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Balancing Pharmaceutical Innovation and the Chinese Public Interest: A Comparative Research of Compulsory Pharmaceutical Licensing Systems

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Abstract: *The COVID-19 pandemic clearly constitutes a matter of public health, and so the prospect of using a compulsory pharmaceutical licensing system in China has received renewed attention in the past year and a half. The compulsory licensing system affecting pharmaceutical patents is regarded as a mechanism for improving public access to health resources. This research considers this practice as conducted in India to evaluate whether the practice can be used to balance pharmaceutical innovation and the public interest in China. The findings of existing studies are that this system performs well with respect to addressing health equality in India, but also that it appears to be of practically unpromising with respect to being implemented within China. This research presents the results of a systematic review and a case study format to investigate the importance of adopting appropriate methods to consider issues relating to China's non-implementation of this practice. This study also considers the extent to which positive changes can be attributed to balancing the interest of different groups within the Chinese system, this mechanism having emerged over an extended period and been drawn upon in relation to relatively few pharmaceutical applications. More studies are therefore required as a means of investigating its application in light of recent developments within public health.*

Keywords: *Pharmaceutical Innovation; Chinese Public Interest; Compulsory Pharmaceutical Licensing System*

1. Introduction

1.1. Background

The inequitable response to COVID-19 has already become evident across many countries. Global demands have intensified with respect to gaining permission to use the pharmaceutical patents of products produced to tackle the virus on the basis that, until everyone is safe, no-one is safe. Two proposals have been made to address this matter: one is the Intellectual property (IP) waiver of certain parts of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as proposed by the Indian delegation and South Africa at the WTO, with Mercurio highlighting the utility of a temporary patent waiver under sections 1, 4, 5 and 7 of the TRIPS Agreement until the world can develop an immunity against the virus [1]; the second proposal relates to the application of the compulsory licensing of pharmaceutical patents, this being a government-granted authorization to use such patents without the patentees' permission requiring to be obtained [2]. This dissertation focuses on the utility of a compulsory pharmaceutical licensing system for the following reasons: first, a waiver should assume institutional capacity and good governance to amend their own legal framework within a short time. However, less-developed countries (LDCs) have thus far not taken advantage – or not been able to take advantage – of existing flexibilities within the international IP system; second, LDCs frequently rely on the latter option in practice because this system is mainly structured for the promotion of global health equality in LDCs, with such aims corresponding with those stated in respect of the present study [1].

This research is conducted under the background of a renewed focus on the compulsory licensing of pharmaceutical patents, with the specific context of China chosen for analysis. The 'zero' implementation of this system in China and the Delta variant, which has become the dominant variant of the virus worldwide, both require to be considered in the need to protect public health. However, Reuters states that China's vaccines, such as Sinopharm's COVID-19 shot, induces weaker antibody responses to the Delta variant [3]. Such changes imply that sustained pharmaceutical innovation is a key

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consideration in confronting the variant in China. This situation also presents an opportunity to investigate the application of compulsory licensing to accelerate the speed of developing new vaccines based on advanced patented technologies, thereby reducing inequitable access to pharmaceutical resources. In considering these matters, the present study utilises a comparative perspective, assessing whether – and, if so, how – the use of such a mechanism can strike a balance with respect to balancing the need to foster and protect pharmaceutical innovation against interests relating to public health.

1.2. Research question

In considering the value of this system for pharmaceutical patents in China, this dissertation considers the following research question: can the compulsory licensing of pharmaceutical patents balance China's needs with respect to pharmaceutical innovation with the matter of public interest? There are three issues that require to be considered in addressing this question: the first is to investigate the legal philosophy of this system in selected jurisdictions; the second is to analyse the enforcement of the compulsory licensing of pharmaceutical patents in selected countries; the third is to consider what strategies and tools can be utilised to improve the functioning of China's compulsory pharmaceutical licensing as a means of considering the implications of its theoretical application.

1.3. Structure of the dissertation

With Chapter 1 having provided the background to the research undertaken, Chapter 2 isolates the gap in the research relating to the legal design of compulsory pharmaceutical licensing in selected jurisdictions, considering matters hindering collaboration in response to the pandemic. Chapter 3 outlines the methodology utilised to ensure that resources drawn from both the literature and legislation are appropriately filtered and evaluated. Chapter 4 reports the findings emerging from key legislation, cases and strategies adopted in India and other jurisdictions, with this being done to consider whether a similar strategy would be appropriate in the Chinese context. Chapter 5 concludes by way of a summary, together with the limitations affecting this research and the implications falling out of its findings.

2. Literature Review

This chapter covers issues relating to the global response mounted to the COVID-19 pandemic. The first issue assessed within this chapter pertains to the legal philosophy relevant to the pharmaceutical compulsory licensing, considering both the theoretical context and the practical realisation of this philosophy. This chapter also considers potential conflicts arising between stakeholders.

2.1. Issues hindering collaboration in the response to COVID-19

2.1.1. Virus mutation and the international vaccine race

It is commonly advanced by Matrajt et al that the ideal response to the COVID-19 pandemic would be to distribute an optimally constructed vaccine as a means of helping vulnerable people [4]. However, weaker antibody levels in people receiving different vaccines stemming from the Delta variant and increasing infection rates post-vaccination have underscored the urgent need for – and the difficulty associated with – the rapid development of vaccines. For example, antibody levels in people receiving China's Sinopharm vaccine demonstrated a 1.38-fold reduction in the Delta variant as compared with an older variant of COVID-19 [3]. Furthermore, the proportion of the vulnerable population eligible for prioritised vaccination is not as was first expected from the global perspective. Taking India as an example, the rate of deaths reached 24% but only 7% of the priority population were fully vaccinated by July 2021 [5]. This chapter therefore considers the gap in the existing research addressed by the present study relates to conflict between the slow pace of pharmaceutical innovation in the international vaccine race and the need for fair vaccine distribution. Given this goal, there is a clear need to address the legal philosophy underpinning the matter of compulsory licensing of pharmaceutical patents.

2.1.2. The rise of patent protection for pharmaceutical innovation

With respect to the theoretical background of the matters, it is essential to consider the trend of enhancing patent protection applying to pharmaceutical innovation. Some researchers have taken a stance against the application of this system on the basis that they perceive it as failing to protect innovation, regarding it as lowering the level of protection afforded to IP [6]. It is the position of the present study, however, that a high level of IP protection does not always encourage a quick pace of

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medical patent innovation and that the limitations imposed by compulsory licensing on pharmaceutical patents has, to a significant extent, been exaggerated.

Fisher summarises the principle economic theories relating to the matter of how IP systems can stimulate technological progress in the pharmaceutical industry. He points out the distinctive characteristics of technological innovations, which he regards as being easily replicated and "non-rivalrous," giving rise to the danger that, once developers reveal the nature of their designs to the public, other developers may take advantage of them without requiring to pay anything, the result of this being that the developers will struggle on the basis of their investment [7]. This basic insight has guided many researchers in their justifying the adoption of systems including strong protection of IP. A classic study in this regard is that of Nordhaus, who frames efforts as prolonging the duration or enhancing the strength of patent holders as a means by which to stimulate inventive activity [8].

However, a higher level of innovation does not necessarily stem from extensive protection of IP. Indeed, such systems have also been argued to have the potential to impede technological progress. First, from the developer's perspective, Levitas et al argue that a stronger IP system is accompanied by higher costs with respect to Research & Development. Furthermore, the innovation of new pharmaceutical technologies may be limited by overly strong protection afforded to IP those owning basic technologies. The extension of patent protection duration offers a visual representation of this negative effect [9]. Second, from the national perspective, Sweet and Maggio test the impact of a strong IP system on innovation by analysing the economic complexity of 94 countries (between 1965 and 2005) and conclude that stronger IP systems contribute to higher levels of economic complexity, with this being regarded as entailing a higher level of development only in the early stages of the protection. In this respect, only such countries may have the opportunity to enjoy the benefits of higher levels of global IP standardisation [10].

On the face of such evidence, it is not so clear that a high level of IP protection guarantees stimulation of pharmaceutical patent innovation. Thus, the extension of IP protection should be appropriately restricted by the compulsory licensing system on pharmaceutical innovation, with the negative effects of this system potentially having been exaggerated within the literature. It is therefore this matter that constitutes the gap that the negative effects of strong IP system appear to have been under-researched with respect to the potentially positive function of compulsory licensing systems of pharmaceutical patents. This seems especially important when one considers the need to strike a balance between pharmaceutical innovation and the public interest.

2.2. Overview of compulsory licensing

General issues relating to the system of compulsory licensing are of obvious relevance to the research question posed. The first primary issue relates to gaps in the research at the legislative level, with it being a matter of importance to consider how these gaps relate to the conflicts arising among different interest groups. This analysis provides the means by which to consider whether there is a potentially positive contribution to made by this system subsequently considered.

2.2.1. The legal philosophy of the compulsory pharmaceutical licensing system

This section considers the legal philosophy relevant to compulsory licensing legislation from both national and international perspectives as a means of identifying what factors modulate the application of this system, with China and India selected as the countries providing the contexts in which to consider these matters.

In considering the compulsory licensing provisions worldwide, this section refers to what might be regarded as the most important agreement, this being the TRIPS Agreement, Articles 8, 30, and 31 of which agreement are especially relevant, with Article 31 being the most significant and the most controversial. In this article, a compulsory license can be granted if: 1) there is a national emergency or other conditions of extreme urgency; 2) the license is to be used for public non-commercial use; 3) the license is used as a remedy for anti-competitive practices [11]. These requirements provide a legal philosophy situated at the international level, enabling state intervention against abuses of IP rights in the protection of the public interest [2].

However, there are several deficiencies in this legal foundation that require to be highlighted. Firstly, it explicitly allows Member States to issue licenses for patented technology without authorisation if the country pays adequate remuneration. In relation to this, however, Yuan stresses that the lack of a specific method for calculating what constitutes "reasonable remuneration" has indirectly resulted in only a small

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number of Member States having formulated clear provisions on how to calculate this remuneration [12]. The absence of clear criteria for calculating remuneration has been considered by a number of researchers considering this matter from the point of view of patent holders. Secondly, Padmanabhan states that, although Article 31 provides flexibility for Member States to regulate appropriate conditions for implementing this system, the variations in medical patent value and the characteristics of different cases give rise to technically legislative difficulties in determining specific conditions [13]. This may be one reason why this scheme has proven beneficial to LDCs. This notwithstanding, they have still struggled with the enforcement of this system. It is a matter of note, however, that the adoption of the Doha Declaration binds its members to act with a view to preserving public welfare, which is an embellishment to the rationale underpinning Article 31 of the TRIPS Agreement [14]. This amounts to a declaration that Member States can decide what constitutes public health crises caused by diseases, with this seeming to enable clarification through the provision of examples [4]. This means that the deficiency of the TRIPS Agreement can be reduced by this declaration such that its goal is nevertheless preserved.

In summary, although there are certain deficiencies, the philosophy of the TRIPS Agreement is to underscore the privileged position of public interest rather than that specifically of pharmaceutical innovation. It must nevertheless be recognised that the idealisation of this agreement, in affording countries a high level of flexibility in making their own laws, also engenders potential deficiencies, requiring that further legal analysis be conducted.

With respect to China and India, the implementation of compulsory pharmaceutical licensing in China stands in complete contrast to that occurring in India, notwithstanding that their legislative philosophies in building this system both comply with the TRIPS Agreement. In this respect, the selection of these two countries provides comparative evidence important to the matters addressed by the research question.

With respect to the legal philosophy of India, although it follows the principle of Article 31 of TRIPS Agreement in the same manner as China, Indian patent law provides greater space in which to expand the scope of applying compulsory licensing, focusing on the interest of the public. For example, Article 84 of the India Patent Act noted the 2005 Amendment, which defined a patentable invention in a manner that included pharmaceuticals while its provisions for compulsory licensing that benefited Indian pharmaceutical manufacturers [15]. Furthermore, Bayer v. Natco featured the application of this article to make drugs available for the public and to interpret the scope of the application of this article in a wider manner. It is therefore clear that India has accrued significant experience in enforce its legal philosophy of benefiting the public rather than medical innovation within this system. However, Sood highlights the potential of such applications to inflict significant damage on innovation occurring within India with respect to medical patents, with many generic medicines destroying local drug innovation in the early stages [16]. This deficiency in India's legal philosophy can therefore be regarded as having at least constituted a major factor in – if not having been solely responsible for – its catastrophic response to the COVID-19 pandemic. In summary, in terms of the performance of the compulsory pharmaceutical licensing system in India, its legal philosophy and the associated legislative deficiency may explain why the country has struggled to balance innovation and the public interest, albeit it has been able to accrue significant experience of the application of this system domestically.

With respect to the legal philosophy of China, although China has already issued laws on the system in compliance with the TRIPS Agreement in China Patent Act Article 49, Articles 53-63, it has not yet implemented these with respect to any specific pharmaceutical patent cases. Indeed, it should be recognised that the most general research gap in China's emerging IP markets and transitional period relates to inadequate law enforcement and weak levels of IP protection [17]. However, the legislative philosophy and the historical background of China has influenced its selection in the field of pharmaceutical patents, showing that China demonstrates a bias towards medical innovation protection rather than the public interest. In practice, however, this description cannot be applied to the real situation with respect to China's IP protection. Moreover, this setup has indirectly resulted in the conservative legal philosophy adopted in protecting the public interest. For example, the China Patent Act is too vague to allow the phrases "public health" and "significant economic value" to be interpreted. The lack of a fixed legal concept with respect to the public interest entails reliance on the discretion of administrative officers in China, inevitably leading to an innovation-oriented interpretation because there are more reliable resources for reference.

Furthermore, Cao points out that China's IP protection system is much younger than that of developed countries, and is thus both less secure and strongly influenced by external powers [17]. Yuan therefore considers the immaturity of the Chinese IP system as being shaped by the legal philosophy characterising that of developed countries. Such philosophies tend to lean towards protecting the development of

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innovation with a view to preventing IP trade friction [12]. In summary, China's legal philosophy demonstrates greater similarity with the promotion of pharmaceutical innovation, thereby enhancing the development of pharmaceutical products in the early stages of China's economic flourishing, the results of which have been that, on the whole, China has coped rather well with the pandemic, and certainly better than India. However, there is also a need to have regard to the deficiency in the legal framework, which may be isolated as the main reason why China has experienced difficulties with responding to later variant of COVID-19 based on the use of prior advanced technologies accessed through the issuing of compulsory licenses.

In conclusion, these advantages and deficiencies associated with the different legal philosophies from the national and international perspectives provide the background against which the present research addresses the gaps in the existing research.

2.2.2. Existing conflicts among interest groups

This section considers the legal philosophy together with the existing conflicts of interest between different groups, thereby enabling the investigation of further potential reasons that it is difficult to utilise this system in a manner that strikes an adequate balance between the competing interests. Although different jurisdictions will require to face different conflicts due to the specific details of their own stages of development and policies, similar main conflicts among interest groups are likely to apply in some form or another across the gamut.

Two main conflicts among different interest groups can be identified with respect to the granting of a compulsory license. Firstly, the contrast in opinions on patents between developed and developing countries is primary driven by their differing economic statuses, with this providing the first source of conflict. Even if a number of compulsory licensing provisions are available to them, developed countries rarely make use of such systems within the scope of their policies, to say nothing of applying them to pharmaceutical products [13]. Resistance against such systems stems primarily from the belief that they disincentivise medical innovation, with IP owners in the country tending to be the licensors. In other words, IP owners from developed countries who invest significant resources into innovation may risk losing what they regard themselves as being entitled to because of their efforts. This is undoubtedly a valid consideration in assessing the prevalence of trade fortresses and trade sanctions following the application of compulsory licensing [13].

Conversely, with respect to developing countries, Padmanabhan states that the decades following the TRIPS Agreement's enactment have provided ample evidence of a trend: governments from developing countries are becoming more cavalier with respect to their application of this system [13]. This tendency is highlighted as increasing levels of trade friction and sanctions, serving as the main difficulty of applying this system to the benefit of the public. However, the means by which to alleviate this conflict appears to take the form of the decision taken by the Biden administration to waive IP protections for COVID-19 vaccines, with the situation presented by this disease being regarded as one in which the matter of public health must be regarded as weighing heavily. It is possible to remove obstacles to the development and production of new vaccines in developing countries on the basis of such an approach while also considering whether the external pressure of this conflict can be eased [18].

Secondly, the conflict on patent holders and the public is driven by the different nature of their rights, viz., public rights and private rights. Chien argues that the patent system gives the patentee the exclusive right within a certain scope. However, the excessive pursuit of exclusive interests by the patentee often exceeds the limitations required by law in practice [19]. On the other hand, in most situations, if the reasonable public demands cannot be met, then conflict materialises. The matter of resolving this issue has proven a recalcitrant problem within the existing literature. In relation to this, Wang argues that there is a consistency between the interests of patentees and the public in some situations if it is possible for them to promote and rely on each other in a mutually beneficial manner [20]. Consider, for example, a reasonable price offered by a patentee in exchange for high sales volumes generated by people's demand in the context of a pandemic. Though such idealised situations tend not to be defined with much sharpness in the existing research, it is the position of this research that the pandemic constitutes exactly the kind of situation in which this conflict must be alleviated in pursuit of the appropriate application of this system in China, and, indeed, worldwide.

2.3. An interim conclusion

Three issues that are not addressed in an adequate manner in the existing literature have been highlighted in this chapter: first, there is insufficient research on the value of compulsory licensing for

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pharmaceutical patents; second, there are deficiencies in different legislative systems situated within different jurisdictions with different legal philosophies, resulting in a lack of a standard with respect to the implementation of compulsory licensing; third, the conflicts of different interest groups should be alleviated by means of the identification of contexts in which the correct balance of both interests groups would be struck by the issuance of compulsory licenses, with it being the position of this research that the COVID-19 pandemic provides exactly such a context. In relation to the research question, these three matters are not only the result of theoretical analysis but also important issues that require to be addressed in considering the feasibility of this system within selected jurisdictions.

3. Methodology

This chapter outlines the analytical approach used in this study, beginning with the research design, with justification also being provided of why the research approach selected can provide a sufficiently detailed analysis. Finally, this chapter considers limitations affecting this methodology.

3.1. Research design

This research design combines a systematic literature review and a case study method to conduct desk-based research, with this involving the following steps. First, it is necessary to select suitable studies within the literature for reference as a means of identifying obvious or potential interactions between different bodies of evidence. Second, there is a need to compare legislative systems across different jurisdictions, with this requiring an integrated approach that considers legal documents. Furthermore, it is essential also to engage with secondary resources as a means of selecting representative cases, with these resources being applied to identify possible valuable dimensions along which to evaluate existing findings in the selected studies for analysis.

3.2. Research approach

3.2.1. Systematic literature review

The systematic literature review is a "form of research that identifies, describes, appraises and synthesises the available research literature,"[21] with the particular approach taken being shaped by the research question to be considered.

In terms of reviewing – and subsequently comparing – the legislative systems and secondary resources on compulsory licensing relating to different jurisdictions for comparison, the context of the COVID-19 pandemic provides an important context to consider, supplementing the findings reported in previous studies and policies. Furthermore, there is a need for the present study to survey literature on the system produced by researchers and governments. The interpretation of associated legislations is covered in the studies for analysis, with the integrated interpretation from the perspectives of multiple groups enabling readers to perceive a more critical analysis considering the design of IP systems across different jurisdictions. Given these needs, a systematic literature review was selected for use within this study. Furthermore, as Ginieis et al note, the literature review constitutes a well-established and frequently applied method assisting with the identification and narrowing of research gaps. It is also particularly useful as a means of minimising bias through drawing comparisons between relevant studies and documents across different points in time [22].

With respect to the matter of reviewing cases applying compulsory licensing to discuss enforcement of this system, this research utilises empirical information to identify particularly suitable cases, many of which may be controversial or especially revelatory within the field. Because the application of compulsory licensing lies at the heart of this study, a high degree of internal validity requires to be achieved through the selection of empirical cases by means of the systematic literature review [23]. Given this need, the criteria formulated for searching suitable cases are outlined below.

3.2.2. Identification of case studies for research

Two requirements were formulated that all chosen cases required to meet, with these relating to 1) their prominent position with respect to this legal mechanism; 2) the presence of positive outcomes in promoting the public interests, albeit not to the extent that any lack of success would preclude such a case from being considered. Bayer v. Natco, which involved Indian compulsory pharmaceutical patent licensing and was decided in 2012, is considered within this research, with specific justification of its inclusion being as follows. Firstly, the case constitutes the first application of the compulsory licensing of pharmaceutical patents in India. Secondly, this is a very particular case in that it results in the issuance of a compulsory license in response to a non-communicable disease. As a result, this case highlights the

ISSN 2616-5783 Vol.6, Issue 16: 47-60, DOI: 10.25236/AJHSS.2023.061608

inherently fuzzy nature of the conditions for the implementation of compulsory licenses. Finally, this case appears to provide particularly lessons for China that are of particular legal relevance. Inclusion of this case was therefore regarded as being beneficial to this research in its addressing the research question posed.

With respect to the matter of comparing India with China, these countries share certain national conditions with respect to certain features of public health, with both having suffered from issues falling within this area with some frequency. With respect to the Chinese context, the legislation of this jurisdiction can be regarded as regulating the compulsory licensing of pharmaceutical patents with respect to the need to address the public health emergency resulting from COVID-19. However, this system was not ultimately drawn upon as a means of enforcing public access to relevant pharmaceutical patents. India therefore provides a useful comparative subject, with its application of compulsory licensing being relevant in this research for the formulation of recommendations addressing the research question.

3.3. Limitations

There are several limitations to the research methodology adopted within the present research. First, as Okoli states, the resources one chooses should provide an independent means of engaging in critical thought, especially with respect to reviewing academic materials [24]. Systematic literature reviews therefore have the disadvantage that, if the given study mainly quotes from legislative systems and formulates its analysis in terms of studies by researchers considering the design of different jurisdictions, the objectivity of their interpretation may not be guaranteed. Second, choosing cases by means of the requirements outlined might be insufficient for considering the sound legal philosophies of the selected jurisdictions, with different features of cases being based on different contexts, all of which are likely to be regarded as complex. The deficiency of relying primarily on one case – albeit one regarded as representative – requires that a fruitful contribution be made to the discussion on external validity through the inclusion of further examples.

4. Findings and Discussion

This chapter presents comparative research on China and India to consider the situation with respect to India is used to consider the feasibility of approaches within the Chinese context. An analysis is then provided of the understanding of ‘zero’ implementation in China. The final section addresses the remaining issues left by the research question in relation to the improvement of China’s pharmaceutical compulsory licensing, considering what strategies to this system could be made to achieve goals.

4.1. An analysis of the Indian situation

4.1.1. The context of India’s compulsory pharmaceutical licensing system

A number of findings are presented in the existing literature in relation to contextual analyses of India’s compulsory licensing system, with these potentially being of relevance in other selected jurisdictions. Mitsumori states that the pharmaceutical industry of India is the fourth largest in the world with this being a matter of some note given the frequency with which public health issues have affected India. However, between 1970 and 2005, the country did not have product patents, the result of which was that India was free to export many medical products to LDCs, leveraging its cheap production costs. It was on this basis that a number of Non-Governmental Organisations, seeking to support LDCs’ access to pharmaceutical products, raised objections against the introduction of pharmaceutical patents in India [25]. However, India ultimately required to introduce patent protection in 2005 to comply with the TRIPS Agreement. Specifically, a compulsory licensing system was issued under sections 84 to 103 and the active application of these in the field of pharmaceutical patents [25].

The context analysis illustrates the external pressure to which India would have been subject such that it ultimately incorporated this system. First, India is a country that has suffered a high number of public health issues; second, India exports many medical products overseas to the benefit of LDCs; third, India appears less devoted to the protection of pharmaceutical patents, meaning that it is subject to pressure associated with the risk of suffering international sanctions and the erection of trade barriers. A number of similar features can be highlighted with respect to the Chinese context, the theoretical effect of which is a significant limitation of the applicability of the compulsory licensing system in this jurisdiction. This notwithstanding, India has developed new teeth with which to guard its intention of protecting the public interest. For example, the Indian judiciary has made explicit its position that it is unacceptable for the public interest to be deprived of benefits on the part of drug giants [16]. It is therefore the nature of India’s decision in Bayer v. Nacto that sheds light on what is required to enhance the Chinese

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position. This can be considered as a means of shedding light on the improvement of the application for China given the need to balance multiple competing interests.

4.1.2. Bayer v. Nacto

The first pharmaceutical compulsory license in India was granted in 2012 by the Indian Controller of Patent in the case of Bayer v. Nacto. This case constitutes a useful example to evaluate with respect to the application of this system in China and its legal interpretation and enforcement.

The facts of this case are as follows: the price of Bayer's drug, called Nexavar (containing Sorafenib) was more expensive than that of Nacto's generic drug (containing Sorafenib) by over 97%. Most Indian cancer patients were therefore unable to afford this drug from Bayer, albeit it was also the case that there was an insufficient supply of this drug India. In 2011, Bayer submitted a patent infringement lawsuit, seeking to stop Natco's production of Nexavar generic drugs. Subsequently, an application for a compulsory license to use Sorafenib was submitted by Nacto [26], which claimed that its application complied with all the conditions applying to the compulsory license stipulated in the India Patent Law: (1) the public's reasonable needs were not being met, for the drug could only be provided to satisfactory levels in the four biggest cities in India, with this amounting to only 1% of the total demand; (2) the public could not obtain this drug at a reasonable or affordable price; (3) the patented drug was not used in India. Ultimately, Natco was granted the right to produce and sell Sorafenib in the Indian territory, requiring to pay Bayer a royalty of 6 percent of the net sales [16].

In this research, the relevant issues of this case are as follows: first, the Indian Intellectual Property Office stated that the public's need was not satisfied. However, Bayer raised that they had been providing sufficient and sustainable supply of medicines to India to meet the reasonable needs of the public. Therefore, the first issue related to whether this condition was satisfied for taking action in this case. Second, the same type of cases issued by other countries were aimed at patented drugs for infectious diseases differing to the cancer drug application in this case. Therefore, it was the second issue that was of particular relevance in terms of whether it was legitimate to implement a compulsory license on the drug, given its use for treating non-communicable diseases [16]. These findings from this particular case underscore the need to comment on the discretion used by the Indian court in arriving at a legal interpretation and enforcing it, with this serving as a useful reference point for guiding the application in China in balancing multiple competing interests.

4.1.3. Comments on the court decision

This decision engendered a number of similar legal issues posing a thorny problem for other jurisdictions in this field. However, it also provides a number of relevant issues to consider in relation to the legal application of the Indian system. Firstly, this decision demonstrated the court's taking a firm position against the right of monopoly of pharmaceutical companies, with this being regarded as being made possible by the relatively loose legislature governing these matters, as discussed in Section 84-92. Secondly, this decision features the interpretation of the legislations such that certain needs are met. The matter of interpreting whether this case "[met] the need of the public" or whether the price charged was "a reasonable and affordable" one over interpreting the definition of "public health" on the part of the court was approached with a view to avoiding a vague or incorrect interpretation of the Indian legislation [27]. In this case, although similar questions remain debatable, a valuable guide is provided as a means of framing the legal design and interpretation of this system within the Chinese context.

Surprisingly, Anu Singhai and Manu Singhai state that only a few related cases have been enforced in the wake of *Bayer*. In Emcure Pharmaceuticals v. Roche, the Department of Industrial Policy and Promotion (DIPP) denied a similar application requesting a national emergency license under section 92 of the India Patents Act. The other case of relevance is BDR Pharma v. Bristol Myers Squibb. BDR "could not make out a prima facie case for the grant of a compulsory license because it failed to make efforts to obtain a voluntary license from the patentee on reasonable conditions. [28]" It can therefore be noted that, although India follows a more flexible attitude with respect to applying this system than that of other countries, the enforcement in India appears to require to be enforced with greater consistency to avoid the abuse of public rights to the unreasonable damage of private rights. In summary, the enforcement of this important case provides a means by which to consider how similar matters might be approached in the Chinese context.

4.2. A comparative analysis of China and India

4.2.1. The context of China's compulsory pharmaceutical licensing system

It has already been noted that the present situation with respect to COVID-19 presents an opportunity for China to implement the pharmaceutical compulsory licensing in terms of the approach outlined in previous sections. There is therefore a need to analyse whether, given the national and legal conditions

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of Chinese, this system provides a means by which to balance the protection and fostering of medical innovation and the public interest.

China, as a growing power in the pharmaceutical industry with sufficient manufacturing capacity and the ability to innovate with respect to medicine, has opportunities to embed more flexibility and material support for LDCs under the TRIPS Agreement as a means of improving access to medicines. It is therefore a matter of some note that China has not issued any compulsory licenses for pharmaceutical patents based on its domestic law notwithstanding the seriousness of the pandemic [29].

There are three main obstacles as to the 'zero' implementation in China as summarised by Yuan. First, the IP trade friction initiated by developed countries makes it difficult to implement such a system. Second, the destruction of drug patent innovation that this system can result in has the potential to lead to a public health crisis, as demonstrated by India's vulnerability with respect to drug development. Finally, the legislative deficiencies in the China Patent Act limit the extent to which this system can be implemented, with, for instance, the vague definition of the legal terms, the narrow scope of the conditions of application and the defective judicial remedies all requiring to be considered [16]. With respect to the first two reasons, already discussed above, it is arguable that these external obstacles have been reduced as a result of the pandemic, with the need to develop new vaccinees and the associated benefit to the public both resulting in the matter of public health weighing heavily in the balance to be struck. Given this, the present study focuses on the third obstacle outlined above with respect to the matter of breaking the deadlock of China's 'zero' implementation in pursuit of a fair balance being struck with respect to medical innovation and the public interest. This appears to be a matter not only of conceptual importance, but also of China's international obligations.

4.2.2. The legal interpretation of terms with respect to China and India

The legal terms within the Indian and Chinese are different according to their associated legal philosophies. In this respect, the differentiation of legislative design is an important reason for the 'zero' implementation of China's compulsory licensing system, with this legislative deficiency having made it difficult to apply this system effectively during the pandemic.

Under the India Patent Act, there are certain pre-requisite conditions that can be summarised in relation to sections 84-92. The compulsory licensing can be implemented if the following conditions are fulfilled: (1) the reasonable needs of the public concerning the invention in question have not been satisfied; (2) the invention is not available to the public at a reasonable and affordable price; (3) the invention is not used in India's territory. Further, compulsory licenses can be issued if there is a "national emergency" or "extreme urgency" or in cases of "public non-commercial use. [30]"

Different to China, which appears to seek only to harmonise its legislation such that it complies with its international obligations, India occupies a different position in that it is the main beneficiary of this system. For example, it can be seen from the decision in Bayer v. Nacto that there was a perfect fit with the required condition, with the interpretation with respect to the strings "reasonable needs," "available to the public" and "used in India's territory" by the court being consistent with its demands. Compared with India, China lacks the legal power that would be necessary to afford it an adequate level of discretion to result in the granting of compulsory licenses in the field of public health. This is a deficiency that underscores the importance of clear legislation in China.

In China's act, the application of compulsory licensing is defined as a system for exploitation of the patent. The intention of this legal design can be interpreted from its pre-requisite conditions concerning Article 48-55, these being as follows: "(1) an invention or utility model has not been exploited successfully within a reasonable period of time; (2) the patentee's conduct is recognised as a monopoly by administrative or judicial proceedings; (3) the invention or utility model, involving essential technical advance of considerable economic significance in association with the latter invention or utility model, may fall into the application of this system upon the request of the later patentee; (4) a national emergency or any extraordinary state of affairs occurs, or the public interest requires that such a license be granted.[31]"

From the comparison of these legal terms with respect to the different requirements, generally, the regulations of China are relatively decentralised and abstract. There are four conditions covering the various legal fields, such as anti-monopoly laws, resulting in the unclear allocation of responsibilities across government departments. Furthermore, the first three conditions focus on developing new patented inventions. In other words, this system is more often used to consider matters of economic or innovative significance, with these differing from the main purpose of pharmaceutical compulsory licensing under the TRIPS Agreement, instead focusing on benefits that can be obtained through the use of other licenses in the IP field [20].

Furthermore, the legal terms used are too vague to be interpreted by either implementors or legal participants. There are three terms that require to be explored in depth. Consider first the matter of

ISSN 2616-5783 Vol.6, Issue 16: 47-60, DOI: 10.25236/AJHSS.2023.061608

whether an invention has not been "exploited successfully." Use of the verb "exploited" has proven controversial in relation to whether, for example, it is not clear that whether an "import" can be construed as belonging to a conduct of exploitation [20]. In this issue, there are respective interests towards different choices, even the TRIPS Agreement does not provide a specific explanation as to this term. It is therefore necessary for China to ensure that a proper interpretation is arrived at in reflection of its position. Second, with respect to whether the conduct of patentees has been "recognised as a monopoly," although this is a requirement relating to those of the TRIPS Agreement, what constitutes a monopoly in this field is not specified in the China Patent Act or its Anti-monopoly Law, making it difficult for applicants to prove that this condition has been met [20]. Third, with respect to the strings "national emergency" and "public interest," these constitute the most common requirement agreed by the TRIPS Agreement and Doha Declaration, albeit there is no objective standard by which to define such terms. It is therefore the scope of the interpretation of such terms that function as the decisive factor for issuing a license. For example, the extensive interpretation has been widely applied in related cases of India with respect to its position. Conversely, China has proven scrupulous with respect to its application as it relates to this condition rather than that of the other three [20].

In sum, the discretion afforded to the Indian court appears to have afforded it greater power and flexibility to arrive at an interpretation as compared with the Chinese court. However, this is not a deficiency that cannot be improved through the use of statute law. As a country that is also frequently affected by issues of public health, the flexibility of the Doha Declaration means that China can afford itself a more liberal interpretation of this term in its legal documents, thereby breaking the deadlock of pharmaceutical compulsory licensing with respect to the current situation. Given the affirmative answer offered to the research question, it is now crucial to consider the legislative perfection of the China Patent Act.

4.2.3. A comparison of the legal enforcement between China and India

The legal enforcement of India and China are dramatically different across two different stages, these being the procedure for enforcement and that for examination. The deficiency in legal enforcement constitutes an important reason relating to the 'zero' implementation of China's compulsory pharmaceutical licensing system within the context of the pandemic.

From the perspective of the enforcement procedure, with respect to the subject of application in China, there are many restrictions on the qualification of applicants. The main requirement of compulsory patent licensing in Article 48 relates to "the implementation of the unit or individual," while the approval department is "the related administrative department for the patent under the State Council." Compared with the Trips Agreement specified in the application subject "to users," the qualification of applicants is relatively strict in China. However, India does not set so many restrictions on the qualification of pharmaceutical compulsory licensing applicants, with the requirements in India being lower than those specified in the TRIPS Agreement [32]. The potential advantage of setting a lower threshold and thereby enabling a greater number of applicants may be evidenced by the findings of Li, who argues that a higher threshold of patent protection has already resulted in public welfare loss suffered by China, from static loss to dynamic loss [29]. This indicates that it is acceptable to lower the threshold for more applicants, thereby reducing the complexity of application. It must of course be conceded that patentees may it particularly onerous to respond to the procedures of this system, with the possibility of issuing voluntary licenses being likely to increase. China should therefore consider setting an appropriate threshold as a means of isolating an acceptable set of potential applicants on the basis of the specifics of its energetic pharmaceutical market.

In terms of the examination procedure, the compulsory licensing examination is divided into administrative review and judicial remedy. As expressed in Article 58, China mainly adopts judicial review, with this including a complicated examination procedure. It is also important the safe status of drug products be confirmed, so, in the administrative review, the subject tasked with examining the compulsory licensing application procedure is the Patent Administration Department under the State Council. Meanwhile, medical production requires to receive formal approval by means of examination on the part of the Drug Regulatory Department. However, it should be noted that this system will also require to make predictions and decisions regarding a number of urgent public health issues. It is therefore likely to be difficult for the whole procedure to result in a license being granted given the demands associated with a given situation qualifying as an emergency or crisis with respect to public health [32].

The post-examination procedure, which constitutes the judicial remedy, is the most important stage for patentees seeking to obtain compensation, and it may influence the development of pharmaceutical innovation in selected countries. In China, there is no clear standard of compensation for issuing a medical compulsory license, with judicial remedy tending to be decided by the court according to the principle of proportionality as implied by administrative litigation law. However, the circumstances in

ISSN 2616-5783 Vol.6, Issue 16: 47-60, DOI: 10.25236/AJHSS.2023.061608

which and the extent to which patentees should be granted compensation may not be easily decided using statute law [31], with it becoming a burden to challenge the effectiveness and fairness of the court. Although the court may present a reasonable choice, it must be conceded that judicial proceedings constitute a time-consuming and complicated procedure, leaving the value of prepositive administrative review being largely ignored. Articles 33 and 36 of the China Patent Compulsory Licensing Implementation Regulation do not introduce the administrative review as an option for patentees in all situations if their cases are brought on the basis of their seeking remuneration [33]. In the case of India, however, the country has opted to use administrative review as a pre-trial proceeding, underscoring the importance of a simplified procedure by which patentees can ensure the protection of their rights. Hence, mandatory pre-trial procedure appears to provide a fuller safeguard against interference affecting patentees [34].

In conclusion, the deficiency of the whole procedure of the application of pharmaceutical compulsory licensing in China has the potential to damage the motivation of patentees to continue innovating through affording insufficient protection of their rights, with this in turn constituting a potential obstacle against the implementation of this system in service of the public interest in China. Hence, this presents an opportunity for China to consider the implementation of a proper pre- and post-procedure together with the enforcement of this system, with the Indian cases and legislative system providing valuable sources of data in this regard. This would constitute a key component in a wider effort to strike a balance in a manner that respects the interests of both the public and innovators within the pharmaceutical industry.

4.3. Recommendations for the improvement of the compulsory pharmaceutical licensing system in China

Having considered the legal deficiencies in China's compulsory pharmaceutical licensing system, there is a need also to consider what strategies can be applied to provide an answer to the research question in a manner informed by the ongoing influence of the COVID-19 pandemic.

4.3.1. Legislative perfection of the compulsory pharmaceutical licensing system

In relation to perfecting legislative design, there are three areas that require to be considered, the first of which relates to clarifying the set of relevant legal terms, which, at present are too abstract and vague. It is recommended that specific definitions be provided with respect to the regulation of patent implementation rules. Indeed, it is worth noting that the definition of a legal term should consider not only the need to protect China's pharmaceutical patent, but also the need to protect public health within the context of global pandemics such as that associated with COVID-19. This is an essential legislative improvement in relation to which the provision could use an enumeration-based method to include infectious diseases in accordance with the guidance of the World Health Organisation (e.g, AIDS, tuberculosis) and thereby include these within the scope of what constitutes a "public health crisis." It is also recommended that one consider which specific types of diseases are most likely to trigger a public health crisis in China. By clarifying these legislative terms in practically informed manner, it may be possible to enhance the feasibility of pharmaceutical compulsory licensing, making this system an effectively implemented one as opposed to a mere point of legal theory.

Second, there is a need also to expand the scope of the set of applicants. That the applicants should meet the "conditions for implementation" is too strict a rule, as discussed previously. To mount a stronger response to the COVID-19 pandemic, China should reduce certain restrictions against issuing medical compulsory licenses. It is recommended that the requirement that India's applicants require to meet – that being that any stakeholders can make an application – be regarded as a source of reference for setting the scope of potential applicants in China. The negative consequences of expanding the scope of applicants can also be reduced through the introduction of strict qualification-related review in China's examination procedure. For example, the Opinion appears to narrow further the scope of "qualified" applicants to a small number by relevant governmental agencies, providing that:

"…the SIPO decides whether to grant a compulsory license, upon an advisory opinion submitted jointly by the National Health Commission (hereinafter "NHC"), the Ministry of Industry and Information Technology (hereinafter "MIIT"), the National Medical Product Administration (hereinafter "NMPA"), and other agencies after examinations and assessments conducted by them. [35]"

Thus, broadening the scope of applicants can provide a means of breaking the deadlock of 'zero' implementation and increase the opportunity to make use of this system. Meanwhile, strict examination at the administrative or judicial level may be used to offset certain negative effects arising from this change.

Third, there is a need to set a reasonable criterion for calculating levels of remuneration, with the direct conflict arising between fostering medical innovation and the public interest as to the patentees

ISSN 2616-5783 Vol.6, Issue 16: 47-60, DOI: 10.25236/AJHSS.2023.061608

and the applicants requiring to be the determination of pharmaceutical patent remuneration standards. In China, negotiation is regulated as a possible approach by which to arrive at a figure of reasonable compensation [31]. But the premise is to set a specific calculation standard for negotiation, which legislative systems appear to provide few examples of. It is therefore the position of the present study that a reasonable standard should be specified using a formal valuation method. Wang states that transparency, predictability, and ease of operation are three important features for the choice of the remuneration method [36]. It is therefore the case that some international communities may provide a variety of methods for this calculation. For example, the basic coefficient for generic drugs as specified in the 2001 United Nations Development Report is 4%, meaning that the rate of remuneration may be based on the degree of innovation and investment into Research & Development such that this modulates any movement within the given range. Taking such an approach would satisfy the essential characteristics for reference, thereby promoting the effective implementation of medical patent compulsory licensing in China [36].

4.3.2. Improving the implementation of the compulsory pharmaceutical licensing system

Given the lack of existing cases that are of relevance to this area, ascertaining the sorts of strategies that might be useful for improving the implementation procedure of this system in China is not an easy task. However, it is recognised that the pre- and post-examination procedures in China overly strict and complicated than those of many other countries. This section therefore considers how these procedures may be improved through simplifying the process of issuing a compulsory license for pharmaceutical patents.

In engaging in simplification of the pre-procedure, it is recommended that the following matters be addressed. First, simplifying the procedure would entail investing in law enforcement. There is currently a shortage of technical and professional officers for implementing associated examination. Given that pharmaceutical compulsory licensing has not yet been used in China, there is a need for training to be delivered to officers on how to formulate this licensing enforcement. This may also affect the expected social effects of this system. Second, the chaos engendered by the distribution of authority between the court and the government has led to conflicts with respect to standards of enforcement. With respect to the two-track method for implementation, it is important to ensure the simplification of the administrative procedure and achieve finality with respect to arbitral award. The international community generally adopts administrative authorisation, for example, Canada and France's Patent Offices are the main bodies granting compulsory licensing. In the case of common law countries, however, such as the UK and US, judicial authorisation finds greater favour [20]. It is therefore the case that the two-track method in China requires that a clear power distribution be achieved to enable effective responses to be mounted to urgent situations, with only a small number of applications to the compulsory licensing system being likely in practice.

Another approach would be to structure the system with diversified remedies for stakeholders in the latter stage of the procedure. First, it should be ensured that the legal procedure of remedy can cover a great range of remedies across the civil, administrative, and criminal range, reducing the length of litigation to ease the burden on stakeholders. Second, administrative review would improve the process of making a decision as compared with the effectiveness of judicial review as regulated in China's legislation. Therefore, a quick response from local governments would be required to set the administrative remedy as the prepositive procedure of each case. This would encourage all stakeholders to exercise their legal rights without this being overly time-consuming or resulting in the incurrence of high costs.

In conclusion, the refinement of China's legislative design constitutes an important basis for the legitimacy of this system, with it being essential to improve its accuracy and thereby allow it to serve as a suitable point of reference for decision makers. From the perspective of enforcement, simplifying the implementation process and setting a flexible remedy method would encourage applicants or patentees to actively exercise their rights, increasing the opportunity to implement or review this license for fair results. In addition, ensuring the effectiveness of the implementation process is also important for reducing the negative effects of the lag of the law in the medical field. Thus, breaking the deadlock of 'zero' implementation in China may be achieved if all these improvements were to be made effectively. This would constitute the first step by to policy makers is striking a balance between the multiple interests requiring to be considered. Furthermore, the very first application of the system would provide the means by which to make positive modification in the future through the accumulation of legal experience.

ISSN 2616-5783 Vol.6, Issue 16: 47-60, DOI: 10.25236/AJHSS.2023.061608

5. Conclusion

5.1. Summary

Given that the demand for pharmaceutical products is on the rise, the value of China's pharmaceutical compulsory licensing in balancing medical innovation and the public interest is a matter of some importance. This research presents a set of recommendations to enable this system to better counter the COVID-19 pandemic. This dissertation analysed the urgent matter of pharmaceutical product supply and considered the value of this system by means of a systematic literature review and case study. In this regard, the possibility of providing a clear affirmative answer to the research question could be increased by analysing deficiencies in this system as it appears across selected cases/jurisdictions. Finally, recommendations were provided for improving this IP system to ensure that it would be possible to mount a more effective response to public health issues. This dissertation also contributes to the consideration of further elements of China's dilemma, framing the lessons provided by India as an impetus to address the Chinese situation. The final section below outlines the limitations of the present research and implications for further research.

5.2. Limitations and Implications of the research

This research discussed the value of the compulsory licensing systems. However, certain limitations should be noted in this section. Firstly, although this study was able to provide evidence of a possible way of addressing the COVID-19 crisis, it is still the case that other such strategies may be possible or even preferable. Another limitation relates to popularising this system on a broader scope. Due to their differing legal systems and national situations, the comparison of India and China's contexts and legal histories may be insufficient. In this research, the small samples accessed did not allow to be provided for all possible results of the application. However, notwithstanding that this research did not consider many cases, it did provide some evidence of how the improvement of this system could assist with breaking the deadlock in China.

Although there are some limitations operating on it, the present study reveals how this less applicable but valuable IP system should be drawn on in this global pandemic. Further research should consider more cases, testing more well-established strategies grounded in this system to enhance its universality and practicability. This dissertation has taken steps to understand the methods in which this system may have a crucial role in changing current market-oriented licensing policies such that the Chinese situation becomes a fairer one. On the one hand, it is also essential that legislators and decision makers renew their knowledge and actions to respond to public health crises in a fair way. On the other hand, the application of this system could foster collaboration among all stakeholders to promote health equality through access to pharmaceutical products. It is to be hoped that an approach to the promotion of health equality can be achieved by stimulating innovation within the medical industry and promoting equity within the public.

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