

# Bibliografía

- Abbott, F. M. (2016), "Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health", *UC Irvine Law Review* 6(3): 281-320.
- Abbott, F. M. y Correa, C. M. (2007), "World Trade Organization Accession Agreements: Intellectual Property Issues", FSU College of Law, Law, Business and Economics Paper, Ginebra: Quaker United Nations Office.
- Abbott, F.M. y Reichman, J.H. (2007), "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions", *Journal of International Economic Law* 10(4): 921-87.
- Aboy, M., Crespo, C., Liddell, K., Liddicoat, J. y Jordan, M. (2018), "Was the *Myriad* decision a surgical strike on isolated DNA patents, or does it have wider impacts?", *Nature Biotechnology* 36: 1146-1149.
- Adlung, R. (2009), "Services Liberalization from a WTO/GATS Perspective: In Search of Volunteers", Staff Working Paper ERSD-2009-05, Ginebra: OMC.
- Adlung, R. (2010), "Trade in healthcare and health insurance services: WTO/GATS as a supporting actor(?)", *Intereconomics* 45(4): 227-238.
- African Union, "African Union Ministers of Health adopt treaty for the establishment of the African Medicines Agency Treaty to be submitted to the Specialised Technical Committee on Justice and Legal Affairs later on this year", comunicado de prensa, 20 de mayo de 2018, disponible en: <https://au.int/en/pressreleases/20180520/african-union-ministers-health-adopt-treaty-establishment-african-medicines>.
- Aitken, M. y Kleinrock, M. (2017), *Lifetime Trends in Biopharmaceutical Innovation: Recent Evidence and Implications*, Parsippany (Nueva Jersey): IQVIA Institute for Human Data Science.
- Albrecht, B., Menu, P., Tsao, J. y Webster, K. (2016), "The next wave of innovation in oncology", McKinsey & Company, disponible en: <https://www.mckinsey.com/~media/McKinsey/Industries/Healthcare%20Systems%20and%20Services/Our%20Insights/The%20next%20wave%20of%20innovation%20in%20oncology/The-next-wave-of-innovation-in-oncology.ashx>.
- Ali, F., Rajagopal, S., Mustafa, M. y Prabhu, C. (2017), "Rejected in India: What the Indian Patent Office Got Right on Pharmaceuticals Patent Applications (2009-2016)", disponible en: <https://www.accessibsa.org/media/2017/12/Rejected-in-India.pdf>.
- Allee, T. y Peinhardt, C. (2011), "Contingent Credibility: The Impact of Investment Treaty Violations on Foreign Direct Investment", *International Organization Journal* 65(3): 401-432.
- Amanam, I. U., Gardner, A. B., Young-Lin, N. y Chan, J. K. (2016), "The increase in FDA-approved novel cancer drugs over the last 5 years: What factors are involved?", *Journal of Clinical Oncology* 34(15): e14111.
- Anderson, R. (2014), "Pharmaceutical industry gets high on fat profits", *BBC News*, versión en línea, 6 de noviembre de 2014, disponible en: <https://www.bbc.com/news/business-28212223>.
- Anderson, R. D., Kovacic, W. E. y Müller, A. C. (2011), "Ensuring Integrity and Competition in Public Procurement Markets: A Dual Challenge for Good Governance", en Arrowsmith, S. y Anderson, R. D. (eds.), *The WTO Regime on Government Procurement: Challenge and Reform*, Cambridge: Cambridge University Press.
- Anderson, R. D., Kovacic, W. E., Müller, A. C. y Sporysheva, N. (2018), "Competition Policy, Trade and the Global Economy: Existing WTO Elements, Commitments in Regional Trade Agreements, Current Challenges and Issues for Reflection", Staff Working Paper ERSD 2018-12, Ginebra: OMC.
- Anderson, R. D., Müller, A. C. y Pelletier, P. (2016), "Regional Trade Agreements and Procurement Rules: Facilitators or Hindrances?", se publicó una versión en *Robert Schuman Centre for Advanced Studies (RSCAS) Research Paper No. RSCAS 2015/81*, diciembre de 2015.
- Anderson, R. D., Pires de Carvalho, N. y Taubman, A. (eds.) (2020), *Competition Policy and Intellectual Property in Today's Global Economy*, Cambridge: Cambridge University Press.
- Aranze, J. (2017), "Italian court upholds Aspen excessive pricing decision", *Global Competition Review*, 3 de agosto de 2017, disponible en: <https://globalcompetitionreview.com/article/1145288/italian-court-upholds-aspen-excessive-pricing-decision>.
- Årdal, C., Findlay, D., Savic, M., et al. (2018), "Revitalizing the antibiotic pipeline: Stimulating innovation while driving sustainable use and global access", disponible en: <http://drive-ab.eu/wp-content/uploads/2018/01/DRIVE-AB-Final-Report-Jan2018.pdf>.
- Armstrong, I. (2019), "Immunotherapy patents: Why CAR-T is driving up patent activity", *World Intellectual Property Review*, versión en línea, 17 de septiembre de 2019.
- Association de lutte contre le SIDA (2018), *Diagnosis and monitoring of hepatitis C (HCV) in Morocco: Current Status and strategies for universal access*, disponible en: <https://www.alcs.ma/1282-diagnosis-and-monitoring-of-hepatitis-c-hcv-in-morocco>.
- Avorn, J. (2015), "The \$2.6 billion pill – Methodologic and policy considerations", *New England Journal of Medicine* 372: 1877-1879.
- Baghdadi-Sabeti, G. y Serhan, F. (2010), "WHO Good Governance for Medicines programme: an innovative approach to prevent corruption in the pharmaceutical sector", World Health Report (2010) Background Paper 25, Ginebra: OMS.
- Bagley, N., Chandra, A., Garthwaite, C. y Stern, A.D. (2018), "It's Time to Reform the Orphan Drug Act", *NEJM Catalyst*, 19 de diciembre de 2018.
- Balasegaram, M., Kolb, P., McKew, J., Menon, J., Olliaro, P., Sablinski, T., et al. (2017), "An open source pharma roadmap", *PLoS Medicine* 14(4): e1002276.
- Ball, D. (2011), "The Regulation of Mark-ups in the Pharmaceutical Supply Chain", WHO/HAI Project on Medicine Prices and Availability, Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper 3, Ginebra: OMSy HAI.
- Banco Mundial (2005), *A Guide to Competitive Vouchers in Health*, Washington D.C.: Banco Mundial.
- Banco Mundial (2009), "Europe and Central Asia: Health Insurance and Competition", Report No. 44316-ECA, Washington D.C.: Banco Mundial.

- Batson, A. (2016), "Global vaccine market". "Global Vaccine and Immunization Research Forum". Marzo de 2016, disponible en: [https://www.who.int/immunization/research/forums\\_and\\_initiatives/1\\_ABatson\\_Global\\_Vaccine\\_Market\\_gvirf16.pdf](https://www.who.int/immunization/research/forums_and_initiatives/1_ABatson_Global_Vaccine_Market_gvirf16.pdf).
- Beall, R. F. y Attaran, A. (2016), Global Challenges Report: Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines, Ginebra: OMSI.
- Beall, R. F. y Kesselheim, A. S. (2018), "Tertiary patenting on drug-device combination products in the United States", *Nature Biotechnology* 36: 142-145.
- Beall, R. F., Darrow, J. J. y Kesselheim, A. S. (2019), "Patent term restoration for top-selling drugs in the United States", *Drug Discovery Today* 24(1): 20-25.
- Beall, R. F., Nickerson, J. W., Kaplan, W. A. y Attaran, A. (2016), "Is patent 'evergreening' restricting access to medicine/device combination products?", *PLoS ONE* 11(2): e0148939.
- Ben-Ayre, E., Schiff, E., Hassan, E., Mutafoglu, K., Lev-Ari, S., Steiner, M. et al. (2012), "Integrative oncology in the Middle East: From traditional herbal knowledge to contemporary cancer care", *Annals of Oncology* 23(1): 211-221.
- Bennett, M. R. (1999), "One hundred years of adrenaline: The discovery of autoreceptors", *Clinical Autonomic Research* 9(3): 145-159.
- Beran, D., Ewen, M. and Laing, R. (2016), "Constraints and challenges in access to insulin: A global perspective", *The Lancet Diabetes and Endocrinology* 4(3): 275-285.
- Berndt, E. y Aitken, M. (2011), "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation," *International Journal of the Economics of Business* 18(2): 177-201.
- Bertram, M. Y., Lauer, J. A., De Joncheere, K., Edejer, T., Hutubessy, R. Kieny, M.-P. et al. (2016), "Cost-effectiveness thresholds: Pros and cons", *Bulletin of the World Health Organization* 94(12): 925-930.
- Beyer, P. (2012), "Developing Socially Responsible Intellectual Property Licensing Policies: Non-Exclusive Licensing Initiatives in the Pharmaceutical Sector", en de Werra, J. (ed.), *La propriété intellectuelle dans l'industrie pharmaceutique: Intellectual Property in the Pharmaceutical Industry*, Ginebra: Schulthess Verlag.
- Black, L. L. (2017), "Patenting and protecting personalized medicine innovation post-Mayo, Myriad, and Limelight", *North Carolina Law Review* 95(2): 493-522.
- Blackstone, E. A. and Fuhr, J. P. (2013), "The economics of biosimilars", *American Health & Drug Benefits* 6(8): 469-478.
- Bloom, N., Jones, C. I., Van Reenen, J. y Webb, M. (2017), "Are Ideas Getting Harder to Find?", Working Paper No. 23782, Cambridge (Massachusetts): National Bureau of Economic Research (NBER).
- Bond, R. S. y Lean, D. F. (1977), "Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets: Staff Report to the Federal Trade Commission", Washington D.C.: Federal Trade Commission.
- Bosco, J. y Chance, K. (2013), "Biosimilars: Stakeholders' Changing Expectations and the Role of Real-World Evidence", presentación en línea, Quintiles.
- Bowers, S. y Cohen, D. (2018), "How lobbying blocked European safety checks for dangerous medical implants", *BMJ* 363: k4999.
- Brazil, R. (2018), "Navigating Drug Discovery with High-Throughput Screening", *Drug Discovery*, versión en línea, 21 de febrero de 2018, disponible en: <https://www.technologynetworks.com/drug-discovery/articles/navigating-drug-discovery-with-high-throughput-screening-297350>.
- Bregonje, M. (2005), "Patents: A unique source for scientific technical information in chemistry related industry?", *World Patent Information* 27(4): 309-315.
- Brett, A. S. (2010), "Spotlight on colchicine: The Colcris controversy", *NEJM Journal Watch*.
- Brigden, G., Castro, J. L., Ditiu, L., Gray, G., Hanna, D., Low, M. et al. (2017), "Tuberculosis and antimicrobial resistance – new models of research and development needed", *Bulletin of the World Health Organization* 95(5): 315.
- Brigden G., Hewison, C. y Varaine, F. (2015), "New developments in the treatment of drug-resistant tuberculosis: clinical utility of bedaquiline and delamanid", *Infection and Drug Resistance* 8: 367-378.
- Bud, R. (2008), "Upheaval in the moral economy of science? Patenting, teamwork and the World War II experience of penicillin", *History and Technology* 24: 173-190.
- Budish, E., Roin, B. N. y Williams, H. (2015), "Do firms underinvest in long-term research? Evidence from cancer clinical trials", *American Economic Review* 105(7): 2044-2085.
- Cameron, A. y Laing, R. (2010), "Cost Savings of Switching Private Sector Consumption from Originator Brand Medicines to Generic Equivalents", *World Health Report* (2010), Background Paper No. 35, Ginebra: OMS.
- Cameron, A., Ewen, N., Ross-Degnan, D., Ball, D. y Laing, R. (2009), "Medicine prices, availability, and affordability in 36 developing and middle-income countries: A secondary analysis", *The Lancet* 373(9659): 240-249.
- Cameron, A., Roubos, I., Ewen, M., Mantel-Teeuwisse, A. K., Leufkens, H. G. M. y Laing, R. O. (2011), "Differences in the availability of medicines for chronic and acute conditions in the public and private sectors of developing countries", *Bulletin of the World Health Organization* 89(6): 412-421.
- Campaign for Access to Essential Medicines (2011), *Untangling the Web of Antiretroviral Price Reductions*, 14<sup>a</sup> ed., Ginebra: Médicos Sin Fronteras.
- Capra International Ltd (2016), *Comprehensive Evaluation of the Implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Corporate evaluation commissioned by the WHO Evaluation Office*, Cumberland (Ontario): Capra International y OMS.
- Caro de Sousa, P. (2019), "Excessive Pricing in Pharmaceutical Markets", *Competition Policy International*, versión en línea, 20 de enero de 2019, disponible en: <https://www.competitionpolicyinternational.com/excessive-pricing-in-pharmaceutical-markets/>.
- Cassier, M. y Sinding C. (2008), "Patenting in the public interest: administration of insulin patents by the University of Toronto", *History and Technology* 24(2): 153-171.
- Cassini et al. (2019), "Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015:

- a population-level modelling analysis", *The Lancet Infectious Diseases* 19(1): 56-66, disponible en: [http://dx.doi.org/10.1016/S1473-3099\(18\)30605-4](http://dx.doi.org/10.1016/S1473-3099(18)30605-4).
- de Chadarevian, S. (2011), "The Making of an Entrepreneurial Science: Biotechnology in Britain, 1975-1995", *Isis* 102(4): 601-633.
- Chakradhar, S. y Khamsi, R. (2017), "Angst about exclusivity: The potential cost of incentivizing makers of generic drugs", *Nature Medicine* 23(10): 1114-1116.
- Chandrasekharan, S., Amin, T., Kim, J., Furrer, E., et al. "Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing-country vaccine manufacturers", *Vaccine* 33(46): 6366-6370.
- Chapman, N., Doubell, A., Oversteegen, L., Chowdhary, V., Rugarabamu, G., Zanetti, R. et al. (2017), *G-FINDER 2017: Neglected Disease Research and Development: Reflecting on a Decade of Global Investment*, Sydney: Policy Cures Research.
- Chaudhuri, S., Goldberg, P. K. y Jia, P. (2006), "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India", *American Economic Review* 96(5): 1477-1514.
- Cheever, M. A. y Higano, C. S. (2011), "PROVENGE (Sipuleucel-T) in Prostate Cancer: The First FDA-Approved Therapeutic Cancer Vaccine", *Clinical Cancer Research* 17: 3520-3526.
- Cherny, N., Sullivan, R., Torode, J., Saar, M. y Eniu, A. (2016), "ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe", *Annals of Oncology* 27(8): 1423-1443.
- Cherny, N. I., Dafni, U., Bogaerts, J., Latino, N. J., Pentheroudakis, G., Douillard, J.-Y. et al. (2017), "ESMO-Magnitude of Clinical Benefit Scale version 1.1", *Annals of Oncology* 28: 2340-2366.
- Cherny, N. I., Sullivan, R., Torode, J., Saar, M. y Eniu, A. (2017), "ESMO International Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in countries outside of Europe", *Annals of Oncology* 28(11): 2633-2647.
- Chien, C. (2003), "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?", *Berkeley Technology Law Journal* 18(3): 853-907.
- Chopra, R. y Lopes, G. (2017), "Improving access to cancer treatments: The role of biosimilars", *Journal of Global Oncology* 3(5): 596-610.
- Christie, A. F., Dent, C., McIntyre, P., Wilson, L., et al. (2013), "Patents Associated with High-Cost Drugs in Australia", *PLoS ONE* 8(4): e60812, disponible en: <https://doi.org/10.1371/journal.pone.0060812>.
- Cleary, E. G., Beierlein, J. M., Khanuja, N. S., McNamee, L. M. y Ledley, F. D. (2018), "Contribution of NIH funding to new drug approvals 2010-2016". *Proceedings of the National Academy of Sciences of the United States of America* 115(10): 2329-2334.
- Clendinen, C., Zhang, Y., Warburton, R. N., y Light, D. W. (2016), "Manufacturing costs of HPV vaccines for developing countries", *Vaccine* 34(48): 5984-5989.
- Cockburn, I. M. (2006), "Is the Pharmaceutical Industry in a Productivity Crisis?", en Jaffe, A. B., Lerner, J. y Stern, S. (eds.), *Innovation Policy and the Economy*, volumen 7, Cambridge (Massachusetts): National Bureau of Economic Research (NBER).
- Cockburn, I. M., Lanjouw, J. O. y Schankerman, M. (2016), "Patents and the global diffusion of new drugs", *American Economic Review* 106(1): 136-164.
- Cohen, J. (2017), "New CRISPR tool can detect tiny amounts of viruses", *Science*, versión en línea, 13 de abril de 2017.
- Cohen, W. M., Nelson, R. R. y Walsh, J. P. (2000), "Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not)", Working Paper No. 7552, Cambridge (Massachusetts): National Bureau of Economic Research (NBER).
- Coller, B.G., Blue, J., Das, R., et al. (2017), "Clinical development of a recombinant Ebola vaccine in the midst of an unprecedented epidemic", *Vaccine* 35: 4465-4469.
- Comanor, W. S. (1986), "The political economy of the pharmaceutical industry", *Journal of Economic Literature* 24(3): 1178-1217.
- Comanor, W. S. (2013), "The political economy of the pharmaceutical industry", *Journal of Economic Literature* 32(1): 106-113.
- Commission on Health Research for Development (1990), *Health Research: Essential Link to Equity in Development*, Oxford: Oxford University Press.
- Comisión de Derechos de Propiedad Intelectual, Innovación y Salud Pública (CIPIH) (2006), *Salud pública, innovación y derechos de propiedad intelectual: informe de la Comisión de Derechos de Propiedad Intelectual, Innovación y Salud Pública*, Ginebra: OMS.
- Comisión Europea (2009a), "Comunicación de la Comisión: Resumen analítico del Informe de investigación sectorial sobre el sector farmacéutico", disponible en: [https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_es.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_es.pdf).
- Comisión Europea (2009b), *Pharmaceutical Sector Inquiry: Final Report. Adoption date: 8 July 2009*, disponible, en dos partes, en: <https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>.
- Comisión Europea (2014a), "German company wins EU's €2 million inducement prize for innovative vaccine technology", comunicado de prensa, 10 de marzo de 2014, disponible en: [https://europa.eu/rapid/press-release\\_IP-14-229\\_en.htm?locale=EN](https://europa.eu/rapid/press-release_IP-14-229_en.htm?locale=EN).
- Comisión Europea (2014b), "Medical Countermeasures That Could Be Procured in Common Under the Joint Procurement Agreement", disponible en: [https://ec.europa.eu/health/sites/health/files/preparedness\\_response/docs/jpa\\_note\\_scope\\_en.pdf](https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_note_scope_en.pdf).
- Comisión Europea (2017), "Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines", comunicado de prensa, 15 de mayo de 2017, disponible en: [http://europa.eu/rapid/press-release\\_IP-17-1323\\_en.htm](http://europa.eu/rapid/press-release_IP-17-1323_en.htm).
- Comisión Europea (2018a), *Innovative Payment Models for High-cost Innovative Medicines: Report of the Expert Panel on Effective Ways of Investing in Health (EXPH)*, Luxemburgo: Oficina de Publicaciones de la Unión Europea.
- Comisión Europea (2018b), *EU R&D Scoreboard: The 2018 EU Industrial R&D Investment Scoreboard*, Luxemburgo: Oficina de Publicaciones de la Unión Europea.
- Comisión Europea (2019a), *Aplicación de las leyes de competencia en el sector farmacéutico (2009-2017): Colaboración entre las autoridades europeas de competencia en favor de unos*

*medicamentos asequibles e innovadores*, Luxemburgo: Oficina de Publicaciones de la Unión Europea.

Comisión Europea (2019b), *Report on the EU Customs Enforcement of Intellectual Property Rights: Results at the EU Border 2018*, Luxemburgo: Oficina de Publicaciones de la Unión Europea.

Comisión Europea, Organización Panamericana de la Salud y Organización Mundial de la Salud (OMS) (2015), *Experiencia cubana en la producción local de medicamentos, transferencia de tecnología y mejoramiento en el acceso a la salud*, Ginebra: OMS.

Conferencia de las Naciones Unidas sobre Comercio y Desarrollo (UNCTAD) (2015a), *Model law on competition*, disponible en: <http://unctad.org/en/Pages/DITC/CompetitionLaw/The-Model-Law-on-Competition.aspx>.

Conferencia de las Naciones Unidas sobre Comercio y Desarrollo (UNCTAD) (2015b), "El papel de la competencia en el sector farmacéutico y sus beneficios para los consumidores", TD/RBP/CONF.8/3.

Conley, J. M., Cook-Deegan, R. y Lázaro-Muñoz, G. (2014), "Myriad after Myriad: The proprietary data dilemma", *North Carolina Journal of Law and Technology* 15(4): 597-637.

Conner-Simons, A. (2017), "Using artificial intelligence to improve early breast cancer detection", *MIT News*, versión en línea, 16 de octubre de 2017.

Contreras, J. L. y Sherkow, J. S. (2017), "CRISPR, surrogate licensing, and scientific discovery", *Science* 355(6326): 698-700.

Copenhagen Economics (2018), *Study on the Economic Impact of Supplementary Protection Certificates, Pharmaceutical Incentives and Rewards in Europe: Final Report*, Bruselas: Comisión Europea.

Cornell University, INSEAD y OMPI (2019), *Global Innovation Index 2019: Creating Healthy Lives – The Future of Medical Innovation*, 12ª edición, Dutto, S., Lanvin, B. y Wunsch-Vincent, S. (eds.), Ithaca (Nueva York), Fontainebleau y Ginebra: Cornell University, INSEAD y OMPI.

Cornish, W., Llewelyn, D. y Aplin, T. (2019), *Intellectual Property: Patents, Copyright, Trademarks & Allied Rights*, 4ª edición, Londres: Sweet and Maxwell.

Correa, C. (2007), *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective: A Working Paper*, Ginebra: ICTSD, OMS y UNCTAD.

Correa, C. M. (2004), "Implementation of the WTO General Council Decision on Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health", *Health Economics and Drugs Series* N° 016, Ginebra: OMS.

Correa, C. M. (2016), *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*, Nueva York: Programa de las Naciones Unidas para el Desarrollo (PNUD).

Costa Chaves, B., Gaspar Britto, W. y Fogaça Vieira, M. (2017), *MERCOSUR-EU Free Trade Agreement: Impact Analysis of TRIPS-Plus Measures Proposed by the EU on Public Purchases and Domestic Production of HIV and Hepatitis C Medicines in Brazil*, disponible en: <https://www.accessibsa.org/media/2018/01/Mercosur-EU-Free-Trade-Agreement-HIV-Hepatitis-C.pdf>.

Cotropia, C. A. (2008), "Compulsory Licensing Under TRIPS and the Supreme Court of the United States' Decision in eBay v.

MercExchange", en Takenaka, T. y Moufang, R. (eds.), *Patent Law: A Handbook of Contemporary Research*, Edward Elgar Publishing Co., disponible en: <https://ssrn.com/abstract=1086142>.

Council for International Organizations of Medical Sciences (CIOMS) (2016), *Pautas éticas internacionales para la investigación relacionada con la salud con seres humanos*, Ginebra: CIOMS.

Creese, A. (2011), "Sales Taxes on Medicines", WHO/HAI Project on Medicine Prices and Availability, Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper 5, Ginebra: OMS y HAI.

Cross, R. W., Mire, C. E., Feldmann, H. y Geisbert, T. W. (2018), "Post-exposure treatments for Ebola and Marburg virus infections", *Nature Reviews Drug Discovery* 17: 413-434.

Crow, D. (2017), "Scientists shrug off failures in hunt for Alzheimer's treatments", *Financial Times*, versión en línea, 26 de noviembre de 2017, disponible en: <https://www.ft.com/content/8d0db012-cda0-11e7-b781-794ce08b24dc>.

Crowe, K. (2017), "Provinces spent \$43M on preemie drug experts say can be made for a fraction of the cost", *CBC News*, versión en línea, 7 de abril de 2017.

Daniel, M. G., Pawlik, T. M., Fader, A. N., Esnaola, N. F. y Makary, M. A. (2016), "The Orphan Drug Act: Restoring the mission to rare diseases", *American Journal of Clinical Oncology* 39(2): 210-213.

Danzon, P. M., Mulcahy, A. W. y Towse, A. K. (2015), "Pharmaceutical pricing in emerging markets: Effects of income, competition, and procurement", *Health Economics* 24(2): 238-252.

Daulaire, N., Bang, A., Tomson, G., Kalyango, J. N. y Cars, O. (2015), "Universal access to effective antibiotics is essential for tackling antibiotic resistance", *Journal of Law, Medicine & Ethics* 43(3): 17-21.

Davis, C., Naci, H., Gurpinar, E., Poplavska, E., Pinto, A. y Aggarwal, A. (2017), "Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: Retrospective cohort study of drug approvals 2009-13", *BMJ* 359: j4530.

Deak, D., Outtersson, K., Powers, J. H. y Kesselheim, A. S. (2016), "Progress in the fight against multidrug-resistant bacteria? A review of U.S. Food and Drug Administration-approved antibiotics, 2010-2015", *Annals of Internal Medicine* 165(5): 363-372.

Deloitte (2018), *2018 Global Life Sciences Outlook: Innovating Life Sciences In the Fourth Industrial Revolution: Embrace, Build, Grow*, disponible en: <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-ls-outlook-2018.pdf>.

Deloitte (2019), *2019 Global life sciences outlook: Focus and transform: Accelerating change in life sciences*, disponible en: <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-ls-outlook-2019.pdf>.

Deloitte Centre for Health Solutions (2018), *Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018*, Londres: Deloitte.

Diependaele, L., Cockbain, J. y Sterckx, S. (2017), "Raising the barriers to access to medicines in the developing world – the relentless push for data exclusivity", *Developing World Bioethics* 17(1): 11-21.

- DiMasi, J. A., Grabowski, H. G. y Hansen, R.W. (2016), "Innovation in the pharmaceutical industry: New estimates of R&D costs", *Journal of Health Economics* 47: 20-33.
- DiMasi, J. A., Hansen, R. W. y Grabowski, H. G. (2003), "The price of innovation: New estimates of drug development costs", *Journal of Health Economics* 22: 151-185.
- DiMasi, J. A., Hansen, R. W., Grabowski, H. G. y Lasagna, L. (1991), "Cost of innovation in the pharmaceutical industry", *Journal of Health Economics* 10(2): 107-142.
- Dong, J. y Mirza, Z. (2016), "Supporting the production of pharmaceuticals in Africa", *Bulletin of the World Health Organization* 94: 71-72.
- Dora, S., Khanna, D., Luo, Y., Poon, L. y Schweizer, C. (2017), "Medtech May Be Emerging Markets' Next New Thing", Boston Consulting Group, disponible en: <https://www.bcg.com/en-ch/publications/2017/globalization-medical-devices-technology-medtech-may-be-emerging-markets-next-new-thing.aspx>.
- Dreyfuss, R. C., Nielsen, J. y Nicol, D. (2018), "Patenting nature-a comparative perspective", *Journal of Law and the Biosciences* 5(3): 550-589.
- Driehaus, J. (2012), "Patent Landscape in Molecular Diagnostics", en Storz, U., Flasche, W., and Driehaus, J. (eds.), *Intellectual Property Issues*, Berlin, Heidelberg: Springer: 73-106.
- Drugs for Neglected Diseases initiative (DNDi) (2014), *An Innovative Approach to R&D for Neglected Patients: Ten Years of Experience & Lessons Learned by DNDi*, Ginebra: DNDi.
- Drugs for Neglected Diseases initiative (DNDi) (2019), *15 Years of Needs-Driven Innovation for Access: Key Lessons, Challenges, and Opportunities for the Future*, Ginebra: DNDi.
- Duggan, M. y Goyal, A. (2012), "Pharmaceutical Patents and Prices: A Preliminary Empirical Assessment Using Data from India", Policy Research Working Paper No. 6063, Washington D.C.: Banco Mundial.
- Ederigton, J. y Rutta, M. (2016), "Non-Tariff Measures and the World Trading System," World Bank Policy Research Working Paper, disponible en: <http://documents.worldbank.org/curated/en/882991467989523068/pdf/WPS7661.pdf>.
- Elks, S. (2018), "Drug buyers' clubs aim to tackle HIV prevention 'crisis'", *Thomson Reuters Foundation News*, 3 de diciembre de 2018, disponible en: <http://news.trust.org/item/20181130235707-qho8y/>.
- Espin, J., Rovira, J. y Olry de Labry, A. (2011), "External Reference Pricing", WHO/HAI Project on Medicine Prices and Availability, Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper 1, Ginebra: OMS y HAI.
- European Federation of Pharmaceutical Industries and Association (EFPIA) (2017), *The Pharmaceutical Industry in Figures, Key Data 2017*, disponible en: [https://www.efpia.eu/media/219735/efpia-pharmafigures2017\\_statisticbroch\\_v04-final.pdf](https://www.efpia.eu/media/219735/efpia-pharmafigures2017_statisticbroch_v04-final.pdf).
- EvaluatePharma [anual], *World Preview*, Londres: Evaluate.
- EvaluatePharma, *World Preview 2013, Outlook to 2018: Returning to Growth*, disponible en: [https://info.evaluategroup.com/worldpreview2018\\_fp\\_ip.html](https://info.evaluategroup.com/worldpreview2018_fp_ip.html).
- EvaluatePharma (2018a), *Orphan Drug Report 2018*, 5ª edición, Londres: Evaluate.
- EvaluatePharma (2018b), *World Preview 2018, Outlook to 2024*, disponible en: <https://www.evaluate.com/thought-leadership/pharma/evaluatepharma-world-preview-2018-outlook-2024#download>.
- Ewen, M., Joosse, H-J, Beran, D. y Laing, R. (2019), "Insulin prices, availability and affordability in 13 low-income and middle-income countries", *BMJ Global Health* 4(3): e001410.
- Eyquem, J., Mansilla-Soto J., Giavridis, T., van der Stegen, S. J., Hamieh, M., Cunanan, K. M. et al. (2017), "Targeting a CAR to the TRAC locus with CRISPR/Cas9 enhances tumour rejection", *Nature* 543(7643): 113-117.
- Ferreira, R., David, F. y Nielsen, J. (2018), "Advancing biotechnology with CRISPR/Cas9: Recent applications and patent landscape", *Journal of Industrial Microbiology & Biotechnology* 45(7): 467-480.
- Fink, C. (2011), "Intellectual Property Rights", en Chauffour, J.-P. and Maur, J.-C. (eds.), *Preferential Trade Agreement Policies for Development: A Handbook*, Washington D.C.: Banco Mundial.
- Flynn, S. M., Hollis, A. y Palmedo, M. (2009), "An economic justification for open access to essential medicine patents in developing countries", *Journal of Law, Medicine and Ethics* 37(2): 184-208.
- Fojo, T., Mailankody, S. y Lo, A. (2014), "Unintended consequences of expensive cancer therapeutics-the pursuit of marginal indications and a me-too mentality that stifles innovation and creativity: The John Conley Lecture", *JAMA Otolaryngology – Head & Neck Surgery* 140(12):1225-1236.
- Fondo Internacional de Emergencia de las Naciones Unidas para la Infancia (UNICEF) (2019), *Human Papillomavirus Vaccine: Supply and Demand Update*, diciembre de 2019, disponible en: <https://www.unicef.org/supply/media/501/file/humanpapillomavirusHPVvaccinesupplyanddemandupdate.pdf>.
- da Fonseca, E. M., Shadlen, K. y Bastos, F. I. (2019), "Brazil's fight against hepatitis C: Universalism, local production, and patents", *New England Journal of Medicine* 380: 605-607.
- Fontein, C., Akker, I. y Sauter, W. (2018), "Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse", ACM Working Paper, disponible en: <http://eplaw.org/wp-content/uploads/2018/03/ACM-working-paper-dominance-and-patented-pharmaceuticals.pdf>.
- "Forging paths to improve diabetes care in low-income settings" (2017), editorial, *The Lancet Diabetes & Endocrinology* 5(8): 565.
- Friede, M., Palkonyay, L., Alfonso, C., Pervikov, Y, et al. (2011), "WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: supporting developing country production capacity through technology transfer", *Vaccine* 29 suplemento 1:A2-7.
- Frost, L. J. y Reich, M. R. (2010), *Access: How Do Good Health Technologies Get to Poor People in Poor Countries?*, Cambridge (Massachusetts): Harvard Center for Population and Development Studies.
- Fry, A. (2012), "Insulin Delivery Device Technology 2012: Where Are We After 90 Years?", *Journal of Diabetes Science and Technology* 6(4): 947-953.
- Gaessler, F. y Wagner, S. (2018), "Patents, Data Exclusivity and the Development of New Drugs", versión preliminar elaborada para la Undécima Conferencia Anual del Searle Centre y la USPTO sobre Economía de la Innovación. Trabajo en curso, 3 de junio de 2018.

- Gainey, L. (2018), "How the EPO treats personalised healthcare patents", *Life Sciences Intellectual Property Review*, versión en línea, 12 de octubre de 2018.
- Gammie, T., Lu, C. Y., y Babar Z. U. (2015), "Access to Orphan Drugs: A Comprehensive Review of Legislations, Regulations and Policies in 35 Countries", *PLoS ONE*, 9 de octubre de 2015; 10: e0140002.
- Gapper, J. (2019), "Keytruda shows the high price of curing cancer", *Financial Times*, versión en línea, 13 de febrero de 2019, <https://www.ft.com/content/c1dacca6-2ec2-11e9-ba00-0251022932c8>.
- Garner, S., Rintoul, A. y Hill, S. R. (2018), "Value-based pricing: L'enfant terrible?", *Pharmacoeconomics* 36(1): 5-6.
- Garrido, M. V., Kristensen, F. B., Nielsen, C. P. y Busse, R. (2008), *Health Technology Assessment and Health Policy-Making in Europe: Current Status, Challenges and Potential*, Observatory Studies Series No. 14, Ginebra: OMS para el Observatorio Europeo sobre los Sistemas y las Políticas de Salud.
- Gaudillière, J. (2008), "How pharmaceuticals became patentable: the production and appropriation of drugs in the twentieth century", *History and Technology*, 24: 99-106.
- Gavi (2018), *Advance Market Commitment for Pneumococcal Vaccines, Annual Report 1 January – 31 December 2018*, disponible en: <https://www.gavi.org/investing/innovative-financing/pneumococcal-amc/>.
- Gavi (2019), "How We Work Together: Quick start guide for new members of the Vaccine Alliance", disponible en: <https://www.gavi.org/library/publications/gavi/how-we-work-together/>.
- GE Healthcare (2011), "Market-relevant design: Making ECGs available across India", *The Pulse on Health, Science & Tech*, 30 de septiembre de 2011.
- Geis, J. R., Brady, A., Wu, C. C., Spencer, J., Kohli, M., Ranschaert, E. et al. (2019), "Ethics of AI in Radiology: European and North American Multisociety Statement".
- Generics and Biosimilars Initiative (GaBI) (2018a), "Guidelines for biosimilars around the world", *GaBI Online*, 13 de abril de 2018.
- Generics and Biosimilars Initiative (GaBI) (2018b), "'Similar biologics' approved and marketed in India", *GaBI Online*, 15 de febrero de 2018.
- Giannuzzi, V., Conte, R., Landi, A., Ottomano, S. A., Bonifazi, D., Baiardi, P. et al. (2017), "Orphan medicinal products in Europe and United States to cover needs of patients with rare diseases: An increased common effort is to be foreseen", *Orphanet Journal of Rare Diseases* 12(1): 64.
- Gilbert, R. (2019), "Competition, mergers and R&D diversity", *Review of Industrial Organization* 54(3): 465-484.
- Gillmore Valenzuela, I. y Santos Ossa Rogat, J., "Protección y exclusividad de datos de prueba de productos farmacéuticos en Chile", disponible en: <https://revistas.uchile.cl/index.php/RDE/article/download/47370/49414/>.
- GlaxoSmithKline (2019a), "GSK announces availability of Authorized Generic Albuterol Sulfate Inhaler for treatment or prevention of bronchospasm", comunicado de prensa, disponible en: <https://us.gsk.com/en-us/products/ventolin-authorized-generic-statement/>.
- GlaxoSmithKline (2019b), "GSK grants exclusive technology license for clinical-stage Ebola vaccines to Sabin Vaccine Institute", comunicado de prensa, disponible en: <https://www.gsk.com/en-gb/media/press-releases/gsk-grants-exclusive-technology-license-for-clinical-stage-ebola-vaccines-to-sabin-vaccine-institute/>.
- Fondo Mundial (2010), *Improving Value for Money in Global Fund-Supported Programs*, Ginebra: Fondo Mundial.
- Fondo Mundial (2018), *Guide to Global Fund Policies on Procurement and Supply Management of Health Products*, Ginebra: Fondo Mundial.
- Goldacre, B., DeVito, N. J., Heneghan, C., Irving, F., Bacon, S., Fleminger, J. et al. (2018), "Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource", *BMJ* 362: k3218.
- Goldman, D. P., Lakdawalla, D. N., Malkin, J. D., Romley, J. y T. Philipson (2011), "The benefits from giving makers of conventional 'small molecule' drugs longer exclusivity over clinical trial data", *Health Affairs* 30(1): 84-90.
- Gómez-Dantés, O., Wirtz, V. J., Reich, M. R., Terrazas, P. et al. (2012), "Nueva entidad para negociar los precios de adquisición pública de los medicamentos patentados en México", *Bulletin of the World Health Organization* 90: 788-792, disponible en: <https://www.who.int/bulletin/volumes/90/10/12-106633-ab/es/>.
- Gordon, R. J. (2018), "Why Has Economic Growth Slowed When Innovation Appears to be Accelerating?", Working Paper No. 24554, Cambridge (Massachusetts): National Bureau of Economic Research (NBER).
- Gornall, J., Hoey, A. y Ozieranski, P. (2016), "A pill too hard to swallow: how the NHS is limiting access to high priced drugs", *BMJ* 354: i4117.
- Gotham, D., Barber, M. J. y Hill, A. (2018), "Production costs and potential prices for biosimilars of human insulin and insulin analogues", *BMJ Global Health* 3(5): e000850.
- Grabowski, H. G. y Kyle, M. (2007), "Generic competition and market exclusivity periods in pharmaceuticals", *Managerial and Decision Economics* 28(4-5): 491-502.
- Greene, J. A. (2010), "When did medicines become essential?", *Bulletin of the World Health Organization* 88(7): 483.
- Griliches, Z. (1994), "Productivity, R&D, and the data constraint", *The American Economic Review* 84(1): 1-23.
- Grohmann, G., Francis, D. P., Sokhey, J. y Robertson, J. (2016), "Challenges and successes for the grantees and the Technical Advisory Group of WHO's influenza vaccine technology transfer initiative", *Vaccine*, 34(45): 5420-5424.
- Gross, N. J. (2007), "Albuterol inhalers", *New England Journal of Medicine* 356(26): respuesta del autor 2749.
- Grössmann N, Del Paggio JC, Wolf S, et al. (2017), "Five years of EMA-approved systemic cancer therapies for solid tumours—a comparison of two thresholds for meaningful clinical benefit", *European Journal of Cancer* 82: 66-71.
- Guebert, J. M. y Bubela, T. (2014), "Implementing socially responsible licensing for global health: Beyond neglected diseases", *Science Translational Medicine* 6(260): 260cm11.
- Gupta, R., Shah, N. D. y Ross J. S. (2016), "The Rising Price of Naloxone-Risks to Efforts to Stem Overdose Deaths", *The New*

- England Journal of Medicine*, 375:2213-2215, disponible en: <http://www.nejm.org/doi/full/10.1056/NEJMp1609578#t=article>.
- Gupta, R., Shah, N. D. y Ross J. S. (2019), "Generic Drugs in the United States: Policies to Address Pricing and Competition", *Clinical Pharmacology & Therapeutics* 105: 329-337.
- Harrer, S., Shah, P., Antony, B. y Hu, J. (2019), "Artificial Intelligence for clinical trial design", *Trends in Pharmacological Sciences* 40(8): 577-591.
- Hawkins, L. (2011), "Competition Policy", WHO/HAI Project on Medicine Prices and Availability, Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper 4, Ginebra: OMS y HAI.
- Henao-Restrepo, A. M., Camacho, A., Longini, I. M., Watson, C. H., Edmunds, J., Egger, M. *et al.* (2017), "Efficacy and effectiveness of an rVSV-vectored vaccine in preventing Ebola virus disease: final results from the Guinea ring vaccination, open-label, cluster-randomised trial (Ebola Ça Suffit!)", *The Lancet* 389(10068): 505-518.
- Herbert, M. (2018), "Enabling Innovation: SME-driven Pharmaceutical and Life Science Market Growth", UK-CPI, disponible en: <https://www.uk-cpi.com/blog/enabling-innovation-sme-driven-pharmaceutical-and-life-science-market-growth>.
- Herper, M. (2012), "The truly staggering cost of inventing new drugs", *Forbes*, versión en línea, 10 de febrero de 2012.
- High-Level Panel on Access to Health Technologies (UNHLP) (2016), *Informe del Grupo de Alto Nivel del Secretario General de las Naciones Unidas sobre el Acceso a los Medicamentos: Promover la innovación y el acceso a las tecnologías de la salud*, Nueva York: UNHLP.
- Hill, A., Simmons, B., Gotham, D. y Fortunak, J. (2016), "Rapid reductions in prices for generic sofosbuvir and daclatasvir to treat hepatitis C", *Journal of Virus Eradication* 2(1): 28-31.
- Hill, A. M., Barber, M. J. y Gotham, D. (2018), "Estimated costs of production and potential prices for the WHO Essential Medicines List", *BMJ Global Health* 3: e000571.
- HM Revenue & Customs (2016), *Policy paper. Vaccine research relief: expiry in 2017*, disponible en: <https://www.gov.uk/government/publications/vaccine-research-relief-expiry-in-2017/vaccine-research-relief-expiry-in-2017>.
- 't Hoen, E., Berger, J., Calmy, A., Moon, S. (2011), "Driving a decade of change: HIV/AIDS, patents and access to medicines for all", *Journal of the International AIDS Society* 14: 15.
- 't Hoen, E. F. M. (2009), *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, Diemen, Países Bajos: AMB Publishers.
- 't Hoen, E. F. M. (2014), *Access to Cancer Treatment: A Study of Medicine Pricing Issues with Recommendations for Improving Access to Cancer Medication: A Report Prepared for Oxfam*.
- 't Hoen, E. F. M., Boulet, P., Baker, B. K. (2017), "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation", *Journal of Pharmaceutical Policy and Practice* 10:19.
- 't Hoen, E. F. M., Veraldi, J., Toebes, B. y Hogerzeil, H. V. (2018), "La adquisición de medicamentos y el uso de las flexibilidades recogidas en el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio, de 2001 a 2016", *Bulletin of the World Health Organization* 96: 185-193.
- Hogarth, S., Hopkins, M. M. y Rodriguez, V. (2012), "A molecular monopoly? HPV testing, the Pap smear and the molecularisation of cervical cancer screening in the USA", *Sociology of Health & Illness* 34(2): 234-250.
- Hogerzeil, H. V. y Mirza, Z. (2011), *The World Medicines Situation 2011: Access to Essential Medicines as Part of the Right to Health*, Ginebra: OMS.
- Hogerzeil, H. V., Samson, M., Casanovas, J. V. y Rahmani-Ocora, L. (2006), "Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?", *The Lancet* 368(9532): 305-311.
- Holloway, K. y van Dijk, L. (2011), *The World Medicines Situation 2011: Rational Use of Medicines*, Ginebra: OMS.
- Holman, C. M. (2014), "Mayo, Myriad, and the future of innovation in molecular diagnostics and personalized medicine", *North Carolina Journal of Law & Technology* 15(4): 639-678.
- Hopkins, M. M. y Hogarth, S. (2012), "Biomarker patents for diagnostics: problem or solution?", *Nature Biotechnology* 30(6): 498-500.
- Hughes, D.A., Poletti-Hughes, J. (2016) "Profitability and Market Value of Orphan Drug Companies: A Retrospective, Propensity-Matched Case-Control Study", *PLoS ONE* 11(10): e0164681.
- Husereau, D. y Cameron, C. (2011), "Value-Based Pricing of Pharmaceuticals in Canada: Opportunities to Expand the Role of Health Technology", CHSRF Series of Reports on Cost Drivers and Health System Efficiency, Paper No. 5, Ottawa: Canadian Health Services Research Foundation (CHSRF).
- IFPMA (2013), "Pharmaceutical R&D Projects to Discover Cures for Patients with Neglected Conditions: 2012 status report on pharmaceutical R&D to address diseases that disproportionately affect people in low- and middle-income countries", Ginebra: IFPMA, disponible en: [https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA\\_R\\_D\\_Status\\_Report\\_Neglected\\_Conditions.pdf](https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_R_D_Status_Report_Neglected_Conditions.pdf).
- IFPMA (2017), "Doing our part: innovating to fight neglected tropical diseases", Ginebra: IFPMA, disponible en: [https://www.ifpma.org/wp-content/uploads/2017/04/IFPMA\\_Innovating\\_to\\_Fight\\_NTDs\\_April2017\\_FINAL.pdf](https://www.ifpma.org/wp-content/uploads/2017/04/IFPMA_Innovating_to_Fight_NTDs_April2017_FINAL.pdf).
- Immelt, J.R., Govindarajan, V. y Trimble, C. (2009), "How GE is disrupting itself", *Harvard Business Review*, versión en línea, octubre de 2009.
- Interagency Coordination Group on Antimicrobial Resistance (IACG) (2018), "Antimicrobial resistance: Invest in innovation and research, and boost R&D and access, IACG discussion paper", junio de 2018, disponible en: [https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG\\_AMR\\_Invest\\_innovation\\_research\\_boost\\_RD\\_and\\_access\\_110618.pdf?ua=1](https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_AMR_Invest_innovation_research_boost_RD_and_access_110618.pdf?ua=1).
- Interagency Coordination Group on Antimicrobial Resistance (IACG) (2019), *No podemos esperar: Asegurar el futuro contra las infecciones fármacorresistentes. Informe para el Secretario General de las Naciones Unidas*.

- International Diabetes Federation (2016), *Access to Medicines and Supplies for People with Diabetes: A Global Survey on Patients' and Health Professionals' Perspective*, disponible en: <https://www.idf.org/component/attachments/?task=download&id=1965>.
- Ivanovska, V., Rademaker, C. M. A., van Dijk, L., Mantel-Teeuwisse, A. K. (2014), "Pediatric drug formulations: A review of challenges and progress", *Pediatrics* 134(2): 361-372.
- Iyengar, S., Tay-Teo, K., Vogler, S., Beyer, P., Wiktor, S., de Joncheere, K. *et al.* (2016), "Prices, costs, and affordability of new medicines for Hepatitis C in 30 countries: An economic analysis", *PLOS Medicine* 13(5): e1002032.
- Jamison, D. T., Summers, L. H., Alleyne, G., Arrow, K. J., Berkley, S., Binagwaho, A. *et al.* (2013), "Global health 2035: A world converging within a generation", *The Lancet* 382: 1898-1955.
- Jaspers, L., Colpani, V., Chaker, L., van der Lee, S. J., Muka, T., Imo, D. *et al.* (2015), "The global impact of non-communicable diseases on households and impoverishment: A systematic review", *European Journal of Epidemiology* 30(3): 163-188.
- Jayasundara, K., Hollis, A., Krahn, M., Mamdani, M., Hoch, J. S. y Grootendorst, P. (2019), "Estimating the clinical cost of drug development for orphan versus non-orphan drugs", *Orphanet Journal of Rare Diseases* 14: 12.
- Jena, A. B., Ho, O., Goldman, D. P. and Karaca-Mandic, P. (2015), "The impact of the US Food and Drug Administration chlorofluorocarbon ban on out-of-pocket costs and use of Albuterol inhalers among individuals with asthma", *JAMA Internal Medicine* 175(7): 1171-1179.
- Jenner, A., Bhagwandin, N. y Kowalski, S. (2017), *Antimicrobial Resistance (AMR) and Multidrug Resistance (MDR): Overview of current approaches, consortia and intellectual property issues*, Ginebra: OMPI.
- Jewell, C. y Balakrishnan, V. S. (2017), "La batalla jurídica por la titularidad de los derechos sobre la herramienta de edición del genoma CRISPR-Cas9", *Revista de la OMPI* 2, versión en línea, abril de 2017.
- de Jongh, T., Radauer, A., Bostyn, S. y Poort, J. (2018), *Effects of supplementary protection mechanisms for pharmaceutical products: Final report, May 2018*, Ámsterdam: Technopolis Group.
- Jürgens, B. y Clarke, N. S. (2019), "Evolution of CAR T-cell immunotherapy in terms of patenting activity", *Nature Biotechnology* 37: 370-375.
- Kahn, J. y Lauerman, J. (2018), "Google taking over health records raises patient privacy fears", *Bloomberg*, versión en línea, 21 de noviembre de 2018.
- Kaltenboeck, A. y Bach, P. B. (2018), "Value-based pricing for drugs: Theme and variations", *JAMA* 319(21): 2165-2166.
- Kampf, R. (2015), "Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation", Staff Working Paper ERSD-2015-07, Ginebra: OMC.
- Kaplan, W. A. y Beall, R. F. (2016), "The global intellectual property ecosystem for insulin and its public health implications: An observational study", *Journal of Pharmaceutical Policy and Practice* 10: 3.
- Kartikeyan, S., Bharmal, R. N., Tiwari, R. P. y Bisen, P. S. (2007), *HIV and AIDS: Basic elements and priorities*, Dordrecht: Springer, 2007.
- Kesselheim, A. S. (2010) "Using market-exclusivity incentives to promote pharmaceutical innovation", *New England Journal of Medicine* 363: 1855-1862.
- Kesselheim, A. S., Misono, A. S., Shrank, W. H., Greene, J. A., Doherty, M., Avorn, J. *et al.* (2013), "Variations in pill appearance of antiepileptic drugs and the risk of nonadherence", *JAMA Internal Medicine* 173(3): 202-208.
- Kesselheim, A. S. y Solomon, D. H. (2010), "Incentives for drug development-the curious case of colchicine", *New England Journal of Medicine* 362: 2045-2047.
- Khor, M. (2007), *Patents, Compulsory Licences and Access to Medicines: Some Recent Experiences*, TWN Intellectual Property Series 10, Penang (Malasia): Third World Network (TWN).
- Kim, C. y Prasad, V. (2015), "Cancer drugs approved on the basis of a surrogate end point and subsequent overall survival: An analysis of 5 years of US Food and Drug Administration approvals", *JAMA Internal Medicine* 359: 1992-1994.
- King, D. R. y Kanavos, P. (2002), "Encouraging the use of generic medicines: Implications for transition economies", *Croatian Medical Journal* 43(4): 462-69.
- Kittittrakul, C. (2018a), exposición realizada en el foro Academic Forum on Lessons Learned of Drug Patents' Opposition and Withdrawal in Thailand, celebrado en la Facultad de Ciencias Farmacéuticas de la Universidad Chulalongkorn, 18 de mayo de 2018.
- Kittittrakul, C. (2018b), exposición realizada en la reunión "Civil Society Organizations' Meeting on Hepatitis C: Emerging Evidences and Scaling-up Response", Bangkok, 6 y 7 de junio de 2018.
- Kmietowicz, Z. (2015a), "Campaigners demand right to generic version of breast cancer drug", *BMJ* 351: h5279.
- Kmietowicz, Z. (2015b), "China rejects patent on hepatitis C drug sofosbuvir", *BMJ* 350: h3429.
- Kneller, R. (2010), "The importance of new companies for drug discovery: Origins of a decade of new drugs", *Nature Reviews Drug Discovery* 9: 867-882.
- Kohli, M. y Geis, R. (2018), "Ethics, Artificial Intelligence, and Radiology", *Journal of the American College of Radiology* 15(9): 1317-1319.
- Kolata, G. (1991), "Patients Going Underground to Buy Experimental Drugs", *New York Times*, sección A, p. 1, disponible en: <https://www.nytimes.com/1991/11/04/us/patients-going-underground-to-buy-experimental-drugs.html?searchResultPosition=22>.
- de Kraker, M.E.A., Stewardson, A.J. y Harbarth, S. (2016), "Will 10 million people die a year due to antimicrobial resistance by 2050?", *PLoS Medicine* 13(11): e1002184.
- Krasovec, K. y Connor, C. (1998), *Using Tax Relief to Support Public Health Goals*, Partners for Health Reformplus.
- Krattiger, A. (2007a), "Freedom to Operate, Public Sector Research, and Product-Development Partnerships, Strategies, and Risk-Management Options", en Krattiger, A. *et al.* (eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Oxford y Davis (California): Centre for the Management of Intellectual Property in Health Research and Development (MIHR) y Public Intellectual Property Resource for Agriculture (PIPRA): 1317-1327.

- Krattiger, A. (2007b), "The Use of Nonassertion Covenants: A Tool to Facilitate Humanitarian Licensing, Manage Liability, and Foster Global Access", en Krattiger, A. *et al.* (eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Oxford y Davis (California): Centre for the Management of Intellectual Property in Health Research and Development (MIHR) y Public Intellectual Property Resource for Agriculture (PIPRA): 739-745.
- Krattiger, A., Bombelles, T., Bartels, H. G., Mirza, Z., Beyer, P., Taubman, A. *et al.* (2015), "Promoting Medical Innovation and Access Together: Trilateral Cooperation between WHO, WIPO and WTO", *Global Challenges Brief on Trilateral Cooperation*, Ginebra: OMPI.
- Kulkarni, P.S., Socquet, M., Jadhav, S.S., Kapre, S.V., LaForce, F.M. y Poonawalla, C.S. (2015), "Challenges and Opportunities While Developing a Group A Meningococcal Conjugate Vaccine Within a Product Development Partnership: A Manufacturer's Perspective from the Serum Institute of India", *Clinical Infectious Diseases* 61: S483-S488.
- Kwon, D. (2019), "A brief guide to the current CRISPR landscape", *The Scientist*, versión en línea, 15 de julio de 2019.
- Kyle, M. y Qian, Y. (2014), "Intellectual Property Rights and Access to Innovation: Evidence from TRIPS", Working Paper No. 20799, Cambridge (Massachusetts): National Bureau of Economic Research (NBER).
- LaMattina, J. L. (2011), "The impact of mergers on pharmaceutical R&D", *Nature Reviews Drug Discovery* 10: 559-560.
- LaMattina, J. L. (2015), "FDA approvals 1996 vs. 2014: The two most prolific years, but stark differences", *Forbes*, versión en línea, 7 de enero de 2015.
- Lander, E., Baylis, F., Zhang, F., Charpentier, E., Berg, P. *et al.* (2019), "Adopt a moratorium on heritable genome editing", *Nature*, versión en línea, 13 de marzo de 2019.
- Langreth, R. (2019), "Alzheimer's Drug Failure Leaves Scientists Seeking New Direction", *Bloomberg*, versión en línea, 22 de marzo de 2019, disponible en: <https://www.bloomberg.com/news/articles/2019-03-22/alzheimer-s-drug-fails-and-scientists-ask-is-it-time-to-move-on>.
- Lanjouw, J. O. (2005), "Patents, Price Control, and Access to New Drugs: How Policy Affects Global Market Entry", Working Paper No. 11321, Cambridge (Massachusetts): National Bureau of Economic Research (NBER).
- Laustsen, A. H., Johansen, K. H., Engmark, M. y Andersen, M. R. (2017), "Recombinant snakebite antivenoms: A cost-competitive solution to a neglected tropical disease?" *PLoS Neglected Tropical Diseases* 11(2): e0005361.
- Laxminarayan, R., Matsoso, P., Pant, S., Brower, C., Røttingen, J.-A., Klugman, K. *et al.* (2016), "Access to effective antimicrobials: A worldwide challenge", *The Lancet* 387(10014):168-175.
- Lesser, N. y Hefner, M. (2017), "R&D partnerships – Partnering for progress: How collaborations are fuelling biomedical advances", *Drug Development*, versión en línea, noviembre-diciembre de 2017.
- Leucht, S., Helfer, B., Gartlehner, G. y Davis, J. M. (2015), "How effective are common medications: A perspective based on meta-analyses of major drugs", *BMC Medicine* 13: 253.
- Levin, R. C., Klevorick, A. K., Nelson, R. R. y Winter, S. G. (1987), "Appropriating the Returns from Industrial Research and Development", *Brookings Papers on Economic Activity* 3: 783-831.
- Lexchin, J. (2012), "International comparison of assessments of pharmaceutical innovation", *Health Policy* 105(2-3): 221-225.
- Lichtenberg, F. (2012), "Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-Income Countries, 2000-2009", Working Paper No. 18235, Cambridge (Massachusetts): National Bureau of Economic Research (NBER).
- Lloyd, M. (2013), "Evergreening by whom? A review of secondary patents for omeprazole", *Pharmaceutical Patent Analyst* 2(6), disponible en: <http://www.future-science.com/doi/abs/10.4155/ppa.13.57>.
- Lock, H. (2019), "Fight the fakes: how to beat the \$200bn medicine counterfeiters", *The Guardian*, 5 de junio de 2019.
- Long, G. (2017), *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development*, Boston (Massachusetts): Analysis Group.
- Love, J. (2003), "Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines", Washington D.C.: Consumer Project on Technology.
- Lunze, A. (2019), "No compulsory licence for Sanofi's Praluent in Germany", disponible en: <https://united-kingdom.taylorwessing.com/synapse/ti-sanofi-licence.html>.
- Luo, J. y Kesselheim, A. S. (2015) "Evolution of insulin patents and market exclusivities in the USA", *The Lancet Diabetes & Endocrinology* 3(11): 835-837.
- Mackey, T. K. y Liang, B. A. (2012), "Patent and exclusivity status of essential medicines for non-communicable disease", *PLoS ONE* 7(11): e51022.
- Madian, A. G., Wheeler, H. E., Jones, R. B. y Dolan, M. E. (2012), "Relating human genetic variation to variation in drug responses", *Trends in Genetics* 28(10): 487-495.
- Magrini, N., Robertson, J., Forte, G., Cappello, B., Moja, L. P., de Joncheere, K. *et al.* (2015), "Tough decisions on essential medicines in 2015", *Bulletin of the World Health Organization* 93: 283-284.
- Maistat, L., Kravchenko, N. y Reddy, A. (2017), "Hepatitis C in Eastern Europe and Central Asia: a survey of epidemiology, treatment access and civil society activity in eleven countries", *Hepatology, Medicine and Policy* 2:9. DOI: 100.1186/s41124-017-0026-z.
- Makin, S. (2018), "The amyloid hypothesis on trial", *Nature*; 559: S4-7.
- Malerba, F. y Orsenigo, L. (2015), "The evolution of the pharmaceutical industry", *Business History* 57(5): 664-687.
- Management Sciences for Health (MSH) (2012), *MDS-3: Managing Access to Medicines and Health Technologies*, Arlington (VA): MSH.
- Mandel, G. N. (2006), "The generic biologics debate: Industry's unintended admission that biotech patents fail enablement", *Virginia Journal of Law & Technology* 11(8).
- Maniadakis, N., Holtorf, A.-P., Otávio Corrêa, J. O., Gialama, F. y Wijaya, K. (2018), *Applied Health Economics and Health Policy* 16(5): 591-607.
- Mansfield, E. (1986), "Patents and innovation: An empirical study", *Management Science* 32(2): 173-181.
- Marks, L. V. (2015), *The Lock and Key of Medicine: Monoclonal Antibodies and the Transformation of Healthcare*. New Haven: Yale University Press.

- Marshall, A. D., Cunningham, E. B., Nielsen, S., Aghemo, A., *et al.* (2018), "Restrictions for reimbursement of interferon-free direct-acting antiviral drugs for HCV infection in Europe", *The Lancet Gastroenterology & Hepatology* 3(2): 125-133.
- Martin-Laffon, J., Kuntz, M. y Ricroch, A. E. (2019), "Worldwide CRISPR patent landscape shows strong geographical biases", *Nature Biotechnology* 37: 613-620.
- Martinez, C. (2010), "Insight into Different Types of Patent Families", *OECD Science, Technology and Industry Working Papers*, N° 2010/02, Paris: OECD Publishing.
- Masini, T., Hauser, J., Kuwana, R., Nhat Linh, N. y Jaramillo, E. (2018), "Will regulatory issues continue to be a major barrier to access to bedaquiline and delamanid?" *European Respiratory Journal* 51(3): 1702480.
- Masum, H. y Harris, R. (2011), *Open Source for Neglected Disease: Magic Bullet or Mirage?*, Washington D.C.: Results for Development Institute.
- Matthijs, G. y van Ommen, G.-J. B. (2009), "Gene Patents: From Discovery to Invention. A Geneticist's View", en Van Overwalle, G. (ed.), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, Cambridge (Reino Unido): Cambridge University Press.
- Maurer, S. (2007), "Open source drug discovery: Finding a niche (or maybe several)", *UMKC Law Review* 76(2): 405-435.
- McConaghie, A. (2019), "Orkambi row: government now considering Crown Use licensing", *PMLive*, 20 de junio de 2019, disponible en: [http://www.pmlive.com/pharma\\_news/orkambi\\_row\\_government\\_says\\_now\\_considering\\_crown\\_licensing\\_1290525](http://www.pmlive.com/pharma_news/orkambi_row_government_says_now_considering_crown_licensing_1290525).
- McDonald, S. A., Mohamed, R., Dahlui, M., Nanning, H., *et al.* (2014), "Bridging the data gaps in the epidemiology of hepatitis C virus infection in Malaysia using multi-parameter evidence synthesis", *BMC Infectious Diseases* 14(564). DOI: 10.1186/s12879-014-0564-6.
- Médicos Sin Fronteras (MSF) (2016), "MSF launches challenge to Pfizer's patent on the pneumonia vaccine in India to increase access to more affordable versions", disponible en: <https://www.msf.org/access-msf-launches-challenge-pfizers-patent-pneumonia-vaccine-india-increase-access-more>.
- Médicos Sin Fronteras (MSF) (2018), "A fair shot for affordable pneumonia vaccine: Why overcoming patent barriers to PCV13 is vital for saving children's lives?", *Rinsho Hyoka (Clinical Evaluation)* 46(2): W45-W48, disponible en: [http://cont.o.oo7.jp/46\\_2/w45-w48.pdf](http://cont.o.oo7.jp/46_2/w45-w48.pdf).
- Megget, K. (2018), "Novartis exit from antibiotics a setback for race against resistance", *Chemistry World*, disponible en: <https://www.chemistryworld.com/news/novartis-exit-from-antibiotics-a-setback-for-race-against-resistance/3009316.article>.
- Merges, R. P. y Mattioli, M. (2017), "Measuring the costs and benefits of patent pools", *Ohio State Law Journal* 78(2): 281-347.
- Miller, J. (2018), "Novartis's pricing might be tested with costly eye therapy", *Reuters*, versión en línea, 23 de noviembre de 2018, disponible en: <https://www.reuters.com/article/us-novartis-luxturna/novartiss-pricing-might-be-tested-with-costly-eye-therapy-idUSKCN1NSOFM>.
- Miller, K. L. y Lanthier, M. (2018), "Investigating the landscape of US orphan product approvals", *Orphanet Journal of Rare Diseases* 13: 183.
- Miller, S. y Hicks G. N. (2015), "Investor-State Dispute Settlement: A Reality Check", Center for Strategic and International Studies, disponible en: [https://csis-prod.s3.amazonaws.com/s3fs-public/legacy\\_files/files/publication/150116\\_Miller\\_InvestorStateDispute\\_Web.pdf](https://csis-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/150116_Miller_InvestorStateDispute_Web.pdf).
- Mirza, Z. (2008), "Thirty years of essential medicines in primary health care", *Eastern Mediterranean Health Journal* 14 (supl.): S74-S81.
- Mohara, A., Yamabhai, I., Chaisiri, K., Tantivess, S. y Teerawattananon, Y. (2012), "Impact of the introduction of government use licenses on the drug expenditure on seven medicines in Thailand", *Value in Health* 15(1, supl.): S95-S99.
- Mok, K. (2018), "IBM combines AI and blockchain to identify counterfeits", *The New Stack*, 22 de junio de 2018.
- Mongan, A.-M. (2018), "Tech Giants Tackle Health Care: An Opportunity or Threat for the Pharmaceutical Industry", *Clinical Trials Arena*, versión en línea, 7 de agosto de 2018, disponible en: <https://www.clinicaltrialsarena.com/comment/tech-giants-tackle-health-care-opportunity-threat-pharmaceutical-industry/>.
- Moon, S. (2011), *Pharmaceutical Production and Related Technology Transfer*, Ginebra: OMS.
- Moon, S. y Erickson, E. (2019), "Universal medicine access through lump-sum remuneration-Australia's approach to Hepatitis C", *The New England Journal of Medicine* 380: 607-610.
- Moran, M., Ropars, A.-L., Guzman, J., Diaz, J. y Garrison, C. (2005), *The New Landscape of Neglected Disease Drug Development*, Londres: The Wellcome Trust.
- Morgan, S., Grootendorst, P., Lexchin, J., Cunningham, C. y Greyson, D. (2011), "The cost of drug development: A systematic review", *Health Policy* 100(1): 4-17.
- Mowery, D. C. y Sampat, B. N. (2001a), "Patenting and licensing university inventions: lessons from the history of the research corporation", *Industrial and Corporate Change*, 10.2: 317-355.
- Mowery, D. C. y Sampat, B. N. (2001b), "University patents and patent policy debates in the USA, 1925-1980", *Industrial and Corporate Change*, 10.3: 781-814.
- MRC Laboratory of Molecular Biology (1984), *1984 Physiology or Medicine Prize – César Milstein & Georges Köhler*, disponible en: <http://www2.mrc-lmb.cam.ac.uk/achievements/lmb-nobel-prizes/1984-cesar-milstein-georges-kohler/>.
- MSF Access Campaign (2015), *The Right Shot: Bringing Down Barriers to Affordable and Adapted Vaccines*, 2ª edición, Ginebra: Médicos Sin Fronteras.
- MSF Access Campaign (2017), *A Fair Shot for Vaccine Affordability: Understanding and Addressing the Effects of Patents on Access to Newer Vaccines*, Ginebra: Médicos Sin Fronteras.
- Mulcahy, A. W., Predmore, Z. y Matkic, S. (2014), *The Cost Savings Potential of Biosimilar Drugs in the United States*, Santa Mónica (California): RAND Corporation.
- Mullard, A. (2019), "Anti-amyloid failures stack up as Alzheimer antibody flops", *Nature Reviews Drug Discovery*, versión en línea, 5 de abril de 2019.
- Mullin, E. (2017), "CRISPR in 2018: Coming to a human near you", *MIT Technology Review*, versión en línea, 18 de diciembre de 2017.

- Murray, C. J. L. y Lopez, A. D. (eds.) (1996), *The Global Burden of Disease: A Comprehensive Assessment of Mortality and Disability from Diseases, Injuries, and Risk Factors in 1990 and Projected to 2020*, Boston (Massachusetts): Harvard School of Public Health.
- National Institutes of Health (NIH) (2001), *Glossary of Terms for Human Subjects Protection and Inclusion Issues*, Washington D.C.: NIH.
- National Research Council (2003), *Patents in the Knowledge-Based Economy*. Washington D.C.: The National Academies Press, disponible en: <https://doi.org/10.17226/10770>.
- National Research Council (2011), *Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease*. Washington D.C.: The National Academies Press, disponible en: <https://doi.org/10.17226/13284>.
- NCD Alliance (2011), "Access to Essential Medicines and Technologies for NCDs", documento de información, Ginebra: NCD Alliance.
- Newsome, C. (2017), "Basaglar", *Clinical Diabetes* 35(3): 181.
- Nguyen, T-Y, Veras, J y Shahzad, M. (2018), "Recent Experiences in Policy Implementation of Socially Responsible Licensing in Select Universities Across Europe and North America: Identifying Key Provisions to Promote Global Access to Health Technologies", *Les Nouvelles: The Journal of the Licensing Executives Society International* LIII(3).
- Niëns, L., Cameron, A., Van de Poel, E., Ewen, M., Brouwer, W. B. y Laing, R. (2010), "Quantifying the impoverishing effects of purchasing medicines: A cross-country comparison of the affordability of medicines in the developing world", *PLoS Medicine* 7(8): e1000333.
- Niraula, S., Seruga, B., Ocana, A., Shao, T., Goldstein, R., Tannock, I. F. et al. (2012), "The price we pay for progress: A meta-analysis of harms of newly approved anticancer drugs", *Journal of Clinical Oncology* 30(24): 3012-3019.
- Nunn, A. S., Fonseca, E. M., Bastos, F. I., Gruskin, S. y Salomon, J. A. (2007), "Evolution of antiretroviral drug costs in Brazil in the context of free and universal access to AIDS treatment", *PLoS Medicine* 4(11): e305.
- Obrist, B., Iteba, N., Lengeler, C., Makemba, A., Mshana, C., Nathan, R. et al. (2007), "Access to health care in contexts of livelihood insecurity: A framework for analysis and action", *PLoS Medicine* 4(10): e308.
- Oficina del Alto Comisionado de las Naciones Unidas para los Derechos Humanos (ACNUDH) y Organización Mundial de la Salud (OMS) (2008), "The Right to Health", Fact Sheet No. 31, Ginebra: ACNUDH y OMS.
- Olcay, M. y Laing, R. (2005), "Pharmaceutical Tariffs: What is Their Effect on Prices, Protection of Local Industry and Revenue Generation?" Documento elaborado para la Comisión de Derechos de Propiedad Intelectual, Innovación y Salud Pública, Ginebra: OMS.
- Olliaro, P. L., Kuesel, A. C., Halleux, C. M., Sullivan, M. y Reeder, J. C. (2018), "Creative use of the priority review voucher by public and not-for-profit actors delivers the first new FDA-approved treatment for river blindness in 20 years", *PLoS Neglected Tropical Diseases* 12(11): e0006837.
- Olson, L. M. y Wendling, B. W. (2013), "The Effect of Generic Drug Competition on Generic Drug Prices during the Hatch-Waxman 180-day Exclusivity Period", Working Paper No. 317, FTC Bureau of Economics, Washington D.C.
- Olson, S. y Berger, A. (2011), *Establishing Precompetitive Collaborations to Stimulate Genomics-Driven Drug Development: Workshop Summary*, Washington D.C.: National Academies Press.
- O'Neill, J. (2016), "The Review on Antimicrobial Resistance. Tackling drug-resistant infections globally: final report and recommendations", disponible en: [https://amr-review.org/sites/default/files/160525\\_Final paper\\_with cover.pdf](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf).
- ONUSIDA (2004), *Informe sobre la epidemia mundial de SIDA 2004*, disponible en: [http://files.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2004/GAR2004\\_es.pdf](http://files.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2004/GAR2004_es.pdf).
- ONUSIDA (2006), *Courting Rights: Case Studies in Litigating the Human Rights of People Living with HIV*, disponible en [http://files.unaids.org/en/media/unaids/contentassets/dataimport/pub/report/2006/jc1189-courtingrights\\_en.pdf](http://files.unaids.org/en/media/unaids/contentassets/dataimport/pub/report/2006/jc1189-courtingrights_en.pdf).
- ONUSIDA, Organización Mundial de la Salud (OMS) y Programa de las Naciones Unidas para el Desarrollo (PNUD) (2011), "Using TRIPS Flexibilities to Improve Access to HIV Treatment", Policy Brief, Ginebra: ONUSIDA, OMS y PNUD.
- Organización de Cooperación y Desarrollo Económicos (OCDE) (2008), *Pharmaceutical Pricing Policies in a Global Market*, París: OCDE.
- Organización de Cooperación y Desarrollo Económicos (OCDE) (2017a), *Health at a Glance 2017: OECD Indicators*, París: OCDE.
- Organización de Cooperación y Desarrollo Económicos (OCDE) (2017b), *Tackling Wasteful Spending on Health*, disponible en: <https://www.oecd.org/els/health-systems/Tackling-Wasteful-Spending-on-Health-Highlights-revised.pdf>.
- Organización de Cooperación y Desarrollo Económicos (OCDE) (2018), *Pharmaceutical Innovation and Access to Medicines*, OECD Health Policy Studies, p. 143, disponible en: <http://www.oecd.org/health/pharmaceutical-innovation-and-access-to-medicines-9789264307391-en.htm>.
- Organización de Cooperación y Desarrollo Económicos (OCDE) y Oficina de Propiedad Intelectual de la Unión Europea (EUIPO) (2019), *Trends in Trade in Counterfeit and Pirated Goods*, París: OECD Publishing.
- Organisation of Eastern Caribbean States (OECS) (2001), *Pharmaceutical Procurement Service Annual Report 2001*, Santa Lucía: OECS.
- Organización Mundial de la Salud (OMS) (2000), *Informe sobre la salud en el mundo 2000: mejorar el desempeño de los sistemas de salud*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2001a), *Macroeconomía y salud: invertir en salud en pro del desarrollo económico: informe de la Comisión sobre Macroeconomía y Salud*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2001b), "Drug procurement: The principles for getting it right", *Essential Drugs Monitor* 30: 13-16.
- Organización Mundial de la Salud (OMS) (2001c), *How to Develop and Implement a National Drug Policy*, 2ª edición, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2003a), "Cómo desarrollar y aplicar una política farmacéutica nacional", Perspectivas políticas de la OMS sobre medicamentos N° 6.

Organización Mundial de la Salud (OMS) (2003b), *Medical Device Regulations: Global Overview and Guiding Principles*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2003c), *The selection and use of essential medicines: report of the WHO Expert Committee, 2002: (including the 12<sup>th</sup> model list of essential medicines)*, WHO technical report series 914, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2004), "Acceso equitativo a los medicamentos esenciales: un marco para la acción colectiva", Perspectivas políticas de la OMS sobre medicamentos N° 8, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2005), "Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies", Health Economics and Drugs TCM Series No. 18, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2006a), *Salud pública, innovación y derechos de propiedad intelectual: informe de la Comisión de Derechos de Propiedad Intelectual, Innovación y Salud Pública*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2006b), *Fortieth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations*, WHO technical report series 937, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2007a), *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2007b), "Lista modelo OMS de medicamentos pediátricos esenciales: 1ª lista, octubre de 2007", Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2009a), Comité de Expertos de la OMS en Patrones Biológicos, Ginebra, 19-23 de octubre de 2009, "Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)", disponible en: [https://www.who.int/biologicals/publications/trs/areas/biological\\_therapeutics/TRS\\_977\\_Annex\\_2.pdf?ua=1](https://www.who.int/biologicals/publications/trs/areas/biological_therapeutics/TRS_977_Annex_2.pdf?ua=1).

Organización Mundial de la Salud (OMS) (2009b), *Global Health Risks: Mortality and Burden of Disease Attributable to Selected Major Risks*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2010), *Assessment of Medicines Regulatory Systems in Sub-Saharan African Countries: An Overview of Findings from 26 Assessment Reports*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2011a), *Increasing Access to Vaccines Through Technology Transfer and Local Production*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2011b), *Local Production for Access to Medical Products: Developing a Framework to Improve Public Health*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2011c), *Preparación para una gripe pandémica: marco para el intercambio de virus gripales y el acceso a las vacunas y otros beneficios*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2011d), "Función de la OMS en la prevención y el control de productos médicos deficientes en cuanto a su calidad, seguridad y eficacia tales como los de calidad subestándar, espurios, de etiquetado engañoso, falsificados o de imitación" (A/SSFFC/WG/3 Rev.1), 17 de febrero de 2011.

Organización Mundial de la Salud (OMS) (2012), *Investigación y desarrollo para atender las necesidades sanitarias de los países en desarrollo: fortalecimiento de la financiación y coordinación mundiales: Informe del Grupo consultivo de expertos en investigación y desarrollo: financiación y coordinación*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2013a), *Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020*, Ginebra: OMS, disponible en: [https://apps.who.int/iris/bitstream/handle/10665/94384/9789241506236\\_eng.pdf?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/94384/9789241506236_eng.pdf?sequence=1).

Organización Mundial de la Salud (OMS) (2013b), *Weekly Epidemiological Record* 1(88): 1-16, disponible en: <https://www.who.int/wer/2013/wer8801.pdf?ua=1> [www.who.int/immunization\\_delivery/new\\_vaccines/technologies\\_aerosol/en/](http://www.who.int/immunization_delivery/new_vaccines/technologies_aerosol/en/).

Organización Mundial de la Salud (OMS) (2014a), *Access to Antiretroviral Drugs in Low- and Middle-Income Countries*, Technical Report, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2014b), *Guidelines for the Screening, Care and Treatment of Persons Diagnosed with Chronic Hepatitis C Virus Infection*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2014c), "Hepatitis E Vaccine: Composition, Safety, Immunogenicity and Efficacy, A document prepared for Strategic Advisory Group of Experts on Immunization (SAGE) by the Hepatitis E Vaccine Working Group", disponible en: [https://www.who.int/immunization/sage/meetings/2014/october/2\\_HepEvaccsafety\\_immunogenicity\\_efficacy\\_final\\_1Oct2014.pdf](https://www.who.int/immunization/sage/meetings/2014/october/2_HepEvaccsafety_immunogenicity_efficacy_final_1Oct2014.pdf).

Organización Mundial de la Salud (OMS) (2014d), *Increasing Access to HIV Treatment in Middle-Income Countries: Key Data on Prices, Regulatory Status, Tariffs and the Intellectual Property Situation*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2015a), *Access to New Medicines in Europe: Technical Review of Policy Initiatives and Opportunities for Collaboration and Research*, Copenhague: Oficina Regional de la OMS para Europa.

Organización Mundial de la Salud (OMS) (2015b), *Health in 2015 from MDGs Millennium Development Goals to SDGs Sustainable Development Goals*, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2015c), *The selection and use of essential medicines: Twentieth report of the WHO Expert Committee 2015 (including 19th WHO Model List of Essential Medicines and 5th WHO Model List of Essential Medicines for Children)*, WHO technical report series no. 994, Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2015d), *Trade and Health: Towards Building a National Strategy*, Smith, R., Blouin, C., Mirza, Z., Beyer, P. y Drager, N. (eds.), Ginebra: OMS.

Organización Mundial de la Salud (OMS) (2015e), *WHO guideline on country pharmaceutical pricing policies*, Ginebra: OMS.

- Organización Mundial de la Salud (OMS) (2015f), "WHO Statement on Public Disclosure of Clinical Trial Results", 9 de abril de 2015, disponible en: [www.who.int/ictpr/results/reporting/en/](http://www.who.int/ictpr/results/reporting/en/).
- Organización Mundial de la Salud (OMS) (2016a), *Global report on access to hepatitis C treatment. Focus on overcoming barriers*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2016b), *The role of intellectual property in local production in developing countries: opportunities and challenges*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2016c), *WHO treatment guidelines for drug-resistant tuberculosis, 2016 update. October 2016 revision*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2016d), "WHO updates patent information on treatment of Hepatitis C", versión en línea.
- Organización Mundial de la Salud (OMS) (2016e), *Working for health and growth: investing in the health workforce. Report of the High-Level Commission on Health Employment and Economic Growth*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017a), *Antibacterial agents in clinical development: an analysis of the antibacterial clinical development pipeline, including tuberculosis*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017b), *Global atlas of medical devices. WHO medical devices technical series*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017c), *Global Hepatitis Report 2017*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017d), *Integrating neglected tropical diseases into global health and development: fourth WHO report on neglected tropical diseases*, Ginebra: OMS, disponible en: <https://apps.who.int/iris/bitstream/handle/10665/255011/9789241565448-eng.pdf?sequence=1>.
- Organización Mundial de la Salud (OMS) (2017e), "Overall programme review of the global strategy and plan of action on public health, innovation and intellectual property. Report of the review panel. Noviembre de 2017".
- Organización Mundial de la Salud (OMS) (2017f), *The selection and use of essential medicines: Twentieth report of the WHO Expert Committee 2017 (including 20th WHO Model List of Essential Medicines and 6th WHO Model List of Essential Medicines for Children)*, WHO technical report series no. 1006, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017g), *A study on the public health and socioeconomic impact of substandard and falsified medical products*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017h), *Together on the road to universal health coverage: a call to action*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017i), "Transición hacia los nuevos antirretrovirales en los programas contra el VIH", Sinopsis de política, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017j), *WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices*, WHO Medical device technical series, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017k), *Sistema mundial OMS de vigilancia y monitoreo de productos médicos de calidad subestándar y falsificados*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2017l), "WHO to begin pilot prequalification of biosimilars for cancer treatment", 4 de mayo de 2017.
- Organización Mundial de la Salud (OMS) (2018a), "Approaches to Seasonal Influenza and Genetic Sequence Data under the PIP Framework", 14 de diciembre de 2018.
- Organización Mundial de la Salud (OMS) (2018b), *Assessing national capacity for the prevention and control of noncommunicable diseases: report of the 2017 global survey*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2018c), *Facilitating access and benefit-sharing (ABS) for pathogens to support public health: workshop report: 11-12 June 2018 workshop*, septiembre de 2018, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2018d), *Global Vaccine Action Plan: Monitoring, Evaluation & Accountability: Secretariat Annual Report 2018*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2018e), *Progress report on access to hepatitis C treatment: focus on overcoming barriers in low- and middle-income countries, March 2018*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2018f), *Rapid communication: key changes to treatment of drug-resistant tuberculosis*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2018g), *Technical Report: Pricing of cancer medicines and its impacts: A comprehensive technical report for the World Health Assembly Resolution 70.12 Operative paragraph 2.9 on pricing approaches and their impacts on availability and affordability of medicines for the prevention and treatment of cancer*. Ginebra: OMS, disponible en: <https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1>.
- Organización Mundial de la Salud (OMS) (2018h), *Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV: interim guidelines. Supplement to the 2016 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2018i), "WHO EML cancer medicines working group (CMWG): report of the meeting 22-23 March 2018, Geneva, Switzerland", Ginebra: OMS, disponible en: <https://apps.who.int/iris/bitstream/handle/10665/272962/WHO-EMP-IAU-2018.03-eng.pdf?sequence=1&isAllowed=y>.
- Organización Mundial de la Salud (OMS) (2019a), *2019 Antibacterial agents in clinical development: an analysis of the antibacterial clinical development pipeline*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2019b), *Executive Summary. The Selection and Use of Essential Medicines 2019. Report of the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines, 1-5 April 2019*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2019c), *Global tuberculosis report 2019*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2019d), *Pandemic Influenza Preparedness Framework: Annual Progress Report 1 January-31 December 2018*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) (2019e), "Universal health coverage (UHC)", 24 de enero de 2019.

- Organización Mundial de la Salud (OMS) (2019f), *WHO global report on traditional and complementary medicine 2019*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) y Health Action International (HAI) (2008), *Measuring medicine prices, availability, affordability and price components*, Ginebra y Ámsterdam: OMS y HAI.
- Organización Mundial de la Salud (OMS) y Banco Internacional de Reconstrucción y Fomento/Banco Mundial (2020), *Global Monitoring Report on Financial Protection in Health 2019*, Ginebra: OMS.
- Organización Mundial de la Salud (OMS) y ONUSIDA (2000), "Patent situation of HIV/AIDS-related drugs in 80 countries", disponible en: <https://www.who.int/3by5/en/patentsshivdrugs.pdf>.
- Organización Mundial de la Salud (OMS) y Organización Mundial del Comercio (OMC) (2002), *Los acuerdos de la OMC y la salud pública: un estudio conjunto de la OMS y la secretaria de la OMC.*, Ginebra: OMS y OMC.
- Organización Mundial de la Salud (OMS), Market Information for Access to Vaccines (MI4A) y WHO Vaccine Product, Price and Procurement (V3P) (2018), "Global Vaccine Market Report", disponible en: [https://www.who.int/immunization/programmes\\_systems/procurement/v3p/platform/module2/MI4A\\_Global\\_Vaccine\\_Market\\_Report.pdf?ua=1](https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module2/MI4A_Global_Vaccine_Market_Report.pdf?ua=1).
- Organización Mundial de la Salud (OMS) Oficina Regional de la OMS para Europa (2019), *Can people afford to pay for health care? New evidence on financial protection in Europe*, Copenhague: Oficina Regional de la OMS para Europa.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2001), "Conocimientos tradicionales: necesidades y expectativas en materia de propiedad intelectual. Informe relativo a las misiones exploratorias sobre propiedad intelectual y conocimientos tradicionales (1998-1999)", Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2007), "Las 45 recomendaciones adoptadas en el marco del Programa de la OMPI para el Desarrollo", disponible en: [www.wipo.int/ip-development/es/agenda/recommendations.html](http://www.wipo.int/ip-development/es/agenda/recommendations.html).
- Organización Mundial de la Propiedad Intelectual (OMPI) (2009), *The Economics of Intellectual Property: Suggestions for Further Research in Developing Countries and Countries with Economies in Transition*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2011a), "WIPO Patent Search Report on Pandemic Influenza Preparedness (PIP)-Related Patents and Patent Applications", Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2011b), *Informe sobre la propiedad intelectual en el mundo. Los nuevos parámetros de la innovación*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2014a), *Alternatives in Patent Search and Examination: Policy Guide*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2014b), "Patent Pools and Antitrust – A Comparative Analysis", Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2015a), *Propiedad intelectual y recursos genéticos, conocimientos tradicionales y expresiones culturales tradicionales*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2015b), *WIPO Guide to Using Patent Information*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2015c), *Informe Mundial sobre la Propiedad Intelectual en 2015: la innovación revolucionaria y el crecimiento económico*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2017a), *Guía para la catalogación de conocimientos tradicionales*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2017b), *Cuestiones clave sobre el requisito de divulgación de recursos genéticos y conocimientos tradicionales en las solicitudes de patente*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2017c), *Proteja y promueva su cultura. Guía práctica sobre la propiedad intelectual para los pueblos indígenas y las comunidades locales*, Ginebra: OMPI, 2017.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2018), *World Intellectual Property Indicators 2018*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2019a), *Patent Cooperation Treaty Yearly Review 2019: The International Patent System*, Ginebra: OMPI.
- Organización Mundial de la Propiedad Intelectual (OMPI) (2019b), *WIPO Technology Trends 2019: Artificial Intelligence*, Ginebra: OMPI.
- World Medical Association (WMA) (2013), *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*.
- Organización Mundial del Comercio (OMC) (2011), *Informe sobre el Comercio Mundial 2011. La OMC y los acuerdos comerciales preferenciales: de la coexistencia a la coherencia*, Ginebra: OMC.
- Organización Mundial del Comercio (OMC) (2012), *A Handbook on the WTO TRIPS Agreement*, Taubman, A., Wager, H. y Watal, J. (eds.), Nueva York: Cambridge University Press.
- Organización Mundial del Comercio (OMC) (2018), *Incorporar el comercio para lograr los Objetivos de Desarrollo Sostenible*, Ginebra: OMC.
- Organización de las Naciones Unidas para la Educación, la Ciencia y la Cultura (UNESCO), International Bioethics Committee (IBC) (2017), "Report of the IBC on Big Data and Health", SHS/YES/IBC-24/17/3 REV.2, París: UNESCO.
- Pagliusi, S., Dennehy, M. y Kim, H. (2018), "Vaccines, inspiring innovation in health", *Vaccine* 36: 7430-7437.
- Pammolli, F., Magazzini, L. y Riccaboni, M. (2011), "The productivity crisis in pharmaceutical R&D", *Nature Reviews Drug Discovery* 10(6): 428-438.
- Paris, V. y Belloni, A. (2013), "Value in Pharmaceutical Pricing", *Health Working Papers* No. 63, París: OCDE.
- Parsons, L. (2019), "Vertex, NHS England and NICE finally reach agreement for Orkambi", *PMLive*, 24 de octubre de 2019, disponible en: [http://www.pmlive.com/pharma\\_news/vertex\\_nhs\\_england\\_and\\_nice\\_finally\\_reach\\_agreement\\_for\\_orkambi\\_1314406?utm\\_source=pmlive&utm\\_medium=email&utm\\_campaign=pmlive\\_daily&](http://www.pmlive.com/pharma_news/vertex_nhs_england_and_nice_finally_reach_agreement_for_orkambi_1314406?utm_source=pmlive&utm_medium=email&utm_campaign=pmlive_daily&).

- Paun, C. (2016), "Skyhigh drug prices made Romania mull patent break", *Político*, versión en línea, 29 de marzo de 2016.
- Penazzato, M., Lewis, L., Watkins, M., Prabhu, V., Pascual, F., Auton, M. *et al.* (2018), "Shortening the decade-long gap between adult and paediatric drug formulations: A new framework based on the HIV experience in low- and middle-income countries", *Journal of the International AIDS Society* 21 (supl.1): e25049.
- Perehudoff, S. K., Toebes, B. y Hogerzeil, H. (2016), "Essential medicines in national constitutions: Progress since 2008", *Health and Human Rights Journal* 18(1): 141-156.
- Pettitt, D., Arshad, Z., Smith, J., Stanic, T., Holländer, G. y Brindley, D. (2018), "CAR-T cells: A systematic review and mixed-methods analysis of the clinical trial landscape", *Molecular Therapy* 26(2): 342-353.
- von Philipsborn, P., Steinbeis, F., Bender, M. E., Regmi, S. y Tinnemann, P. (2015), "Poverty-related and neglected diseases: An economic and epidemiological analysis of poverty relatedness and neglect in research and development", *Global Health Action* 8(1), versión en línea, 22 de enero de 2015.
- PhRMA, "PhRMA Annual Membership Survey 2018", disponible en: <https://heatinformatics.com/posts/2018-phrma-annual-membership-survey>.
- Prasad, V. y Mailankody, S. (2017), "Research and development spending to bring a single cancer drug to market and revenues after approval", *JAMA Internal Medicine* 177(11): 1569-1575.
- Pray, L. (2008), "Personalized medicine: Hope or hype?", *Nature Education* 1(1):72.
- Price, W. N. y Rai, A. K. (2015), "Are trade secrets delaying biosimilars?", *Science* 348(6231): 188-189.
- Price, W. N. y Rai, A. K. (2016), "Manufacturing barriers to biologics competition and innovation", *Iowa Law Review* 101(3): 1023-1063.
- Pricewaterhousecoopers International Ltd (PwC) (2008), *Pharma 2020: Virtual R&D – Which path will you take?*, PwC.
- Programa de las Naciones Unidas para el Desarrollo (PNUD) (2014), *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries*, versión en línea, disponible en: <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html>.
- Programa de las Naciones Unidas para el Desarrollo (PNUD) (2017), "Using Competition Law to Promote Access to Medicines and Related Health Technologies in Low- and Middle-Income Countries", versión en línea, disponible en: [http://adphealth.org/upload/resource/Competition\\_Law\\_Issue\\_Brief\\_final\\_15Aug.pdf](http://adphealth.org/upload/resource/Competition_Law_Issue_Brief_final_15Aug.pdf).
- Programa de las Naciones Unidas para el Medio Ambiente (PNUMA) (2019), *Frontiers 2018/19: Emerging Issues of Environmental Concern*, Nairobi: PNUMA, disponible en: <https://wedocs.unep.org/bitstream/handle/20.500.11822/27538/Frontiers1819.pdf?sequence=1&isAllowed=y>.
- Pulcini, C., Mohrs, S., Beovic, B., Gyssens, I., Theuretzbacher, U. y Cars, O. (2016), "Forgotten antibiotics: A follow-up inventory study in Europe, the USA, Canada and Australia", *International Journal of Antimicrobial Agents* 49(1): 98-101.
- Quinn, R. (2013), "Rethinking antibiotic research and development: World War II and the penicillin collaborative", *American Journal of Public Health* 103(3): 426-434.
- Quintilio, W., Kubrusly, F.S., Iourtov, D., Miyaki, C., Sakauchi, M.A., *et al.* (2009), "*Bordetella pertussis* monophosphoryl lipid A as adjuvant for inactivated split virion influenza vaccine in mice", *Vaccine* 27(31): 4219-4224.
- Rägo, L. y Santoso, B. (2008), "Drug Regulation: History, Present and Future", en van Boxtel, C. J., Santoso, B. y Edwards, I. R. (eds.), *Drug Benefits and Risks: International Textbook of Clinical Pharmacology*, 2ª edición, Ámsterdam: IOS Press.
- Rao, A. (2011), "New technologies for neglected diseases: Can tax credits help biotechnology companies advance global health?", *Journal of Commercial Biotechnology* 17: 290-292, disponible en: <https://paperity.org/p/76961659/new-technologies-for-neglected-diseases-can-tax-credits-help-biotechnology-companies>.
- Reardon, S. (2014), "Ebola treatments caught in limbo", *Nature* 511(7511): 520.
- Reátegui Valdiviezo, M. (2016), "Datos de Prueba de Productos Farmacéuticos. Análisis de la Legislación Peruana y Tratados Aplicables", *Revista Derecho & Sociedad* 49: 143-159, disponible en: <http://revistas.pucp.edu.pe/index.php/derechysociedad/articledownload/19884/19923>.
- Reich, M. R., Harris, J., Ikegami, N., Maeda, A., Cashin, C., Araujo, E. C., *et al.* (2016), "Moving towards universal health coverage: Lessons from 11 country studies", *The Lancet* 387(10020): 811-816.
- Relias Media (2005), "FDA drug approvals jump in 2004", versión en línea, 1 de mayo de 2005, disponible en: <https://www.reliasmedia.com/articles/87040-fda-drug-approvals-jump-in-2004>.
- Renwick, M.J., Simpkin V, Mossialos, E. (2016), *International and European Initiatives Targeting Innovation in Antibiotic Drug Discovery and Development, The Need for a One Health – One Europe – One World Framework*, Health Policy Series 45.
- Reuters (2016), "Beijing buyers club? China's cancer patients gamble on gray market", *Business Insider*, versión en línea, 25 de diciembre de 2016, disponible en: <http://static3.businessinsider.com/r-beijing-buyers-club-chinas-cancer-patients-gamble-on-gray-market-2016-12>.
- Reuters (2018), "Impatient patients turn to online 'buyers club' for new drugs", *CNBC*, versión en línea, 3 de octubre de 2018, disponible en: <https://www.cnbc.com/2018/10/03/impatient-patients-turn-to-online-buyers-club-for-new-drugs.html>.
- Ridley, D. B. y Régnier, S. A. (2016), "The commercial market for priority review vouchers", *Health Affairs* 35(5): 776-783.
- Rietveld, H. (2008), "A New Class of Malaria Drugs: The Coartem Breakthrough from Novartis and its Chinese Partners", presentación de PowerPoint realizada en el taller Workshop on Access and Benefit Sharing, Bonn, 26 de mayo de 2008.
- Robertson, J., Forte, G., Trapsida, J.-M. y Hill, S. (2009), "What essential medicines for children are on the shelf?", *Bulletin of the World Health Organization* 87(3): 231-237.
- Rodríguez, P.C., Rodríguez, G., González, G. y Lage, A. (2010), "Clinical Development and Perspectives of CIMAvax EGF, Cuban Vaccine for Non-small-cell Lung Cancer Therapy", *MEDICC Review* 12(1): 17-23.
- Roger, S. D. y Goldsmith, D. (2008), "Biosimilars: It's not as simple as cost alone", *Journal of Clinical Pharmacy and Therapeutics* 33(5): 459-464.
- Rosenfeld, L. (2002), "Insulin: discovery and controversy", *Clinical Chemistry* 48(12): 2270-2288.

- Roth, V. J. (2012), "Will FDA data exclusivity make biologic patents passé?", *Santa Clara High Technology Law Journal* 29(2): 249-304.
- Röttingen, J.-A., Chamas, C., Goyal, L. C., Harb, H., Lagrada, L. y Mayosi, B. M. (2012), "Securing the public good of health research and development for developing countries", *Bulletin of the World Health Organization* 90(5): 398-400.
- Roughhead, E. E., Kim, D. S., Ong, B. y Kemp-Casey, A. (2018), "Pricing policies for generic medicines in Australia, New Zealand, the Republic of Korea and Singapore: patent expiry and influence on atorvastatin price", *WHO South-East Asia Journal of Public Health*, septiembre de 2018, 7(2): 99-106.
- Roughhead, L., Semple, S. y Rosenfeld, E. (2013), *Literature Review: Medication Safety in Australia*, Darlinghurst (Nueva Gales del Sur): Australian Commission on Quality and Safety in Health Care.
- Russian Federation Ministry of Health y Organización Mundial de la Salud (OMS) (2017), "Declaración de Moscú para Poner Fin a la Tuberculosis", Primera Conferencia Ministerial Mundial de la OMS. Poner Fin a la Tuberculosis en la Era del Desarrollo Sostenible: una Respuesta Multisectorial, 16-17 de noviembre de 2017, Moscú (Federación de Rusia).
- Sag, M. (2009), "Copyright and copy-reliant technology", *Northwestern University Law Review* 103(4): 1607-1682.
- Sagonowsky, E. (2017), "Promising Ebola vaccines from Merck, Johnson & Johnson win BARDA funding", *FiercePharma*, versión en línea, 2 de octubre de 2017, disponible en: <https://www.fiercepharma.com/vaccines/promising-ebola-vaccines-from-merck-j-j-win-barda-funding>.
- Sagonowsky, E. (2018), "Merck Starts Rolling FDA Submission for Its Ebola Vaccine, Aiming to Finish Next Year", *Fiercepharma*, versión en línea, 15 de noviembre de 2018, disponible en: <https://www.fiercepharma.com/vaccines/merck-starts-fda-submission-for-ebola-vaccine-aiming-to-finish-next-year>.
- El Said, M. K. (2010), *Public Health Related Trips-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region*, Ginebra: OMS e ICTSD.
- Sampat, B. N. (2015), "Intellectual Property Rights and Pharmaceuticals: The Case of Antibiotics", Economic Research Working Paper No. 26, Ginebra: OMPI.
- Sampat, B. N. y Shadlen, K. (2016), "The Effects of Restrictions on Secondary Pharmaceutical Patents: Brazil and India in Comparative Perspective", disponible en: <http://www.hbs.edu/faculty/Lists/Events/Attachments/1124/Secondary%20Pharma.pdf>.
- Sanchez-Luna, M., Burgos-Pol, R., Oyagüez, I., Figueras-Aloy, J., Sánchez-Solis, M., Martínón-Torres, F. et al. (2017), "Cost-utility analysis of Palivizumab for Respiratory Syncytial Virus infection prophylaxis in preterm infants: Update based on the clinical evidence in Spain", *BMC Infectious Diseases* 17(1): 687.
- Sarbacker, G. B. y Urteaga, E. M. (2016), "Adherence to Insulin Therapy", *Diabetes Spectrum* 29(3): 166-170.
- Savedoff, W. D. (2011), "Governance in the Health Sector: A Strategy for Measuring Determinants and Performance", Policy Research Working Paper No. 5655, Washington D.C.: Banco Mundial.
- Scaria, A. G. y Mammen, K. S. (2018), "Non-Traditional Marks in the Pharmaceutical Sector: Non-Traditional Barriers to Access to Medicine?" in Calboli, I. y Senftleben, M. (eds.), *The Protection of Non-Traditional Trademarks: Critical Perspectives*, Oxford: Oxford University Press.
- Schafer, J., Tapella, M., Kantarelis, T. (2016), "Biosimilars: Why deep discounts may become the dominant paradigm", *Pharmaceutical Commerce*, versión en línea, 22 de febrero de 2016.
- Schell, J. (2013), "Neurim: a new definition of 'product' in supplementary protection certificates?", *Journal of Intellectual Property Law & Practice* 8(9): 723-728, disponible en: <https://doi.org/10.1093/jiplp/jpt130>.
- Scherer, F. M. y Watal, J. (2002), "Post-TRIPS options for access to patented medicines in developing nations", *Journal of International Economic Law* 5(4): 913-939.
- Schmucker, C., Schell, L. K., Portalupi, S., Oeller, P., Cabrera, L., Bassler, D. et al. (2014), "Extent of non-publication in cohorts of studies approved by research ethics committees or included in trial registries", *PLoS ONE* 9: e114023.
- Schuhmacher, A., Gassman, O. y Hinder, M. (2016), "Changing R&D models in research-based pharmaceutical companies", *Journal of Translational Medicine*, 14(1): 105.
- Schuhmacher, A., Gassman, O., McCracken, N. y Hinder, M. (2018), "Open innovation and external sources of innovation. An opportunity to fuel the R&D pipeline and enhance decision making?", *Journal of Translational Medicine* 16:119.
- Schwieterman, W. D. (2006), "Regulating biopharmaceuticals under CDER versus CBER: an insider's perspective", *Drug Discovery Today* 11(19-20): 945-951.
- Scutti, S. (2018), "Gene therapy for rare retinal disorder to cost \$425,000 per eye", *CNN*, versión en línea, 3 de enero de 2018, disponible en: <https://www.cnn.com/2018/01/03/health/luxturna-price-blindness-drug-bn/index.html>.
- Shapiro, C. (2001), "Navigating the Patent Thicket: Cross Licences, Patent Pools and Standard Setting", en Jaffe, A. B., Lerner, J. y Stern, S. (eds.), *Innovation Policy and the Economy*, vol. 1, Cambridge (Massachusetts): MIT Press.
- Shcherbakova, N., Shepherd, M., Lawson, K. y Richards, K. (2011), "The role of authorized generics in the prescription drug marketplace", *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 8: 28-40.
- Shedden, K. (2018), exposición realizada en el simposio técnico trilateral organizado por la OMC, la OMPI y la OMS titulado Objetivos de Desarrollo Sostenible: Tecnologías Innovadoras para Fomentar la Vida Sana y el Bienestar, Ginebra, 26 de febrero de 2018.
- Shum, T., Kruse, R. L. y Rooney, C. M. (2018), "Strategies for enhancing adoptive T-cell immunotherapy against solid tumors using engineered cytokine signaling and other modalities", *Expert Opinion on Biological Therapy* 18(6): 653-664.
- Silverman, E. (2017a), "Netherlands health minister threatens compulsory licenses over 'absurd prices'", *STAT News*, disponible en: <https://www.statnews.com/pharmalot/2017/11/27/netherlands-patents-compulsory-licenses-vertex/>.
- Silverman, E. (2017b), "Under pressure, Gilead expands Sovaldi licensing deal to four middle-income countries", *STAT News*, disponible en: <https://www.statnews.com/pharmalot/2017/08/24/gilead-sovaldi-malaysia-ukraine/>.

- Simon-Kucher & Partners (2016), *Payers' price & market access policies supporting a sustainable biosimilar medicines market: Final report*, Bonn: Simon-Kucher & Partners.
- Son, K., Lopert, R., Gleeson, D. y Lee, T. (2018), "Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States", *Globalization and Health* 14(101), disponible en: <https://doi.org/10.1186/s12992-018-0423-0>.
- Srivastava, R. K. y More, A. T. (2010), "Some aesthetic considerations for over-the-counter (OTC) pharmaceutical products", *International Journal of Biotechnology* 11(3-4): 267-283.
- Stanaway, J. D., Afshin, A., Gakidou, E., Lim, S. S., Abate, D., Abate, K. H., et al. (2018), "Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks for 195 countries and territories, 1990-2017: A systematic analysis for the Global Burden of Disease Study 2017", *The Lancet* 392(10159): 1923-1994.
- Stenberg, K., Hanssen, O., Edejer T.-T., T., Bertram, M., Brindley, C., Meshreky, A. et al. (2017), "Financing transformative health systems towards achievement of the health Sustainable Development Goals: A model for projected resource needs in 67 low-income and middle-income countries", *The Lancet Global Health* 5(9): e875-e887.
- Stevens, A. J. y Effort, A. E. (2008), "Using academic license agreements to promote global social responsibility", *Les Nouvelles* 43: 85.
- Stevens, A. J., Jensen, J. J., Wyller, K., Kilgore, P. C., Chatterjee, S. y Rohrbaugh, M. L. (2011), "The role of public-sector research in the discovery of drugs and vaccines", *New England Journal of Medicine* 364(6): 535-541.
- Sussex, J., Feng, Y., Mestre-Ferrandiz, J., et al. (2016), "Quantifying the economic impact of government and charity funding of medical research on private research and development funding in the United Kingdom", *BMC Medicine* 14(32), versión en línea, 25 de febrero de 2016.
- Tängdén, T., Pulcini, C., Aagaard, H., Balasegaram, M., et al. (2018), "Unavailability of old antibiotics threatens effective treatment for common bacterial infections", *The Lancet Infectious Diseases* 18(3): 242-244.
- Tay-Teo, K., Ilbawi, A. y Hill, S. R. (2019), "Comparison of sales income and research and development costs for FDA-approved cancer drugs sold by originator drug companies", *JAMA Network Open* 2(1): e186875.
- Taylor, C. T. y Silberston, Z. A. (1973), *The Economic Impact of the Patent System: A Study of the British Experience*, Cambridge: Cambridge University Press.
- Temin, P. (1979), "Technology, regulation, and market structure in the modern pharmaceutical industry", *The Bell Journal of Economics* 10(2): 429-446.
- Tenn, S. & Wendling, B. W. (2014), "Entry threats and pricing in the generic drug industry", *Review of Economics and Statistics* 96: 214-228.
- Thomas, J. R. (2014), *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation*, Washington D.C.: Congressional Research Service.
- Thomas, J. R. (2015), *Pharmaceutical Patent Law*, 3ª edición, Arlington (Virginia): Bloomberg BNA.
- Todd, Matthew (2010), "A Summary of What Is Needed Right Now", The Synaptic Leap's Synthetic Praziquantel Project, disponible en: <http://www.thesynapticleap.org/node/286>.
- Toebe, B., Ferguson, R., Markovic, M. M. y Nnamuchi, O. (eds.) (2014), *The Right to Health, A Multi-Country Study of Law, Policy and Practice*, La Haya: Asser Press.
- Toland, A. E., Forman, A., Couch, F. J., Culver, J. O., et al. en nombre del Comité Directivo del Breast Cancer Information Core (BIC) (2018), "Clinical testing of BRCA1 and BRCA2: a worldwide snapshot of technological practices", *npj Genomic Medicine* 3(7), disponible en: 10.1038/s41525-018-0046-7.
- Tomas Gomez-Arostegui, H. (2010), "Prospective Compensation in Lieu of a Final Injunction in Patent and Copyright Cases", *Fordham Law Review* 78(4), disponible en: <http://ir.lawnet.fordham.edu/flr/vol78/iss4/2>.
- Topol, E. J. (2019), "High-performance medicine: The convergence of human and artificial intelligence", *Nature Medicine* 25: 44-56.
- Tripathi, P., Rawat, G., Yadav, S. y Saxena, R. K. (2015), "Shikimic acid, a base compound for the formulation of swine/avian flu drug: statistical optimization, fed-batch and scale up studies along with its application as an antibacterial agent", *Antonie van Leeuwenhoek: Journal of Microbiology*, 107: 419-431.
- Trippe, A. (2015), *Guidelines for Preparing Patent Landscape Reports*, Ginebra: OMPI.
- Unitaid (2014a), *A Review of the Bedaquiline Patent Landscape: A scoping report*, Ginebra: Unitaid Secretariat.
- Unitaid (2014b), *HIV/AIDS Diagnostics Technology Landscape*, 4ª edición, disponible en: [https://unitaid.org/assets/UNITAID-HIV\\_Diagnostic\\_Landscape-4th\\_edition.pdf](https://unitaid.org/assets/UNITAID-HIV_Diagnostic_Landscape-4th_edition.pdf).
- Unitaid (2017), *Tuberculosis Diagnostics Technology Landscape*, 5ª edición, mayo de 2017, disponible en: <https://unitaid.org/assets/2017-Unitaid-TB-Diagnostics-Technology-Landscape.pdf>.
- Unitaid y Medicines Patent Pool (2015), *Patents and licences on antiretrovirals: A snapshot*, Ginebra: Unitaid Secretariat.
- United Kingdom, Intellectual Property Office (IPO), Patent Informatics Team (2011), *Patent thickets: An overview: Subject to peer review*, Newport (Reino Unido): IPO.
- United States Congress, Congressional Budget Office (USCBO) (2006), *Research and Development in the Pharmaceutical Industry*, Washington D.C.: USCBO.
- United States Congress, Office of Technology Assessment (1993), *Pharmaceutical R&D: Costs, Risks and Rewards*, OTA-H-522, Washington D.C.: U.S. Government Printing Office.
- United States Federal Trade Commission (FTC) (2009), *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, Washington D.C.: FTC.
- United States Federal Trade Commission (FTC) (2017), "Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2015: A Report by the Bureau of Competition", disponible en: <https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-9>.

- United States Federal Trade Commission (FTC) (2019), "Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company 'Reverse Payments'", comunicado de prensa, 28 de febrero de 2019, disponible en: <https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme>.
- United States Food and Drug Administration (FDA) (2017a), "FDA approval brings first gene therapy to the United States", comunicado de prensa, disponible en: <https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states>.
- United States Food and Drug Administration (FDA) (2017b), "FDA approves novel gene therapy to treat patients with a rare form of inherited vision loss", comunicado de prensa, disponible en: <https://www.fda.gov/news-events/press-announcements/fda-approves-novel-gene-therapy-treat-patients-rare-form-inherited-vision-loss>.
- United States Food and Drug Administration (FDA) (2018), "FDA approves first generic version of EpiPen", comunicado de prensa, disponible en: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-version-epipen>.
- United States Food and Drug Administration (FDA) (2019a), *Advancing Health through Innovation: 2018 New Drug Therapy Approvals*, disponible en: <https://www.fda.gov/media/120357/download>.
- United States Food and Drug Administration (FDA) (2019b), *Considerations in Demonstrating Interchangeability with a Reference Product: Guidance for Industry*, Washington D.C.: FDA.
- United States Government Accountability Office (2017), *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40, disponible en: <https://www.gao.gov/assets/690/688472.pdf>.
- United States Patent and Trademark Office (USPTO) (2001), "Final Guidelines for Determining Utility of Gene-Related Inventions", comunicado de prensa, 4 de enero de 2001.
- United States Patent and Trademark Office (USPTO) (2018), *New PTAB Studies in AIA Proceedings: Expanded Panels and Trial Outcomes for Orange Book-listed Patents*, disponible en: [https://www.uspto.gov/sites/default/files/documents/chat\\_with\\_the\\_chief\\_march\\_2018.pdf](https://www.uspto.gov/sites/default/files/documents/chat_with_the_chief_march_2018.pdf).
- United States Patent and Trademark Office (USPTO) (2019), *Revised Patent Subject Matter Eligibility Guidance*; página publicada el 7 de enero de 2019 y actualizada el 17 de octubre de 2019, disponible en: <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility>.
- Uzuner, H., Bauer, R., Fan, T. P., Guo, D. A., Diaz, A., El-Nezami, H. et al. (2012), "Traditional Chinese medicine research in the post-genomic era: Good practice, priorities, challenges and opportunities", *Journal of Ethnopharmacology* 140(3): 458-468.
- van den Ham, R., Bero, L. y Laing, R. (2011), *The World Medicines Situation 2011: Selection of Essential Medicines*, Ginebra: OMS.
- van den Heuvel, R., Stirling, C., Kapadia, A., Zhou, J. (2018), *Medical Devices 2030: Making a power play to avoid the commodity trap*, KPMG, disponible en <https://institutes.kpmg.us/content/dam/institutes/en/healthcare-life-sciences/pdfs/2018/medical-devices-2030.pdf>.
- van Luijn, J. C., Gribnau, F. W. y Leufkens, H. G. (2010), "Superior efficacy of new medicines?", *European Journal of Clinical Pharmacology*, 66(5): 445-448.
- Viergever, R. F. y Hendriks, T. C. C. (2016), "The 10 largest public and philanthropic funders of health research in the world: What they fund and how they distribute their funds", *Health Research Policy and Systems* 14: 12.
- Vitry, A. I., Shin, N. H. y Vitre, P. (2013), "Assessment of the therapeutic value of new medicines marketed in Australia", *Journal of Pharmaceutical Policy and Practice*, 6(1): 2.
- Vivot, A., Jacot, J., Zeitoun, J.-D., Ravaud, P., Crequit, P. y Porcher, R. (2017), "Clinical benefit, price and approval characteristics of FDA-approved new drugs for treating advanced solid cancer, 2000-2015", *Annals of Oncology*; 28: 1111-1116.
- Vogler, S. y Schneider, P. (2019), "Medicine Price Data Sources", in *Medicine Price Surveys, Analyses and Comparisons*, Vogler, S. (ed.), Londres: Academic Press.
- Vogler, S., Zimmermann, N., Habl, C., Piessnegger, J. y Bucsecs, A. (2012), "Discounts and rebates granted to public payers for medicines in European countries", *Southern Med Review* 5(1): 38-46.
- Von Der Ropp, A. y Taubman, T. (2006), "Bioética y derecho de patentes: El caso de Myriad", *Revista de la OMPI* 4: 8-9.
- Vondeling, G. T., Cao, Q., Postma, M. J. y Rozenbaum, M. A. (2018), "The impact of patent expiry on drug prices: A systematic literature review", *Applied Health Economics and Health Policy* 16(5): 653-660.
- Wang, H., Sun, Q., Vitry, A. y Nguyen, T. A. (2017), "Availability, price, and affordability of selected essential medicines for chronic diseases in 11 countries of the Asia Pacific Region: A secondary analysis", *Asia Pacific Journal of Public Health* 29(4), 268-277.
- Wang, H., Vinyals Torres, L., Travis, P. (2018), "Catastrophic health expenditure and financial protection in eight countries in the WHO South-East Asia Region", *Bulletin of the World Health Organization* 96(9), 610-620E.
- Ward, A. (2015), "Medical Research Council faces budget crunch from 'patent cliff'", *Financial Times*, versión en línea, 16 de agosto de 2015, disponible en: <https://www.ft.com/content/bdd435c6-4293-11e5-b98b-87c7270955cf>.
- Wasserman, E. (2016), "Takeda loses again to Hikma in gout drug patent battle", *FiercePharma*, versión en línea, 24 de mayo de 2016.
- Watal, J. (2001), "Taller sobre Fijación Diferenciada de Precios y Financiamiento de Medicamentos Esenciales", nota de antecedentes elaborada por Jayashree Watal, Consejera de la Secretaría de la OMC, Ginebra: OMC.
- Watal, J. y Dai, R. (2019), "Product Patents and Access to Innovative Medicines in a Post-TRIPS-Era", Staff Working Paper ERSD-2019-05, Ginebra: OMC.
- Weires, R. (2019), "Recent advances in biologics manufacturing diminish the importance of trade secrets: a response to Price and Rai", *Written Description*, 4 de marzo de 2019.
- Welch, A. R. (2016a), "The Norwegian biosimilar phenomenon: From biosimilar to 'biogeneric'", *Biosimilar Development*, versión en línea, 26 de julio de 2016.
- Welch, A. R. (2016b), "What to know about emerging market biosimilar pathways", *Biosimilar Development*, versión en línea, 24 de junio de 2016.

- Wendland, W. y Jiao, F. (2018), "Intellectual Property Rights and Traditional Medical Knowledge in Africa: Issues and Development", en Wambebe, C. (ed.), *African Indigenous Medical Knowledge and Human Health: Research, Development, and Delivery*, Boca Ratón (Florida): CRC Press.
- West, D. M., Villasenor, J. y Schneider, J. (2017), *Private Sector Investment in Global Health R&D: Spending Levels, Barriers and Opportunities*, Washington D.C.: The Brookings Institution.
- Wieseler, B., McGauran, N. y Kaiser, T. (2019), "New drugs: where did we go wrong and what can we do better?", *BMJ* 366: l4340.
- Williams, H. L. (2017), "How do patents affect research investments?", *Annual Review of Economics* 9: 441-469.
- Wingrove, J. (2019), "SPC waiver may drive innovator investment in secondary patents and litigation", *Patent Strategy*, versión en línea, 9 de mayo de 2019, disponible en: <https://patentstrategy.managingip.com/Articles/38>.
- Wirtz, V. J., Hogerzeil, H. V., Gray, A. L., Bigdeli, M., de Joncheere, C. P., Ewen, M. A., et al. (2017), "Essential medicines for universal health coverage", *The Lancet* 389(10067): 403-476.
- Workman, P., Draetta, G. F., Schellens, J. H. M. y Bernards, R. (2017), "How much longer will we put up with \$100,000 cancer drugs?", *Cell* 168(4): 579-583.
- Wouters, O. J., Kanavos, P. G. y McKee, M. (2017), "Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes and Spending", *Millbank Quarterly* 95(3): 554-601.
- Wouters, O. J., Sandberg, D. M., Pillay, A. y Kanavos, P. G. (2019), "The impact of pharmaceutical tendering on prices and market concentration in South Africa over a 14-year period", *Social Science & Medicine* 220: 362-370.
- Yadav, P. (2010), *Differential Pricing for Pharmaceuticals: Review of current knowledge, new findings and ideas for action: A study conducted for the UK Department for International Development (DFID)*, Zaragoza.
- Yamane, H. (2011), *Interpreting TRIPS: Globalisation of Intellectual Property Rights and Access to Medicines*, Oxford y Portland (Oregón): Hart Publishing.
- Young, R., Bekele, T., Gunn, A., Chapman, N., Chowdhary, V., Corrigan, K. et al. (2018), "Developing new health technologies for neglected diseases: A pipeline portfolio review and cost model", *Gates Open Research* 2: 23.
- Zain, S. (2014), "Antitrust Liability for Maintaining Baseless Litigation", *Santa Clara Law Review* 54(3): 729-759, disponible en: <http://digitalcommons.law.scu.edu/lawreview/vol54/iss3/5>.
- Ziegler, N. Gassmann, O. y Friesike, S. (2014), "Why do firms give away their patents for free?", *World Patent Information* 37: 19-25.