european biopharmaceutical enterprises

2 August 2018

EBE VIEW ON THE SPC MANUFACTURING WAIVER

What is a Supplementary Protection Certificate (SPC)?

The duration of a regular patent for a pharmaceutical product in the EU is 20 years from the date of approval of the patent and generally begins years before the product has reached the market. An SPC can extend this patent right for a maximum of five years to offset the loss of patent protection that occurs due to the lengthy time required for product development and obtaining regulatory marketing approval.

What is the SPC Manufacturing Waiver as proposed by the European Commission on 28 May 2018?

With a manufacturing waiver, generic and biosimilar drug makers can manufacture SPC-protected drugs in the EU to sell them in other non-SPC protected markets, and to prepare stocks for when the SPC expires.

Context

In today's environment of economic competition, accentuated by globalisation, Industrial Property in its various aspects (patents, trademarks, designs, trade secrets, licensing agreements…) is growing in importance. The challenges of IP for a company, even just in safeguarding the development of its activity or improving its position against competitors are very real, and are inevitably expressed in terms of market share and jobs. Large pharmaceutical companies are facing numerous patent expiries which is already benefiting generic manufacturers worldwide. The global generic and biosimilar drugs market is expected to grow at an annual growth rate of 10.5% from 2016 through 2020. In a recent report, it is estimated that the global generic drugs market will benefit from the patent expiry of drugs worth $150 billion by 2020 **(1)**. Generics and biosimilars could indeed represent 80% of the volume of medicines by 2020 **(2)**. The market trend is clearly in favour of generic companies.

The EU has many highly innovative SMEs for whom the ability to protect their innovation is crucial to maintaining their competitive edge. It is essential for the entire pharmaceutical ecosystem to closely work with SMEs as larger companies increasingly rely on them to secure their product pipelines. There is an awareness that the Unitary Patent and Unified Patent Court will simplify administration, reduce costs and provide greater legal certainty. Such benefits are seen as a potential tool for helping innovative SMEs. However, many SMEs still have only limited knowledge of IP and the impact it may have on their business. Indeed, smaller companies rarely make a proper use of intellectual property rights (IPRs). That is why specific SME incentives are urgently needed in order: 1) to limit the IP cost burden, 2) to improve specific resources and expertise, and 3) to maximise the value of their IP assets. The SPC manufacturing waiver appears as a negative signal from the EC.

Expected Impact of the SPC manufacturing waiver

The stated objective of an SPC manufacturing waiver for exports to countries outside the EU is to allow both the EU generic and biosimilar industries to create thousands of high-tech jobs in the EU and fuel the creation of numerous new companies. It is said that the waiver would improve the international competitiveness of EU-based generics & biosimilars manufacturers. While generics and biosimilars could represent 80% of the volume of medicines by 2020, between 54% and 70% of the active pharmaceutical ingredients market in Europe (depending on the member states) is supplied by India, China and Israel.

Whereas the European Commission stated that this waiver will: 1) help create growth and high-skilled jobs in the EU, and, 2) generate €1 billion net additional sales per year and up to 25.000 new jobs over

10 years, a study (3), commissioned by the pharmaceutical industry and the US Chamber of Commerce, is in direct opposition to the Commission's findings. The latter study finds that the implementation of an EU-wide SPC manufacturing and export exemption would potentially result in annual losses for the global innovative biopharmaceutical industry ranging of between €2.2bn and €4.5bn. Of these losses, up to €1.9bn concern the European innovative biopharmaceutical industry, mainly SMEs. The study also states that a manufacturing waiver would cause between 4,500 and 7,700 direct R&D job losses (with an additional 19,000-32,000 indirect job losses) and a decrease in R&D investment of between €215m and €364m (2).

During a first event held at the European Parliament held in September 2017, Ahmed Bouzidi, CEO of Vaxeal representing innovative SMEs, underlined his scepticism towards the positive impact of an SPC manufacturing waiver on manufacturing in Europe given that countries such as India and China have protectionist policies in place to prevent foreign companies from exporting to their countries. He also expressed concerns that such a waiver would lower investment in R&D for new drugs should the protection on the EU market be shortened as a result of the waiver.

Could the SPC manufacturing waiver really help boost exports (for example to China and India)?

In 2015, the Chinese pharmaceutical industry was valued at $108bn with 95 percent of drugs approved by the China Food and Drug Administration being generics. In April 2018, China chose to give preferential tax rates to local generic drug makers. The State Council said it would draw up new incentives aimed at encouraging the development and production of generic drugs, a move it said would help safeguard public health, reduce costs and spur innovation. The document published by the State Council said China would aim to create a system that encourages producers to copy "clinically necessary" drugs, including those in short supply and used to treat children, prevent major communicable diseases, or handle public health emergencies. Quality standards of drug materials and packing materials would be modified to promote new materials and new techniques, so that dependency on imports for some materials would end. Tax and price preferences would be offered, as well as incentives regarding basic healthcare insurance (4).

The Indian Pharmaceutical market (IPM) accounts for approximately 1.4% of the global pharmaceutical industry in value terms and 20% in the volume terms. Generic drugs are currently the highest earners within India's pharmaceutical landscape, accounting for 70% of market share by revenues. India is the largest global provider of generic drugs and exports to more than 200 countries.

Over the years, the Indian Government has initiated several attempts to promote the production of generics by local pharma companies. In April 2008, the Government launched the 'Jan Aushadhi Campaign', to provide quality generic medicines at lower prices than their counterpart branded drugs available on the market. In the 2016-2017 budgets, the Government set the goal of opening 3000 "Jan Aushadhi Stores" across the country (5).

Both China and India, as other countries, have anticipated the SPC manufacturing waiver with a number of locally aimed initiatives that clearly undermine its potential impact.

Expected Impact on EU-based Innovative SMEs

Strong patents are the lifeblood of the innovative biopharmaceutical industry. They are critical in ensuring a steady stream of capital to biopharmaceutical companies developing innovative medicines. And they are essential to the technology transfer process from inventions in the lab to products for patients. The majority of biopharmaceutical companies are SMEs that are at pre-profit stage (no marketed product), and thus their research and development activities rely on very large amounts of private sector investment over many years. Without an economic and institutional environment that is conducive to entrepreneurship and innovation including a strong, predictable and enforceable protection for patented inventions, investors will shy away from investing in biopharmaceutical innovation, reducing the ability of SMEs to provide solutions for the most pressing medical challenges facing Europe and the world. The setting up of the SPC regime in the 1990s in Europe gave the region a

boost in terms of increasing its attractiveness for investors and was considered a major step forward in terms of rewarding innovation and better valuing innovation and innovative SMEs in Europe.

For EU innovative SMEs, the ability to protect their innovation is crucial to maintaining their competitive edge. EBE feels very strongly that an SPC manufacturing waiver would create uncertainties in term of market potential for innovative biopharmaceutical SMEs, making it more difficult for them to access financing. In addition, allowing biosimilar companies to prepare stocks before the SPC expires will lead to a loss of sustained competitiveness for biopharmaceutical SMEs.

How will the SPC manufacturing waiver significantly impact exports from the EU?

The impact of exports will be very limited for a very limited time for generics and biosimilars manufacturers while third countries implement their generic policies. Pricing policies will still remain an issue. However, the waiver will have a direct and long-term negative impact on innovative SMEs because: 1) IP represents the main asset to value innovative SMEs, 2) the waiver will decrease the attractiveness of EU-based innovative SMEs, and 3) it will also decrease the value of innovative SMEs.

What positive economic and social impact do we expect from the SPC manufacturing waiver?

Such a manufacturing waiver would cause more direct and indirect job losses in innovative EU-based companies that it would create jobs in the generics industry during a very limited period of time. The uncertainty it would create would also directly negatively impact R&D investments in the EU.

EBE Concern

We believe that allowing generic and biosimilar drug makers to manufacture for export before the SPC expires would be unfair to EU biopharmaceutical companies and in particular to innovative SMEs. While the waiver will only have a very limited positive impact for the biosimilar and generic industry, it will be detrimental to the biopharmaceutical innovation in the EU on the long term. EBE requests that policy makers to consider its concern and stands ready to engage in a constructive dialogue on the issue.

REFERENCES

1- https://www.businesswire.com/news/home/20160616006037/en/Global-Generic-Drugs-Market-2016-2020---Patent, announcing the "Global Generic Drugs Market 2016-2020" report by Research and Markets (www.researchandmarkets.com)

2- Sarantis Michalopoulous, EURACTIV.com | 13 OCTOBER 2017; https://www.euractiv.com/section/health-consumers/news/new-commission-study-fuels-generic-drugs-industry-manufacturing-dispute/

3- http://www.pugatch-consilium.com/reports/Unintended_Consequences_October_%202017.pdf

4- Business News | 3 APRIL, 2018; https://www.reuters.com/article/us-china-drug-tax/china-gives-preferential-tax-rate-for-generic-drugmakers-idUSKCN1HA17E

5- Pharmacy & Pharmacology International Journal | 2 JUNE, 2017
Galani V (2017) Choice of Better Medicine in India: Branded Vs Generic Medicine. Pharm Pharmacol Int J 5(3): 00125. DOI: 10.15406/ppij.2017.05.00125
http://medcraveonline.com/PPIJ/PPIJ-05-00125.php

Authors:

[redacted]