CODAIP XVI

3 de novembro de 2022

Desenvolvimento tecnológico e acesso universal a produtos de saúde: repensar o regime jurídico do direito de patente e os outros exclusivos industriais

J. P. REMÉDIO MARQUES

1. Introdução

Cinco grandes temas abrangentes podem ser identificados nesta complexa problemática. São eles:

A) Os acordos comerciais (divididos em TLCs da UE e aqueles que incluem os EUA);

B) O uso das flexibilidades do TRIPS (divididas em: licenciamento compulsório e importação paralela / esgotamento do direito de patente);

C) A expiração ou caducidade de patente/entrada de medicamentos genéricos no mercado / via genérica (referência a estudos comparativos e estudos de país único);

D) As políticas legislativas de patenteamento (também divididas em estudos comparativos e estudos de país único) e as regras TRIPS-*plus* (divididas em: exclusividade de dados, extensões de prazo do direito de patente e patentes secundárias);

E) As alternativas (complementares) ao direito de patente farmacêutica.

2. Licenciamento compulsório

3. Importações paralelas (de medicamentos e/ou ingredientes ativos)

4. Caducidade dos direitos de patente *versus* entrada de medicamentos genéricos no mercado

5. Estudos comparativos / políticas legislativas

6. Prazo de proteção dos dados (farmacológicos, toxicológicos, pré-clínicos e clínicos)

7. Extensão do prazo do direito de patente / certificado complementar de proteção

8. Estratégias de patenteamento destinadas a prolongar a vida das patentes dos medicamentos (e*vergreening*) – novos sais, ésteres, polimorfismos, segundas e subsequentes indicações terapêuticas, novas dosagens, novos auditórios de pacientes, etc.

9. Conflitos de interesses

10. Discussão dos resultados

11. Conclusões

12. Alternativas ao direito de patente

Bibliografia:

Amin, T./Kesselheim, AS., "Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades!, in: *Health Aff* (Millwood). 2012;31(10):2286-94.

Asif, M./Tasleem, S./Akram, M., "Access to medicine: induction of novel drugs in the post era of new patent regulation in Pakistan", in: *Biosci Res*. 2019;16(2):5.

Barlow P./McKee M./Basu S./Stuckler, D. "The health impact of trade and investment agreements: a quantitative systematic review and network co-citation Analysis", in: *Glob Health*. 2017;13(1):1-9.

Beall, RF./Hardcastle, L./Clement, F./Hollis, A., "How will recent trade agreements that extend market protections for brand-name prescription pharmaceuticals impact expenditures and generic access in Canada?", in: *Health Policy*. 2019;123(12):1251–8.

Berndt, E. R./Dubois, P., "Impacts of patent expiry on daily cost of pharmaceutical treatments in eight OECD countries, 2004-2010, in: *Int J Econ Bus*. 2016;23(2):125-47.

Bokhari, F. A. S./Fournier, G. M., "Entry in the ADHD drugs market: welfare impact of generics and me-too's", in: *J Ind Econ*. 2013;61(2):339–92.

Bollyky, TJ. A, "Dose of TPP's medicine: why U.S. trade deals have not exported U.S. drug prices (March 22, 2016)", Council on Foreign Relations Working Paper. Disponível no seguinte endereço: SSRN: https://ssrn.com/abstract=2755754.

Cockburn, I./Lanjouw, J. O./Schankerman, M., "Patents and the global diffusion of new drugs", in: *Am Econ Rev*. 2014;106(1):136-164.

Drahos, P., "Trust me": patent offices in developing countries", in: *Am J Law Med*. 2008;34(2-3):151-174.

Duggan, M./Garthwaite, C./Goyal, A., "The market impacts of pharmaceutical product patents in developing countries: evidence from India", in: *Am Econ Rev*. 2014;106(1):99–135.

Duso, T./Herr, A./Suppliet, M., "The welfare impact of parallel imports: a structural approach applied to the German market for oral anti-diabetics" Düsseldorf: DICE Discussion Paper, No. 137, Düsseldorf Institute for Competition Economics (DICE). 2014.

GERVAIS, Daniel, "The patent option", *North Carolina Journal of Law & Technology*. 2019; 20(3), pp. 357-403.

Hellerstein, R., "What do drug monopolies cost consumers in developing countries?", in: *Econ Lett*. 2012;116(1):108-111.

Hemphill, C. S./Sampat, B. N., "Evergreening, patent challenges, and effective market life in pharmaceuticals", in: *J Health Econ*. 2012;31(2):327-39.

Hill, A./Redd, C./Gotham, D./Erbacher, I./Meldrum, J./Harada, R., "Estimated generic prices of cancer medicines deemed cost-ineffective in England: a cost estimation Analysis", in: *British Medical Journal*, Open. 2017;7(1).

't Hoen, E. F./Veraldi, J./Toebe, B./Hogerzeil, H.V., "Medicine procurement and the use of flexibilities in the agreement on trade-related aspects of intellectual property rights, 2001–2016", in: *Bulletin of the World Health Organisation*. 2018;96(3):185, acessível em: https://pubmed.ncbi.nlm.nih.gov/29531417/

Islam MD/ Kaplan, WA/Trachtenberg, D./Thrasher R./Gallagher, KP./Wirtz, VJ., "Impacts of intellectual property provisions in trade treaties on access to medicine in low and middle income countries: a systematic Review", in: *Glob Health*. 2019;15(1):88.

Jung, Y./Kwon, S., "The effects of intellectual property rights on access to medicines and catastrophic expenditure", in: *Int J Health Serv*. 2015;45(3):507-529.

Kessomboon, N./Limpananont, J./Kulsomboon, V./Maleewong, U./ Eksaengsri, A./Paothong, P., "Impact on access to medicines from TRIPS-Plus: a case study of Thai-US FTA", in: *Southeast Asian J Trop Med Public Health*. 2010;41(3):667-677.

Lexchin, J., "Increase in drug spending in Canada due to extension of data protection for biologics: a descriptive study", in: *Healthc Policy*. 2019;14(3):10.

Lexchin, J./Gagnon, MA., "CETA and pharmaceuticals: impact of the trade agreement between Europe and Canada on the costs of prescription drugs", in: *Glob Health*. 2014;10:30.

Marques, J. P. Remédio, *Licenças (Voluntárias e Obrigatórias) de Direitos de Propriedade Industrial*. Coimbra: Almedina. 2008.

Marques, J. P. Remédio, *Biotecnologia(s) e Propriedade Intelectual*. 2 vols. Coimbra: Almedina. 2007.

Marques, J. P. Remédio, *Patentes versus Medicamentos*. Coimbra: Coimbra Editora. 2008.

Marques, J. P. Remédio, "Pandemias e epidemias: Reequacionar o regime jurídico do licenciamento obrigatório do direito de patente", in: *Revista de Direito Industrial*. 2021(2):139-176.

Marques, J. P. Remédio, "São os direitos de propriedade industrial úteis para a nossa saúde? A articulação entre o direito de patente e a regulação farmacêutica perante as epidemias e as pandemias", in: *Revista de Direito* Intelectual. 2020(2):121-158.

Marques, J. P. Remédio, "Biotechnological Patents, Compulsory Licensing and SARS-COV-2 in a Pandemic and Epidemic Context", in: Garcia, Maria da Glória / Cortês, António (org.), *Blue Planet Law - The Ecology of our Economic and Technological WorldSpringer's*. Sustainable Development Goals Series, Springer Nature. 2022.

Mohara, A./Yamabhai, I./Chaisiri K./Tantivess, S./Teerawattananon, Y., "Impact of the introduction of government use licenses on the drug expenditure on seven medicines in Thailand", in: *Value Health*. 2012;15(1 Suppl):S95–9.

Moir, HVJ./Tenni, B./Gleeson, D./Lopert, R., "The Trans Pacific Partnership Agreement and access to HIV treatment in Vietnam", in: *Glob Public Health.* 2018;13(4):400–13. Disponível em: https://doi.org/10.1080/17441692.2016.1256418

Morton, F. M. S./Stern, A. D./Stern, S., "The impact of the entry of biosimilars: evidence from Europe", in: *Rev Ind Organ*. 2018;53(1):173-210.

Ramani, SV./Urias, E., "When access to drugs meets catch-up: Insights from the use of CL threats to improve access to ARV drugs in Brazil", in: *Res Policy*, Elsevier. 2018;47(8):1538–52.

Scopel, C.T./Chaves, G. C., "Initiatives to challenge patent barriers and their relationship with the price of medicines procured by the Brazilian Unified National Health System", in: *Cadernos de Saúde Publica*. 2016;32(11):12.

Son, K. B./Lee, T. J., "Compulsory licensing of pharmaceuticals reconsidered: Current situation and implications for access to medicines", in: *Glob Public Health*. 2017. https://doi.org/10.1080/17441692.2017.1407811.

Thrasher, R. D./Wirtz, V. J./Kaplan, W./Gallagher, K. P./Werk, H., *Rethinking trade treaties and access to medicines by the working group on trade, investment treaties, and access to medicines*. Boston: Boston University, 2019.

Watal, J./Dai, R., *Product patents and access to innovative medicines in a post TRIPS era*. 2019. Disponível em: SSRN 3394851.