Supplementary Protection Certificates in EU Legislation: The Access Challenge For Emerging States

By:

Theona Elizee

April 3, 2020

This essay addresses the interplay of patent protection for pharmaceutical products and access issues for emerging states. It identifies the challenge of finding the right balance between term extensions and generic access and recommends proactive measures. **[1]**

The Challenge

The right to health consists of four principles: availability; accessibility, acceptability and quality[2]. In addressing accessible matters, governments must ensure that the pillars of the Right to Health are met, thus it appears imperative that the main focus for governments would be to ensure an efficient system of utilising generics as an alternative to branded products.

A major cost factor is enshrined in the life cycle of a pharmaceutical product: from R&D to distribution significant amounts are expended even before the issue of regulatory delays and patenting costs are added, thus increasing the cost of bringing a drug to the market. For a generic drug to enter the market these steps are by-passed since they would have already been undertaken by the originator. However, generic companies are required to uphold the industry's tradition of quality, safety and efficacy.[3] Therefore, generics and originator products are authorised to the same standards of safety, quality and efficacy and generics are bioequivalent to the original product, which means they deliver equal medical benefits to the patient. Generic medicines are therefore interchangeable with the equivalent branded product as products are required to follow strict formulas and must adhere to all safety and efficacy regulations prior to marketing authorisation.

The importance of generics should not be understated and this is evident in the European Generics Association's conclusion that the economic benefits of generic medicines are purely based on the fact that generic medicines manufacturers also engage in innovation dedicating on average up to 17% of turnover invested in R&D; Generic medicines lead in pharmaceutical manufacturing in the Europe, while creating a multi-supplier market.[4]

EU-Supplementary Protection Certificates (SPC) Regulations of 1992 and 1996

Among the standards of novelty, inventive step, utility and enablement an invention is allowed, under TRIPS Term of Protection, 20 years of protection[5] from the filing date.[6] The legal entry to the market of a generic medicine is after the originator's patent has expired. However, originators maximise patent rules and impede activities associated with bringing drugs to the market sooner .[7]

The introduction of "Term Extensions"[8] in the EU creates a hurdle to generic manufacturers. SPCs confer a separate right that comes into effect immediately on patent expiry but confers, in relation to the relevant active ingredient authorized as a medical product the same rights as that conferred by the basic patent. It is also subject to the same limitations and the same obligations[9].

Approximately 1,650 SPC applications were filed in Member States in 2014 and 19,000 SPC between 1991 and 2014, confirming the importance for the pharmaceutical industry of this protection right.[10] The SPC has had the effect of prolonging the effective protection period by approximately 2.6 years for products where the SPC is the last IP protection scheme to expire. In effect, it delays the introduction of a generic product for up to five years, during that which time prices remain high. This presents a cost and availability issue for emerging states; particularly where there is little or no manufacturing, ultimately resulting in a longer wait for cheaper drugs or paying the higher prices for a longer period.

Making it work

Presently there is no international framework regulating schemes for access. Thus, each country produces its own schemes that takes into account the domestic pharmaceutical context, particularly innovation and capacity to manufacture. Funding of manufacturing presents an avenue for advancement. Increasing the value of spending on medicines and promoting better communication and dialogue between payers, policy, makers, pharmaceutical companies and the general public provides a huge leap towards improving access. However, emerging States are encouraged to, most importantly, conduct in-depth scrutiny of Trade Agreements with the EU.

Recently the EC-Canada Trade Agreement, (CETA)[11] saw the introduction of term extensions affecting pharmaceuticals. Prior to 2017, Canada did not utilize any form of extension. However, the new CSP provisions of the Patent Act and the Certificate of Supplementary Protection Regulations[12] involves: committing Canada to adopt a system of term restoration thereby delaying generic entry by up to 2 years; locking up Canada's current term of data protection and creating barriers for future governments wanting to reverse it; implementing a new right of appeal under the patent linkage system that will create further delays for generic entry.

It is estimated that CETA will increase Canada's drug cost by 6.2% to 12.9% in 2023.[13] The Parliamentary Budget Officer has conservatively estimated that the two-year patent term extension included in CETA will cost Canadians more $500 million annually.[14]

Thus, emerging States are urged to be more proactive in treaty making and the language contained therein. In essence, the inclusion of provisions to prevent misuse/ abuse of IPRs and anti-competitive practices in FTAs should be encouraged added to in-depth scrutiny of relevant IP provisions frequently found in TAs and/or that have been identified as bearing particular importance to the generic and biosimilar industries.

---

[1] Supplementary Protection Certificates are term extensions under EU, a sui generis system of added protection for pharmaceutical patents.

[2] (United Nations Covenant on Economic, Social and Cultural Rights, General Comment No.14 (2000), See also Article 12 of the International Convention on Economic, Social and Cultural Rights, 22nd Session. E/C. 12/2000/4, 11 August 2000: Paragraph 12.

[3] Source: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1 Source: EGA Internal survey 2014, IMS Institute (2015) – The role of generic medicines in sustaining healthcare systems: a European perspective.

[4] Source: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1 Source: EGA Internal survey 2014, IMS Institute (2015) – The role of generic medicines in sustaining healthcare systems: a European perspective.

[5] Article 33, Trade Related Aspects of Intellectual Property, TRIPs 1994- https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art33_jur.pdf

[6] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

[7] Novartis Case and Case C-74/03, SmithKline Beecham - https://books.google.co.uk/books?id=NEK8DAAAQBAJ&pg=PA240&lpg=PA240&dq=novarti

[8] Trevor Cook, Pharmaceuticals Biotechnology and the Law, Reed Elsevier (UK) Ltd, (2009), 576

[9] REGULATION (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) (Text with EEA relevance)

[10] European Commission's 2017 INCEPTION IMPACT ASSESSMENT - "Optimising the Internal Market's industrial property legal framework relating to supplementary protection certificates (SPC) and patent research exemptions for sectors whose products are subject to regulated market authorisations.", pg.5., accessed online via the EC website.@ 14th April 2019 @20:00 P.M.

[11] Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act (in force on September 21, 2017).

[12] Guidance Document: Certificate of Supplementary Protection Regulations Date adopted: 2017/09/21, Revised Date: 2018/06/26 Effective date: 2018/09/04

[13] Lexchin and Gagnon, "CETA and pharmaceuticals: The impact of the trade agreement between Europe and Canada on the cost of prescription drugs", Globalization and Health 2014, 10:30 http://www.globalizationandhealth.com/content/10/1/30

[14] The Canadian Generic Pharmaceutical Association (CGPA), News Release, October 1st 2018.

View online: Supplementary Protection Certificates in EU Legislation: The Access Challenge For Emerging States

Provided by Afronomicslaw