

DATA EXCLUSIVITY AND OTHER “TRIPS-PLUS” MEASURES

REGULATING MEDICINES

The pharmaceutical market is highly regulated. Two sets of laws and regulations play a crucial role in this market. These are i) the intellectual property laws and ii) the laws and regulations about drug registration. These two sets of laws have different objectives, and are administered by different government agencies.

Intellectual property rights, notably patents (on which this briefing note will focus, since they have the most profound implications on access to medicines) are meant to reward innovation by providing inventors with temporary monopoly rights. Patents, however, confer negative rights: a patent on a certain pharmaceutical product means that the patent holder can prevent others from producing or selling that product. But it does not give the patent holder the right to actually sell that medicine. In order to be allowed to sell a medicine, it has to be registered by the national Drug Regulatory Authority.

The drug regulatory system, or registration system, seeks to ensure that only medicines of assured safety, quality and efficacy are available on the national market. This is important, since consumers do not normally have sufficient information and knowledge about a pharmaceutical product to make their own assessment about its quality, safety and efficacy. In addition, medicines that are ineffective or of poor quality can be dangerous, both for the patient and for public health.

In order to assess the quality, safety and efficacy of a product, the Drug Regulatory Authority will normally require the manufacturer to provide relevant information. For instance, in order to assess the quality of the product, samples will have to be tested, the production procedures will have to be documented and validated, and the production facility may have to be inspected.

Meanwhile, the safety and efficacy of pharmaceuticals is demonstrated mainly via pre-clinical and clinical trials. Safety and efficacy can also be demonstrated by showing that a product is chemically and biologically equivalent to an existing medicine (the safety and efficacy of which are already known). However, by definition, ‘bio-equivalence’ can *not* be demonstrated for

entirely *new* pharmaceuticals, since there will be no similar existing medicines with which to compare them. Thus, in practice, only generic manufacturers can demonstrate the safety and efficacy of their products via bio-equivalence tests.

This latter point is important, since bio-equivalence tests are much smaller in scale than full-fledged clinical and pre-clinical trials. Thus, they can be conducted faster, and are considerably less expensive.

DATA EXCLUSIVITY

The clinical and pre-clinical trial data that originator companies submit to the Regulatory Authority are at the centre of the debate on “data exclusivity”.

Because bio-equivalence data only prove that a generic medicine behaves in the body in the same way as the original product (the safety and efficacy of which have already been established), one could say that the generic company and the Regulatory Authority indirectly rely on the clinical trial data provided by the originator company.

Originator companies argue that, since they made substantial investment in these trials, they deserve a period of “data exclusivity”; a certain length of time during which the Regulatory Authority cannot rely on the originator’s data in order to register a generic version of the same product.

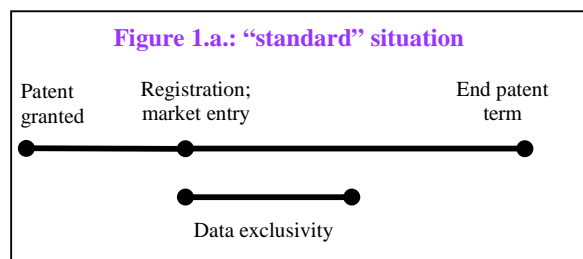
By implication, as long as the exclusivity lasts, generic producers would have to submit their own data to prove safety and efficacy, which would oblige them to repeat the clinical trials and other tests. This is something that would cause significant delay, and that many generic manufacturers cannot afford. Moreover, it would raise serious ethical questions, since it would mean that clinical trials will have to be repeated, purely for commercial reasons.

Alternatively –and in practice much more likely– generic producers would have to delay the launch of their product until the end of the exclusivity period¹. Thus, data exclusivity diminishes the likelihood of speedy marketing of generics, and delays competition and price reductions.

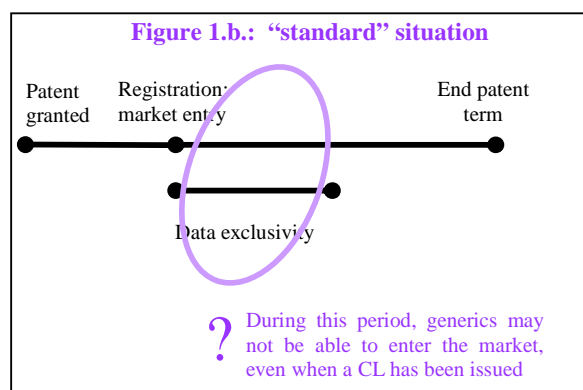
¹ In the United States, data exclusivity lasts five years for new chemical entities and three years for new indications. In the European Union, it is 10 years with a possible one year extension in case the drug is registered for a significant new indication.

IMPLICATIONS OF DATA EXCLUSIVITY

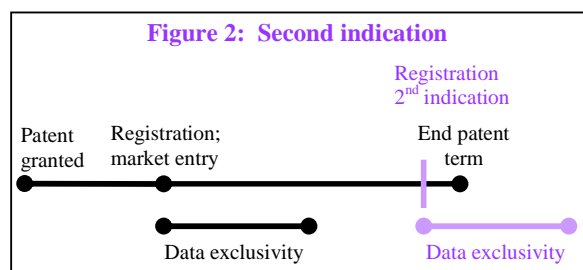
Proponents of data exclusivity at times point out that data exclusivity does not have major implications, since the period of data exclusivity would normally be shorter than the patent duration (see Figure 1a).



Yet, there are some questions as to whether data exclusivity could prevent the registration of medicines produced under a compulsory license (see Figure 1b). If so, data exclusivity would effectively render the compulsory license useless.



Secondly, if a period of data exclusivity is also granted when an existing medicine obtains marketing authorization (or registration) for a second or new indication, data exclusivity could (be used to) extend the period of exclusivity of the originator product (see Figure 2).



Finally, data exclusivity could prevent the registration of generic versions of medicines even when there is no patent on a medicine, for example when a pharmaceutical does not meet the standards for patentability (e.g. because it is not new), when a country has no patent law, or when no patents are granted for pharmaceuticals. The latter situation can arise in least-developed World Trade Organization (WTO) Member

Countries, which do not have to grant patents for pharmaceuticals until 2016.²

TRIPS DOES NOT REQUIRE DATA EXCLUSIVITY

It has at times been argued that Article 39.3 of the TRIPS Agreement makes it mandatory for countries to grant data exclusivity. However, careful reading of Article 39.3 (see Box 3) does not warrant this conclusion; the text of the Article does not make any reference whatsoever to exclusivity or exclusive rights.

Article 39.3 requires countries to protect undisclosed registration data about new chemical entities i) against disclosure and ii) against unfair commercial use. Thus, regulatory authorities may not publish registration data³, or share them with third parties (e.g. generic competitors). This is a clear requirement. But there is some debate as to what exactly is meant by 'unfair commercial use'. Does the use of bio-equivalence studies instead of full clinical trials represent 'unfair commercial use'?

Clearly, there is no 'unfair commercial use' by the generic company. The generic manufacturer never uses the originator's data, and does not even have access to them. Meanwhile, the regulatory authorities also do not normally use the originator's data – though, as mentioned above, they may (indirectly) rely on them. But even if the regulators would use those data, this is not commercial use, since the regulatory agency is not a commercial organization. Legal experts have also pointed out that, in the context of Article 39 of TRIPS, the term 'unfair commercial use' refers to, and prohibits, practices such as industrial espionage, but was not meant to provide exclusive rights (Correa, 2002). Nor was it meant to interfere with the work of a government body tasked with protecting the public.

Thus, legal and public health experts believe that TRIPS requires data protection, but not data exclusivity – and national laws do not need to be more stringent or more restrictive than TRIPS.

Box 3: Article 39.3 of TRIPS

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.

² According to the Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Doha, Nov. 2001 (or the "Doha Declaration").

³ Though it is important to note that they may do so when this is necessary to protect the public.

It is also worthwhile to note that in developing countries, regulatory authorities often rely on data that are already published or otherwise in the public domain – and that therefore do not fall within the scope of Article 39.3 (which only imposes protection for *undisclosed* data).

MITIGATING THE IMPACT

As mentioned above, from the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection.

But if a country, for some reason (see below), *does* grant data exclusivity or otherwise provides data protection beyond that mandated by TRIPS, it is important to limit its potential negative implications on access to medicines. This can for example be done by limiting its duration and/or scope (e.g. only for new chemical entities) and by providing that reliance on the originator’s safety and efficacy data is allowed in case of compulsory licensing.

OTHER “TRIPS-PLUS” PROVISIONS

Requirements to offer exclusive rights to originator products that go beyond what is mandated by the TRIPS Agreement are sometimes referred to as “TRIPS-plus” requirements. Data exclusivity is an important example. But it is not the only example. Other “TRIPS-plus” requirements are for instance:

- *Patent term extensions*, i.e. provisions to extend the duration of a patent beyond the 20 years required by TRIPS, in order to compensate for delays in granting the patent or in registering the medicine. It is important to note that there is no obligation, from an international/legal perspective, to grant such extensions⁴.
- *Limitations of the grounds for compulsory licenses*, which may preclude issuing a compulsory license for reasons of public health. Requirements to limit the grounds (or reasons) for issuing a compulsory license go directly against the Doha Declaration⁵, which has unambiguously confirmed that countries are free to determine the reasons for granting compulsory licenses.
- *Linkage between patent status and generic registration*, meaning that the Regulatory Authority may not register generic versions of a pharmaceutical that is under patent. This would be problematic, since the Regulatory Authority would probably lack the resources and manpower to check the patent status of each product. Moreover, in case there is a patent, regulators may not have the

⁴ Moreover, it should also be noted that at times the patent holder is responsible for those delays.

⁵ Declaration on the TRIPS Agreement and Public Health, see footnote 2.

expertise to assess whether the patent is valid and would be infringed⁶. As a result, it is likely that they will enforce *all* patents, even invalid ones – and thus create additional and unnecessary hurdles for generic competition⁷. “Linkage” is also problematic in view of the fact that patents are private rights; as such, they should be enforced by the right holders, not by the government.

Other “TRIPS-plus” requirements deal with the administrative procedures related to patent applications and/or the granting and revocation of patents. The common feature of all “TRIPS-plus” provisions is that they have the effect to complicate and/or delay the marketing of generics, and thereby reduce access to medicines.

Yet, while these requirements are going beyond the TRIPS Agreement –or, in other words, are not required by TRIPS– in recent years, “TRIPS-plus” requirements have at times been incorporated in bilateral or regional free trade negotiations, in bilateral investment agreements and in other international agreements and treaties. From the perspective of access to medicines, this is a worrying trend; countries should therefore be vigilant and should not ‘trade away’ their people’s right to have access to medicines.

Box 4: Expanding data exclusivity requirements

Initially, requirements for data exclusivity focused on undisclosed data that have been submitted to regulatory authorities. However, more recently, there have been cases where such demands just referred to ‘information’ – which could potentially expand the scope of data exclusivity significantly by preventing regulators from relying on data that are in the public domain in order to register a generic medicine.

CONCLUSION

Medicines fall under two separate legal and regulatory systems: the intellectual property system and the drug regulatory system. These systems have different objectives, are administered separately and function independently. Recent efforts to integrate these two systems via data exclusivity, “linkage” or other means are likely to have negative implications for access to medicines. Thus, (developing) countries would be well advised to keep these systems separate, and to reject any and all efforts to make connections between them.

⁶ For these reasons, Regulatory Agencies in the EU have so far refused to implement such “linkage” between patent status and registration of medicines.

⁷ In 2002, the US Federal Trade Commission found that when generic companies initiate patent litigation, they prevail in a significant number of cases.

REFERENCES AND FURTHER READING

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4. Robert Weissman. Public health-friendly options for protecting pharmaceutical registration data. International Journal of Intellectual Property Management ([forthcoming](#)).