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THE PATENT LINKAGE SCHEME FOR PHARMACEUTICALS IN SINGAPORE: ASSESSMENT AND SUGGESTIONS FOR REFORM

Since 2004, Singapore adopted the patent linkage scheme from the US to meet its obligations under the US–Singapore Free Trade Agreement. The patent linkage scheme requires a generic drug manufacturer that wishes to obtain a licence from the Health Science Authority to notify the patent holder of its application. If the generic licence applicant files a Category B application, claiming invalidity or non-infringement of the patent, the patent holder may, within 45 days of being notified, initiate an infringement proceeding that will trigger a 30-month moratorium against marketing approval of the applicant's drug. While the patent linkage scheme has generally been well received in the US, the form of the patent linkage scheme in Singapore is significantly different – Singapore has modified its version of the scheme to be more pro-patentee. Most notably, it has left out the *exclusivity bounty* to incentivise generic manufacturers to file Category B applications. While it is important for new medicines to be innovated, this article submits that a better balance ought to be achieved, especially since Singapore has a robust generic pharmaceuticals industry. Moreover, the patent linkage scheme in the US has its limitations, including reverse payment settlement agreements and the provision of *exclusivity* for unmeritorious first generic applications. This article shall explore these issues and suggest how the patent linkage scheme may be reformed.

Edwin **NEO** Xuan Hao
JD (Singapore Management University), MSc, BEngSc (Nanyang Technological University);
Advocate and Solicitor (Singapore);
Legal Associate, WFW & WTL.

LEE Kwang Chian
JD (Singapore Management University), BBA (Nanyang Technological University);
Advocate and Solicitor (Singapore), Solicitor (England and Wales);
Legal Associate, Michael Hwang Chambers LLC.

I. Introduction

1 In 2004, Singapore introduced the patent linkage scheme to meet its obligations under the US–Singapore Free Trade Agreement ("USSFTA"). Under the patent linkage scheme, a relationship is created between the market approval of a generic drug and the patent status of its branded equivalent, *ie*, there is a nexus that "links" the granting of the right to market the generic drug and the patent status of the innovator drug. This dictates that marketing approval for a generic product cannot be granted until:[1]

(a) approval has been granted by the patent holder; or

(b) the patent is invalid or the generic product will not infringe upon the patent.

2 Beyond the protection which the usual intellectual property ("IP") system provides, *ie*, providing the IP holder with reliefs in the form of, *inter alia*, injunction, damages or account of profit for successful IP infringement proceedings in the court,[2] the patent linkage scheme provides an administrative pre-emption against prospective infringement. Specifically, if the drug registration authorities deem that the generic drug may infringe upon the branded equivalent, the generic manufacturer will not be allowed to market the generic equivalent. Accordingly, potential infringers will be stopped before the product in question is even permitted to enter the market, and pharmaceutical innovators will thereby be bulwarked from infringement.

3 This article accepts that it is necessary for new drugs to be innovated to combat new diseases or to deal with existing ones more effectively. However, as will be apparent, the generic industry in Singapore has hitherto been robust, and it is apposite that both the branded and generic drugs industries are able to flourish under Singapore's patent rules. Moreover, while the patent linkage scheme has generally been well received in the US (from which it originated), it presents a whole host of issues.[3]

4 Therefore, this article will argue that Singapore should modify its existing patent linkage scheme rules and introduce pro-generic measures to balance the pro-patentee measures, and will provide recommendations

1 Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23.

2 Patents Act 1994 (2020 Rev Ed) s 67.

3 See for example, Kyung-Bok Son *et al*, "Moderating the Impact of Patent Linkage Scheme on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada, and the United States" (2018) 14 *Globalization and Health* 101.

to achieve such a balance. Further, recommendations will also be made to circumvent the limitations of the patent linkage scheme in the US.

II. Genesis of the patent linkage scheme

5 The patent linkage scheme began in the US, through the Drug Price Competition & Term Restoration Act passed in 1984, also known as the Hatch-Waxman Act.[4] Prior to the Hatch-Waxman Act, the composition of drugs was protected as a trade secret: generic competitors were unable to access the data submitted to the Food and Drug Administration ("FDA") by originators. Although generic manufacturers were still permitted to perform clinical trials to arrive at the same data, they were generally deterred from doing so due to the complexity of such clinical trials and the risk of not fully recovering the costs incurred in research and development[5] ("R&D").

6 With the patent linkage scheme in place, the patent holder, when applying for marketing approval of a newly developed drug by way of a New Drug Application ("NDA") to the FDA, must submit the patent information with the NDA.[6] After the new drug has been approved by the FDA, it would be added to the list of Approved Drug Products with Therapeutic Equivalence (otherwise known as the "Orange Book"). The patent information submitted by the originator would then be published.[7]

7 Similarly, a generic competitor may apply for an Abbreviated New Drug Application ("ANDA") by submitting information showing its drug is bioequivalent to one listed in the Orange Book.[8] In doing so, the generic manufacturer may then use the clinical and safety data submitted by the originator for regulatory approval. However, the FDA will not grant marketing approval to the generic competitor unless it shows, to the best of its knowledge:[9]

> (I) that such patent information for the listed drug has not been filed,
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or

4 Drug Price Competition and Patent Term Restoration Act of 1984, Pub L No 98-417, § 1538, 98 Stat 1585 (1984) ("Hatch-Waxman Act").

5 *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options* (Bryan Mercurio & Daria Kim eds) (Routledge, 1st Ed, 2017) at p 102.

6 Federal Food, Drug and Cosmetic Act 21 USC (US) § 314.53(d).

7 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(b)(1).

8 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(2)(A)(iv).

9 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(2)(A)(vii).

> (IV) that such patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.

Notably, if an ANDA applicant wishes to use the exception listed under paragraph IV above, it will need to notify the patent holder of its application[10] and describe the reasons for invalidity or non-infringement, as the case may be.[11] The patent holder, upon receiving such notification, has up to 45 days to file an infringement lawsuit. Doing so would trigger a 30-month moratorium – during which the FDA will not grant marketing approval to the generic drug.[12] The duration of the moratorium may be varied by the court if either party does not reasonably co-operate in expediting the process.[13]

8 Additionally, the patent linkage scheme was not introduced in isolation, but with a marketing exclusivity bounty of 180 days for the first substantially complete paragraph IV challenge – during which other generics may not be approved for marketing.[14] Such a scheme incentivises generics to challenge the existing listed patents. In fact, these measures were introduced together as part of a "grand bargain", in the hopes that, quoting US Senator Orrin Hatch, "the public receives the best of both worlds – cheaper drugs today and better drugs tomorrow".[15]

III. Success and limitations of the US patent linkage scheme

A. Successes of the US patent linkage scheme

9 In the US, it is hard to deny that Senator Hatch's vision has generally been achieved. Firstly, the generics industry has flourished under the patent linkage scheme. In 1984, prior to the passage of the Hatch-Waxman Act, there were 150 off-patent branded drugs with no generic competition. Moreover, among the top selling drugs, merely 35% (with expired patents) encountered generic competition. Today, most, if not all, off-patent drugs face generic competition,[16] arising from the

10 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(2)(B)(i).
11 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(2)(B)(iv)(II).
12 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(c)(3)(C).
13 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(c)(3)(C).
14 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(b)(5)(B)(iv)(I), read with § 355(b)(5)(B)(iv)(II)(bb) and § 355(b)(5)(B)(iv)(II)(cc).
15 *Congressional Record* vol 130, part 17 (98th Congress, 2nd Session, 7 September 1984) at p 23764.
16 Linda P Nussbaum & John D Radice, "Where Do We Go Now? The Hatch-Waxman Act Twenty-Five Years Later: Successes, Failures, and Prescriptions for the Future" (2009) 41 *Rutgers Law Journal* 229 at 243.

streamlined ANDA approval process which is quicker and cheaper than the approval required in an NDA.[17]

10 Additionally, a study conducted by the FDA to investigate the effect of generic competition on drug prices yielded startling results. After the entry of the first generic drugs into the market, the prices of branded drugs generally decreased by an average of 6%.[18] However, the introduction of the second to sixth generic drugs decreased the prices of branded drugs by 48% and 74% respectively.[19] This is a clear indication that competition posed by effective generic drugs prevented price inelasticity of the branded drugs.

11 Moreover, with the ease of approval for generic products, the price difference (known as the "price index") between a generic drug two years after its launch has drastically increased. Based on data obtained from 1984 to 1991, it was reported that the average price of generic drugs fell from 100% to 80% one year after initial launch, and then to 65% two years after the initial launch.[20] By contrast, based on data collected from 2005 to 2009, the one year price index was 68% and the two year price index was 28%.[21]

12 With the increasingly depressed prices of generic drugs, prescriptions for generics have correspondingly increased. The percentage of prescriptions of generics in the US burgeoned from 18.6%

17 Colleen Kelly, "The Balance Between Innovation and Competition: The Hatch-Waxman Act, The 2003 Amendments, and Beyond" (2011) 66 *Food & Drug Law Journal* 417 at 426.

18 "Generic Competition and Drug Prices" *US Food and Drug Administration* (4 April 2006) <https://wayback.archive-it.org/7993/20180126012339/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (accessed 30 May 2022).

19 "Generic Competition and Drug Prices" *US Food and Drug Administration* (4 April 2006) <https://wayback.archive-it.org/7993/20180126012339/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (accessed 30 May 2022).

20 Ernst R Berndt & Murray Aitken, "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the Waxman-Hatch Legislation" (NBER Working Paper No 16431, 2010) at p 9, referring to Henry G Grabowski & John M Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act" (1992) 35 *Journal of Law and Economics* 331.

21 Ernst R Berndt & Murray Aitken, "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the Waxman-Hatch Legislation" (NBER Working Paper No 16431, 2010) at p 9.

in 1984 to 74.5% in 2009, with accelerated growth in the latter years.[22] This shows a far more widespread acceptance of generic replacements, in part fuelled by the increase in competition posed by generic drugs and lowered prices.

13 Secondly, in contrast to doomsayers who predicted that allowing generic competition would erase the drive to pursue R&D for branded drugs, there has in fact been a corresponding growth in R&D for the branded drug industry. Consequently, the number of drug approvals 25 years after the Hatch-Waxman Act is 68% higher than the number of drug approvals 25 years before the Hatch-Waxman Act.[23] Moreover, while R&D expenditure among pharmaceutical manufacturers in the US totalled $1.3bn before the passage of the Hatch-Waxman Act, it skyrocketed to $32bn by 2003.[24]

14 Indeed, the timely availability of generic drugs should be seen as a reinforcing factor to push branded drug companies to constantly innovate, since the latter will have to rely on the sale of new products when cheaper alternatives to existing products become available to the market.[25] A study has found that the loss of exclusivity on a current product is "the most important predictor" of the arrival (and number) of new product introductions.[26]

B. Criticisms of the US patent linkage scheme

15 Of course, the success of the patent linkage scheme in the US is not without criticism. One of the issues that arose out of the US patent linkage scheme is the reverse payment patent settlement, also known as the "pay-for-delay" settlement, in which a patent holder pays the generic

22 Ernst R Berndt & Murray Aitken, "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the Waxman-Hatch Legislation" (NBER Working Paper No 16431, 2010) at p 4.

23 Jonathan J Darrow & Aaron S Kesselheim, "Trends in Drug Development and Approval, 1938–2013" (2014) 370 N Engl J Med 39. It can be determined from the data that the number of new molecular entities ("NMEs") approved during the 25 years after Hatch-Waxman Act was passed (711 NMEs were approved from 1985 to 2009) was a 68% increase from the 25 years before the Hatch-Waxman Act was passed (424 NMEs were approved from 1960 to 1984).

24 Elizabeth Scotland Weiswasser & Scott D Danzis, "The Hatch-Waxman Act: History, Structure, and Legacy" (2003) 71 *Antitrust Law Journal* 585 at 607.

25 See generally Kenneth J Arrow, "Economic Welfare and the Allocation of Resources for Invention" in *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton University Press, 1962) at p 619 (arguing that "the incentive to invent is less under monopolistic than competitive conditions").

26 Stuart J Graham & Matthew J Higgins, "The Impact of Patenting on New Product Introductions in the Pharmaceutical Industry" (2007) *MPRA Paper* 4574 at p 2.

challenger to delay market entry of its generic product. As such, the patent holder is allowed to maintain a monopoly over the price of the branded drug.[27]

16 Another criticism that arose is that unmeritorious ANDAs, with paragraph IV certification, may be filed by the first generic drug applicants to obtain the 180 day exclusivity.[28] This is due to a lack of requirement(s) for the ANDA applicant to successfully defend its case (in a lawsuit or otherwise) before it is awarded the 180 day exclusivity bounty.[29]

17 However, when compared with the benefits, it is clear that the patent linkage scheme has generally been successful in achieving its goals of providing "cheaper drugs today, and better drugs tomorrow." [30]

18 Having discussed the success and limitations of the patent linkage scheme in the US, where it originated, this article shall now turn to Singapore. Firstly, section IV will illustrate how Singapore's present pharmaceutical landscape has allowed generics to thrive. Section V will then discuss the suitability of adopting the patent linkage scheme, in its present form, in said pharmaceutical landscape, the current case law regarding patent linkage and shall provide recommendations for modifications to the present patent linkage scheme based on lessons drawn from other jurisdictions. Finally, section VI will explore the aforementioned limitations of the patent linkage scheme in the US and recommend measures Singapore can take to avoid such limitations.

IV. Singapore's present pharmaceutical landscape

A. The current patent linkage scheme in Singapore

19 The patent linkage scheme was introduced into Singapore pursuant to Article 16.8(4) of the USSFTA,[31] which stipulates that:[32]

27 Margherita Colangelo, "Reverse Payment Patent Settlements in the Pharmaceutical Sector under EU and US Competition Laws: A Comparative Analysis" (2017) 40(3) *World Competition* 471 at 1.

28 Wendy H Schacht & John R Thomas, *The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents* (CRS Issue Brief for Congress, 8 May 2003) at CRS-5–6.

29 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(5)(B)(iv).

30 *Congressional Record* vol 130, part 17 (98th Congress, 2nd Session, 7 September 1984) at p 23764.

31 US–Singapore Free Trade Agreement (6 May 2003); Singapore Parl Debates; Vol 78; Col 151; [15 June 2004].

32 US–Singapore Free Trade Agreement (6 May 2003) Art 16.8.4(b)–(c).

> With respect to any pharmaceutical product that is subject to a patent:
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> …
>
> (b) the Party shall provide that the patent owner shall be notified of the identity of any third-party requesting marketing approval effective during the term of the patent; and
>
> has the Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner.

20 Pursuant to the USSFTA, s 12A was introduced into the Singapore Medicines Act[33] ("MA"). Section 12A of the MA requires that a generic manufacturer who wishes to apply for marketing approval will first have to make a declaration to the Health Sciences Authority ("HSA") with the form in Part I of the Sixth Schedule of the Medicines (Licensing, Standard Provisions and Fees) Regulations[34] ("MR").

21 It may apply under one of the four categories,[35] most (except for Category A2) of which bear a close resemblance to the ANDA certifications in the US. Notably, applicants under Category B (equivalent of the US paragraph IV certification) may challenge the patent's validity or claim that the patent is not infringed by providing notice – using the form in Part II of the Sixth Schedule – to the patent holder.[36]

22 Pursuant to s 12A of the MA read with reg 5B of the MR, if the patent holder does not, within 45 days of being served the notice,[37] initiate infringement proceedings against the generic manufacturer and notify the HSA, the HSA may grant the licence to the generic manufacturer if it is satisfied that a notice has been served on the patent holder.[38] Otherwise, an automatic 30-month-long moratorium against marketing approval[39] will be triggered.[40] It is also noteworthy that it is an offence for the applicant to provide a statement in a declaration, or evidence of

33 Medicines Act 1975 (2020 Rev Ed) s 12A.

34 Medicines Act 1975 (2020 Rev Ed) s 12A(2) read with Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(1) and Sixth Schedule, Part I.

35 Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) Sixth Schedule, Part I.

36 Medicines Act 1975 (2020 Rev Ed) s 12A(3) read with Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(2).

37 Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(3).

38 Medicines Act 1975 (2020 Rev Ed) s 12A(5).

39 Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(4).

40 Medicines Act 1975 (2020 Rev Ed) s 12A(6)(*b*).

notice, that he knows or reasonably ought to know to be materially false, and if convicted he can be punished with a fine of up to $5,000 and/or imprisonment of up to two years.[41]

23 In 2016, reg 5B and the Sixth Schedule were both repealed from the MR. The former (indicating the 45 days for the patent owner to initiate infringement proceedings and the automatic 30-months moratorium) now subsists in reg 23 of the Health Products (Therapeutic Products) Regulations 2016[42] ("HPTPR"). The latter (indicating the forms that the proprietor needs to fill in order to apply for marketing approval under the HSA) now subsists on the HSA website.[43] Although s 12A of the MA remains in force, it has been effectively replaced by provisions in reg 23 of the HPTPR.[44]

24 Moreover, if the generic applicant makes a declaration to the HSA with information that he knows or reasonably ought to know to be false, or incomplete and misleading information, he may be fined up to $20,000 and/or jailed for up to a year.[45]

B. The current state of the pharmaceutical industry in Singapore

25 Even against the current patent linkage scheme backdrop, it is undisputable that Singapore has a thriving generics industry.

26 Indeed, Singapore clearly shows that "establishing high-quality manufacturing processes is not prohibitively costly",[46] as proven by the profitability of its generic companies. Indeed, Singapore has established itself as "a highly attractive manufacturing base" for pharmaceutical

41 Medicines Act 1975 (2020 Rev Ed) s 20(3).
42 Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23(8)–23(9).
43 See HSA website: <https://www.hsa.gov.sg/docs/default-source/hprg-tpb/guidances/appendix-1_patent-declaration-forms.pdf> (accessed 18 May 2022)
44 Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23(1)–23(7).
45 Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 25.
46 *Pharmaceuticals in Singapore* (Datamonitor, March 2019) at p 21.

giants[47] and numerous top medical companies have chosen Singapore as the location of their global manufacturing headquarters.[48]

27 Notably, the total revenue of the local generics market is significant, with a compound annual growth rate ("CAGR") of 8.2% from 2013 to 2017, amounting to $341.1m in 2017.[49] This value has been forecast to increase at a CAGR of 6.3% to reach $463.1m by 2022.[50] Moreover, the market consumption volume of local generics had a corresponding increase of 0.6% CAGR from 2013 to 2017, amounting to 88.2% of all drugs consumed in 2017.[51] This value was similarly forecast to increase at a CAGR of 0.9% to reach 92.1% by 2022.[52]

28 Indeed, the present state of Singapore's pharmaceutical landscape is highly beneficial to the government. This is because medicine in Singapore is funded (and subsidised) by government intervention, through subsidies and the government-backed insurance, MediShield.[53] Similar to the US, the increase in generic competitors will push down the rising drug costs in Singapore.[54] If "governments of developed markets … with publicly funded health care plans … support the wider use of generic alternatives", it can help "curb drug spending" by the government, which is especially important in Singapore given the subsidised cost of public healthcare.[55]

47 Danielle Isaac, "Value of Singapore's Pharma Market hit $1.22b in 2017: BMI Research" *Singapore Business Review* (15 April 2018) <https://sbr.com.sg/healthcare/news/value-singapores-pharma-market-hit-122b-in-2017-bmi-research#:~:text=4%20years%20ago-,Value%20of%20Singapore's%20pharma%20market%20hit%20%241.22b%20in%202017,previous%20year%2C%20BMI%20Research%20revealed.> (accessed 18 May 2022).

48 Danielle Isaac, "Value of Singapore's Pharma Market hit $1.22b in 2017: BMI Research" *Singapore Business Review* (15 April 2018) <https://sbr.com.sg/healthcare/news/value-singapores-pharma-market-hit-122b-in-2017-bmi-research#:~:text=4%20years%20ago-,Value%20of%20Singapore's%20pharma%20market%20hit%20%241.22b%20in%202017,previous%20year%2C%20BMI%20Research%20revealed.> (accessed 18 May 2022); "Why Singapore Attracts the World's Pharma & Medtech" *DPS Education* <http://dpseng.com.sg/attracting-medtech/> (accessed 30 May 2022).

49 *Generics in Singapore* (MarketLine, August 2018) at p 9, Table 1.

50 *Generics in Singapore* (MarketLine, August 2018) at p 12, Table 4.

51 *Generics in Singapore* (MarketLine, August 2018) at p 10, Table 2.

52 *Generics in Singapore* (MarketLine, August 2018) at p 13, Table 5.

53 *Pharmaceuticals in Singapore* (Datamonitor, March 2019) at pp 12–13.

54 *Pharmaceuticals in Singapore* (Datamonitor, March 2019) at p 13.

55 *Generics in Singapore* (MarketLine, August 2018) at p 17.

V. Issues with the current patent linkage scheme in Singapore

29 However, there are clear problems with the current patent linkage scheme in Singapore, especially in light of the state of the domestic pharmaceutical industry, which shall be discussed below.

A. Lack of incentives for generic challengers

30 In the parliamentary debates leading up to the adoption of the patent linkage scheme, it was argued by Member of Parliament, Dr Lily Neo, that enhancing protection for patented drugs is an attractive option for Singapore, even if not for the obligations under the USSFTA. Since extensive time, cost and effort are required for R&D, bulwarking the efforts of inventors would encourage inventors to keep innovating so that better medicines will be invented to combat new diseases. As such, it would advance Singapore's aim of being a medical and R&D hub.[56]

31 Admittedly, "the amount of new medicines produced has not increased significantly along with" the astronomical increase in R&D expenditure, and innovators have been failing "to engender new drugs to replenish the patented products pipeline".[57] Therefore, the need to strengthen protection for innovative drugs and to create an environment where medical R&D can flourish is a valid concern.

32 However, such an environment should not be inimical to the growth of the generics industry. As discussed in section IV above, Singapore's pharmaceutical landscape is presently dominated with generic manufacturers, and it is submitted that growth of the branded drug industry does not necessitate the stymieing of the generics industry. It is proposed that Singapore must find a way to balance both branded and generic producers, just as the US has sought to do.

33 While it is true that the statistics in section IV illustrate that generic manufacturers have survived against the current disadvantages they are faced with, it can hardly be denied that generic manufacturers are prejudiced by Singapore's patent linkage scheme in its present form. Instead, by adopting a balanced approach, Singapore could simultaneously produce better medicines while further leveraging on its strengths in generics to yield enormous savings for its government.

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56 Singapore Parl Debates; Vol 78; Col 155; [15 June 2004].

57 "Pharmaceuticals & Biotechnology" *Fide Consultant Group* <https://www.fideconsultantgroup.com/singapore-pharmaceuticals-industry> (accessed 30 May 2022).

B. Singaporean case law is pro-patentee

34 Indeed, it is clear from recent case law that Singapore is highly pro-patentee, with little to no protections or safeguards given to generic drug manufacturers. This will be discussed in greater detail below.

(1) Litigation between AstraZeneca AB (SE) and Sanofi-Aventis (Singapore) Pte Ltd[58]

35 The patent linkage scheme was applied in two related judgments between AstraZeneca AB (SE) ("AstraZeneca") and Sanofi-Aventis (Singapore) Pte Ltd ("Sanofi-Aventis"). Sanofi-Aventis, the defendant, applied to the HSA for licensing approval of its drugs. It declared in its application form that the patent (Patent No 89993) belonging to AstraZeneca, the plaintiff, would not be infringed. The invention comprised of an active ingredient (Rosuvastatin Calcium) and a stabilising agent (an inorganic salt with multivalent cation).[59]

36 Sanofi-Aventis then, upon the HSA's request, served a notice on AstraZeneca in the form set out in Part II of the Sixth Schedule,[60] indicating its belief that there was no infringement in seeking the licence, because its drug did not contain an inorganic salt with multivalent cation set out in the patent.[61] The notice, also pursuant to Sixth Schedule requirements, further indicated that the licence may be granted to Sanofi-Aventis if AstraZeneca did not initiate infringement proceedings within 45 days.[62] AstraZeneca then filed its Statement of Claim which automatically triggered a 30-month moratorium.[63] No particulars as to why Sanofi-Aventis's drug was infringing were provided.[64] Sanofi-Aventis's request for further and better particulars ("F&BPs"), which AstraZeneca argued was "wholly misconceived", was rejected.[65]

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58 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 and *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 are collectively referred to as "*AstraZeneca*".

59 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [2]; *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [2].

60 Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) Sixth Schedule.

61 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [5]; *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [5].

62 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [5].

63 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [6]; *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [6].

64 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [6].

65 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [7].

37 In *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 ("*AstraZeneca* 1"), Sanofi-Aventis applied to court under O 18 r 19 of the Rules of Court[66] ("Rules of Court 2014") to strike out AstraZeneca's pleadings for, *inter alia*, having no reasonable cause of action.[67] Proceeding on the basis that AstraZeneca was initiating an infringement proceeding pursuant to ss 66 and 67 of the Patents Act, Sanofi-Aventis argued that AstraZeneca needed to establish at least one instance of past infringement, but since there has not been any past infringement, an action pursuant to the Patents Act would fail.[68] Sanofi-Aventis further argued that s 12A of the MA did not provide for a cause of action that was separate and independent from that pursuant to the Patents Act, but merely provided for a notification mechanism requirement.[69]

38 This argument was rejected by the High Court, which held that s 12A of the MA did not merely provide for the requirement of notification of the licensing application. When the MA was read with reg 5B and the Sixth Schedule of the HPTPR, it provided for a separate and independent cause of action from that under the Patents Act – the latter required the plaintiff to establish a *past* infringement while the former merely required the plaintiff to establish a *prospective* infringement.[70] Since it was only in plain and obvious cases that pleadings may be struck out,[71] it was held that the plaintiff's case could not be struck out because the contemplation of a separate and independent cause of action for establishing prospective infringement meant that the plaintiff's case was at least arguable.[72]

39 AstraZeneca then applied for discovery for Sanofi-Aventis's product descriptions to understand how its patent might be infringed. The application was allowed, and Sanofi-Aventis disclosed its drug's chemical composition, along with the amount and weight of active ingredients and excipients.[73] Sanofi-Aventis's solicitors requested for F&BPs from AstraZeneca again, but the latter's solicitors refused.[74] In *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7

66 Rules of Court (Cap 322, R 5, 2014 Rev Ed).
67 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [7] and [14].
68 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [8].
69 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [10].
70 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at[30]–[35].
71 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [15]–[16].
72 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [35].
73 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [9].
74 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [10].

("*AstraZeneca* 2"), Sanofi-Aventis applied to the High Court for F&BPs.[75] The High Court then granted the application in part.[76]

40 To the authors' knowledge, no judgment on the eventual outcome of the suit in *AstraZeneca* has been reported and no additional details could be retrieved online.[77] However, it can be observed from a search in the HSA Registrar of Therapeutic Products that two products by Sanofi-Aventis were granted licensing approval on 2 December 2013, which was only several months after the decision in *AstraZeneca* 2.[78] It is therefore safe to assume that the suit was discontinued and possibly settled after Sanofi-Aventis received its F&BPs. It is apparent even from the two judgments that AstraZeneca was highly incentivised to trigger the moratorium and disincentivised from expediting the infringement proceedings. AstraZeneca's behaviour can be traced to four observations of Singapore's patent linkage scheme that shall be discussed in turn.

(a) Reversal of burden of proof to generic manufacturer

41 The most notable observation of the patent linkage scheme that can be made in *AstraZeneca* is the reversal of the burden of proof throughout the duration of the moratorium. AstraZeneca did not state in its amended Statement of Claim ("SOC") any particulars of how Sanofi-Aventis's drug infringed its patent claims,[79] but merely repeated the acts of infringement found in s 66(1)(*a*) of the Patents Act.[80] Despite AstraZeneca's understanding that the Rules of Court governing Patents Act actions similarly govern actions pursuant to the MA[81] (which was eventually accepted by the High Court), it is curious why it saw no need to file any F&BPs[82] despite what was stated in O 87A r 2(2):[83]

> The plaintiff in such an action [of patent infringement] must serve with his statement of claim *particulars of the infringement relied on*, showing *which of the claims* in the specification of the patent are alleged to be infringed and *giving at least one instance of each type of infringement alleged*. [emphasis added]

75 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [10].
76 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [72].
77 The authors' request to inspect the case file was rejected as the case was sealed. The authors then approached the duty registrar in a Registrar's Chamber but could not retrieve any further information.
78 A search for "Rosuvastatin Calcium" was done in the HSA Register of Therapeutic Products: <https://eservice.hsa.gov.sg/prism/common/enquirepublic/SearchDRBProduct.do?action=load> (accessed 30 May 2022).
79 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [6].
80 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [51]. The specific provision referred to was s 66(1)(*a*) of the Patents Act.
81 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [11].
82 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [6].
83 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 87A r 2(2).

42 Two requests for F&BPs were made by Sanofi-Aventis, both of which were rejected by AstraZeneca,[84] before the order for the provision of F&BPs was finally granted by the High Court more than a year after the first request was made.[85]

43 The starting point for discussing such a reversal of burden of proof is the Evidence Act, which provides that if a party wishes to use the court's machinery to uphold its legal right or liability based on asserted facts, the burden of proof lies on him and he must prove those facts exist.[86] Where both sides do not provide any evidence, the action fails and the *status quo* remains.[87]

44 Under the traditional patent infringement actions pursuant to the Patents Act, since the patent holder wishes to use the court's machinery to seek reliefs for patent infringement,[88] the burden of proof is on him. He ought to know that failing to provide particulars would contravene O 87A r 2(2).[89] Incentivised by the need to change the *status quo* (*ie*, no judgment of infringement), he would therefore put forth his best case by fulfilling the requirements in O 87A r 2(2).[90]

45 With the introduction of Singapore's patent linkage scheme, a 30-month moratorium is automatically and administratively activated upon the patent holder initiating an infringement proceeding. Before the end of the 30-month period, the burden of proof lies on the generic manufacturer requesting for F&BPs to show that the patent holder did not fulfil the requirements in O 87A r 2(2)[91]. Similarly, the new Rules of Court, which came into operation on 1 April 2022 ("Rules of Court 2021") do not shift the burden of proof to the patent holder.[92] In such a situation, the court's machinery, instead of being used to prevent infringement, is now used to undo an administratively-triggered moratorium. While such a reversal of burden of proof makes little difference where the patent holder files a meritorious infringement proceeding, the same cannot be said for the patent holder with an unmeritorious one. As the *status quo*

84 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [7]; *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [10].
85 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [72].
86 Evidence Act (Cap 97, 1997 Rev Ed) s 103.
87 Evidence Act (Cap 97, 1997 Rev Ed) s 104.
88 Patents Act 1994 (2020 Rev Ed) s 67(1). Possible remedies include an injunction on the defendant against further infringement, order to destroy infringing products, damages, account of profits, and declaration of infringement.
89 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 87A r 2(2).
90 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 87A r 2(2).
91 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 87A r 2(2).
92 See Rules of Court 2021 (2020 Rev Ed) O 69 rr 2(2)–2(3), which maintains the wording in O 87A r 2(2)–2(3) of the Rules of Court (Cap 322, R 5, 2014 Rev Ed).

of a moratorium is in its favour, a patent holder that knows its claim is unmeritorious would likely only seek to delay judgment to buy time and ensure its continued monopoly.

46 Such a reversal of burden of proof essentially transforms the patent's challengeable presumption of validity into a secure property right.[93] Moreover, this property right is now a public right enforced by government authorities and financed by taxpayers.[94] Such a transformation flies in the face of the cornerstone of patent rights, in which generic manufacturers may take calculated risks by entering the market believing that their patents are invalid or are not infringed.[95] Further, the holding in *AstraZeneca* augments the burden of proof on the generic applicant one step further by requiring it to prove the lack of *prospective* infringement, and not merely the lack of *past* infringement.

47 Short of removing the patent linkage scheme altogether, there does not appear to be a solution that eliminates this draconian measure against generic applicants. However, several pro-generic countermeasures in the sections that follow can help to mitigate it.

(b) Lack of penalty or compensation system for patent holder

48 The second observation is that there is no penalty or compensation system that requires the patent holder to pay for losses suffered by the generic applicant when a moratorium is triggered by an unmeritorious infringement proceeding. This feature of the patent linkage scheme is highly unfair when juxtaposed with the reliefs in an infringement action under the Patents Act, which may include damages or account of profits.[96] If a generic manufacturer that is found to have infringed a patent under the Patents Act needs to compensate for losses by the patent holder, it is unclear why the patent holder that is responsible for the generic applicant's loss in the patent linkage scheme is not required to provide corresponding compensation.

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93 *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options* (Bryan Mercurio & Daria Kim eds) (Routledge, 1st Ed, 2017) at p 114.

94 Kyung-Bok Son *et al*, "Moderating the Impact of Patent Linkage Scheme on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada, and the United States" (2018) 14 *Globalization and Health* 101 at p 3.

95 *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options* (Bryan Mercurio & Daria Kim eds) (Routledge, 1st Ed, 2017) at pp 114–115.

96 Patents Act 1994 (2020 Rev Ed) ss 67(1)–67(2).

49 Parliament introduced a penalty system for false declaration by the generic applicant, with Dr Lily Neo even arguing that the penalty of $5000 and/or imprisonment of up to two years[97] was too low.[98] While having a penalty for a false declaration to the HSA is not *per se* objectionable (indeed, it makes perfect sense to curb fraudulent behaviour), it is curious why a parallel measure has not been put in place to guard against unmeritorious infringement proceedings by the patent holder.

50 Relating to the point earlier that there is a reversal of burden of proof, any rational patent holder would realise the lack of risk in triggering a moratorium: if it wins in the infringement proceedings, its monopoly continues; if it loses, its monopoly merely ceases but it does not have to pay for the losses it was responsible for.[99] Therefore, it is submitted that in the absence of either a penalty system that deters abuses of the patent linkage scheme, or a compensation system requiring the patent holder to cover losses suffered by the generic manufacturer, the drug patent holder would most certainly activate the moratorium to prolong the monopoly it enjoys *regardless of how underserving of the monopoly the drug is*. In the Singapore context, it is important for legislators to consider the penalty or compensation provisions in Australia[100] and Canada[101] – in the case of Australia (even the Commonwealth, a State or a Territory in Australia), a patentee would have to pay the generic manufacturer for losses suffered from its pursuit of vexatious litigation.

(c) Lengthy duration and inflexibility of moratorium

51 The third observation is that the duration of the moratorium is both lengthy and inflexible.[102] In the parliamentary debates, the obligations under the patent linkage scheme of the USSFTA were merely raised and there was no substantive discussion as to the precise details of the patent linkage scheme – such as the duration of the moratorium – to be adopted.[103]

97 Medicines Act 1975 (2020 Rev Ed) s 20(5).

98 Singapore Parl Debates; Vol 78; Col 155; [15 June 2004]. This is possibly why the penalty under the Health Products (Therapeutic Products) Regulations 2016 was raised to $20,000.

99 However, it would likely have to pay the costs of the litigation, since costs generally follow the event. See Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 59 r 3(2).

100 Therapeutic Goods Act 1989 (No 21 of 1990) (Aus) ss 26D(4) and 26D(5).

101 Patented Medicines (Notice of Compliance) Regulations (SOR/93-133) (Can) paras 8(1) and 8(2).

102 Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(4).

103 Singapore Parl Debates; Vol 78; Cols 151–152; [15 June 2004].

52 Firstly, the 30-month duration of the moratorium is arguably too long. Although the moratorium in the US also lasts 30 months, that duration should not be set in stone. Other jurisdictions that have adopted the patent linkage scheme through bilateral or multilateral treaties with the US do not necessarily stipulate a moratorium with the same 30-month duration: Korea has a moratorium of nine months,[104] Taiwan has a moratorium of 12 months,[105] while Canada has a moratorium of 24 months.[106]

53 The duration of 30 months in the US is likely related to the median time-to-trial for patent infringements. Studies on patent litigation conducted by PricewaterhouseCoopers determined that from 1997, the median time-to-trial for patent infringement tended to be two to two-and-a-half years.[107] This result coheres with a study conducted by the Free Trade Commission ("FTC") in 2002, which reported that the average duration between a complaint and the district court's decision is 25 months and 13 days, taking into account 53 cases involving first and second generic applicants.[108] While there are no available studies that have determined the median time-to-trial for patent infringement in 1984 (in which the Hatch-Waxman Act was enacted), the median time-to-trial prior to 1997 appeared to trend towards three years or longer,[109] making the 30 months duration proportionally shorter. In contrast, a patent infringement trial in Singapore usually takes 18 to 24 months,[110] and adopting the 30-month moratorium from the US like a cookie-cutter solution would afford a disproportionate protection to local patent holders and too draconian a measure against generic licence applicants.

54 Secondly, the provisions relating to the 30-month duration for Singapore's moratorium do not appear to suggest that these are subject

104 Pharmaceutical Affairs Act (No 14328 of 2016) (Kor) Art 50-6(2).
105 Pharmaceutical Affairs Act (No 117 of 2013) (Taiwan) Art 48-13(2).
106 Patented Medicines (Notice of Compliance) Regulations (SOR/93-133) (Can) para 7(1)(d).
107 Chris Barry *et al*, *Patent Litigation Study 2010* (PricewaterhouseCoopers, 2010) at Chart 7b; Landan Ansell *et al*, *Patent Litigation Study 2018* (PricewaterhouseCoopers, 2018) at Fig 4.
108 US Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration, an FTC Study* (July 2002) at 47 (Chairman: Timothy J Muris).
109 Chris Barry *et al*, *Patent Litigation Study 2010* (PricewaterhouseCoopers, 2010) at Chart 7b.
110 Jason Chen & Liza Lam, "Patent Litigation in Singapore: Overview" *Thompson Reuters Practical Law* <https://uk.practicallaw.thomsonreuters.com/w-014-9923?transitionType=Default&contextData=(sc.Default)&firstPage=true> (accessed 18 May 2022).

to adjustments.[111] In contrast, the 30-month duration in the US patent linkage scheme is adjustable by the court if either party does not reasonably co-operate in expediting the process. Canada has also adopted the same flexibility only where the court finds it necessary.[112] It is submitted that the courts should be allowed to adjust the duration of the moratorium when the patent holder is seen to be profligately dragging the proceedings to take advantage of the lengthy moratorium, for example, by triggering the moratorium with no particulars of infringement provided to the generic applicant as observed in *AstraZeneca*.

(d) Duration for patent holder to initiate infringement proceedings is too short and malleable

55 The final observation is that the duration granted to the patent holder to file an injunction is too short and malleable. Similar to the adoption of the duration for the moratorium, the 45-day duration for initiating infringement proceedings and triggering the moratorium from the Hatch-Waxman Act was lifted into the MA[113] without any substantive debate.[114] This section, however, proposes that the duration for the patent holder to initiate infringement proceedings should be prolonged and fixed.

56 In *AstraZeneca* 1, it was determined that the plaintiff had a cause of action despite not submitting relevant facts to support its claim of prospective infringement. This was because the short time frame of 45 days granted by s 12A required the patent holder to act fast to obtain the 30-month moratorium it sought.[115] With a lack of consequences for commencing unmeritorious infringement proceedings (discussed above), coupled with the short duration to file infringement proceedings, the patent holder is likely to adopt an "act first, think later" attitude even if its case was unmeritorious.

57 Admittedly, the generic applicant should not be unduly held up by protracted delays arising from the patent holder's need to determine

111 Previously, Medicines Act 1975 (2020 Rev Ed) s 12A(6)(*b*) read with Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(4); presently, Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23(9).

112 Patented Medicines (Notice of Compliance) Regulations (SOR/93-133) (Can) para 7(8).

113 Previously, Medicines Act 1975 (2020 Rev Ed) s 12A(5) read with Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(3); presently, Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23(8).

114 Singapore Parl Debates; Vol 78; Cols 151–152; [15 June 2004].

115 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [47].

if there would be prospective infringement – if there would not be any prospective infringement, the HSA should grant the generic applicant the licence for the drug as soon as possible. However, providing for such a short 45-day timeframe with automatic injunction would hardly be of help to the generic applicant. Instead, given the complexity of pharmaceutical products, a longer duration may be considered for the patent holder to determine if it should initiate infringement proceedings. Moreover, to weed out unmeritorious proceedings in which the patent holder does not submit relevant facts supporting its claim, the moratorium should be granted only if a *prima facie* case can be made out.

58 It can also be observed from *AstraZeneca* that the HSA, with the discretionary power it was conferred with, can further augment the pro-patentee measures. The notice was served on AstraZeneca on 19 April 2011.[116] AstraZeneca filed its original SOC on 10 June 2011 (exceeding the 45-day period by 10 days) but it was unclear why the HSA still activated the 30-month moratorium.[117]

59 Section 12A(5) of the MA, read with reg 5B(3) of the MR, provides that if the patent holder does not initiate infringement proceedings and notify the HSA within 45 days, the HSA *may* grant the licence to the generic applicant.[118] Therefore, discretionary power is granted to the HSA. However, it is curious why the Singapore Parliament adopted an approach different from the US, which requires that if the patent holder initiates infringement proceedings within 45 days after notification, "the approval *shall* be made effective"[119] [emphasis added].

60 It is submitted that conferring discretion to the HSA is unnecessary. This is especially so if the proposal of extending the 45-day timeframe is adopted such that the patent holder would have had more than sufficient time to initiate infringement proceedings. Presumptively, discretion is not conferred to the HSA in the converse situation – where the patent holder initiates infringement proceedings and notifies the HSA within 45 days, the HSA shall not grant the licence to the generic applicant. By removing the discretion of the HSA in situations where infringement proceedings were not initiated and the HSA was not notified within 45 days, greater certainty in the patent linkage scheme will be ensured.

116 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [5].
117 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [6].
118 Medicines Act 1975 (2020 Rev Ed) s 12A(5) read with Medicines (Licensing, Standard Provisions and Fees) Regulations (Cap 176, Rg 6, 2000 Rev Ed) reg 5B(3).
119 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(5)(B)(iii).

61 Although this article submits that the duration of the moratorium should be adjustable by the courts, the same flexibility cannot apply to the period within which the patent holder has to initiate infringement proceedings. The duration required before a judgment is made at trial depends on the patent holder, the generic applicant and the court's availability. In contrast, the duration required to initiate infringement proceedings is fully dependent on the patent holder, and if the patent holder fails to expedite the process and approval is granted to the generic applicant, it is merely getting its just desert.

(2) Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd[120]

62 The patent linkage scheme in the later HPTPR has been clarified in numerous decisions involving Millennium Pharmaceuticals, Inc and Drug Houses of Australia Pte Ltd.

63 In the initial High Court case of *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 ("*Millennium Pharmaceuticals (HC)*"), the defendant, Drug Houses of Australia Pte Ltd ("DHA"), received the HSA's approval to register a therapeutic product, Bortezomib.[121] The plaintiff, Millennium Pharmaceuticals, Inc ("MP"), owned a process patent for manufacturing Bortezomib.[122] MP was not served any notice[123] under reg 23(5) of the HPTPR,[124] and had not seen DHA's declaration[125] under reg 23(2) of the HPTPR.[126] DHA did not apprise MP of its declaration because it believed that its products were not manufactured with the processes patented by MP and thus did not infringe MP's patents.[127] MP sought, *inter alia*, a prospective infringement

120 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149.
121 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [13].
122 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [11].
123 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [14].
124 Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23(5).
125 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [14].
126 Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 23(2).
127 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [16].

declaration from DHA,[128] but DHA sought to strike out the claim under O 18 r 19 of the Rules of Court 2014.[129]

64 The High Court held that since no notice was required by reg 23(5) to begin with, the mechanism under reg 23 for the patent holder to challenge a drug application did not arise.[130] Well aware of the limitations of reg 23(5) when no notice pursuant to the regulation was served on MP, MP attempted to circumvent this difficulty by arguing a more-inclusive meaning of reg 24(1)(*a*)(i) of the HPTPR.[131] It contended that reg 24(1)(*a*)(i), stipulating that a court-determined infringement that would allow the HSA to remove a drug's registration,[132] also extended to prospective infringement.[133] It attempted to justify such an expansion by arguing that, based on *AstraZeneca* 1,[134] the legislation intended "to create a pro-patentee regime".[135]

65 The High Court held that such an interpretation was untenable as the purposive approach in statutory interpretation should be consistent with the literal wording, and that reading "infringes" in reg 24(1)(*a*)(i) interchangeably with "will be infringed" would therefore "stretch unreasonably" the literal meaning of the regulation.[136] Moreover, MP's interpretation would render the framework in reg 23 otiose.[137] Therefore, the High Court struck out MP's application.

66 However, the Court of Appeal in *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2019] SGCA 31 ("*Millennium Pharmaceuticals (CA)*") reversed the High Court's decision, noting

128 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [31].

129 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [22].

130 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [41]. The High Court was clearly referring to an application for infringement proceedings under reg 23(8), which then automatically triggers a 30-month moratorium under reg 23(9).

131 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [42].

132 Health Products (Therapeutic Products) Regulations 2016 (S 329/2016) reg 24(1)(*a*)(i).

133 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [43].

134 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [47]–[48].

135 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [45].

136 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [45].

137 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [46].

that "reg 24(1)(*a*)(i) is not necessarily about proving actual or past infringement", but instead envisaged a situation where "the Court … considers an act authorised by the registration of the therapeutic product and determines whether that act amounts to infringement … the act may or may not have taken place",[138] thereby allowing for *prospective* infringements to come under the ambit of the court. The court also added that even if actual infringement were required, particulars of the infringement could subsequently be provided after discovery and/or interrogatories.[139]

67 Relatedly, to remove all doubt, the court also stated that *process* patents fell within reg 23 of the HPTPR, an opinion it repeated in *Zyfas Medical Co v Millennium Pharmaceuticals, Inc*.[140]

(a) Clarification of Singapore's pro-patentee stance in *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd*

68 The Court of Appeal's decision in *Millennium Pharmaceuticals (CA)* aligns with Singapore's pro-patentee position admitted by the High Court in *AstraZeneca* 1.[141]

69 Indeed, the High Court in *AstraZeneca* 2 had already implied that an interpretation of prospective infringement may, through extrapolation, be read into the meaning of any provision requiring a past infringement. Specifically, since there was no contention between the parties in *AstraZeneca* 2 that O 87A r 2(2)[142] applied to prospective infringement in the MA, the High Court proceeded with that interpretation,[143] notwithstanding that O 87A seemed to apply to the Patents Act[144] and O 87A r 2(2) provided that particulars of infringement must be served when the patent is alleged "to be infringed".[145]

70 However, such an interpretation contradicted with the interpretation of reg 24(1)(*a*)(i) in *Millennium Pharmaceuticals (HC)* (*ie*, that the ambit of protection by reg 24(1)(*a*)(i) should not cover prospective infringements).

138 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2019] SGCA 31 at [7].
139 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2019] SGCA 31 at [8].
140 [2020] SGCA 84.
141 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2012] SGHC 16 at [47]–[48].
142 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 87A.
143 *AstraZeneca AB (SE) v Sanofi-Aventis Singapore Pte Ltd* [2013] SGHCR 7 at [21].
144 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 87A.
145 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 87A r 2(2).

71 Although this contradiction has now been solved in *Millennium Pharmaceuticals (CA)*, it is submitted that the High Court's interpretation in *Millennium Pharmaceuticals (HC)* is the more principled one, because O 87A of the Rules of Court was originally drafted before s 12A of the MA,[146] and the legislative drafters could not have contemplated O 87A to have applied to a patent linkage scheme that was absent at the point of drafting. It would not befit the court to impute an interpretation that was not (and could not have been) determined by parliament at the relevant time. Indeed, since it is ostensible that MP was strenuously trying to fit its case into reg 24(1)(*a*)(i) to attain disproportionate pro-patentee protections, the courts should have been careful not to expand the ambit of reg 24(1)(*a*)(i), notwithstanding the "pro-patentee regime" that the Singapore Parliament intended to create.[147]

72 In any case, for greater clarity and for avoidance of conflicting positions in separate cases, it is submitted that, if the Court of Appeal's decision were to stand, O 69(2) of the Rules of Court 2021 (which replaced but did not substantively amend O 87A(2) of the Rules of Court 2014) should be updated to include *prospective* infringements under the patent linkage scheme. Respectfully, any changes to the interpretation of reg 24 of the HPTPR should come from *legislative* amendments, and not *judicial* activism.

73 Given the almost entirely *pro-patentee* stances that have been applied in the courts thus far, it is submitted that pro-generic measures ought to be established at the parliamentary level. Recommendations on how Singapore may create pro-generic measures will be discussed below.

C. Problems with the pro-patentee stance

74 Revisiting the origins of patent linkage scheme in the US, the patent linkage scheme was introduced together with an exclusivity bounty to encourage patent litigation as a "grand bargain" to balance innovation with access to medicines. It is noteworthy that the USSFTA only stipulates pro-patentee measures in the form of patent linkage scheme but is silent on the pro-generic measures in the Hatch-Waxman Act. Accordingly, the exclusivity bounty was not discussed in the parliamentary debates and similarly not provided for in the statutes.

146 O 87A of the Rules of Court was originally drafted in 1997, while s 12A of the Medicines Act was drafted in 2004.

147 *Millennium Pharmaceuticals, Inc v Drug Houses of Australia Pte Ltd* [2018] SGHC 149 at [45].

75 This is hardly ideal for Singapore, especially given its reliance on the generics industry, and the generic drugs that are produced. The lack of incentives for generic manufacturers, while simultaneously keeping *pro-patentee* measures, means that Singapore is no longer a conducive environment for the development (and sale) of generic products.

76 In fact, lessons can be drawn from the patent linkage scheme in Canada, where similar *pro-patentee* measures were initiated without corresponding *pro-generic* measures. Prior to the introduction of the patent linkage scheme, with compulsory licensing at a fixed royalty rate of 4% and provincial programmes that reimbursed the cost of drugs for senior citizens and social assistance recipients,[148] generic drugs were highly affordable.[149] The patent linkage scheme was then introduced in 1993[150] without an accompanying system of market exclusivity for the first generic manufacturer, that challenged the validity of the patent. Such a system drastically transformed Canada from a regime in which the generic industry was burgeoning to one with increasing drug prices.[151]

77 In addition to stymieing the growth of the generics industry, the absence of an incentive for generic manufacturers to challenge existing patents would also mean that weak patents would be less likely to be challenged. In general, the Intellectual Property Office of Singapore does not have sufficient resources to police abuses of the patent regime in Singapore and only grants valid patents, an issue that plagues many IP authorities worldwide.

D. Recommendations based on the US market exclusivity system

78 In most IP systems, competitors are generally depended upon to invalidate unmeritorious patents because they are usually "aware of the most relevant prior art" and are able to "uncover areas unknown to the examiners".[152] However, without a generics reward system, potential

148 Margaret Smith, *Patent Protection for Pharmaceutical Products* (Library of Parliament, 1993) at p 3.

149 Christopher Scott Harrison, "Protection of Pharmaceuticals as Foreign Policy: the Canada–U.S. Trade Agreement and Bill C-22 *versus* the North American Free Trade Agreement and Bill C-91" (2001) 26 *North Carolina Journal of International Law & Commercial Regulation* 460.

150 Patented Medicines (Notice of Compliance) Regulations (SOR/93-133) (Can) paras 5(1) and 5(2.1).

151 Joel Lexchin, "Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go from Here?" (2005) 35(2) *International Journal of Health Services* 237 at 243.

152 Michael A Carrier, "Post-Grant Opposition: A Proposal and a Comparison to the America Invents Act" (2011) 45 *UC Davis Law Review* 114.

generic challengers may be deterred from challenging patents due to the high costs of litigation. In Singapore, the cost of litigation far outweighs any benefit that a generic applicant could obtain by invalidating a weak (or wrongly filed) patent.

79 This deterrence is compounded by the perennial free-rider problem in patent challenges, in which a successful invalidation by a generic manufacturer would invite other generic manufacturers to piggy-back on the fruits of its efforts. Consequently, any benefit of invalidating a patent would be diluted with other generic competitors.

80 However, a lack of incentives for challenging the validity of weak patents also means that undeserving patent holders would not be weeded out from holding a monopoly. The mere existence of unmeritorious patents would decrease the number of non-infringing substitutes for customers, leading to unnecessary increases in drug prices.[153]

81 The imperative for introducing market exclusivity is even more accentuated in Singapore, due to its small market. Unlike larger markets, such as the US, where the benefits of entry into market are high, a successful generic drug application in smaller markets like Singapore is not as rewarding to the generic manufacturer.

82 Hence, it is submitted that Singapore should follow the US in adopting a market exclusivity system to reward generic manufacturers, instead of protecting only the *patentee*. Indeed, the length of the market exclusivity system should be lengthened as compared to the US, to provide more incentives for generic competitors to challenge weak or unfair patents. It is submitted that this is the only way that generic applicants would be willing to engage in (potentially costly) litigation to invalidate patents in a small market like Singapore's.

VI. Additional lessons from the patent linkage scheme in the US

83 Indeed, in light of the Singaporean approach to the patent linkage scheme, it is perhaps pertinent to draw further lessons from the US patent linkage scheme, to deal with the present state of patent linkage (and its related case law) in Singapore.

153 Christopher R Leslie, "Antitrust and Patent Law as Component Parts of Innovation Policy" (2009) 34 J Corp L 1259 at 1270.

A. Reverse payment patent settlement (pay-for-delay)

84 As briefly discussed earlier in Section III(B) above, a patent holder may pay the generic challenger for the latter to refrain from entering the market, thus extending the monopoly by the patent holder.[154] This option is generally known as a reverse payment settlement or "pay-for-delay" settlement.

85 This option is financially irresistible for both the patent holder and the generic competitor, because of the economic realities presented to both parties; the profit that the generic competitor gets from selling generics is far less than the profit that the patent holder loses when it loses its monopoly and is forced to compete with generics. Therefore, paying a generic manufacturer to delay entering the market results in a win-win situation for both the generic competitor and the patent holder.

86 However, the result is that the market loses the price elasticity that comes with healthy competition, essentially allowing the patent holder to maintain its monopolistic behaviour (as well as prices) in the market.[155]

(1) Examples of pay-for-delay settlements

87 The most notable case regarding pay-for-delay settlements is the *Federal Trade Commission v Actavis, Inc*[156] ("*Actavis*"). In *Actavis*, respondents Actavis and Paddock filed ANDAs for generic drugs modelled after the patented drug AndroGel, submitting a paragraph IV certification that the patent was invalid and would not be infringed upon.[157] The patent holder, Solvay Pharmaceuticals, initiated infringement proceedings but Actavis's generic product was eventually approved.

88 Solvay Pharmaceuticals then entered into a reverse payment settlement agreement with Actavis, Paddock and Par (another manufacturer which joined forces with Paddock in the same litigation); in exchange for not introducing their generic equivalents into the market for a specified number of years and promoting AndroGel to doctors,

154 Margherita Colangelo, "Reverse Payment Patent Settlements in the Pharmaceutical Sector under EU and US Competition Laws: A Comparative Analysis" (2017) 40(3) *World Competition* 471 at p 1.

155 Margherita Colangelo, "Reverse Payment Patent Settlements in the Pharmaceutical Sector under EU and US Competition Laws: A Comparative Analysis" (2017) 40(3) *World Competition* 471 at p 2.

156 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013).

157 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2225.

they would receive compensation amounting to millions of dollars.[158] The Federal Trade Commission ("FTC") then sued the respondents for violating § 5 of the Federal Trade Commission Act.[159]

89 Although the FTC lost in both first instance and appeal, it sought *certiorari* and succeeded in the Supreme Court.[160] The Supreme Court held that reverse payment settlements violated antitrust laws because such settlements would adversely affect competition.[161] The Supreme Court, elaborating on why antitrust laws would be violated in patent-related settlement agreements, cited its previous decision in *United States v Singer*,[162] which held that a patent monopoly was granted as a *quid pro quo* for giving a novel and useful invention to the public.[163] By contrast, permitting reverse payment settlement agreements would result in the public continually paying "tribute to would-be monopolists without need or justifications".[164] Although the Supreme Court acknowledged that settlement agreements (in which the alleged infringer pays to the patent holder a settlement sum lower than the claimed damage) are generally common in intellectual property infringement litigation, the specific type of settlement agreement involving reverse payment is atypical and should not be viewed in the same light.[165]

(2) How should the Singapore courts deal with "pay-for-delay" agreements?

90 Granted, there are policy reasons for why settlements of disputes are generally looked upon favourably by the courts, especially in patent cases which may be "time consuming, complex, and expensive".[166] Nonetheless, to also support reverse payment settlements with the same sweeping justification is akin to throwing the baby out with the bath water, because the time and cost saved cannot similarly justify anti-competitive agreements.[167] Since the huge sums from reverse payments suggest that the patent holder doubts the validity of its own patent, such reverse payment becomes "a workable surrogate for a patent's weakness,

158 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2225.
159 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2225.
160 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2225.
161 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2231.
162 *United States v Singer Mfg Co* 374 US 174 (1963).
163 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2232.
164 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2233, citing *Lear, Inc v Adkins*, 395 US 653 (1969).
165 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2233.
166 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2234.
167 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2236.

all without forcing a court to conduct a detailed exploration of the validity of the patent itself".[168]

91 Admittedly, Singapore courts are similarly very concerned with efficiency in disposing of cases. Out of court settlements have generally been encouraged, as can be seen from the incentivisation in O 22A of the Rules of Court 2014.[169] As Chao Hick Tin JA stated, "[t]he whole object of O 22A is to spur the parties to bring litigation to an expeditious end without judgment and thus to save costs and judicial time".[170]

92 While it is noted that O 22A has been removed in the new Rules of Court 2021, the spirit of O 22A (to encourage out of court settlements) is still present in O 5 of the Rules of Court 2021. Indeed, O 5 of the Rules of Court 2021 can be seen to be more far-reaching, as it imposes a duty on the parties to "make an offer of amicable resolution before commencing the action unless the party has reasonable grounds not to do so"[171] and further compels the parties not to "reject an offer of amicable resolution unless the party has reasonable grounds to do so".[172] This is in contrast with O 22A of the Rules of Court 2014, which only provides parties with the *right* (but not duty) to make an offer to settle. Additionally, while the cost consequences of rejecting a reasonable offer to settle (based on O 22A of the Rules of Court 2014) are no longer present in the Rules of Court 2021, one would still expect discretionary cost consequences to be imposed by the court for non-compliance with the spirit of O 5 of the Rules of Court 2021 (see O 21 r 2).[173]

93 However, similar to the US, settlement agreements envisaged by O 22A of the Rules of Court 2014[174] (and/or amicable resolutions envisaged by O 5 of the Rules of Court 2021) involve payment by the defendant to the claimant, and the drafters did not intend for parties to offer reverse payment(s) in exchange for collusion to distort the market. Quoting the former Chief Justice Chan Sek Keong, although "justice delayed is justice denied", we should also remember that "justice hurried is justice buried".[175] Since both procedural justice and substantive justice

168 *Federal Trade Commission v Actavis, Inc* 570 US 133 (2013) at 2236–2237.

169 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 22A rr 9(1) and 9(3). Specifically, a party rejecting an offer to settle that would have been at least as favourable for him as the judgment eventually granted would likely have to pay additional party-to-party costs.

170 *Singapore Airlines Ltd v Tan Shwu Leng* [2001] 3 SLR(R) 439 at [37].

171 Rules of Court 2021 (2020 Rev Ed) O 5 r 1(2).

172 Rules of Court 2021 (2020 Rev Ed) O 5 r 1(3).

173 Rules of Court 2021 (2020 Rev Ed) O 21 r 2.

174 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 22A.

175 Chief Justice Chan Sek Keong, welcome address at the Third Roundtable Meeting of the Asia-Pacific Judicial Reform Forum (20 January 2009).

are imperative in Singapore,[176] it is imprudent to permit reverse payment patent settlements merely due to the one-track mindset of saving precious court resources.

94 Additionally, in the Rules of Court 2014, an offer to settle must be made through Form 33,[177] which provides the following template:[178]

> The (party) offers to settle this proceeding (or the following claims in this proceeding) on the following terms: (set out terms in consecutively numbered paragraphs).

95 Noticeably, there does not appear to be any restriction on how parties formulate the offer to settle. Similarly, in the new Rules of Court 2021, parties who make an "offer of amicable resolution" under O 5 do not need to follow any prescribed format, so long as the offered *resolution* is not illegal.

96 The lack of "ground rules" for a *bona fide* offer to settle is likely an intentional omission by the legislators, who most likely wanted to give the parties the freedom (and creativity) to resolve their disputes. However, while it is important for the parties to maintain a certain level of autonomy when making *bona fide* offers to settle, this must be balanced by the dangers of allowing the parties to collude or maintain monopolies via reverse payments (as discussed above). It is therefore submitted that an addendum to proscribe offers involving reverse settlements or pay-for-delay provisions should be added to O 5 of the Rules of Court 2021.

B. Considerations for the proposed market exclusivity period – Unmeritorious first generic applicant

97 An initiative strongly supported in this article is the market exclusivity scheme for the first generic applicant. However, it is pertinent to explore the issues arising from the provision of said exclusivity. While, as discussed thoroughly above, providing a moratorium for the patent holder may invite abuse, the same may be true for the grant of the exclusivity period for the first generic applicant.

(1) The US approach

98 In the US market exclusivity scheme, the FDA initially required an ANDA filer with a paragraph IV certification to "successfully defend"

176 *United Overseas Bank Ltd v Ng Huat Foundations* [2005] SGHC 50 at [9].
177 Rules of Court (Cap 322, R 5, 2014 Rev Ed) O 22A r 1.
178 Rules of Court (Cap 322, R 5, 2014 Rev Ed) Form 33.

itself from an infringement proceeding by the patent holder, before it would be rewarded with the 180-day marketing exclusivity, believing that requiring otherwise would create "an incentive for frivolous claims of patent invalidity or noninfringement".[179]

99 However, in *Mova Pharmaceuticals Corp v Shalala*[180] ("*Mova*") the FDA's successful defence requirement was rejected by the US Court of Appeal of the District of Columbia, which held that the requirement was incompatible with the literal reading of the statute.[181] This was notwithstanding the court's recognition that the statutory scheme could unfairly penalise a meritorious ANDA applicant – where a subsequent ANDA applicant with paragraph IV certification was not sued, and was willing and ready to enter the market, it would be prevented from doing so while the first filer was undergoing litigation.[182]

100 In response to the rejection of the successful defence requirement in the court, it was removed from the FDA regulations.[183] This removal was later approved by the same court in *Purepac Pharmaceutical Company v Thompson* as being consistent with the statute and the decision in *Mova*.[184]

101 It has been criticised that this approach would invite sham paragraph IV submissions, such that generic companies rush to be the first to file the ANDA and then settle with the patent owner to delay the introduction of the generic drug.[185] Moreover, the aforementioned FTC study reported that there were instances in which the 180-day exclusivity

179 Abbreviated New Drug Application Regulations (59 FR 50338-01, 1994 WL 530014) (US) at para 76.

180 *Mova Pharmaceuticals Corp v Shalala* 140 F 3d 1060 (DC Cir, 1998).

181 *Mova Pharmaceuticals Corp v Shalala* 140 F 3d 1060 at 1069 (DC Cir, 1998). Referring to the Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(5)(B)(iv).

182 *Mova Pharmaceuticals Corp v Shalala* 140 F 3d 1060 (DC Cir, 1998) at 1072. The first filer who lost at the trial court would sensibly not begin marketing until a decision is made at the appellate court, even though it is technically granted marketing exclusivity. This is sensibly so because marketing an infringing product would invite suits for monetary damages. As a result, the marketing exclusivity period would be triggered later, and later applicants would have to wait even if they were willing and able to market their products.

183 Effective Date of Approval for an Abbreviated New Drug Application (63 FR 59710-01, 1998 WL 766539) (US) at V.

184 *Purepac Pharmaceutical Company v Thompson* 162 F 3d 1201 (DC Cir, 1998) at 1204.

185 Wendy H Schacht & John R Thomas, *The Hatch-Waxman Act: Proposed Legislative Changes Affecting Pharmaceutical Patents* (United States Congressional Research Service, 2004) at CSR-5–6.

was parked such that the first generic applicant did not trigger it, resulting in delays for later generic competitors.[186]

(2) Dealing with issues arising from the market exclusivity scheme

102 Fortunately, the US did not leave this shortcoming completely unmitigated. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act[187] which resulted in a provision for the marketing exclusivity to be forfeited.[188] Pursuant to the added provision, marketing exclusivity may be lost by the first ANDA applicant with paragraph IV certification if:[189]

(a) it fails to market the drug by stipulated durations;

(b) it withdraws its ANDA application;

(c) it withdraws or amends its paragraph IV certification;

(d) it does not obtain tentative approval for the application;

(e) it enters a settlement agreement with another generic drug company or the patent holder, and the settlement agreement is held to be anti-competitive in a final decision in which no further appeal has been or can be made (excluding an appeal to the Supreme Court); or

(f) all the patents in the application has expired.

Therefore, the incentives to file sham paragraph IV certifications and collude in settlement agreements are effectively removed.[190] Moreover, the exclusivity period may no longer be "parked" by the first generic applicant, *ie*, obtaining the exclusivity bounty without triggering it, thereby delaying generic entry.[191]

103 Speaking on the Senate floor with respect to the Medicare Reform Bill ("Bill") leading to MMA, Senator Hatch discussed that when

186 US Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration, an FTC Study* (July 2002) at 47 (Chairman: Timothy J Muris) (reporting challenges involving 130 drugs between 1984 and 2000).

187 Medicare Prescription Drug, Improvement, and Modernization Act 108 PL 173 (2003) at § 1102.

188 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(5)(D).

189 Federal Food, Drug and Cosmetic Act 21 USC (US) § 355(j)(5)(D)(i) & (ii).

190 Scott A Backus, "Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has *Schering-Plough* Created the Blueprint for Defensible Antitrust Violations?" (2007) 60 *Oklahoma Law Review* 375 at 391.

191 Scott A Backus, "Reversing Course on Reverse Payment Settlements in the Pharmaceutical Industry: Has *Schering-Plough* Created the Blueprint for Defensible Antitrust Violations?" (2007) 60 *Oklahoma Law Review* 375 at 391.

the patent linkage scheme was first introduced, the 180-day marketing exclusivity was meant to reward the first *successful* ANDA applicant with paragraph IV certification.[192] However, the courts construed the drafters' language to mean that the first ANDA applicant with paragraph IV certification was the party to be so rewarded.[193]

104 Senator Hatch then commended that the signed Bill would avoid the issues of anti-competitive agreements and protracted exclusivity parking.[194] However, he noted that the issue of the meritorious second applicant still subsists.[195] He then acknowledged that it would be "exceedingly difficult to reopen these provisions" with the Bill already signed into law, and that the senate in so allowing a loophole in the patent linkage scheme "got this aspect wrong" and "should try to fix it".[196]

105 Indeed, even with the MMA amendments, the effect on encouraging patent invalidation by generic exclusivity reward was limited. A study was done to examine instances of the exclusivity reward from 2005 to 2009. [197] Of the instances in which the exclusivity was granted, the generic applicant mostly "did little or nothing to earn the exclusivity award". Of the 49 instances, 23 were no-suits awards, nine ended up as settlement cases and eight involved launches at risk.[198] Only in the remaining nine instances did the generic first filer successfully defend against the patent holder in the infringement proceeding.[199]

106 Several further proposals have been made to resolve the issue of meritorious second applicants. For instance, an additional forfeiture provision has been proposed in which the marketing exclusivity of the first filer must give way to a later applicant that succeeds first.[200] In this way, the patent holder would be forced to sue later infringing applicants

192 *Congressional Record* vol 149 (9 December 2003) at 16104–16105.
193 *Congressional Record* vol 149 (9 December 2003) at 16105.
194 *Congressional Record* vol 149 (9 December 2003) at 16105.
195 *Congressional Record* vol 149 (9 December 2003) at 16105.
196 *Congressional Record* vol 149 (9 December 2003) at 16106.
197 C Scott Hemphill & Mark A Lemley, "Earning Exclusivity: Generic Drug Incentives and The Hatch-Waxman Act" (2011) 77 *Antitrust Law Journal* 947 at 956–957.
198 C Scott Hemphill & Mark A Lemley, "Earning Exclusivity: Generic Drug Incentives and The Hatch-Waxman Act" (2011) 77 *Antitrust Law Journal* 947 at 956–957. A launch is "at risk" if the infringement proceeding has not been resolved by the end of the moratorium, and the generic applicant markets the product but eventually loses the lawsuit.
199 C Scott Hemphill & Mark A Lemley, "Earning Exclusivity: Generic Drug Incentives and The Hatch-Waxman Act" (2011) 77 *Antitrust Law Journal* 947 at 956–957.
200 Ashlee B Mehl, "The Hatch-Waxman Act and Market Exclusivity for *Generic* Drug Manufacturers: An Entitlement or an Incentive?" (2006) 81 *Chicago-Kent Law Review* 649 at 672.

because their generics would not be "frozen out of the market until the resolution of the pioneer's litigation with the first filer".[201] Another proposal suggested that the generic first filer would receive the 180 day-exclusivity where "it successfully defeats the patent owner,[202] obtains a settlement that permits immediate entry, or receives FDA approval having never been sued".[203]

107 However, while these proposals made were close to adopting the rule that the first ANDA applicant that successfully defends its suit shall receive the exclusivity bounty, these stopped short of doing so. This is apparently because the statute in the US has progressed in significant ways since 1984 and reinstating that requirement would be difficult.[204]

(3) Adopting the US approach in the Singapore market

108 In the Singaporean context, since the patent linkage scheme is still relatively nascent and the generic exclusivity reward has yet to be introduced, the same reasoning does not apply. Therefore, to avoid the same complications that have arisen in the US, it is submitted that domestic legislators could consider the merits of adopting the "successful defence" requirement, as was the initial intention of the Hatch-Waxman Act.

109 As argued by the later applicant in *Mova*, *ie*, Mylan Pharmaceuticals, Inc, if the later applicant does a better job than the first filer in designing the drug to circumvent infringement of the patent, it is bizarre that the public is denied of the ingenuity of the later applicant.[205] Rewarding the first successful applicant is, therefore, in no way unfair because both the first filer and later applicant are merely obtaining suitable rewards for their innovation.

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201 Ashlee B Mehl, "The Hatch-Waxman Act and Market Exclusivity for *Generic* Drug Manufacturers: An Entitlement or an Incentive?" (2006) 81 *Chicago-Kent Law Review* 649 at 676.

202 Note that this proposal is still different from the successful defence rule initially intended because the exclusivity bounty is not granted for a later ANDA applicant that first successfully defends infringement proceedings.

203 C Scott Hemphill & Mark A Lemley, "Earning Exclusivity: Generic Drug Incentives and The Hatch-Waxman Act" (2011) 77 *Antitrust Law Journal* 947 at 989.

204 C Scott Hemphill & Mark A Lemley, "Earning Exclusivity: Generic Drug Incentives and The Hatch-Waxman Act" (2011) 77 *Antitrust Law Journal* 947 at 989.

205 *Mova Pharmaceuticals Corp v Shalala* 140 F 3d 1060 at 1072 (DC Cir, 1998). Although the court eventually rejected the requirement of successful defence, it acknowledged Mylan's argument to be "compelling" and that the meritorious second applicant problem "is a real one". See also *Mova Pharmaceuticals Corp v Shalala* 140 F 3d 1060 at 1072 and 1074 (DC Cir, 1998).

VII. Conclusion

110 As a superior form of protection for the pharmaceutical industry, the patent linkage scheme is likely a "novel and evolving intellectual property paradigm for pharmaceutical products" which is "poised to become an important determinant of the availability and cost of essential medications worldwide".[206] Despite the rising pertinence of the topic, there appears to be a dearth of writing on this topic in Singapore due to the relative novelty of the patent linkage scheme. This article is a modest step towards ameliorating that deficiency.

111 Taking stock of the findings in this article as a whole, it is curious why Singapore only adopted, through the USSFTA, the pro-patentee aspect of the "grand bargain" but stayed silent on the pro-generic aspect of the "grand bargain".

112 As remarked by Senator Hatch, "[i]t was and is very clear that the [Hatch-Waxman Act] was not designed to allow deals between brand and generic companies to delay competition".[207] Thus, to disregard the pro-generic measures would stultify the adoption of the patent linkage scheme in Singapore. In any case, even if it serves Singapore's economic interests to abide by the USSFTA, introducing pro-generic measures in tandem with the required patent linkage scheme cannot be said to be contravening the USSFTA.

113 At this point, it can hardly be gainsaid that Singapore's position is sufficiently pro-generic. With all due respect, it is submitted that this is largely because there was no substantive discussion during the parliamentary debates preceding the adoption of the patent linkage scheme, as Singapore was facing significant international pressure to adopt the patent linkage scheme as quickly as possible at the time, in order to protect patentee interests.

114 As canvassed throughout this article, several pro-patentee measures of the patent linkage scheme were adopted (near wholesale) by parliament, while simultaneously removing many of the pro-generic measures of the patent linkage scheme, without due consideration of the local circumstances.

206 Ronald A Bouchard *et al*, "Structure-Function Analysis of Global Pharmaceutical Linkage Regulations" (2011) 12 *Minnesota Journal of Law, Science & Technology* 391 at 454.

207 *Congressional Record* vol 148 (25 July 2002) at 14437.

115 To mitigate the issue, Singapore should draw lessons from the failures (and successes) of the patent linkage scheme in the US. It is respectfully submitted that the time is ripe to reform the patent linkage scheme, and for our legislators to consider the proposals made in this article, which are summarised in Table A below:

Section	Recommendation
5.2.1.2.	Introduce penalty or compensation for patent holders that trigger the moratorium to pursue a vexatious litigation.
5.2.1.3.	Shorten the duration of the moratorium and permit courts to adjust it where the patent holder does not expedite the infringement proceedings.
5.2.1.4.	Lengthen the duration for the patent holder to file infringement proceedings so that particulars can be provided, trigger the moratorium only where a *prima facie* case can be made from the particulars provided, and require the HSA to take a robust approach for failure to meet this deadline.
5.2.2.1.	Update O 69 of the Rules of Court 2021 to include prospective infringements under the patent linkage scheme.
5.4.	Introduce market exclusivity bounty to encourage Category B applications.
6.1.2.	Insert an addendum to O 5 of the Rules of Court 2021 such that offers for amicable resolution involving reverse payment are proscribed.
6.2.3	Introduce successful defence requirement for market exclusivity to be granted.

Table A: Summary of recommendations