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Data Exclusivity in the Regional Comprehensive Economic Partnership (RCEP)[1]

A rule proposed by Japan and South Korea in negotiations for the Regional Comprehensive Economic Partnership (RCEP) would be substantially more harmful for access to medicines than similar rules proposed in prior free trade agreements (FTAs).

Background

Many recent FTAs include provisions on data and/or market exclusivity. Marketing and data exclusivity rules are separate from patents. These rules provide backstop protection for pharmaceutical companies in cases where patents are not sufficient. Even where there are no unexpired patents for a medicine, exclusivity rules serve as a broad barrier to the manufacturing of competing products at lower prices.

Pharmaceutical companies are increasingly intent on using data and/or marketing exclusivities as their most effective monopoly tool, because, unlike patents, these exclusivities take effect from the time a medicine is actually introduced into a given market. The exclusivities may outlast patents, or provide greater clarity of monopoly periods to investors while limiting prospective litigation costs and uncertainty. Framing data exclusivity in terms of innovation was the industry's successful effort to persuade the policymakers in the U.S. and European Union to lengthen these drug registration-related monopolies and to export them via trade agreements.

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Data protection v. data exclusivity

Data protection (TRIPS): Article 39.3[i] of TRIPS covers the protection of undisclosed information, which relates broadly to what are generally known as trade secrets.[ii] It does not require "data exclusivity," which prevents regulators from relying on a pharmaceutical company's data to evaluate competing products.[iii] Instead, Article 39.3 only requires protection of undisclosed test data on new chemical entities, the collection of which involved considerable effort, against disclosure unless steps are taken to ensure that the data is protected against unfair commercial use.

Under Article 39.3, each Member is required at a minimum to protect data against unfair commercial use and disclosure that meet the following five criteria:

- The test data was submitted as a condition for obtaining marketing approval for a product in that Member country.
- The product for which marketing approval was sought was a pharmaceutical or agricultural chemical product.
- The product for which marketing approval was sought contained a new chemical entity.
- The test data was undisclosed at the time of submission.
- The generation of the test data required considerable effort.

It should be noted that Members are not required to protect test data for products that are not considered pharmaceutical or agricultural chemical products. By way of illustration, if a Member requires the submission of test data to obtain approval to market certain industrial chemicals, i.e. dyes or detergents that could contain new chemical entities, the regulatory authorities cannot be required, pursuant to Article 39.3, to protect undisclosed information related to these products.

Additionally, the protection of data is subject to two exceptions:

- Protection of the public: This is an unobjectionable exception, which requires disclosure without any confidentiality restrictions. For example, making public a health threat posed by a given agrochemical or pharmaceutical product is a vital function of regulatory agencies. This is a clear instance when the public interest need must override industry desires for confidentiality.
- Honest commercial practices: A regulatory agency should not disclose test data without taking measures to protect against unfair commercial use. Each country's notion of 'honest commercial practices' is taken into account to distinguish between fair and unfair use.

Article 39.3 makes it clear that the public is the ultimate beneficiary of the information that is submitted to regulatory authorities. Thus, Article 39.3 does not prevent those authorities from disclosing information to protect the public interest, including public health, nor from allowing medical test data to be publically scrutinized rather than shrouded in secrecy.

Data exclusivity (NAFTA): The North American Free Trade Agreement (NAFTA) includes a similar passage, but also specifically prevents *regulators from relying on an originator's data for a reasonable period*.[2] The U.S. sought a provision in TRIPS based on this NAFTA paragraph. This proposed provision was excised from the TRIPS Dunkel Draft in 1991 and was never restored to the TRIPS Final Act of 1994.[3]

The TRIPS drafters' refusal to adopt the NAFTA provision is one of several factors demonstrating their intention to provide for some level of data protection, but not data exclusivity, in TRIPS.

[2] North American Free Trade Agreement Art.1711.5, Dec. 8, 1993, 32 I.L.M. 289 (1993).
[3] Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary On the TRIPS Agreement* 23 at 385-87 (2007).

Exclusivity rules delay generic drug registration for a specified period of time, by limiting the ability of generics manufacturers and regulatory authorities to make use of an originator companies' data to demonstrate safety and efficacy of their own products and thereby grant generics marketing approval.

If a drug truly had five years of data exclusivity, the marketing authority would not be able to consider a generic application for five years, which would, in turn, provide the innovator another one to three years of market monopoly after the data exclusivity period expires before a generic could be approved and enter the market. This is because it takes that long for the marketing authority to analyze the generic's application and grant it marketing approval.

Market Exclusivity

The U.S.-model exclusivity provisions require governments not to permit third parties to market the same or similar product using the same test or other data concerning the safety and efficacy of the product.

The distinction between data and market exclusivity is important. Marketing exclusivity means the generic CAN apply during this period for marketing approval, but such a generic application would not be eligible for approval until the exclusivity period (five years) has elapsed. However, the generic can enter the market the day after the marketing exclusivity period is over.

Article 5.16 Treatment of Test Data in Marketing Approval Procedure

Leaked draft proposals by Japan and South Korea have revealed that RCEP is substantially similar to the Trans-Pacific Partnership (TPP), particularly in respect to the intellectual property chapter.[4] Therefore, intellectual property rights and access to affordable medicines is as precarious in RCEP negotiations as it was in the TPP talks.[5]

Among all, one provision in the leaked-text requires particular attention:

[4] Chatterjee, *supra* note 8.
[5] *Id.*

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Article 5.16: Treatment of Test Data in Marketing Approval Procedure

[JP/KR propose; ASN/AU/IN/NZ/CN oppose

Each Party shall prevent applicants for marketing approval for pharmaceutical products which utilize new chemical entities from relying on or from referring to test or other data submitted to its competent authority by the first applicant for a certain period of time counted from the date of approval of that application. As of the date of entry into force of this Agreement, such period of time is stipulated as being no less than five years by the relevant laws of each Party.35]

FN35: [JP/KR propose; ASN/AU/IN/NZ/CN oppose: "pharmaceutical products" shall include import products.]

This Japan and Korea proposed provision provides very strict **data exclusivity** (which goes far and beyond the TRIPS agreement and even the TPP which is TRIPS-plus and even TPP-plus) for the test or other data submitted to the marketing authorities. The leaked provision is more aggressive than prior FTAs in many ways.

- **Subject Matter:** The exclusivity applies to marketing approval for pharmaceutical products which utilize new chemical entities. Small molecule drugs are referred to as new chemical entities (NCEs). Large molecule drugs that are derived from living cells or organisms, such as animal or human blood, are called biologics or biopharmaceuticals. The exclusivity does not apply to biologics because biologics are treated differently from chemically synthesized pharmaceutical products.
- **Obligation:** If a country imposes an obligation to submit data as a condition to obtain marketing approval, the national regulatory authority has to provide exclusivity to the first applicant. The authority has the obligation to prevent other applicants (generic manufacturers) from relying on or referring to test data. This means the authority would not be able to accept or consider a generic application that references or relies on the test data of the brand-name company during the exclusivity term. In other words, regulatory review of a generic drug application cannot begin until after the exclusivity period expires. Generics, then, in practice, would be kept off the market for considerably longer than five years.

If the national authority relies on marketing approval conferred in another country, with no data submitted to the national regulatory authority, then the obligation need not apply. If a national authority relies on marketing approval conferred in another country but still requires submission of data, or if data is submitted on a voluntary basis, the exclusivity is provided for the first applicant.

- **Scope:** The data exclusivity applies to the test or other data submitted by the first applicant in support of marketing approval, which may well be disclosed and in the public domain. Given the broad scope of the provision, the data voluntarily submitted by an applicant, or in excess of those required for approval are also subject to protection.
- **Term:** The term shall not be less than 5 years.
- **Public Health safeguards:** Data exclusivity rules are separate from patents. Patents have well-established flexibilities, such as compulsory licensing, to protect health. The text includes no express public health safeguards to deal with data exclusivity. Governments have limited experience overriding data exclusivity in order to protect health.

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Public Health Safeguards: A myth or reality?

All of the recent U.S. FTAs, including the TPP, contain a provision providing safeguards for governments to take measures to protect public health in accordance with the TRIPS Agreement and Doha Declaration[iv]. The provision borrows the language from the May 10 Agreement[v] and previous FTAs (Peru–U.S. FTA, Korea-U.S. FTA). Those involved in drafting the provision say it was designed precisely to overcome data exclusivity and facilitate the use of generics when governments so choose. It was meant to be analogous to compulsory licensing for patents: a tool to introduce generic competition when an exclusive right poses an obstacle for health.

But are these safeguards specific enough to protect health? The increasing prevalence of public health interventions creates a need to analyze the scope of governments' ability to supersede exclusivity provisions. The U.S.FTA-style Doha safeguards provide little specific guidance. The inbuilt flexibility for compulsory licenses is not reflected under the exclusivity provisions.

Professor Carlos Correa highlights this problem in his analysis of the TPP intellectual property chapter:

> *"this language has little or no practical effect. It would not limit in any manner the obligations imposed by the agreement. The referred to Declaration only confirms the flexibilities allowed by the TRIPS Agreement in relation to public health matters (such as compulsory licenses and parallel imports), but it is unlikely to provide a sufficient legal basis to derogate from the obligations established by the TPP."* [vi]

The Doha Declaration confirms the flexibilities of the TRIPS agreement. Its protections may be interpreted by some as not relevant to the provisions going beyond TRIPS in FTAs. Multinational pharmaceutical companies could seek to take advantage of this.

In the absence of an explicit public health exception overriding data exclusivity in appropriate circumstances, a compulsory license on a patent could be rendered moot. Although the compulsory license would prevent patent obligations from standing in the way of needed domestic production or export of a patented drug, production of the drug would still be blocked by data/market exclusivity since generic firms must still obtain marketing approval.

Article 31 of TRIPS[vii], which provides for compulsory licensing, is explicitly about patents. FTAs, like RCEP, do not explicitly require that compulsory licenses be effective or override any data/market exclusivity to allow generics to enter the market. Article 31 only ensures that a compulsory license can be issued on the patent.

A European Commission communication from 20 February 2006[viii] claimed that compulsory licenses on patents did not allow the overriding of data exclusivity, as the exclusivity law did not allow it:

> *"However the Community pharmaceutical acquis does not currently contain any provision allowing the waiver of the rules on data exclusivity and marketing protection periods described above in the case of a national or an EU-wide emergency.*
>
> *Before the expiry of the data exclusivity and marketing protection periods provided for by the European pharmaceutical legislation, applicants for a generic marketing authorization have to either (1) provide the relevant authority with the required documentation on pre-clinical tests and clinical trials or confirm that the marketing authorization holder has consented to the use of the required documentation by the applicant. "*

The general and vague language of this provision may not give countries the confidence to override exclusivity provisions with compulsory licensing-like mechanisms in cases where there is a compulsory license on pharmaceutical patents. Above all, the provision does not address how these safeguards can be used to override exclusivity on unpatented drugs.

Conclusion

Governments are responsible for maintaining an appropriate balance between promoting access to, and fostering innovation in, medicines. Any exclusivity rules will unduly expand pharmaceutical industry monopoly power and limit governments' ability to formulate sensible policies to promote access and keep medicines affordable, and should be rejected.

In the Japan- and Korea-proposed text, there are no clear, express safeguards to protect public health. Any future proposed safeguards should be evaluated for their clarity and likely effectiveness. Indeed, the rule as formulated is even more harmful than the similar TPP rule, because in practical terms it would extend market monopolies beyond the statutory period. That is because it imposes data exclusivity, rather than marketing exclusivity – meaning generics likely cannot even begin the regulatory process until the period expires.

The RCEP countries should reject the inclusion of any exclusivity provisions as TRIPS-plus and harmful to access to medicines. Negotiators should be especially wary of the proposed data exclusivity rule, which includes the worst of all proposals.

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[i] "*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use*."

[ii] The Agreement on Trade Related Aspects of Intellectual Property Rights Art.39.3 Apr. 15, 1994, 1869 U.N.T.S. 299, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm#7

[iii] *Data exclusivity in international trade agreements: What consequences for access to medicines?,* MSF technical brief (May 2004), *available at* http://www.citizen.org/documents/dataexclusivitymay04.pdf.

[iv] TPP Article 18.50.3 "Notwithstanding paragraphs 1 and 2 and Article 18.52 (Biologics), a Party may take measures to protect public health in accordance with: (a) the Declaration on the TRIPS [Agreement] and Public Health (WT/MIN(01)/DEC/2) (the "Declaration"); (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; or (c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties."

[v] "For pharmaceutical products, Article 16.10.2(e)(i) of the Agreement provides an exception to the data exclusivity obligations for measures to protect public health in accordance with the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Doha Declaration"). Thus, where a Party issues a compulsory license in accordance with Article 31 of the TRIPS Agreement and the Doha Declaration, the data exclusivity obligations in Chapter Sixteen of the Agreement will not prevent the adoption or implementation of such a public health measure. In addition, in a case in which there is no patent on the pharmaceutical product, and, therefore, no need to issue a compulsory license, the data exclusivity obligations in Chapter Sixteen will not prevent the adoption or implementation of such a measure."
The United States – Colombia Trade Promotion Agreement Implementation Act, P. 30, http://waysandmeans.house.gov/UploadedFiles/COLOMBIA_Statement_of_Administrative_Action.pdf.

[vi] Carlos M. Correa, *Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines,* South Centre Research Paper 62 (Sep 2015), *available at* http://www.southcentre.int/wp-content/uploads/2015/08/RP62_IP-in-TPP-Increasing-the-Barriers-Access-to-Affordable-Medicines_EN.pdf.

[vii] Article 31 of the TRIPS Agreement (other use without authorization of the right holder): Compulsory licensing is only part of this since "other use" includes use by governments for their own purposes.

[viii] Terberger M, *Tamiflu applications and data exclusivity in an emergency compulsory license situation*, Letter to the European Generic Medicines Association, Brussels: Enterprise and Industry Directorate-General, European Commission (2006), *available at* https://www.google.ch/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=0ahUKEwiz1OCUqozLAhUsJpoKHflCAyYQFgglMAE&url=https%3A%2F%2Fwww.wcl.american.edu%2Fpijip%2Fgo%2Feu02202006&usg=AFQjCNHb_3sp23argriMcYCo1qbL-iaZ9w.