regulatory system system for biotechnology products and adheres to the principles of case-by-case analysis and substantial equivalence. Gene-edited crops that do not introduce exogenous genes, as well as varietal variations that can be obtained through natural or traditional breeding means, are considered non-GMOs and do not require regulation. This regulatory attitude is also held by Argentina, Canada, Israel, Colombia, Japan, the Philippines, Brazil, India, Chile, Australia, Bangladesh, Nigeria, Kenya, Uruguay, Paraguay, Norway, etc. 2) The strict school, represented by the European Union, has adopted a technically oriented system of regulatory system for biotechnology products, which considers that all organisms obtained by means of artificial intervention in biotechnology are considered to be genetically modified. In 2018, the ruling of the Court of Justice of the European Union clearly regards recombinant DNA, cell fusion and even radiation mutation and other organisms produced by means of artificial intervention biotechnology as GMOs, and considers them to be included in strict regulation. However, some EU countries, industry and academics want to relax restrictions on the industrialization of gene edited products: France already considers GMOs as non-GMOs, while the UK announced that it will develop new regulations to simplify the administrative regulatory process for GMOs[11], but in that country GMOs are still classified as GMOs and their commercial cultivation and derived food products are still subject to approval authorization according to the rules. New Zealand and the EU have similar regulatory policies.

China's regulatory policy is similar to that of the EU, and the attitude towards GM crops has always been "independent innovation, bold research, ensure safety, and prudent promotion"; strict control is exercised in the whole process of research, testing, production, processing, and operation, and key monitoring is conducted on laboratory research and field trials of GM agricultural products

[11]UK announces new regulations for gene editing, 2022-02-16, https://www.moa.gov.cn/ztzl/zjyqwgz/ckzl/202203/t20220328_6394250.htm.

with potential risks. China is the only country in the world that adopts mandatory labeling by catalog, requiring the operation or production of GM foods to be prominently labeled. China's strict safety review standards for GM seeds have reduced the market impact of GM seeds from overseas on the one hand, and reduced domestic enthusiasm for research and development of the corresponding technology on the other hand, resulting in insufficient reserves of the corresponding technology and patents. Although China has not yet issued a clear regulatory policy for gene-edited crops, it is good to note that there are signs of relaxation in recent years, and the pace of approval of safety certificates has been significantly accelerated. Policy documents such as the Work Plan for the Regulation of Agricultural GMOs in 2021, the Notice on Encouraging Original Innovation of Agricultural GMOs and Regulating the Transfer of Biological Materials for Trans-breeding, and the Guidelines for Safety Evaluation of Gene Edited Plants for Agricultural Use (for Trial Implementation) in 2022 have released important signals that China will prepare for the full-scale industrialization of GMOs, especially gene edited organisms, on the basis of strict safety evaluation.

3. Analysis of the Competitive Environment in the Seed Industry Market

Globally, the current mainstream technologies in the breeding industry are transgenic (GMO), gene editing (CRISPR, TALENs, ZFNs, etc.) and breeding strategies, with genome editing technologies born in 2012 as the key growth area. With the addition of such high-tech genetic engineering technologies, the current competitive landscape of the breeding industry shows four major characteristics: 1) High R&D investment, the average funding required to develop a new trait is about 135 million USD; 2) Long lead time, an innovative new variety needs 10 - 12 years to obtain safety certificate and another 3 - 6 years to commercialize; 3) Stronger than strong, high funding for R&D and long time barriers restrict new entrants, high conversion costs lock down downstream customers, industry concentration is increasing, and giants have obvious first-mover advantages. 4) subject to safety regulation policy, whether new varieties can be marketed is obviously affected by national policies on GMO safety regulation. However, gene editing technology is expected to break the current competitive landscape[12], and the technology itself is more accurate, improving the success rate of genetically engineered crops and reducing the food and environmental safety risks that may result from the introduction of exogenous genes.

3.1. Analysis of the Current State of Competition in the International Seed Market

According to the statistical results of market research institutions, this paper conducted patent analysis in the field of seed industry and made the following analysis results:

[12]Biological breeding: New agriculture transformed by cutting-edge biotechnology|Huaxing Report, 2022.7.8, https://t.10jqka.com.cn/pid_228970398.shtml.

3.1.1. The Number of Patents in the Seed Industry of Each Country Does Not Fully Match the Size of Its Seed Market

From the perspective of the global patent layout of major seed companies, the proportion of each country's global seed market share does not fully match with it. The reason why the patent share and market share of each country do not exactly match each other is mainly due to the difference in the regulatory attitude and research strength of each country towards transgenic seeds. The more lenient the regulation, the stronger the research capacity, and the larger the market size, the greater the number of patent applications. On the contrary, if the regulation is very strict and GM seeds cannot gain market access, many homologous patents of multinational seed companies will not enter the market of that country even if the market size is large. This explains why China ranks second in the world in terms of market size of the seed industry, but it ranks low in the patent layout of large multinational seed companies. In addition, the strict exclusion review policy of the Chinese patent protection object for new plant varieties is also one of the important reasons. This leads to the fact that the patent layouts of large multinational seed companies in China, Brazil and other countries with high market share but strict regulation and patent object restrictions are not sufficient, leaving a more relaxed patent restriction environment for the development of local local seed companies. According to the statistical results of the World Intellectual Property Organization about the average PCT application of developed countries into 3 - 5 countries, many seed-related patents do not enter all the countries with high market share of the seed industry, China's seed enterprises can make full use of patent analysis to avoid the risk of patent infringement and achieve technology and product substitution.

3.1.2. Large Factory Patent Applications by the Policy and Disruptive Technology Impact

After the peak in 2003, the number of applications by large multinational seed companies entered a downward path, then reached a trough in 2009's, but gradually rebounded from 2010 to reach the peak of patent applications again in 2014, and then entered a downward trend again. As mentioned above, in 2001, the U.S. Supreme Court confirmed that plant varieties including seeds belonged to the objects protected by patent law, which greatly stimulated the enthusiasm of enterprises to apply for seed patents and contributed to the peak in 2003. Subsequently, the number of patent applications began to decline due to the lack of favorable policies and technological breakthroughs. The scope of gene patent protection was clarified by the European Court of Justice in 2010, which again boosted the enthusiasm of companies to apply for patents, while the number of patent applications reached a new high in 2014, accompanied by the disruptive innovation of gene editing technology in 2012. The last eight years have seen a slow decline in patent filings again, accompanied by the release of seed research and development dynamics brought about by new technologies[13].

[13]The filing data for 2021 and 2022 do not reflect the true situation due to the 18-month disclosure rule for patent applications.

3.1.3. Disruptive Technologies Have Lowered the Threshold of Innovation, and a Large Number of Applications from Small and Medium-Sized Enterprises Have Climbed

The overall number of patent applications related to the breeding industry has been on an upward trend since 2010 and has not declined significantly (influenced by the rule of disclosing patent applications for a full 18 months, the application data for 2021 and 2022 cannot reflect the real situation). This conclusion is also consistent with the conclusion of the report "Patent Navigation Research Results of Biological Breeding Industry" released by the Intellectual Property Development Research Center of the State Intellectual Property Office at the end of 2021: "The current global patent applications in the field of biological breeding are on the rise, and the number of patent applications has been increasing rapidly in the past decade". This indicates that in the era of transgenic breeding, the high investment and long development cycle of transgenic technology make the barriers to entry very high. In contrast, gene editing breeding has a relatively low barrier to entry, a fragmented industry chain, and the cost of commercialization is usually only one-tenth of that of transgenics, so small and medium-sized companies have a large opportunity to enter, resulting in a continuous increase in patent applications. The industry chain of gene editing breeding is more finely divided, and each link is in the early stage of development, so after the gene editing technology is created, its subsequent innovation in the breeding field has been continuing, including gene function research, gene editing tool enzymes, gene discovery and trait matching, etc. This also suggests a new bending opportunity for China's seed industry. In the past, in the field of basic research with high barriers and long return cycles, such as gene mining and target design, the domestic start was late and little accumulation, and the willingness of enterprises to invest in R&D was weak. And when the industry ushers in the innovation of disruptive gene editing technology, the capital demand is reduced, the R&D cycle is shortened, and the industry is at the same starting line, the opportunity for Chinese enterprises to break through the neck link comes. According to the analysis of industry researchers[14], the downstream breeding end and application scenarios, such as microbial agrochemicals, digital agriculture, plant cell factories, vertical agriculture, etc., will put forward new demands or give more assistance to upstream breeding, and upstream breeding will also promote the speed of development of downstream trends, thus achieving mutual promotion and synergistic development. Therefore, breeding companies that are more closely integrated with the downstream are expected to seize new long-term opportunity points. Chinese local seed companies are more familiar with the domestic planting scenario and end-use demand, and have a better sense of direction for innovation.

3.2. Analysis of the Current State of Competition in China's Seed Industry Market

Although China is the second largest seed market share country in the world, the

[14]Biological Breeding: New Agriculture under the Transformation of Frontier Biotechnology|China Renaissance Report, China Renaissance IBD Team Published by China Renaissance on 2022-07-08.

layout of new plant varieties and homologous patents in China presents its own characteristics due to the influence of the strict national regulation and cautious attitude towards genetically modified seeds, the strength and scope of new plant variety protection differing from UPOV1991, and the exclusion of new plant varieties from the scope of protected objects by the patent law.

3.2.1. Differences in Regulatory Policies and Patent Systems Create Space for Domestic Substitution and Bending

Through comparison, we can find that: on the one hand, there are still relatively big differences between Chinese local seed enterprises and international majors in terms of patent layout; on the other hand, the gap between the number of patents of international majors in China and Chinese enterprises has narrowed. This suggests that, due to the differences in domestic regulatory policies and patent systems, on the one hand, the international seed companies have not laid out all their technologies in China, leaving room for domestic substitution by domestic enterprises; on the other hand, the differences in patent reserves of major seed companies in China have narrowed, and in the context of gene editing technology reducing R&D costs, domestic enterprises have the competitive space to overtake them.

3.2.2. Domestic Technological Innovation Is Dominated by Research Institutes

Through patent analysis, it is easy to find that most of the applicants with a large number of applications in China are scientific research institutions, and the number of applications from enterprises is relatively small; globally, there are more enterprises among the applicants with a large number of applications. Therefore, the seed industry in China has a large space for the transformation of scientific and technological achievements, and enterprises need to fully cooperate with research institutions to obtain innovative technologies by means of patent transfer and licensing. Enterprises can search for patents to find research institutions with the required technology for precise cooperation, and also can evaluate the research direction, level and quality of partners through patent analysis to improve the efficiency of cooperation.

3.2.3. New Plant Variety Protection Is Mainly Domestic and Overseas Layout Is Low

By analyzing the data released by the International Union for the Protection of Plant Varieties (UPOV)[15], we know that domestic applicants mainly apply for the protection of new plant varieties in China, and the trend is rapidly increasing year by year. During the same period, the number of foreign applications has maintained a relatively stable and slow upward trend, and the number is small compared with that of domestic applications. Compared with the huge number of domestic applications, the number of overseas applications and authorizations of Chinese applicants for new plant varieties is small, and the number of overseas applications accounts for only 0.33% of the domestic applications in 2021,

[15]Plant Variety Protection Statistics (upov.int), https://www.upov.int/databases/en/statistics.html.

and the number is relatively stable each year and does not show an upward trend. The global share of Chinese applicants in foreign applications has hovered between 0.5% - 0.7% for many years, less than 1% (Deng & Chen, 2022), which is extremely disproportionate to the number of domestic applications and the scale of the seed industry market. This situation partly explains why China's seed trade has maintained a deficit for many years[16]: weak seed technology innovation and low overseas layout of new plant varieties.

4. Conclusion

For the seed industry to gain a foothold in the fierce market competition and achieve breakthroughs in technology, products and markets, the most important thing is to bring into play the unique value of intellectual property. The use of IPR search and analysis can be effectively informed of the real competitive environment, understand the development of technology, layout, gap vulnerability and other information, providing legal risk analysis, technological innovation guidance, cooperation ecological construction, M&A financing assistance and other aspects of value for domestic seeds to achieve leapfrog development. The operation of intellectual property rights in the seed industry requires, on the basis of grasping the special characteristics of the industry, and on the premise of making a good tracking judgment of the legal environment and market environment, designing specific intellectual property management and operation strategies that fit the actual situation according to the company's overall business plan, development stage, technical strength and other factors, and making comprehensive use of various types of intellectual property rights such as new variety rights, patent rights, trademark rights and trade secrets. IPR operation in the seed industry has both the general functions of general IPR operation and the special features of the seed industry such as strong regulation and object restrictions, etc. A complete operation system and value play requires an organic combination of these two. In view of the limitation of space, this paper focuses on the construction and value realization of the operation system based on the special characteristics of the seed industry, and does not cover all aspects of the operation system. In practice, seed companies should not ignore the general functions of IPR operation, such as IPR due diligence, value assessment and risk assessment in technical cooperation or commercial collaboration, financing by financial means such as IPR securitization when long-term stable licensing income is available, reward for inventions in function, and cultivation of IPR awareness and culture in the company.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

[16]Data on China's foreign trade deficit in seeds are compiled based on statistics from the International Seed Federation, https://worldseed.org/resources/seed-statistics/.

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