TAY & PARTNERS

Introduction

A great deal of pressure and attention has in recent years been devoted by competition authorities across jurisdictions on commercial behaviour and conduct of pharmaceutical companies which contribute to generic delays. The European Commission has identified in its *Pharmaceutical Sector Inquiry Final Report* which was released on 8 July 2009[1] several "tool-box" strategies developed and used by originator companies to delay generic entries in order to continue reaping maximum profits from their originator blockbuster drugs. These strategies are – strategic patenting (so-called "patent cluster"), patent disputes and litigation, patent settlements, interventions before national regulatory authorities and life cycle strategies for follow-on products.

"Pay-for-Delay" Agreement

This article focuses on the patent settlement strategy which gives rise to anti-competitive effects in the pharmaceutical sector or the mechanism more popularly known as the "Pay-for-Delay" Agreement. A "Pay-for-Delay" Agreement is generally a form of patent dispute settlement where an originator company or pharmaceutical patent holder extends to a generic company some sort of value transfer, for instance direct monetary payment, distribution or licensing rights and/or other forms of side commercial deals in return for which the generic company acknowledges the validity of the patent in dispute and undertakes to refrain from marketing a generic version of drugs which is equivalent to the originator drugs for a specified period of time at the end of the life of the patent. It is worth noting that settlements which allow generics to enter into the market before the patent is set to expire may also be subject to antitrust scrutiny from competition authorities.[2] Such deals are not only predisposed to depriving the public of equitable access to cheaper medicines and affordable treatments but could also facilitate the drop in innovation and enhance the tax burden financing the health system.

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[1] Available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html.
[2] FTC v Actavis, Inc., 570 U.S. 136 (2013).
[3] Available at https://www.mycc.gov.my/market-review.

It is observed by the Malaysia Competition Commission ("**MyCC**") in the Market Review on Priority Sector under Competition Act 2010: Pharmaceutical Sector[3] that patent settlements between originator and generic companies in other parts of the world may have impacts on the Malaysian market. The patent settlement agreements in relation to Novartis' imatinib (a blockbuster drug for the treatment of chronic myeloid leukaemia sold under the brand name of "*Gleevec*" or "*Glivec*") is a case in point. In Malaysia, although the National Pharmaceutical Regulatory Agency (NPRA) has granted marketing approval for generic imatinib to Cipla Malaysia Sdn. Bhd. in March 2013 and Dr. Reddy`s Laboratories Malaysia Sdn. Bhd. in August 2017, both companies have not proceeded with the supply of the generics in Malaysia. Similarly, Ranbaxy Laboratories Limited filed a patent application for its generic imatinib on 15 February 2013 in Malaysia but the application was subsequently withdrawn.[4]

Around 2014, Novartis launched patent infringement lawsuits against, among others, Dr Reddy's Laboratories and Ranbaxy for the latter's filing of the Abbreviated New Drug Applications (ANDA) with the US Food and Drug Administration (FDA) for approval to market generic versions of the imatinib prior to the expiration of Novartis' imatinib patents in the US. The validity of the US patents was also challenged by the generic companies. The MyCC noted that these companies or their related companies had subsequently gone into settlement with Novartis and the potential global reach effect of these settlements could circumvent the entry of generic imatinib into Malaysia.[5]

The adverse effects of the "Pay-for-Delay" Agreement has signalled a greater vigilance of enforcement across jurisdictions. Regular monitoring by the European Commission of patent settlements between originator and generic companies has been actively progressing since 2010. We have seen the European Commission imposing fines of up to €93,8 million on the Danish pharmaceutical company, Lundbeck and of €52,2 million on four generic companies for blocking the supply of the generic anti-depressant, citalopram in 2013.[6] Being dissatisfied with the European Commission's decision, Lundbeck and the generic companies filed an appeal to the EU General Court, which subsequently upheld the Commission's decision and ruled for the first time in 2016 that "Pay-for-Delay" Agreements breached the EU antitrust rules.[7] On top of that, Johnson & Johnson and Novartis were also inflicted with fines totalling €16 million for delaying market entry of the generic pain-killer notably used for cancer patients, fentanyl.[8] Later in 2014, the French pharmaceutical company Servier and five other generic companies were fined by the European Commission a total of €427.7 million for concluding a series of deals aimed at protecting the former's bestselling cardiovascular medicine, perindopril from price competition,[9] a decision which was subsequently annulled in part by the EU General Court and the total fines were reduced to €315 million[10].

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[4] Ibid.
[5] Ibid.
[6] "Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines", 19 June 2013, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_13_563.
[7] "Antitrust: Commission welcomes General Court judgments upholding its Lundbeck decision in first pharma pay-for-delay case", 8 September 2016, available at https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_2994.
[8] "Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl", 10 December 2013, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_13_1233.
[9] "Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine", 9 July 2014, available at https://ec.europa.eu/commission/presscorner/detail/en/IP_14_799.
[10] "The General Court annuls in part the European Commission's decision finding the existence of restrictive agreements and an abuse of a dominant position on the market for perindopril, a medicine used to treat hypertension and heart failure", 12 December 2018, available at https://curia.europa.eu/jcms/jcms/Jo2_7052/en/?annee=2018.

The US Federal Trade Commission and the UK Competition and Markets Authority ("CMA") have also taken similar approaches in the cracking down on such anti-competitive practices.

MyCC's View on "Pay-for-Delay" Agreement

Although the MyCC has not issued any decision on competition issues relating to the pharmaceutical sector, it has in its *Guidelines on Intellectual Property Rights and Competition Law* published on 5 April 2019 (in force from 6 April 2019)[11] recognized that a "Pay-for-Delay" Agreement may be anti-competitive and thus fall foul of sub-section 4(2)(c)[12] of the Competition Act 2010 ("**Act**") having the object of significantly preventing, restricting or distorting competition in the market. Such agreements may also be an abuse of dominant position under section 10 of the Act.

If a "Pay-for-Delay" Agreement is indeed caught under sub-section 4(2)(c), the "safe harbor" threshold[13] does not afford any defence or absolve a "Pay-for-Delay" Agreement from liability. Under such circumstances, the MyCC is under no obligation to define the relevant market and determine the market shares of the parties nor its anti-competitive effect.[14] Parties to such anti-competitive agreement may nevertheless invoke section 5 of the Act to be relieved of their liabilities by demonstrating the following:

a. there are significant identifiable technological, efficiency or social benefits directly arising from the agreement;
b. the benefits could not reasonably have been provided by the parties to the agreement without the agreement having the effect of preventing, restricting or distorting competition;
c. the detrimental effect of the agreement on competition is proportionate to the benefits provided; and
d. the agreement does not allow the enterprise concerned to eliminate competition completely in respect of a substantial part of the goods or services

The burden of proof lies on the parties seeking an exemption under section 5 to demonstrate all the above criteria by means of legal arguments and factual evidence. Patentees might argue that the agreement at issue proffers the incentive required to innovate whilst its effect brings no actual or potential net harm to society at large. Whether the agreement does result in direct technological, efficiency or social benefits, and whether it generates appreciable objective advantage would have to be appraised in the light of the business norms and social and economic realities within the pharmaceutical realm. Concepts of "reasonableness" and "proportionality" being moulded into the legal test suggests that while objective appreciation of the social and economic realities of the case is a necessity, subjective elements such as practical considerations affecting the parties cannot be ignored. Does the ultimate strategy of the parties have the ability to sidestep competition resulting in exclusionary effects going beyond the specific anti-competitive effects of the

[11] Available at https://www.mycc.gov.my/guidelines.
[12] A horizontal agreement which has the object to limit or control production; market outlets or market access; technical or technological development; or investment, is deemed to have the object of significantly preventing, restricting, or distorting competition in any market for goods or services.
[13] Anti-competitive agreements will not be considered "significant" if:
· the parties to the agreement are competitors in the same market and their combined market share in the relevant market does not exceed 20%;
· the parties to the agreement are not competitors and each of them have less than 25% of market share in the relevant market.
[14] Supra note 11.

individual agreements? In answering this, it should be open to the patentee to demonstrate that such exclusionary effects are outweighed by advantages in terms of efficiency that benefits consumers.

Malaysia presently has no precedents relating to disputes on pharmaceutical products or generic entries in the antitrust arena. Inquiries and reports by the European Commission or judgment from the EU courts are to a great degree illuminating in shedding light on issues pertaining to "Pay-for-Delay" Agreements due to the similarity between the competition laws of both jurisdictions.

Are They All Bad?

Different types of settlement agreements could receive different levels of competition law scrutiny. The European Commission remarks that settlement agreements which do not restrict generic entries and those which restrict generic entries but involve no value transfer are generally regarded as unproblematic from a competition law perspective whereas agreements which restrict generic entries and foresee a value transfer should be accorded the highest degree of competition law scrutiny.[15]

The European Commission further notes that licensing agreements restraining a generic company from entering the market with its own product or from setting the conditions for the commercialization of its product freely constitutes an agreement limiting generic entries to some extent. However, an exception applies in cases where royalty free licenses allow generic companies to launch their products without constraints on quantities, composition, pricing or other marketing conditions of the generic products.[16]

The EU General Court[17] has also endorsed the view that a licensing agreement which is concluded ancillary to a settlement agreement may serve as a legitimate means for settling disputes and does not constitute a strong indication of a reverse payment[18]. Whilst it is true that there is a transfer of value from the originator company or patent holder to the generic company in the form of an authorization to use a particular patent in order for the generic company to enter the market without risk, the burden lies on the competition authority to demonstrate that the royalty paid by the generic company to the originator company is bizarrely low and that the transaction was not concluded at arm's length, or in other words, under the normal competitive conditions, and that it actually glosses over a reverse payment inducing the generic company to accept the non-marketing and non-challenge clauses in the settlement agreement.

Similarly, an agreement which includes no other limiting conditions other than determining the date of the generic entry with the originator's undertaking not to challenge such entry at that point in time is also unlikely to attract the highest degree of scrutiny from the European Commission.[19]

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[15] European Commission, "The 8th Report on the Monitoring of Patent Settlements (period: January-December 2016)", 9 March 2018, available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html, paras 15 – 17.
[16] *Ibid* at para 9.
[17] Judgement of 12.12.2018, Servier and others v Commission, T-691/14, EU:T:2018:922. Note: The judgment of the EU General Court is currently under appeal brought by the European Commission (Case C-176/19 P) and Servier SAS and others (Case C-201/19 P), respectively in February 2019.
[18] As a general rule, a valid patent is intended to reward the patentee by allowing him to generate a fair share of profits from his investment. However, there may be instances in the context of a patent dispute settlement where a value transfer flows from the patentee to a generic company which is seen as a form of inducive benefit to impel the generic company into agreeing to not market its generic products and challenge the validity of the patent in dispute. Such form of payment is known as a "reverse payment".
[19] Supra note 15 at para 12.

In construing whether an agreement will be seen as limiting generic entries and stifling competition in the market, the list of potential limitations and possible value transfers are not meant to be exhaustive as every case should be examined on its own facts and merits.

***Paroxetine* – Judgment by the ECJ**

The recent judgment of the European Court of Justice ("**ECJ**") in *Paroxetine*[20] provides a compelling insight into several fundamental issues plaguing "Pay-for-Delay" Agreements.

In February 2016, the UK CMA imposed a fine of approximately £45 million on GlaxoSmithKline ("**GSK**") and several other generic manufacturers for patent settlement agreements between the parties for an anti-depressant medication, *paroxetine*. Under the settlement agreements, the generic manufacturers agreed to refrain from marketing their generic version of *paroxetine* for a specified period of time in exchange for payment of money and supply of a considerable but limited quantity of originator *paroxetine* from GSK. The agreements were found anti-competitive and abusive of GSK's dominant position in the market. Thereafter, GSK and the generic companies filed an appeal to the UK Competition Appeal Tribunal ("**CAT**") against CMA's decision. The CAT sought preliminary ruling from the ECJ on the application of the EU competition law rules in the context of a "Pay-for-Delay" Agreement.

Some of the issues which were deliberated by the ECJ are set out below in brief:

(a) Whether the generic manufacturers are potential competitors?

In answering this question, the ECJ held that it must be determined whether there are "real and concrete possibilities" of the generic manufacturers joining the market and competing with the other undertakings which are already present in that particular market.

The questions that should be asked are firstly, whether at the time when the agreement in dispute was concluded, the generic manufacturers had taken sufficient preparatory steps to enable them to enter the market within such a period of time as would impose competitive pressure on the manufacturer of the originator medicines. Secondly, the court must determine that the market entry of the generic manufacturers does not meet entry barriers that are insurmountable. In this regard, the ECJ highlighted that patent rights cannot be regarded as an insurmountable barrier as its validity may be challenged in court proceedings.

(b) Whether the settlement agreements constitute restrictions of competition "by object"?

For agreements characterized as restrictions by object, there is no need to investigate their effects nor to demonstrate their effects on competition in order to classify them as "restrictions of competition", in so far as experience shows that such behaviour leads to falls in production and price increases, resulting in poor allocation of resources to the detriment of consumers.

The ECJ further cautioned that the concept of restriction of competition by object must be interpreted strictly and may only be applied in cases where the content and objectives of the agreements, taking into

[20] Judgement of 30.1.2020, Generics (UK) and others, C-307/18, EU:C:2020:52.

account the economic and legal context in which they are formed, reveal a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects.

Notwithstanding that an agreement may involve value transfer (pecuniary or non-pecuniary), the ECJ observed that this is not sufficient to classify the agreement as a restriction by object in view that such transfer of value may prove to be justified in that it is appropriate and strictly necessary having regard to the legitimate objectives of parties to the agreement.

However, if the value transfer reveals only the commercial interest of parties not to engage in competition on the merits, the agreement must be characterised as a restriction of competition by object. Having said so, if an agreement is capable of demonstrating sufficient traits of pro-competitiveness, this may cast a reasonable doubt on whether it causes a sufficient degree of harm to competition.

(c) Whether the settlement agreements constitute restrictions of competition "by effect"?

In the event that an analysis of the settlement agreement does not reveal a sufficient degree of harm to competition as to amount to a restriction of competition by object, it is then necessary to examine the effects of the settlement and to identify the factors which establish that competition was in fact prevented or restricted to an appreciable extent. In achieving this, it is necessary to take into consideration the actual context in which the conduct in question occurs, in particular the economic and legal context in which the parties concerned operate, the nature of the goods or services affected, as well as the real conditions of the functioning and the structure of the market in question.

It is to be noted that the restrictive effects on competition may be both real and potential but they must be sufficiently appreciable. The ECJ further held that in determining whether a settlement agreement is to be characterized as a restriction by effect, it is not necessary for the CAT to find either the generic manufacturer would have been successful in the patent proceedings, or that parties to the settlement agreement would probably have concluded a less restrictive settlement agreement.

(d) Definition of "relevant market"

Before delving into whether there is an abuse of dominant position, the relevant market in which the competition takes place must first be defined to determine whether GSK holds a dominant position.

The ECJ was asked whether the generic version of medicines should be taken into consideration for purposes of defining the relevant product market, although they would not be able to legally enter the market before the expiry of the process patent in question, validity of which is uncertain. In response to this, the ECJ indicated an affirmative view contingent on the ability of the generic manufacturers concerned to present themselves within a short period of time on that particular market with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicines.

Further, the ECJ also remarked that in defining a relevant product market, the test is whether there is a

sufficient degree of interchangeability between the originator medicines and the generic medicines in dispute. In view that the case concerns pharmaceutical products, the ECJ has extended due recognition to the views of healthcare practitioners when it says "*a supply of generic medicines containing the same active ingredient … could lead to a situation where the originator medicine is considered, in the professional circles concerned, to be interchangeable only with those generic medicines and, consequently, to belong to a specific market …*"[21].

(e) Abuse of dominant position

The ECJ was further asked to provide guidance on whether entering into a settlement agreement would constitute an abuse of dominant position, on the assumption that GSK holds a dominant position in the relevant market.

The ECJ held that the overall strategy of a patent holder which leads to a patent dispute settlement agreement which has at least the effect of keeping potential competitors outside the market temporarily constitutes an abuse of a dominant position, provided that the strategy has the capacity to sidestep competition and to have exclusionary effects going beyond the specific anti-competitive effects of the individual agreements. It is however open to the dominant undertaking to demonstrate that such exclusionary effects are outweighed by advantages in terms of efficiency that benefits consumers.

The ECJ further held that notwithstanding an agreement is not penalised under the anti-competitive agreement provision, it does not necessarily mean that the agreement does not itself carry any anti-competitive effects.

Although it is not a requirement to establish that the dominant undertaking retains an anti-competitive intent, evidence of such intent may nevertheless be taken into consideration in assessing whether a dominant position has been abused.

The case has been remanded to the CAT for the final judgment.

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[21] Ibid at para 131.

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The Way Forward

The ECJ's preliminary ruling in *Paroxetine* has provided, in principle, a clearer understanding of the construction of "Pay-for-Delay" Agreements.

Whilst a patent holder is free to exercise its exclusive rights which include reaching an amicable settlement with parties allegedly infringing its rights conferred by a patent grant, it should be mindful of entering into a "Pay-for-Delay" Agreement as such agreements attract the scrutiny of competition authorities and risks severe penalties if found to be in breach of competition laws, particularly where the deal effectively blocks entry of competitive drugs into the relevant market and involves value transfers.

Nevertheless, the question of whether a settlement agreement may be regarded as compatible with competition laws and policies should be examined on a case-by-case basis in light of the social, economic and legal context. It is also important to ensure that the regulation of such agreements is not too oppressive that it intrudes upon the legitimate interests of the parties in reaching a mutually agreeable compromise.

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