

Reassessing Failed Legal Battles Over Misuse of IP Rights Under Competition Law in Asian Jurisdictions

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Abstract

In this research the author reconsiders the history of failure of the implementation of competition laws to deal with the abuse of the intellectual property (IP) rights in different Asian local jurisdictions. When using legal tools to dampen the trend of monopolistic behaviors based on IP ownership, challenges based on antitrust laws have hardly ever gained success despite the growth in the specifics of probe concerning overlapping provisions on the same. The article examines the procedural aspects of major court trends, regulatory uncertainty and doctrinal variance that have slowed down proper enforcement. There are some issues as well about the way emerging jurisprudence and regional trade patterns are creating a more sophisticated balance between the need to encourage innovation and the need to maintain market fairness. This research using comparative legal analysis indicates a necessity to harmonize legal approaches towards combating anti-competitive ordinances which are dressed in an IP protection.

Keywords: Competition law, intellectual property rights, antitrust enforcement, Asia, monopolistic practices, legal challenges, regulatory failure, IP abuse, market regulation, comparative jurisprudence.

1.Introduction

The overlapping between intellectual property (IP) rights and competition law constitutes one of the most vibrant but controversial areas in the legal and economic regulation especially in pharmaceutical industry. The regulation of monopoly activities of IP owners is, in Asia, an issue that presents challenges of both legal and developmental complexities since economies in the region are progressively shifting towards the innovation-based growth pattern, instead of the manufacturing-based growth model that had been in use previously. Historically, international agreements like the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) have provided the developing nations with ways to incorporate competition protection to their intellectual property systems. Nevertheless, in the context of such theoretical possibilities, the actual implementation of the competition law in relation to IP abuses, especially pharmaceutical markets, has not produced desirable results in numerous countries in the Asian region. Such failures highlight a major difference in the legal desire and the actual effectiveness of regulations(1).

The current paper attempts to retheorise the inadequacies of the current regulatory framework of competition law in the face of established patent monopolies in Asia. This study invokes a shift of the usual concentration on successful instances of antitrust intervention in favour of what one might learn emanating out of legal defeats of astronomical dimensions. This question is timely and also a requirement. With counties such as China, India, Thailand, and Indonesia making great strides in their activities in pharmaceutical research and development, and at the same time increasing access to generics and much needed medicines, there is an increased pressure among regulators and courts to develop mechanisms that can better address anti-competitive activities under the pretext of IP exclusivity.

During such times, competition law has been advanced as a critical remedy against the misuse of the patent rights particularly in the pharmaceutical market where drugs that are critical to save lives are often cushioned in an ocean of Intellectual Property rights. The bodies such as the World Health Organization (WHO) and the United Nations Development Programme (UNDP) have promoted the use of the competition tools to guarantee the access of essential medicines to the population long ago. An example is the case of the WHO in its seminal report of 2006 where it argued that one of the strategies to improve the state of public health in the developing world was the implementation of competition policies. The same has been done with IP-law teaching modules deployed internationally, with Western case precedents to publicize a more active deployment of competition systems to challenge the power of the pharmaceutical giants always cited: the European Union taking action on AstraZeneca

Reassessing Failed Legal Battles Over Misuse of IP Rights Under Competition Law in Asian Jurisdictions

(or, the Hazel Tau judgment in South Africa). The attempts to precede such precedents into Asian legal domains have however been far less successful or as some would say inconclusive⁽²⁾.

This finding reveals the necessity to pay more attention to legal and institutional ideas that restrict the effectiveness of competition authorities in Asia in fighting with the abuses of patents. Doctrinal constraints in national legal systems, immaturity of regulatory regimes, the difficulty of establishing a case of appreciable adverse consequences on competitive conditions in the market and the incapability of specifying market dominance in categories of therapeutic competition where substitutes are available are all among these factors. Besides, multinational drug firms are usually financially endowed and legally savvy enough to design licensing deals and settlement agreements including pay-for-delay agreements that strategically sideline effective analysis by antitrust regulators.

This issue was of a significant concern in the context of the Thai and the Indonesian failed antitrust challenges, as it was highlighted in the 2018 paper by Kiyoshi Adachi. These examples pointed to procedural and substantive obstacles to using the laws against competition to resolve purported abuse of patent rights on pharmaceuticals. In Thailand, Abbott Laboratories refusal to offer a major antiretroviral drug on the basis of a compulsory license granted by the government was not subject to legal action because there was lack of a market definition. Likewise, in Indonesia, licensing agreement between Pfizer and a local pharmaceutical company was questioned but later cleared by the Government on the availability of alternative drugs and the inability to dominate the market. Such cases showed that such practices, even though retaliatory or exclusionary, can still not meet the level demanded by the laws guiding competition.

It is on the basis of this that this paper has set out to examine some newer and equally educative cases of India and China. India An antitrust criminal prosecution of firms, such as Vifor international and Sanofi, based on infringement of licensing exclusivity and refusal to deal have been rejected by courts as lacking in substantiation of market forcible closure and negative effect on consumer access. In the meantime, the development of China of the so-called pay-for-delay deals, which is an example of the case of AstraZeneca and Jiangsu Aosaikang, represents a new dimension of concern to competition authorities. In the current scenario, although there are a few concerns of late market introduction and the withdrawal of patent disputes the Chinese Supreme People court still did not make a judgment on the antitrust aspect of the reverse settlement deal hence producing blurry legal standards⁽³⁾.

The sequence of such legal blowbacks criticizes the sustained discourse that competition laws can be a powerful tool to check the monopolistic inclinations of patent holders in pharmaceutical markets. They also indicate the necessity of generation of jurisdiction-based frameworks that enhance the maturity of local institutions as well as reflect the unique market conditions of economies in Asia. To give an example, the European Union applies well developed legal concepts, including the concept of essential facilities, and abuse of dominant position, which concept may not be fully worked out or consistently applied in a large number of legal systems in Asia.

Thus, this paper will aim not only to report failure but also to derive the positive lessons out of these failures. It argues that the failure to make antitrust claims against pharmaceutical patent abuse may be explained and this knowledge is paramount in developing more successful legal approaches. This insight can guide competition authority training, motivate lawmakers to fix flaws in the law that create ambiguity in the merger review and anti-competitive conduct standards and influence judges to develop or expand more adaptive, variable interpretive laws.

What is more, the effect of this analysis is not limited to law and economics. The very idea of life-saving and life-enhancing health goals at regional and global levels including the availability of cheaper medicines in time to the millions of consumers in the entire region is at stake here. With Asia emerging into a medicine powerhouse, it is becoming more and more urgent to achieve a difficult balance between innovation stimulus and market competition.

In this paper, by relying on comparative legal analysis and current case studies, the aim is to throw some light on the strategic blinds of the existing regulatory practice. By so doing it proposes a better rooted and locally customized role of competition law as part of a collective governance of pharmaceutical intellectual property. It is only when the policymakers, researchers, and activists address the impetus behind the failed antitrusts that they will be able to create a more equitable and effective structure to address the management of patent power in the developing pharmaceutical markets of Asia.

2. Background

The major debate regarding the connection between competition law and intellectual property (IP) rights across the world has been significantly informed by the perceived or actual impact of antitrust enforced policies towards ensuring monopoly malpractices within a country especially in the issue of pharmaceutical patent-related malpractices. In the past, international legal instruments, including the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), and input of international organizations, including the World Health Organization (WHO), have promoted competition mechanisms as an important solution to the exclusivity generated by patent rights. Article 8.2 and 40.2 of TRIPS make specific and clear reference to the fact that the members are at liberty to enact measures that will curb the misuse of IP rights and anti-competitive licensing agreements⁽⁴⁾. But although this legal basis seems promising, its functionality has been restricted by great margins especially in the third world countries. The antitrust law has not been used in Asia to control the abuses of the IP to any significant degree, being more often than not a dead letter as applied, failing or fading under judicial or administrative heat. It is against this background that the need to know what the law permits, but more importantly why it fails many a time in furnishing some form of accountability in the same market exclusion game when entrenched using patent rights is a very strong motive.

TABLE 1 Key Themes and Challenges in Applying Competition Law

Theme	Description	Implication
Global Legal Framework	TRIPS Articles 8.2 and 40.2 permit member states to act against IP abuse and anti-competitive licensing practices.	Legal foundation exists, but operationalization in Asia remains weak or inconsistent.
Role of International Organizations	WHO and UNDP recommend using antitrust law to increase access to medicines, especially in LMICs.	Creates policy pressure for regulatory action, but not always supported by legal tools or enforcement power.
Western Legal Influence	Developed countries' antitrust doctrines (e.g., EU, US) often emulated in Asia.	May not align with local market structures or institutional maturity.
Institutional Weaknesses	Many Asian competition authorities are young, underfunded, or lack technical capacity.	Limits ability to pursue complex IP abuse cases effectively.
Market Complexity in Pharmaceuticals	IP strategies such as evergreening, licensing exclusivity, and pay-for-delay complicate enforcement.	Abusive practices are difficult to classify or prosecute under current legal interpretations.
Legal Interpretation Challenges	Terms like "dominant position" or "relevant market" are inconsistently defined in Asian contexts.	Courts often dismiss cases due to technical or definitional insufficiencies.

The relationship between exclusivity and competition is particularly controversial in the pharmaceutical field, where the implications go beyond monetary profit but to the health of citizens. The availability of accessible and affordable medicines is an element of the WHO that has continually highlighted the need to ensure healthy lives and promote well-being of all ages according to Sustainable Development Goal 3. The requirements as set by the WHO in 2006 apply to the developing countries to establish and institute competition laws to combat abusive conducts of medicinal patents. Similar advice by the United Nations Development Programme (UNDP) has supported the view that low- and middle-income countries (LMICs) ought to engage competition law more actively as a remedial force to enforce extra-ordinary prices, refusal to license, and other restrictive acts in the pharmaceutical industry. Such global accord has filtered into the scholarly community and legal studies to an extent that lawsuits such as the Hazel Tau litigation in South Africa which encompassed the overpricing of antiretroviral drugs have been referred to as a prime example of positive civic and legal action⁽⁵⁾.

Still, this focusing on the victories may cover a more common picture of the losses in the legal courts, particularly in Asia. Competition authorities in the region are, in most cases, young, underfunded and working within a regulatory framework that involves much political economy and foreign investment conditionalities which tend to diffuse enforcement issues. Intellectual property regimes in most of these nations have improved at a fast rate as a consequence of international trade agreements and economic reforms but this has not been followed by

Reassessing Failed Legal Battles Over Misuse of IP Rights Under Competition Law in Asian Jurisdictions

equivalent development of anti-trust jurisprudence. Consequently, when local governments make an attempt to confront pharmaceutical giants over their supposed violations of patent privileges their actions are usually thwarted by frivolous technicalities of the law, the production of evidence and limited definitions of market supremacy or anti-competitive practices.

Enforcement is also complicated by the practice of developing countries to adopt western ideas on antitrust without reform and localization of its principles to their local setting and economy. As an illustration, the definition of a market power or a dominant position in either United States or the European Union might not be meaningfully applicable in jurisdictions where the drug distribution systems are not in any way fully consolidated and where the regulatory control is not well developed. Lawyers like Cheng (2013) and Drex1 (2008) have observed that the use of doctrinal instruments of a developed law system can yield skewed or inept results in the global South without formatting them in response to local context. This can be very disadvantageous in the pharmaceuticals market where the availability of more than one branded or generic products can be read by the courts as a sign of competition when in fact the pricing power and ability to control supply are concentrated in a relative few companies holding the licenses (6).

What adds to the problem is the complexity of patent strategies in pharmaceutical sector which has come into the picture. Pharmaceutical industries indefinitely refreshing patents much like a Christmas tree is properly called evergreening and settlements made over price payments to delay the generic version of the drug or product, commonly referred to as pay-for-delay, are becoming more challenging to monitor and prosecute using the existing antitrust statutes. Such practices commonly exist in the legal grey areas and quite frequently avoid any disciplinary measures, not due to the fact that they are harmless but because they are cleverly designed to prevent any manifest violation. In addition, numerous IP abuses are done in the pre-market or regulatory phases, e.g. in the context of a licensing agreement, a marketing authorization or a withdrawal of a patent application, and here it is hard to see how the competition law can interfere, which traditionally requires evidence of an effect in a well-defined market. Such a gap between theory and practice was perfectly demonstrated in the analysis dated earlier in 2018 that examined two unsuccessful Thai and Indonesian antitrust cases. Abbott Laboratories had abandoned its bid to sell a stabilized HIV drug in Thailand soon after the country granted a compulsory license on a similar drug. Although there were some signs that this was a way of retaliation, the case by the competition commission in the country was rejected based on the argument that there was no trading market at the said time. Likewise, Pfizer had a case to answer in Indonesia in relation to the accusations of pricing collusion with a local firm to limit competition on an anti-hypertension drug. The case was however dropped later when courts found that since there were other medicines with same treatment classification then consumers had a way out invalidating arguments of market foreclosure.

The experience of these cases does not pertain only to their jurisdiction, but it is symptomatic of the more expansive regulatory and judicial problems being experienced throughout the region. They demonstrate that procedural gaps like the failure to identify a relevant market, or adherence to conceptual inflexibility when it comes to defining dominant position or abuse can eliminate valid complaints, perhaps before they were ever valid. They equally beg questions about the place of national competition commissions, most of which still do not possess either the institutional independence or the legal muscle to challenge mighty multinationals with international trade protections(7).

None of these losses detracts from the necessity of more fluid and knowledgeable competition policies in response to the developing pharmaceutical environment of Asia where domestic research and development capacities are growing and generic production is becoming more assertive. A country such as China, India and Thailand is no longer a mere importer of patented drugs but an upstart that also has the potential to dislodge incumbents all over the world. This transition might offer the incentive and the tool to reconsider the approaches to the enforcement of antitrusts. But to become effective such strategies need to be crafted on the basis of lessons learnt in the previous failure rather than on successful precedents in far-away lands.

3.Insights from India and China on Legal Barriers to Antitrust Enforcement in IP-Related Disputes

The intricacy of applying competition law to the curb of abusive intellectual property conducts is very well seen in the current experiences of the ongoing legal proceedings in the Asian context particularly in India and China. Such jurisdictions, where some of the most vibrant pharmaceutical industries in the region are based, represent a

good hunting ground to evaluate how current antitrust regimes are not keeping pace with the changing patent tactics and exclusionary licensing practices. Although these nations have established substantial legal framework regarding IP protection and competition in the market, their usage in the high profile cases of pharmaceutical controversy illustrates that there are setbacks that are repetitive both in regulation and in terms of doctrine. The presented case studies emphasize structural factors which inhibit the conversion of benevolent legal principles into practical regulatory results.

Comparing Competition Law Applications in India



FIGURE 1 Comparing Competition Law Applications in India

In 2022, a case was filed with Competition Commission (CCI) in India against a Swiss pharmaceutical company, Vifor International AG, that has a patent on ferric carboxymaltose (FCM) injectables to treat iron deficiency. It was claimed by the complainant that in allotting the right of exclusive marketing and manufacturing to two Indian companies only (Lupin and Emcure), Vifor had successfully created a monopoly and consequently the market was restricted hence creating an abusive dominant position. The complaint attested to anti-competitive terms of licensing, locking out of prospective rivals, and imposing discriminating prices. On close examination the CCI however ruled that the licensing practices had not contravened Section 4 or 3(4) of the Indian Competition Act. It was the logic that the licensing contracts were within the limits of the commercial standards and did not freeze the entrance into the market by other market participants. According to the Commission, simply being dominant was yet not the same as being abusive, particularly, in the cases where some obstacles exist to the actions of other companies operating in the same area by denying them an opportunity (8). This ruling speaks of a judicious stance of the court- standards are very strict to demonstrate that exclusivity is equivalent to a foreclosure on the market. This trend was supported by the second case in India. The local entity of Sanofi Sa France is the Sanofi India Limited, which was accused of an unwarranted denial of distributing off-patent pharmaceutical commodities to a location in Surat in Gujarat. The complainant referred to the Drug Price Control Order (DPCO) and pointed out that the continuous refusal of Sanofi to sell at wholesale prices amounted to contravention of fair trade practices and unfair use of dominance. The distributor emphasized its reliance on the supply chain of Sanofi to acquire important medicines to ease attacks of allergy and diabetes as well as pain. However, once again the CCI declined the argument. It observed that other manufacturers were available with easy and ample availability of substitutes of the drugs in question and that market competition was not harmed substantially. The Commission made an order that the complainant had failed to prove the requisite notice of an appreciable adverse effect under the Act, thus it disqualified the complaint to be investigated at all.

These Indian examples repeat one of the main downsides of the existing antitrust structure: mere efforts to prove the market foreclosure, or anti-competitive damages, in a sphere with some available alternatives technically, though less convenient ones may be inferior to, or more expensive than, the monopolistic company in questions. Such strict reading can make the competition law impotent when dealing with monopolistic conduct under the guise of the acceptable commercial tactics that are otherwise within the law. Besides, it emphasizes the tendency

Reassessing Failed Legal Battles Over Misuse of IP Rights Under Competition Law in Asian Jurisdictions

of competition commission in developing countries to err on the side of conservatism, perhaps not to be seen as militating against property rights in intellectual property or put foreign investment off.

The case study of China brings another aspect to this discussion; the development of the concept of a pay-for-delay agreement in recently developed but not entirely wholesome strategy of delaying the introduction of generics. In a historical case against AstraZeneca and the Jiangsu Aosaikang pharmaceutical, a settlement agreement was decided upon after a intellectual property rights case on saxagliptin which is a diabetes drug jointly developed by Bristol-Myers Squibb and AstraZeneca. The local firm connected to Aosaikang, Jiangsu Vcare, had first applied to have the patent declared invalid but later accepted to drop the request in favor of immunity to infringement proceedings and not to enter the market until 2016, five years prior to the actual expiration of the patent.

These legal implications to this reverse payment settlement raised their heads in later instances when AstraZeneca itself filed a complaint against Aosaikang to the patent infringement. Nevertheless, the Nanjing Intermediate Court sided with the China-based manufacturer saying that such settlements forbid the claim of infringement. When AstraZeneca took the case to the Supreme People's Court it surprisingly dropped the appeal before a decision could be rendered. Although withdrawn, the Court still saw the occasion to formulate, as an original contribution of Chinese law, what it termed as the analytical standards to assessing so-called pay-for-delay settlements, under antitrust legislation⁽⁹⁾.

Comparing Antitrust Challenges in India and China



FIGURE 2 Comparing Antitrust Challenges in India and China

They were: (1) is the agreement the elimination or restraint of competition; (2) is the agreement an exclusionary extension in the patent interest; (3) is the generic company was compelled or induced in his renunciation of a challenge against the patent by a consideration; and (4) the compensation is not economically or legally justified. Although the Court did not make the decision on the merits of the case, its position was useful guidance to the future litigation of such arrangements. However, there were also loopholes presented in the case, notably the fact that such terms as a substantial delay and unjustified compensation have not been defined and thus introduce ambiguity that may be used to avoid competition by patent holders without being charged with law violations.

The similarities of these two cases in India and China together depict a common predicament of enforcing competition laws against complex types of patent exploitation in the fields of pharmaceuticals. In the two jurisdictions a refusal to do broad interpretations of antitrust provisions applied to IP can be seen in both the enforcement agencies and the courts. Although this concern can be based on fears of suppressing innovation or breaking international trade pledges, the effect of the same can only leave the regulatory influence with little choice but to act when the patent rights are used in de-monopolizing or predatory modes.

The two activities also have a wider implication on drug access in Asia, where health systems are already burdened by coverage deficiencies and unequal distribution of drugs. With pharmaceutical innovation in the area picking up, particularly in China, India and South Korea, it is high time that we got some clarity on enforceable,

contextualized standards against which cases of IP-related competition can be decided. In the absence of such clarity, the pattern of legal failures is most probably going to continue as it gives the upper hand to the powerful companies to explore the grey areas of the law in terms of patent protection versus market monopoly.

More importantly, these case studies gave a guideline on reform⁽¹⁰⁾. Their recommendations emphasize the necessity to reinforce standards in the evidence requirements and in the market definition methodologies, to widen the scope of what forms market harm and to provide regulatory agencies with improved analysis platforms to assess the licensing plans and settlement agreements. No less important, they highlight that the judicial confidence and political volition to put the competition law to meaningful usage is necessary even in cases when it challenges the strong actors in the pharmaceutical market or it has implications against international patent owners.

4. Conclusion

The recurring inability to succeed in competition law challenges of abusive intellectual property practices in Asia is not an indicator the irrelevance of the antitrust law, it points to a weakness in the capacity of the antitrust law to deal with complex patent stacks, imprecise intellectual legal standards, and unprepared institutions. As revealed in this paper, attempts to challenge pharmaceutical patent misuse in other jurisdictions such as Thailand, Indonesia, India and China have not been effective in most cases because of the limited judicial provisions, technicality against patent misuse, and the reluctance to re-imagine the constraints between intellectual property rights exclusivity and market equity.

Out of these case studies what has come out is not a set of judicial setbacks but lessons that are very critical. First, they point out how formalistic interpretations of market dominance and abuse tend to deny authorities the opportunity to overcome the market forces of reality and displace it with notions of abstract Ottoman-Nickelismese. As an example, the dismissal of the Thai complaint on the grounds that at the time of patent retaliation there was no so-called active market, or the refusal of the Indian authorities to entertain the refusal-to-deal claims since there were generic substitutes, indicate the strict utilitarian fixation on the doctrine rather than on the circumstances. This makes the case that interpretative frameworks ought to acknowledge the general public good and the nature of health related markets.

Second, the issue of the recent increase in reverse payment or pay-for-delay settlements in the Asian region, as exemplified by the Chinese AstraZeneca case, is one issue requiring attention. These cartels are a form of anti-competitive strategy that are more of a new frontier that is hard to solve to by conventional means. Although the Chinese Supreme People Court took a major stride consisting of providing a test to be used to analyze such settlements, it failed to provide enforceable standards. Failing to define the key terms, such as a term of an unjustified compensation or a term of a substantial market delay, the future enforcement work remains in the legal limbo.

Third, the reviews of the cases show that there is a systemic unwillingness on the part of Asian competition authorities and courts to actively pursue IP holders particularly multinational pharmaceutical firms. It may indicate an institutional insecurity, insufficient technical aptitude or the policy trade-off, in which the overriding interests lay in foreign investment and innovation inducements rather than market competition. Nevertheless, this type of caution presupposes that it runs the risk of legitimizing monopolistic behavior and by doing so, weakens the whole purpose of a competition policy and its role in serving as a restraint against market power.

Asian jurisdictions need to adopt a multi-prong approach in order to make any progress. In IP-intensive sectors especially, legal changes must focus on making the definitions of market dominance and anti-competitive behavior clearer, paying special attention to the practice of licensing and exclusivity deals on their impact on the structure of markets and on consumer welfare. The competition authorities need to be provided with technical ability to study complex patent licensing patterns and come up with guidelines which fit pharmaceutical industry. Judges, in their turn, will have to create a jurisprudence based on economic reality as well as a well-being of people, at least when judging on a paragraph about access to vital medicines.

In addition to that, there is a necessity to change the way the competition law is taught in academic institutions, and legal training programs in the Asian might be changed so that the instructional focus is not on the global success stories but the local failures of the enforcement. It is in such unsuccessful cases that scholars, regulators, as well as practitioners may realize strategic blind spots, evidence-based policies as well as yield a vigorous yet receptive culture of the law.

Reassessing Failed Legal Battles Over Misuse of IP Rights Under Competition Law in Asian Jurisdictions

Notably, the meaning of the word reform does not entail weakening or distinctly damaging intellectual property rights. Quite the opposite, an optimal competition regime builds the desirability of IP systems, since it is proven that monopolies being in the interests of the greater objectives of innovation and social welfare rather than just corporate dominance. It is difficult to balance these interests in the fast-changing Asian pharmaceutical environment where a booming innovation base is failing to provide equitable access.

In the end, Asian law systems will be able to deal with patent-based market abuses, not because they copy Western antitrust systems, but because they are willing and smart to adjust them to their national needs. The way ahead is not only in bringing back the international best practices but in recasting them into rights in the rule of law not only in the sense of legal principle but in the sense of developmental necessity.

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The authors have no conflicts of interest to declare

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