

Re-visiting Unsuccessful Competition Law Challenges to Abuse of Intellectual Property Rights in Asia

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While the teaching of international intellectual property law has traditionally emphasized the important role that competition policies play in addressing instances of abuse of patent rights by rights holders, building a successful competition claim can often be a difficult task. This paper argues that the emphasis on examining successful cases of competition policy-based claims to address abuse of pharmaceutical patent rights needs to be complemented by an examination of unsuccessful cases so that stakeholders can be better aware of how to construct a strong argument that may convince competition and/or judicial authorities. This paper updates my earlier work on cases where competition policies were unsuccessfully applied in Asia, a region which has had, in general, less experience with competition cases involving intellectual property and the pharmaceutical sector compared with Western countries.

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International economic law has traditionally highlighted the potential for using competition policy to check the abuse of intellectual property rights (IPRs). According to Article 8.2 of the World Trade Organization's Agreement on the Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), "measures may be taken to prevent the abuse of intellectual property rights by right holders and the resort to practices that unreasonably restrain trade". Article 40.2 of TRIPS stipulates that members may adopt appropriate measures that, in particular cases, could constitute an abuse of IPRs having an adverse effect on competition. These treaty provisions are used to justify the inclusion of provisions in national law that permit challenges to the abuse of patent rights utilizing competition policies.

While there is no comparable universal treaty dealing with competition policies, the commentary to the Model Law on Competition endorsed by the United Nations General Assembly notes that

[t]he reference to intellectual property is consistent with virtually all antitrust laws, which treat license of technology as "agreements" and scrutinize them for restrictions or abuses like any other agreement, except that the legal exclusivity

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granted by the State to investors might justify some restrictions that would not be acceptable in other contexts.¹

The commentary therefore emphasizes that exclusive patent rights are not absolute and subject to certain checks through, *inter alia*, competition policies.

This paper builds on my earlier research on this issue, which was published by CUTS International in 2018 (Adachi). As there were few cases in Asia at the time involving competition law and intellectual property abuse in the pharmaceutical sector, the paper relied principally on two unsuccessful but widely publicized case studies from Thailand and Indonesia, respectively, to demonstrate the difficulties of using competition law as a remedy for the abuse of patent rights by its owner. While these cases will be briefly reviewed again in this work, there have been cases and developments since then that, while not necessarily changing the conclusions of the earlier research, shed additional light on the problems that need to be overcome in order to maintain a successful competition claim for abuse of IPRs with respect to pharmaceutical products.

The pharmaceutical sector has seen rapid growth in Asia during the last few years and various industrial publications examine the growth of the sector (CPhI). Such reports highlight both the longstanding expertise of manufacturing generic medicines for local markets in countries such as Bangladesh, Indonesia, and Viet Nam, but also demonstrate how many countries are strategically moving to the research and development of new medicines. China is frequently cited in this regard.

Asia is also becoming an important source of R&D innovation. While the US still accounts for around half of novel pipeline assets, Asia is closing ranks. According to Pharmaprojects, China is second only to the US, accounting for 14%, followed by Japan and Korea at around 5% each. In recent Nature Reviews Drug Discovery research, China boasted more than 2,000 investigational agents as of July 2021, of which 418 were first-in-class and 216 fell into the next-generation category; the latter includes cell and gene therapies, nucleic acid therapies, and approaches in proteolysis targeting chimera (PROTAC). (Liu, 2022)

CPhI also notes Thailand's efforts to become a future hub for medical R&D under their Thailand 4.0 initiative.

In the regulation of instances of patent abuse through competition policies, some of the literature points to the need for developing countries to have their own standards for examining cases of refusals to license, abuse of monopoly power, and the like (Cheng, 2013). The arguments in favor of such an approach look to the sophistication of competition authorities, which tend to be relatively younger and less experienced in developing countries, as well as the different structure of the markets in question, among other factors. Pharmaceuticals pose a unique issue as access to medicines is an important development goal under Sustainable Development Goal No. 3, and countries vary widely in the means to pay for and ensure access to needed medicines. Nonetheless, in the absence of concrete guidance on a developing country approach, most competition authorities apply what Priest refers to as an "absolutist" approach that uniformly applies developed country notions of competition policy and law to claims of abuse of patent rights (Priest, 2013). Reference works on competition law generally cite examples from the United States, Japan, and European Union (Drexl, 2008).

The current paper reviews additional cases from the previous few years from China and India and includes an examination of the emergence of "pay-for-delay" agreements in the pharmaceutical sector in Asian

¹ Model Law on Competition: Draft commentaries to possible elements for articles of a model law or laws. TD/RBP/CONF.5/7 (2000).

jurisdictions as a possible issue in the interface between competition and IP law. Like the 2018 paper, this research relies on a case study approach and attempts to draw findings and conclusions therefrom.

Background

The genesis of this paper as well as my earlier work can be traced to the tendency pedagogically to emphasize the potential role of competition law in curbing abusive behavior by pharmaceutical patent holders as contemplated by the TRIPS Agreement. International organizations and academics teaching international intellectual property issues have generally been at the forefront of encouraging the use of competition policies in this manner (UNCTAD-ICTSD, 2005; Flynn, 2008). The World Health Organization (WHO) has recommended, for instance, that “[d]eveloping countries should adopt or effectively implement competition policies and apply the pro-competitive measures allowed under the TRIPS [a]greement in order to prevent or remedy anti-competitive practices related to the use of medicinal patents” (WHO, 2006, Recommendation 4.23). The United Nations Development Program (UNDP) has also argued for more aggressive use of competition policies to curb abusive behavior by pharmaceutical patent owners (UNDP, 2017). As a result, it has become common when teaching international intellectual property law to emphasize that competition law can be an effective check on the abuse of IPRs. Typically, such exercises cite the 2002 Competition Commission case from South Africa of *Hazel Tau*, where a claim of excessive pricing of anti-retroviral drugs (ARVs) was successfully brought by civil society organizations to secure a lower price (Berger, 2006), and the 2006 European case of *Dobfar*, in which a court granted relief to a generic manufacturer for a refusal to license an active ingredient of an antibiotic by a multinational company where the ingredient was considered an essential facility (Correa, 2007).

It was in this context that the 2018 paper examined the case studies of Thailand and Indonesia, respectively, to examine why competition challenges to abuse of IP patent rights were in these two instances unsuccessful. In Thailand, a group of non-governmental organizations (NGOs) filed a complaint with the Office of Trade Competition Commission (OTCC) alleging that the decision by Abbott Laboratories Co., Ltd. to withdraw marketing registration applications of certain drugs following the Thai Ministry of Public Health’s issuance of government-use compulsory licenses in early 2007 constituted retaliation against the legitimate use of compulsory licenses by Thailand. The withdrawal included a heat-stabilized version of an ARV to treat HIV/AIDS that would have been important to a tropical country like Thailand. The OTCC rejected the NGOs claim because, *inter alia*, a market needed to exist before competition law could be invoked, and in this case, the drug had not yet been marketed in Thailand. In Indonesia, the Anti-Monopoly Commission (KPPU) investigated licensing contracts between Pfizer Inc. and a large generic Indonesia firm, PR Dexa Medica, claiming that the two firms colluded to fix the price of a hypertension drug, amlodipine, and of forming a cartel to abuse its dominant position. One of the main reasons that the judiciary authorities overturned the findings of the KPPU was that dominance cannot be established when there are alternative medicines to which patients can easily turn to treat hypertension even if such collusion and price fixing had occurred (Adachi, 2018).

The relevant body of judgements of unsuccessful use of competition law to address abuse of pharmaceutical patents in Asia has expanded since this initial examination, prompting an update of the earlier paper. Two recent cases from India and one case from China are examined below.

Recent Cases

India (1)

Vifor International (AG), a Swiss pharmaceutical firm, held a patent over an active pharmaceutical ingredient (API) for injectables used to treat iron deficiency, ferric carboxymaltose (FCM injectables). Acting on a complaint by an informant, a claim was filed against Vifor that FCM injectables were sold by only the two Indian firms that were authorized by Vifor to import, manufacture, and sell soluble FCM injectables in India, namely Lupin and Emcure.² The complaint against Vifor alleges that it had abused its dominant position by entering into exclusive licensing arrangements to restrict the production and supply of FCM injectables; the complaint also alleged discriminatory and excessive pricing.

The Indian Competition Commission rejected the informant's claims under Section 4 and Section 3(4) of India's Competition Act. The Commission first examined the terms and conditions of the licensing contract and found them to be reasonable and in line with general commercial practices. Further, according to the Commission members, even though Vifor was a dominant player in the market, there was "nothing to suggest that construct of the market is such that impedes the free entry of other manufacturer[s] of soluble iron injectables, should they like to operate in the market either independently or through India pharma companies, save the *inter se* restrictions between Vifor and its two licensees". There was therefore no evidence that Emcure and Lupin could exclude rivals and that there was nothing to impede the entry of new suppliers of iron injectables.

India (2)

Also in 2022, a partner at a local Indian pharmaceutical distributor lodged a complaint with the Indian Competition Commission, requesting Sanofi India Limited, Sanofi SA France's subsidiary in India, to supply some of its off-patent pharmaceutical products to them at wholesale prices under the Drug Prices Control Order of 2013 for the territory of Surat, Gujarat, a request that had been made to Sanofi India on repeated occasions. Sanofi India refused citing no shortage of existing stocks and suggested that the local firm procure these drugs from Sanofi's existing suppliers in Surat. According to the local firm, however, it would only be able to procure from local firms at retail prices, and only Sanofi could provide the drugs in question at wholesale prices. The local partner proceeded to file a complaint with the Competition Commission for refusal to deal, citing provisions of the Drugs Prices Control Order requiring manufacturers to refrain from refusals to sell without sufficient reasons.³ The drugs in question were popular medications to treat allergies, oral pain relief, and diabetes, among others.

The Competition Commission dismissed the claim by the local distributor, noting that "the drugs as aforementioned appear to have generics/substitutes in the market which are sold by other manufacturers and the Informant is not foreclosed absolutely in dealing in such products". The Commission pointed out that the complainant did not establish any appreciable adverse effect on competition to warrant examination under Section 3(4) of India's Competition Act.

China—"Pay-for-Delay" Agreements

The rising phenomenon of "pay-for-delay" agreements in Asia, where pharmaceutical patent owners agree to pay a generic manufacturer to refrain from introducing a competing product for a certain time and/or to refrain

² Competition Commission of India, Case No. 05 (2022).

³ Competition Commission of India, Case No. 31 (2022).

from litigation to challenge the validity of the originator's patent, poses a relatively new problem for competition authorities in Asia. Such reverse payment agreements have typically been subject to scrutiny under a country's competition laws in Western jurisdictions. The judicial precedent that has had the most influence in encouraging the use of antitrust laws to test the propriety of such contracts is the 2013 U.S. Supreme Court case of *Federal Trade Commission v. Actavis Inc.*⁴ where the owner of a patent on a medicine used to treat low testosterone levels, Solvay, sued two generic manufacturers for patent infringement following their application for an Abbreviated New Drug Application (ANDA)⁵ for the same compound shortly after the patent had been granted to Solvay, and then proceeded to settle with them in a deal to share in Solvay's profits while the two generic manufacturers committed to refraining from entering the market until approximately five years before the patent expired and to abandon any challenges to Solvay's patent. The Supreme Court held in this case that reverse payment settlement agreements should be subject to a "rule of reason" analysis to determine whether they violate antitrust laws.

Asian jurisdictions have had less experience with the review of these contracts and the standards that will be used to review their legality is not yet clear. It is useful in the context of this update to examine one case from China. *AstraZeneca v. Jiangsu Aosaikang Pharmaceutical*⁶ involved a settlement agreement with respect to saxagliptin, which is a compound used to treat Type II diabetes. The drug was developed and marketed jointly by Bristol-Myers Squibb (hereafter BMS) and AstraZeneca. In 2011, Jiangsu Vcare PharmaTech Co., Ltd. initiated a request for invalidation of the saxagliptin patent in China. At the end of that year, BMS and Jiangsu Vcare entered into a settlement agreement under which the Chinese company agreed to withdraw its request for patent invalidation within five days of the settlement's effective date, and BMS agreed not to make any claims for infringing the patent against Jiangsu Vcare and/or its affiliates (including Aosaikang as the principal manufacturer and distributor) after January 1, 2016. This agreement would thus allow Aosaikang to enter the market prior to the expiration of the patent on March 5, 2021.

AstraZeneca, which had since been assigned the patent rights to saxagliptin in China by BMS, filed a lawsuit against the Chinese manufacturer with the Nanjing Intermediate Court in 2020 after it had started manufacturing saxagliptin. The lower court ruled in favor of Aosaikang applying a *per se* rule, i.e., that as stipulated in the settlement agreement, the manufacturer made and sold saxagliptin tablets within the agreed period, which automatically would not amount to an infringement of the patent. AstraZeneca then appealed the judgment to the Intellectual Property Court of the Supreme People's Court in March 2021. One month later, however, AstraZeneca filed a motion to withdraw the appeal. The judgment in this case was rendered as part of the Supreme People's Court decision on whether to allow AstraZeneca to withdraw the appeal and is considered the first court case in the country to authoritatively pronounce an opinion on reverse payment agreements (Hu & Li, 2022).

In this case, the Supreme People's Court accepted AstraZeneca's motion to withdraw the appeal, which subsequently led to a settlement between AstraZeneca and Aosaikang. By permitting the withdrawal, the Court

⁴ *Federal Trade Commission v. Actavis Inc.*, 570 U.S. 136 (2013).

⁵ An ANDA is an application for approval of a generic drug in the United States for an existing medication or approved drug based on the U.S.'s Hatch-Waxman Act; see footnote 6, *supra*.

⁶ Supreme People's Court, Docket No. 388: 最高法知民终 (2021).

declined to make an assessment of whether the initial “pay for delay” agreement between BMS and Jiangsu Vcare violated Chinese competition laws. While its status as an “unsuccessful” competition claim is therefore not clear cut, the court did clarify that reverse payment agreements in the pharmaceutical sector are subject to antitrust scrutiny utilizing the following factors:

1. Does the contract potentially eliminate or restrict competition in the relevant market or otherwise constitute a monopolistic agreement?

2. Does the contract substantially prolong the duration of the patent holder’s market exclusivity and delay or exclude market entry by generic drug applicants?

3. Where the reverse payment settlement involves a covenant not to challenge the underlying patent and had the generic drug applicant not withdrawn its petition for invalidation, whether the patent could have been invalidated?

4. Whether unjustified compensation has been offered to the generic firm for withdrawing its request for patent invalidation, as this could be evidence that the patent could likely have been invalidated?⁷

Although these questions provide guidance when analyzing cases concerning reverse payment agreements, some legal practitioners have pointed out that the Supreme People’s Court did not define what they meant by terms such as “substantially prolong” or “unjustified compensation” (Mak, 2022).

Findings and Conclusions

The new cases from China and India generally reinforce the findings from the 2018 study, which concludes that there is much that can be learned from unsuccessful cases, especially in terms of potential pitfalls when constructing competition claims to address potential abuse of pharmaceutical patents. The two cases from India highlight similar insights from the earlier cases in Thailand and Indonesia, while the case from China is designed to show emerging issues in competition law that Asian countries, particularly those with pharmaceutical production capacity, need to be aware of.

First, not all behavior by patent owners is going to be actionable under competition law regardless of how unfair this may seem to a complainant. The Thai case showed that even if the action in question was in fact retaliation for the government’s issuance of government-use compulsory licenses, the act cannot be a violation of competition law if, in effect, there was not yet any market for a drug which had not received approval by the drug regulatory authority for sale domestically. A bar was set in the Sanofi case from India where the Competition Commission decided that the complainant was unable to show that there was any appreciable adverse effect on competition to warrant further examination.

Second, it is difficult to establish a case for abuse of pharmaceutical patent rights under competition law where there are other alternative medications available to patients and distributors. In the case from Indonesia and both Indian cases, the competition authorities pointed out that alternative means to obtain medicines was not foreclosed to the complainant. A major distinction between these cases and the *Hazel Tau* case in South Africa was the ability of the NGOs to argue that the ARVs in question were a unique first-line treatment, and that other

⁷ Summary of the Annual Report of the Supreme People’s Court on Intellectual Property Cases 最高人民法院知识产权案件年度报告 (2021), Case No. 47.

treatments, while available, were, at the time, medically considered second- and third-line treatments that would be initiated only when the first-line treatment proved ineffective.

Finally, the new emerging area of reverse payment agreements constitutes a major challenge for countries in Asia as local manufacturers become more adept at producing generic alternatives to on-patent medicines. In the absence of a series of available and binding precedents, the People's Supreme Court provided a first attempt at guidelines to assess the propriety of "pay-for-delay" agreements, opting to examine such contracts on a case-by-case basis as opposed to a *per se* prohibition.

While international instruments do suggest the use of competition policies to curb the abuse of patent rights, the above cases show that it is not necessarily easy to construct such a successful competition claim. In teaching the interface between intellectual property law and competition policies, it may therefore be prudent to include both instances where the check on abuse was successful along with instances where it was not.

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