Singapore Association of Pharmaceutical Industries Headline: How Singapore can lead biopharma innovation Media: The Business Times (Print and Digital), Page 16 Date: 4 March, 2020 By: Andrew Jenner, Christina Teo



For pharmaceutical com patents are the primary way to offset the high R&D costs that can stretch over decades, and re sustainable investm into the medicines of tomorro BT PHOTO: KUA CHEE SIONG

How Singapore can lead biopharma innovation

The Republic needs to align its patent term extension regime with international standards, and so start attracting more clinical trials. BY ANDREW JENNER AND CHRISTINA TEO

INGAPORE is known by the global in-INCAPORE is known by the global in-solution and intellectual property (iP) expert community as a leader in the protection of iP rights. The latest inter-national Property Rights index for 2019 again listed Singapore as having Asa's strongest protection of intellectual property (IP) rights; globally, it ranks fourth. Multinationals and homegrown companies alike can rest assured that their inventions are clef from theft in Singapore. The city-state is

safe from theft in Singapore. The city-state is also an advocate for more robust IP protections in Asean, where short-term gains can sometimes be prioritised over a country's long-term credibility and development

credibility and development. This leadership position is hard-earned, and a result of Singapore's commitment to fostering innovation and a knowledge-based economy. The country's policymakers, in their consistent efforts to keep Singapore's economy at a lead-ing edge globally, are cognisant of the imperat-tive to sustain efforts to leverage IP as a key driver of economic growth. driver of economic growth.

Among the key recommendations of the ommittee on Future Economy released in Committee on Future Economy released in 2017 is the increased focus on proactive encour-agement of IP creation in Singapore, versus just protecting existing IP rights. In response, the In-tellectual Property Office of Singapore (ipos) up-dated its intellectual Property Hub Master Han to transform 'ideas into assets' and launched a \$31 billion innovation fund to attract compan-ies from around the world, with potential to scale across Asia, to Singapore. This is a good plan and Singapore is in a

This is a good plan, and Singapore is in a strong position to drive thought leadership and transformative policies in the region.

DRIVING BIOPHARMA INNOVATION

The biopharmaceutical industry, in particular, has been a beneficiary of this ecosystem. Singa-pore is home to 50 biopharmaceutical research and development centres and another 50 manufacturing plants. Indeed, biopharma is now the accuring paints, indeed, organization is now the second largest contributor to the country's man-ufacturing sector, producing over S\$16 billion worth of exports. Thirty international pharmaceutical compan-tes how chosen these more the billions and the pharmaceutical compan-tes how chosen these transmissions and the sector of the sec-tor sector sector sector and the sector sector sector.

ies have chosen Singapore as their regional hub. Eight of the world's 10 largest pharma compan-ies have facilities here. In recognition of the bio-pharmaceutical sector's continued contribution to Singapore's economic growth, the Research on and Enterprise (RIE) 2020 plan has al-Innovat located S\$4 billion to the health and biomedical nces sector.

as in recognition of Singapore's import ance as a biopharmaceutical centre of excel-lence in the region and globally that Interpat, a global non-profit association comprised of phar-

maceutical executives responsible for IP issues. held its 2019 Annual General Assembly in Singa pore. It was the first time the meeting was held in Asia.

These commercial activities all in turn con-These commercial activities all in turn con-tribute investment and high value employment and training opportunities to Singapore. The sector currently employs over 6,000 skilled workers, more than twice the number in the early 2000s. In 2016, the R&D investment of pharmaceut-ical companies alone amounted to over S3945 million, which does not include their invest-ment in manufacturing and corporate func-

ment in manufacturing and corporate functions. Singapore's pharmaceutical market may only represent 0.09 per cent of the global market, but the country's pharmaceutical invest ment comprises 0.43 per cent of global pharma ceutical investment. However, Singapore is still relatively young as a patent jurisdiction, and there is so me work to be done to grow the num-

there is some work to be done to grow the num-ber and quality of patent filings. For pharmaceutical companies, patents are the primary way to offset the high R&D costs that can stretch over decades, and ensure sus-tainable investment into the medicines of to-morrow. In developed markets (and major bio-pharmaceutical manufacturing centres) such as the United States and the European Union, pat-ent systems compensate drug developers for the phase following clinical trials and developthe phase following clinical trials and develop-ment when marketing approval is being sought, before the drug can go to market. This is referred to as patent term extension (PTE).

This PTE system incentivises companies to eate more effective drugs to address illcreate m nesses, for example novel heart disease or can-cer treatments. More drugs being developed in Singapore could mean not just more opportunit-ies for Singaporean scientists and researchers, but also more access to innovative medicines for Singaporean patients. However, the existing patent system in Singapore is not aligned with PTE regimes in the US, EU and other countries such as Australia and Japan. Under the Singapore system, drug denesses, for example novel heart disease or can

Under the Singapore system, drug de-velopers are only considered for PTE when there are delays resulting from the regulatory administrative process for obtaining marketing approval. As Singapore's market approval sys tem is remarkably efficient, PTE has been gran ted only once since the system was introduced in 2004. While the rapid market approval pro cess is an asset to Singapore's system, the lack of recognition of the years spent in clinical trials of recognition of the years spent in clinical trans when it comes to patent terms makes other jur-isdictions more attractive places in which to file patents. Clinical trails across Asia are rising in number, but falling in Singapore. Granted, there are costs and challenges in-volved in the process of reviewing Singapore's

PTE regime, but in the long run, the benefits will outv

atweigh any cost and effort required. A PTE regime that is aligned with interna-onal standards such as that of the US and EU tior tional standards such as that of the US and EU would enable Singapore to gain greater recogni-tion as a global IP hub. This would in turn en-able Singapore to capture opportunities presen-ted by growing IP activities internationally to drive husiness and economic growth. A globally competitive PTE framework would also rein-force ipos' partnerships with IP offices in other countries, such as the Patent Prosecution High-way (PPI) and Assan Patent Examination Go-operation (Aspec), which allow patents filed in Singapore to be fast-tracked in partner coun-tries, and vice versa. tries, and vice-versa.

MAINTAINING COMPETITIVENESS

Sustaining investments and growth in the bio pharmaceutical and other IP-intensive indus-tries is crucial to maintaining an innovative ecosystem in Singapore. A compelling PTE regime creates new incentives for research and devel opment of new products that are subject to premarket regulatory approval, thereby boosting Singapore's competitive position as a leading hub for biopharma R&D innovation. On the other hand, a PTE framework that is not aligned with global best practices may erode Singapore's competitive advantage vis-a-vis ambitious developing markets, where costs are

As new medicines develop and launch in the Singapore market, Singapore will benefit from granting the same PTE treatments as the US and EU today. The global pharmaceutical market is expected to exceed US31.15 trillion in 2023, from US51.2 trillion in 2018, and Singapore is in pole position to capitalise on this economic oppor-tunity. However, all the elements must be in place to ensure a mutually reinforcing ecosys-tem of growth and innovation. Singapore has many strong qualities that make it an attractive investment destination – robust regulations, a deep talent base and As new medicines develop and launch in the

robust regulations, a deep talent base and world-class infrastructure, among others. Government agencies such as Ipos, the Economic Development Board (EDB) and the National Research Foundation (NRF) have done much to cre ate a nurturing environment for innovators. These efforts have set a strong foundation in place for Singapore to be a regional leader in both IP and biopharmaceutical innovation. A robust and competitive PTE framework may just be the key to unlocking the doors leading to the next wave of growth.

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Full Text

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For pharmaceutical companies, patents are the primary way to offset the high R&D costs that can stretch over decades, and ensure sustainable investment into the medicines of tomorrow.

SINGAPORE is known by the global innovation and intellectual property (IP) expert community as a leader in the protection of IP rights. The latest International Property Rights Index for 2019 again listed Singapore as having Asia's strongest protection of intellectual property (IP) rights; globally, it ranks fourth.

Multinationals and homegrown companies alike can rest assured that their inventions are safe from theft in Singapore. The city-state is also an advocate for more robust IP protections in Asean, where short-term gains can sometimes be prioritised over a country's long-term credibility and development.

This leadership position is hard-earned, and a result of Singapore's commitment to fostering innovation and a knowledge-based economy. The country's policymakers, in their consistent efforts to keep Singapore's economy at a leading edge globally, are cognisant of the imperative to sustain efforts to leverage IP as a key driver of economic growth.

Among the key recommendations of the Committee on Future Economy released in 2017 is the increased focus on proactive encouragement of IP creation in Singapore, versus just protecting existing IP rights. In response, the Intellectual Property Office of Singapore (Ipos) updated its Intellectual Property Hub Master Plan to transform "ideas into assets" and launched a S\$1 billion innovation fund to attract companies from around the world, with potential to scale across Asia, to Singapore.

This is a good plan, and Singapore is in a strong position to drive thought leadership and transformative policies in the region.

The biopharmaceutical industry, in particular, has been a beneficiary of this ecosystem. Singapore is home to 50 biopharmaceutical research and development centres and another 50 manufacturing plants. Indeed, biopharma is now the second largest contributor to the country's manufacturing sector, producing over \$\$16 billion worth of exports.

Thirty international pharmaceutical companies have chosen Singapore as their regional hub. Eight of the world's 10 largest pharma companies have facilities here. In recognition of the biopharmaceutical sector's continued contribution to Singapore's economic growth, the Research Innovation and Enterprise (RIE) 2020 plan has allocated S\$4 billion to the health and biomedical sciences sector.

It was in recognition of Singapore's importance as a biopharmaceutical centre of excellence in the region and globally that Interpat, a global non-profit association comprised of pharmaceutical

executives responsible for IP issues, held its 2019 Annual General Assembly in Singapore. It was the first time the meeting was held in Asia.

These commercial activities all in turn contribute investment and high-value employment and training opportunities to Singapore. The sector currently employs over 6,000 skilled workers, more than twice the number in the early 2000s.

In 2016, the R&D investment of pharmaceutical companies alone amounted to over S\$945 million, which does not include their investment in manufacturing and corporate functions. Singapore's pharmaceutical market may only represent 0.09 per cent of the global market, but the country's pharmaceutical investment comprises 0.43 per cent of global pharmaceutical investment. However, Singapore is still relatively young as a patent jurisdiction, and there is some work to be done to grow the number and quality of patent filings.

For pharmaceutical companies, patents are the primary way to offset the high R&D costs that can stretch over decades, and ensure sustainable investment into the medicines of tomorrow. In developed markets (and major biopharmaceutical manufacturing centres) such as the United States and the European Union, patent systems compensate drug developers for the phase following clinical trials and development when marketing approval is being sought, before the drug can go to market. This is referred to as patent term extension (PTE).

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Under the Singapore system, drug developers are only considered for PTE when there are delays resulting from the regulatory administrative process for obtaining marketing approval. As Singapore's market approval system is remarkably efficient, PTE has been granted only once since the system was introduced in 2004. While the rapid market approval process is an asset to Singapore's system, the lack of recognition of the years spent in clinical trials when it comes to patent terms makes other jurisdictions more attractive places in which to file patents. Clinical trials across Asia are rising in number, but falling in Singapore.

Granted, there are costs and challenges involved in the process of reviewing Singapore's PTE regime, but in the long run, the benefits will outweigh any cost and effort required.

A PTE regime that is aligned with international standards such as that of the US and EU would enable Singapore to gain greater recognition as a global IP hub. This would in turn enable Singapore to capture opportunities presented by growing IP activities internationally to drive business and economic growth. A globally competitive PTE framework would also reinforce Ipos' partnerships with IP offices in other countries, such as the Patent Prosecution Highway (PPH) and Asean Patent Examination Co-operation (Aspec), which allow patents filed in Singapore to be fast-tracked in partner countries, and vice-versa.

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innovation. On the other hand, a PTE framework that is not aligned with global best practices may erode Singapore's competitive advantage vis-a-vis ambitious developing markets, where costs are lower.

As new medicines develop and launch in the Singapore market, Singapore will benefit from granting the same PTE treatments as the US and EU today. The global pharmaceutical market is expected to exceed US\$1.5 trillion in 2023, from US\$1.2 trillion in 2018, and Singapore is in pole position to capitalise on this economic opportunity. However, all the elements must be in place to ensure a mutually reinforcing ecosystem of growth and innovation.

Singapore has many strong qualities that make it an attractive investment destination - robust regulations, a deep talent base and world-class infrastructure, among others. Government agencies such as Ipos, the Economic Development Board (EDB) and the National Research Foundation (NRF) have done much to create a nurturing environment for innovators. These efforts have set a strong foundation in place for Singapore to be a regional leader in both IP and biopharmaceutical innovation. A robust and competitive PTE framework may just be the key to unlocking the doors leading to the next wave of growth.

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