On the Determination of "For Production or Operational Purposes" in Patent Infringement

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Abstract: The legislative purpose of patent law is to protect the rights and interests of inventors, encourage creation and innovation, promote the dissemination and progress of technology, and achieve a balance between the private interest protection of the patentee and the public interest in the dissemination of technology. This is the fundamental principle upheld by patent legislation. The element "for production or operational purposes" in the constitutive elements of patent infringement in China limits patent protection to a certain scope, implementing and reflecting the inherent requirements of the purpose and principles of patent legislation. However, due to the lack of a clear definition of its specific scope during legislation, the concept remains ambiguous, leading to divergent judicial standards, a lack of uniform adjudication scale, and inconsistent judgments in similar cases. Therefore, this paper explores the legal connotation of "for production or operational purposes," revealing the basic meaning and criteria for determining the term "production or operation" in the application of patent infringement law, aiming to clarify the reasonable boundary between the protection of private rights and the non-infringing use by the public.

Keywords: Patent Infringement; Production or Operational Purposes; Criteria for Determination

1. Introduction

In today's era of flourishing knowledge economy, the patent system, as a core mechanism for incentivizing creation and innovation and protecting intellectual property, plays extremely important role in promoting technological and economic progress development. However, with the acceleration of economic globalization and the increasing complexity of technological innovation, patent infringement disputes occur frequently, posing

many challenges to patent protection. Among these, the issue of determining the infringing element "for production or operational purposes" is controversial in both theoretical and judicial practice.

"For production or operational purposes" is one of the key elements in determining patent infringement. Its legislative intent is reasonably define the boundaries of patent protection while aiming to balance the interests between the patentee and the public. However, in judicial practice, the determination of this element faces numerous difficulties: divergent understandings of the connotation of "production or operation"; varying impacts of different subjects' understanding of this element. These dilemmas make it difficult to form a unified adjudication standard in judicial practice, also rendering the outcomes of patent infringement cases uncertain. This not only affects the legitimate rights and interests of patentees but also undermines public trust and confidence in the patent system.

As an important framework in international intellectual property protection, the TRIPS Agreement sets clear provisions on the purpose and scope of patent protection, providing reference national important for legislation and judicial practice. Therefore, this paper will explore the understanding and definition of the "for production or operational purposes" element by comparing the legislative purposes of the TRIPS Agreement and China's Patent Law, combined with extensive foreign experience. This will also help us examine the connotation and legal application of this element from a broader perspective.

- 2. Judicial Dilemmas in Determining the "For Production or Operational Purposes" Infringement Element
- 2.1 Legislative Status of the "For Production or Operational Purposes" Infringement Element

unless otherwise provided by law, no entity or individual may, without the authorization of the patentee, exploit the patent for production or operational purposes. This includes manufacturing, using, offering to sell, selling, or importing its patented product for production or operational purposes, or using its patented process, or using, offering to sell, selling, or importing the product directly obtained by the patented process for production or operational purposes. This provision aims to protect the legitimate rights and interests of the patentee and prevent others from unauthorized acts of manufacturing, using, selling, importing, etc., that infringe the patent right. For design patents, the Patent Law provides similar protection. After the grant of a design patent, no entity or individual may, without the authorization of the patentee, exploit the patent, i.e., not manufacture, offer to sell, sell, or import its patented design product for production or operational purposes. According to the legal text, the "for production or operational purposes" element demonstrates overarching importance in legislative provisions. However, as the legislative level does not provide a clear definition for it, the connotation of this element has long relied on doctrinal and judicial interpretation. Furthermore, China has not yet issued judicial interpretations specifically targeting the "for production or operational purposes" element. Only Legislative Affairs Department of the CNIPA emphasized in the "Explanation of the New Patent Law" that "production or operational purposes" is not limited to direct profit-making activities but includes non-profit activities such as industrial and agricultural production, commercial operations, and public utilities, while explicitly excluding personal or household use or consumption. This interpretation provides

According to Article 11 of the Patent Law, after

the grant of an invention or utility model patent,

standard at the level of legal effect.

According to the Legislation Law, the enactment of any legal norm must be based on specific legal principles and guided by the value of achieving clear legislative purposes. The purpose of patent legislation is to achieve the value goals of protecting private rights and promoting the dissemination of technology and socio-economic development. Therefore, the provision of the "for production or operational purposes" infringement element also carries certain legal

direction for practice but still lacks a unified

significance: protecting the patentee's market interests by restricting commercial use, and balancing public and private interests by preventing the patentee from monopolizing technology.

Currently, the abstract nature of this element has led to significant divergence in the academic understanding of "for production or operational purposes," forming two schools of thought. The broad school advocates breaking through the limitation of direct profit-making, emphasizing the substantive standard of market participation. It argues that non-profit organizations and market-substitutive behaviors, although lacking direct profit-making attributes, should still be regulated if they involve market competition or may diminish the patentee's interests. Its logic lies in strictly distinguishing between the private and public domains to prevent disguised infringement. The narrow school adheres to the direct profit-making standard, advocates for public-interest exempting behaviors, opposes including the use by government agencies, public welfare organizations, and individuals for non-commercial purposes within the scope. It emphasizes the need to protect reasonable use space for scientific research experiments and public services [1]. This school worries that excessive expansion will compress the channels for technology dissemination and hinder social innovation.

In summary, due to the ambiguity of the legislative status, the adaptation of legal meaning, and the divergence between the two schools, the judicial practice regarding the "for production or operational purposes" element has seen different judgments in similar cases, urgently requiring a unified adjudication scale at the normative level.

2.2 Judicial Dilemmas in Determining the "For Production or Operational Purposes" Element

2.2.1 Divergence in connotative understanding Article 11 of the Patent Law establishes "for production or operational purposes" as a core element for determining patent infringement. However, the abstract nature of the legal text expression and the complexity of balancing social interests lead to the ambiguity of this element's connotation.

First, there is a divergence in the determination regarding the type of subject, specifically manifested in the theoretical opposition within academia on whether the behavior should be deemed "for production or operational purposes" directly based on the institutional nature of the implementing subject, i.e., the question of "whether non-profit organizations can exempted." Scholars of the broad school [2] argue that the establishment of infringement should be determined by the nature of the act rather than the nature of the subject. If a non-profit organization implements patented technology in its operations, it should still be regulated because it may objectively squeeze out the patentee's market share. Furthermore, some scholars point out that the use of patented products by units is inherently market-substitutive, and regardless of whether it is for profit, it may harm the patentee's exclusive right. Scholars of the narrow school argue that the public service activities of non-profit organizations are inherently public in nature. Including them within "production operational purposes" would blur the boundary between public and private domains and even inhibit the development of public welfare undertakings.

Second. there is a divergence in determination regarding the nature of the act, with specific definitional disputes focusing on the debate between "market participation" and "direct profit-making," i.e., whether direct economic gain must exist to constitute "production or operational purposes." Scholars of the broad school argue that as long as the act objectively participates in market activities or has a potential impact on the patentee's market interests. it constitutes "production operational purposes." For example, if an enterprise uses patented equipment to improve production efficiency, even if it does not directly sell products, it may still be deemed infringing because it could indirectly enhance market competitiveness by reducing costs [3]. The essence of this school is to distinguish the boundaries between the private and public domains. Scholars of the narrow school [4] emphasize that only commercial acts directly aimed at profit should be regulated, and non-profit activities should be excluded due to their lack of market profit-seeking attributes. The divergence between the two schools makes it difficult to unify the boundary of "production or operational purposes" in legal application. For instance, whether the use of patented technology organization constitutes non-profit

infringement often leads to different conclusions depending on the adopted interpretative path.

Clearly, the abstract nature of the legal text leads to a lack of operable standards for the "for production or operational purposes" element. The opposition of scholarly views further amplifies the uncertainty in judicial application. In the future, it is necessary to further clarify the connotation and denotation of "production or operational purposes" through judicial interpretation or typical cases to resolve this judicial dilemma and achieve uniformity and predictability in legal application.

2.2.2 Inconsistent adjudication standards

Simultaneously, in judicial practice, Chinese courts have long had divergent adjudication standards for determining "for production or operational purposes" in patent infringement, primarily manifested in two different interpretive approaches:

The first standard takes the nature of the implementing subject as the core criterion, emphasizing that the non-profit nature of the legal subject can naturally preclude the establishment of infringement. Under this standard, courts often directly invoke documents like the "Regulations on the Administration of Registration of Public Institutions" to confirm the subject's nature, equating the public welfare function attributes of public institutions and government agencies with the non-market nature of the act's purpose. For example, in the Shanxi Museum case, the court directly excluded infringement liability for the use of patented products by a government agency based on its non-profit nature. In the first-instance case [5], the court held that the agricultural technology promotion activities of the Agriculture and Rural Affairs Bureau, as an administrative organ, and the Feed Research Institute, as a scientific research institution, belonged to the realm of public service. Such judgments implicitly presuppose that "acts of non-profit organizations necessarily do not produce market competition effects," essentially equating "non-profit" with "non-market," creating a behavioral exemption for public institutions.

The second standard breaks through the limitation of subject identity, using the market effect of the implemented act as the substantive criterion. It argues that even if the implementing subject has a non-profit nature, if its act substantially involves market activities, generates economic benefits, or weakens the

patentee's competitive advantage, it should still be deemed to meet the "for production or operational purposes" requirement. Recent judicial practice has also shown new trends. In the 'Huawei v. Conversant' case, the Supreme People's Court explicitly pointed out that even if the defendant claimed its act belonged to technical cooperation, if this cooperation substantially led to the free diffusion of patented technology to the downstream industry chain, eroding the plaintiff's market share, it still constituted "for production or operational purposes." This judgment further strengthened the judicial application of the behavioral standard, highlighting the core of examining the substantive impact on market competition. Meanwhile, the Supreme People's Court overturned the first-instance conclusion in the second-instance case, focusing on examining the specific operation of the "institute-district cooperation + demonstration base + farmers" model: this project, through a collaborative mechanism of government funding support and research institution technology manufactured and promoted patented technology products on a large scale, cumulatively creating 114 million RMB in economic benefits and directly covering over 4,500 farmers, objectively forming a market competition relationship with the patentee vying for the user base. Such judgments focus on quantifying the economic benefits of the act, market substitution effects, and competitive harm, establishing a recognition rule centered on the substantive impact of the act.

3. Extraterritorial Examination of the "For Production or Operational Purposes" Element

3.1 Relevant Provisions in the TRIPS Agreement

The TRIPS Agreement (Agreement Trade-Related Aspects of Intellectual Property Rights) is an important international legal framework for patent protection [6], profoundly influencing the patent laws and practices of member states. The provisions of the TRIPS Agreement imply an emphasis "commerciality." Article 61 of the Agreement requires members to provide for criminal procedures and penalties for willful trademark counterfeiting or copyright piracy on a commercial scale, indicating the Agreement's

regulatory focus on commercial activities that disrupt market order.

Furthermore, the WTO Dispute Settlement Body in 'United States — Measures Affecting the Protection and Enforcement of Intellectual Property Rights (DS362)' [7] also pointed out that the protection of patent rights under the TRIPS Agreement needs to be coordinated with commercial practices in international trade, and infringing acts must cause harm to market order and the commercial interests of the right holder. The 2023 WTO "Framework on TRIPS proposed a more inclusive Flexibilities" interpretation of infringement determination on a "commercial scale." According to this framework, members can differentially define the threshold of "commercial scale" based on their national development needs. For instance, regarding the implementation of some vaccine production technology patents in the field of public health, developing countries could exempt limited use by non-profit institutions; while for high-value-added industries like semiconductors, regulation of commercialized behaviors needs to be strengthened. This dynamic adjustment mechanism coincides with the flexible interpretation needs of China's "for production or operational purposes" element, providing a basis in international law for China in balancing patent protection and public interest.

Although the TRIPS Agreement does not explicitly stipulate "production or operational purposes," its clause design and treaty interpretation both point to the regulation of commercial infringing acts. Members limiting infringement liability to commercial activities through domestic legislation not only conforms to the flexibility requirements of TRIPS but also reflects the consideration of balancing patent protection and public interest. This supports that "production or operational purposes" element in China's Patent Law can adjust the standards for infringement determination according to national conditions, which is essentially a localized transformation of the TRIPS commercial context [8], possessing legitimacy in terms of treaty interpretation and practice.

3.2 Examination of Relevant Provisions in Major Foreign Countries

Although national legislations do not directly adopt the "production or operational purposes"

members indirectly reflect the element, connotation of this element through their standards for patent infringement determination. As a developed country, the United States has comprehensive and strict legal provisions for patent protection. In the U.S., a patent is an important means to protect innovative technologies and inventions. Anyone who invents or discovers any new and useful process, machine, manufacture, or composition of matter. or any new and useful improvement thereof, may obtain a patent. Notably, the 2022 revision of the U.S. Patent Act added an "indirect commercial benefit" clause in Section 101, explicitly considering the competitive effects of technology implementation. This is reflected in 'Tesla v. Battery Tech Co', where the court found that although the defendant did not directly sell the patented batteries, its technical optimization reduced vehicle manufacturing costs and significantly increased market share, constituting infringement due to "indirect commercial benefit." This legislative dynamic highly aligns with the "market substitution effect" emphasized in China's judicial practice, highlighting the global trend of behavioral nature review. In 'Roche v. Bolar', the court found that the experimental use by a generic drug manufacturer for early market entry constituted infringement due to its clear commercial purpose, directly leading to the enactment of the 'Hatch-Waxman Act', establishing the "Bolar exception" [9] to balance innovation and generic interests. Meanwhile, in 'WesternGeco' [10], the U.S. Supreme Court supported the patentee's claim for extraterritorial lost profits damages, extending the scope of patent protection to overseas commercial activities, indicating the U.S.'s broad interpretation of "commercial impact," even breaking through the territorial principle to protect core industry interests. Thus, the U.S. forms a substantive commercial impact standard through case law, emphasizing the potential threat of the act to the patentee's market interests. Therefore, production or operational activities are not identical to commercial activities; the scope of production or operational activities is broader than that of commercial activities.

Compared to the development path of U.S. case law, the EU presents characteristics of mutual support between statutory law and case law. Although European patent regulations do not directly define "production or operation," the EU,

through Article 27 and Article 52 of the Community Patent Convention, excludes "acts done privately and for non-commercial purposes" from the scope of patent infringement, also indirectly indicating that patent infringement in Europe typically includes unauthorized acts of making, using, offering for sale, selling, or importing patented products for "production or operational" purposes. For example, if someone hires a carpenter to make a patented photo frame product for household use, for the hirer, commissioning the frame is for household use, meeting the conditions of "privately" and "non-commercial purposes," so the act does not constitute patent infringement. However, the act of making the frame by the hired carpenter, if for profit, constitutes infringement. This provision connection reflects the close between "production or operational purposes" and commercial activities [11]. In judicial practice, the European Court of Justice further refined the standards through precedents. 'Simvastatin' case [12], the German Federal Supreme Court (BGH) held that even if an offer for sale targets a period after patent expiration, as long as it has the commercial intention to preempt the market, it still constitutes infringement. This shows that the EU's determination of "production or operational purposes" is not limited to the actual sales stage but also includes the layout of commercial competition strategies. Subsequently, in the 2022 German case 'Bosch v. Tesla', the court found that although Tesla did not directly sell the autonomous driving module, its provision of functional optimization to users through OTA updates substantially enhanced competitiveness, constituting implementation for "commercial purposes." This judgment highly aligns with the logic of the second instance in China's 'Jiao Mou' case, demonstrating the international trend of the behavioral standard. Unlike the European and American paths focusing on commercial purposiveness, Japan's Patent Law constructs a more expansive determination system through the unique "for business" ('eigyo tou') standard. Article 101 of Japan's Patent Law uses "for business," i.e., continuous, professional implementation, as the standard for infringement determination. It holds that non-profit acts may also constitute infringement as long as the act is repetitive and professional, even if non-profit. In the 'Dwango' case, the Japanese Intellectual Property High

Court held that even if the server was located overseas, as long as the user terminal was in Japan and the system's overall function was realized in Japan, it still constituted patent infringement. This judgment broke through the traditional territorial principle, emphasizing the commercial impact of technical characteristics. Similarly, scholar Aya Monoya points out that Japanese law, through a broad interpretation of the "for business" concept, essentially expands "production or operational purposes" to non-directly profitable professional activities, strengthening patent protection. Another Japanese scholar, Hiroya Kawaguchi, also believes that the law itself does not define "for business," but in practice, the interpretation of this term is so broad that it can only exclude individual acts [13].

For China, foreign experience provides an important reference for improving determination of "production or operational purposes." On the one hand, we can learn from the U.S. "commercial impact" standard, incorporating potential threats to market competition caused by infringing acts, such as market preemption intent. technological substitution risks, etc., into consideration factors, avoiding mechanical reliance on the apparent characteristics of the act. On the other hand, we can refer to the EU legislation's clear boundaries for "non-profit exceptions," setting clear exemption conditions for personal use, scientific research experiments, etc., to over-expansion of infringement liability [14]. Furthermore, the emphasis on the entirety and continuity of technology implementation in Japan's "for business" standard is enlightening for China's judicial practice in dealing with networked systematic and technology infringement. In patent disputes involving cloud computing or the Internet of Things, we can break through the single act element and comprehensively assess the overall commercial purpose of the technical solution. In general, China should, under the flexible framework of the TRIPS Agreement and combined with the needs of local industrial upgrading, construct a determination system for "production or operational purposes" that is both adaptable and operable, strengthening the protection of core technological innovation while reasonable space for small and micro entities and non-commercial use, ultimately achieving the dual goals of the patent system: incentivizing innovation and maintaining public welfare.

4. Reasonable Definition of the Connotation of "For Production or Operational Purposes"

4.1 Doctrinal Analysis of "For Production or Operational Purposes"

Comparing the TRIPS flexibility framework with the revision of the U.S. Patent Act reveals that the international community is gradually transitioning from a "direct profit-making" standard to a "comprehensive commercial impact" standard. The former allows flexible adjustment based on public interest, while the latter clarifies the infringing nature of indirect benefits through legislation. China can learn from both experiences. From the perspective of legal doctrine, penetrating the surface of the text, analyzing this element, systematically explaining the normative structure of the "for production or operational purposes" element, reveals its institutional value as a balance of interests and social operation in patent law.

From a general semantic perspective, the 'Xinhua Dictionary' defines "production" as the activity and process by which humans use tools to create various means of livelihood and means of production. "Operation" refers to planning, management, and organization. The combination of these two constitutes the core semantics of "production and operation," i.e., manufacturing and commercial operation, pointing both to the physical manufacturing process of material products and covering value-added activities such as service provision and technology implementation.

However, the Patent Law endowed "for production or operational purposes" with a deeper connotation upon its establishment. Combining the legislative purpose of Article 1 of the Patent Law, "to protect the lawful rights and interests of patentees, encourage inventions and creations, promote the application of inventions creations, enhance scientific and technological progress, and economic and social development" [15], "production or operational purposes" in this sense serves to regulate market competition order, prevent the commercial implementation of patented technology without permission; it also aims to guarantee space for technology dissemination, exempting purely scientific experimental acts; and further, to public interests, avoiding over-expansion of patent rights [16]. Therefore,

its connotation should be given a purposive expansive interpretation, including both acts directly obtaining commercial benefits and implementation acts that, although not immediately profitable, have a market preparation nature.

Meanwhile, judicial practice further reveals the connotation of the "for production or operational purposes" element, mainly reflected in whether the act of the implementing subject is a production/operational act non-production/operational act, forming an opposition. Among them, non-production/operational acts are mainly manifested as purely personal or internal household consumption acts, whose core characteristic is that the purpose of the act is completely decoupled from market activities, possessing neither commercial circulation attributes nor the possibility of market application of technological results Production/operational acts refer to acts where market subjects or natural persons implement patented technology through organized, continuous methods, directly participating in competition or making technical preparations for market entry, which may substantially affect the distribution pattern of the patentee's market interests. Their essence lies in the substantive connection between the act and market operation, rather than taking the nature of the acting subject or direct profitability as the sole criterion.

Based on the above analysis, this paper argues that "for production or operational purposes" can be defined as: the purpose of any organization or individual, oriented towards participating in market competition or obtaining competitive advantages, to directly affect the distribution pattern of market interests through implementation of patented technology, or to make technical preparations for market entry, which may substantially diminish the patentee's market monopoly position. Its core criterion lies in whether the act has a direct or potential substantive connection with market operation, rather than simply relying on the nature of the acting subject or direct profitability as the basis for determination.

4.2 Judicial Practice Exploration of "For Production or Operational Purposes"

The determination of "for production or operational purposes" in China's Patent Law is a

core issue in patent infringement determination. In traditional judicial practice, courts often made formalistic determinations based on the profit-making attributes of the implementing subject or the result of direct gain. However, with the development of modern business models, judicial practice has shifted towards the standard of substantive connection between the act and market operation. This shift is reflected in recent typical cases, along with several aspects of consideration.

Whether separate examination of subject nature and act purpose is necessary. The Supreme People's Court in the 'Jiao Ruili' case clarified that when non-profit organizations use patented technology in public service activities, although superficially possessing public welfare characteristics, if their service scope covers an unspecified majority and objectively forms a substitution effect for commercial service supply, it may still be deemed to have production/operational attributes [18]. adjudication logic aligns with the market preparation theory discussed in section 4.1, revealing that judicial practice has abandoned the traditional path of using subject nature as a direct judgment basis, in turn focusing on the potential impact of the act itself on the distribution pattern of market interests.

Whether identification of the market orientation of R&D activities is necessary. In response to manufacturing enterprises claiming that "R&D testing does not constitute production or operation," judicial organs employ specific examine methods, focusing on whether the technology implementation act subsequent commercial application. Even if the product has not entered the circulation stage, R&D testing, as a necessary part of the production chain, essentially constitutes the technical preparation stage for market entry. This judgment standard echoes the purposive expansive interpretation in section 4.1, extending the temporal dimension of "production or operational purposes" to the preparation stage before market entry, effectively curbing acts evading patent licensing obligations under the guise of R&D. It further confirms the substantive connection between R&D activities and production/operational purposes; even if no actual benefits have been generated yet, as long as there is a reasonably foreseeable possibility of commercial benefit conversion, it should be deemed to constitute "production or operation"

in the sense of the Patent Law.

Whether a substantive determination paradigm for market substitution effects is necessary. In the 'Apple v. Samsung' patent dispute [19], judicial organs broke through the traditional standard of directly implementing patented technology. By analyzing the erosion effect of the accused product on the patentee's market position, they established the substantive examine rule for determining "production or operational purposes." The gist of the judgment in this case shows that when the accused act forms a competitive relationship with the patentee through technology implementation, or substantially compresses the market value space of the patented technology, even if not all the technical features recorded in the patent claims are directly implemented, it may still be deemed to have production/operational purposes due to the market substitution effect. This adjudication logic forms a systematic connection with the emphasis on the impact on market interest distribution in section 4.1, highlighting that judicial organs have shifted from examining the appearance of the act to substantive analysis of market competition relationships.

The above judicial evolution indicates that Chinese courts are continuously enriching the connotation of the "for production or operational purposes" element through case adjudication. Its determination standard has developed from early single dimensions like subject nature and direct profit-making to an analytical framework containing multiple elements such as the stage of technology implementation, market competition relationships, and market interest substitution.

5. Criteria for Determining "For Production or Operational Purposes"

patent infringement disputes, the determination of "for production or operational purposes" is a key link in delineating the boundaries of patent protection. The traditional judicial practice of relying solely on formalistic standards based on subject nature can no longer cope with the complexity of market behaviors. Based on this, modern patent judicial protection urgently needs to construct a reasonable and feasible examine system, achieving dynamic between patent protection maintaining the innovation ecosystem through the innovation of judicial examine logic and the improvement of applicable rules.

5.1 Subject Standard

When determining the connotation of "for production or operational purposes" using the subject standard, the core is reflected in the nature of the acting subject. Therefore, "production or operation" can be narrowly defined as direct market transaction behaviors by for-profit subjects. In specific determination, one should judge the attributes of the acting subject, such as whether it is a for-profit organization like an enterprise legal person or individual business; simultaneously, judge its subjective purpose, i.e., whether the motive for the act is direct profit-seeking. This line of thinking was reflected in the first instance of 'Jiao Mou v. Feed Research Institute', where the court held that the Feed Research Institute and Daixing District Agriculture Bureau did not have production/operational qualifications, and the cooperation project aimed at agricultural technology promotion, thus not constituting infringement. It can be seen that the essence of the subject standard is to exclude the possibility of infringement based on institutional nature.

In judicial practice, the subject standard determination method is easy to operate and clear in direction, avoiding excessive interference with the public functions of non-profit subjects. However, the subject standard is a determination method under formalistic logic, neglecting the substance of the act and difficult to covering new business models, such as 3D printing technology. Therefore, it may lead to market subjects abusing the "public welfare" name to evade liability, causing damage to the patentee's market interests due to exemption based on subject nature, resulting in imbalance of interests.

5.2 Act Standard

When determining the connotation of "for production or operational purposes" using the act standard, it breaks through the limitation of subject nature, expanding "production or operation" to any act that substantially participates in market activities and affects the patentee's interests. Therefore, in specific determination, one should judge the nature of the act, determining whether it belongs to market transactions or competitive activities; and the market substitution effect, judging whether it squeezes out the patentee's potential market share; simultaneously, the consequence of technology diffusion is also an aspect to consider,

i.e., judging whether it leads to there free use or substitutive promotion of patented technology. Therefore, under the determination method using the act standard, the Supreme Court in the second instance of the 'Jiao Mou' overturned the first-instance conclusion, pointing out that although the promotion act of the Feed Research Institute had public welfare attributes, it pushed the patented technology into the market for free through the "institute-district cooperation + farmers" model, substantially affecting the patentee's economic interests, thus constituting infringement. [20] This judgment took the consequences of the act as the core, negating the absolute defense effect of subject nature.

Based on this, in current judicial practice, using the act standard can better reflect the substantive fairness of the law. It can penetrate formal appearances to protect the patentee's market interests and better adapt to complex business ecosystems, such as government-led technology promotion. university scientific research achievement transformation, and other scenarios. [21] However, if courts use this standard to determine cases, they need to analyze the corresponding market impact case by case, which increases judicial costs and prolongs case processing time. Simultaneously, whether it causes damage to market activities can also lead to disputes in definition.

5.3 Summary

The determination standard for "for production or operational purposes" in patent infringement disputes has evolved from a formal subject standard to a substantive act standard. The subject standard, by judging the nature of the acting subject and its subjective purpose, has the advantage of operational convenience but suffers from defects such as neglecting the substance of the act and difficulty in coping with new business models. The act standard focuses on the nature of the act, market substitution effects, and technology diffusion consequences, achieving greater substantive fairness through penetrating examine. However, the subject standard may cause imbalance of interests but is more efficient; the act standard, although more substantively reasonable, faces challenges of increased judicial costs and definition disputes. It is evident that both standards have their pros and cons.

Therefore, while summarizing the above two determination standards, this paper further

suggests that in judicial practice, infringement determination examine should be conducted with the act standard as the main approach and the subject standard as supplementary. In specific practice, first use subject nature as a preliminary screening tool to grant preliminary exemption to non-profit subjects with obvious public welfare attributes. Then, focus on using the act standard substantive examine, comprehensively judging by analyzing elements such as the substance of market transactions, competitive relationships, and technology diffusion effects. For situations with market substitution effects, technological substitution risks, etc., even if the acting subject has public welfare attributes, it should still be deemed to constitute "for production or operational purposes."[22] This can avoid the imbalance of interests caused by the mechanical application of the subject standard while reducing judicial costs through the preliminary screening of the subject standard, achieving a dynamic balance between patent protection and the maintenance of public interests.

6. Conclusion

Against the background of the innovation-driven development strategy, the legal interpretation dilemma of the "for production or operational purposes" element in Article 11 of the Patent Law reflects the lag of the traditional patent system in responding to the technological revolution and market economic development. Through legislative and judicial empirical research on this element, this paper finds that although this element aims to balance the interests of the patentee and social public interests as its legislative original intention, its connotation and denotation have failed to evolve synchronously with economic development, leading to inconsistent judicial determination standards, thereby affecting the stability and predictability of patent protection.

Examining relevant foreign systems from a comparative law perspective reveals that foreign legislation has gradually shifted towards using the nature of the act rather than subjective intent as the standard for infringement determination. International experience shows that the traditional subjective purpose element is being replaced by an objective act standard, a trend of significant enlightenment for China.

Combining the evolution of judicial practice and foreign legislative trends, the determination of

the "for production or operational purposes" element in China urgently needs to construct a hierarchical and operable examine system. Based on the foregoing analysis, this paper recommends constructing a examine system with the act nature standard as the core and the subject attribute standard as the foundation. This has theoretical value for improving the standard system for patent infringement determination and enhancing the uniformity of judicial adjudication, providing a feasible solution for the modernization of the patent system in the digital economy era.

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