Symposium on the Evolution of the Regulatory Framework of Test Data – From the Property of the Intellect to the Intellect of Property

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Test Data Protection - The WIPO Perspective

Global Challenges Division

INTRODUCTION – A BRIEF EXPLANATION OF THE TITLE

Intellectual property can be defined as a set of principles and rules that discipline the acquisition, the use and the loss of rights and interests in differentiating intangible assets susceptible of being used in competition.

The core function of IP is to differentiate, by means of distinctive signs, of knowledge, of expressions.

It is because of that core function that notions like novelty, inventiveness, non-obviousness, creativity, originality are so important for IP. In their essence, they mean the same: differentiation.

IP, in its various branches, is formed by differentiating assets. But not all differentiating assets are part of IP.

For example, not all forms of new knowledge are protected by IP, such as pure or scientific knowledge. In general, only knowledge that is the result of inventive activity is the subject of IP.

This is what the title refers to as “the property of the intellect” – intellectual property anchored on invention at a certain level.

However, there is a trend in moving towards the protection of knowledge that is the result of pure observation or of efforts of collection, such as non-original contents of databases and gene sequences (associated with a specific function).

This is what the title refers to as “the intellect of property” – intellectual property almost in abstract, without the anchor of the creative effort.

THE WIPO PERSPECTIVE

"In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect […] data submitted to governments or governmental agencies […]."

Because the Paris Convention is administered by WIPO, it should follow that Article 39.1 of the TRIPS Agreement inherently expresses WIPO perspective.

However, this is not true.

Test data are those data – any sort of data – submitted to governments, upon their request, as a condition to obtain marketing approval. They are trade secrets because they are undisclosed. Under 39.3, they must also pass a proportion test, because only test the origination of which involves a considerable effort are under mandatory protection.

Test data are knowledge about certain characteristics of a pharmaceutical product. They do not differentiate the product because they are not incorporated into the product. They are extrinsic to the product, they do not concern the composition of the product or its use. They are not the result of invention or creation, they are the product of observation.

However, they are nevertheless differentiating of the company, which has the data necessary to persuade the government to grant marketing approval.

But not all differentiation is protected. And indeed Contracting Parties to the Paris Convention have refused to extend the repression of unfair competition to information.

This matter was debated in the Diplomatic Conferences of the Hague, in 1925, and London, of 1934.

At the Hague, the delegation of Serbia-Croatia-Slovenia proposed to include in Article 10bis of the Paris Convention an additional example of subject matter protected against unfair competition.

"All news obtained by a newspaper or a news agency, in whatever form, their content or the method by means of which they would be transmitted … as long as their commercial value will subsist."

Spain supported this proposal but other delegations refused to approve it.

In 1934, in London, Czechoslovakia reintroduced the 1925 proposal, with a caveat: protection would be available only during the first 24 hours that followed the first publication of the news.

Later Czechoslovakia dropped its proposal and supported Germany’s motion:

“The disclosure, without authorization and with commercial purposes, of news reports, regardless of their content or means of transmission, made before the expiry of one day following the first publication, as well as any disclosure with commercial purposes without indication of the source.”

Italy opposed this, because it would imply the recognition of property rights in information, “which is inadmissible.”

Italy would accept to protect the notion of priority: “the effort of the person who first, due sometimes to a considerable financial sacrifice, brought [the news] to the knowledge of the public.”

Germany’s proposal was rejected because of lack of consensus: 13 votes in favor, 5 votes against [Austria, Denmark, United States, Finland, Japan]; 13 abstentions.

Therefore, it may be submitted that test data are not covered by Article 10bis because, like press reports, they are information.

Are they covered, nevertheless, as trade secrets, because they are undisclosed?

There is no immediate answer to this question, other than by resorting to the implementation of the Paris Convention at the national level. And, indeed, even if a large number of developing countries, during the TRIPS negotiations, denied the IP-dimension of trade secrets, the reality is that a large number of them have enacted measures to protect trade secrets as a modality of repressing unfair competition.

But, interestingly, in the whole history of negotiations of the Paris Convention, during the six diplomatic conferences between 1883 and 1967, the term ‘trade secrets’ was used one single time, at the conference of the Hague (1925), by a delegate of Poland who submitted a rather theoretical paper on the repression against unfair competition.

It can be said that there is no authority in the history of the Paris Convention that permits to say with certainty that Article 10bis covers trade secrets.

Moreover, a literal reading of Article 10bis leads us to believe that its provisions aim at preventing confusion through the elimination of the **external** differentiation of the products, the establishments or the businesses. However, trade secrets, because they concern information, are elements of **internal** differentiation of products (or services).

Test data are a different sort of trade secrets. They are secret information with a value for competitors, yes, but the business model at stake in 39.3 is not one of a competitor (mis)appropriating valuable trade secrets that are in possession of another.

Article 39.3 is about data that are submitted by private companies to governments. This is a matter generally dealt with by constitutional, administrative or civil law. Generally, it is a matter for each State to decide what to do with confidential information submitted by citizens in the daily business of government administration.

The disclosure of that information by the governmental agencies in question may have a negative impact on the businesses that submit them, but it is not an act of competition.

Besides, to use that information to benefit a competitor may be prejudicial and discriminatory against the submitter, but it is not a dishonest practice in industrial or commercial matters.

Therefore, WTO Members may protect test data while ensuring effective protection against unfair competition, as provided in Article 10bis of the Paris Convention.

But WIPO Member States that are not WTO Members are not obliged to do so or to give that same interpretation to Article 10bis.

IS IT THE WIPO PERSPECTIVE THAT TEST DATA SHOULD STAY OUT OF IP?

NO!

It was said above that IP is about protecting differentiating intangible assets and that test data are differentiating.

It is up to society to establish the qualifiers that justify that a differentiating asset be protected.

In the case of test data, that qualifier may very well be the investment and the efforts put in the origination of the data.

And indeed the history of IP shows that society has resorted to proprietary protection for intangible assets the origination of which was based on non-inventive or creative efforts, such as financial investment, allocation of time and human resources.

For example, before the emerging of copyright, several European countries granted privileges for the exclusive publication of certain works.

Those privileges were justified on the investment made by the publishers in purchasing the manuscripts of classical works and hiring reviewers, as Erasmus wrote in defense of Froben, a publisher in Basel (c. 1460-1527).

A modern example of protection against parasitism (in the absence of fraud and deceit) is the repression of ambush marketing, by which companies that did not financially contributed to sponsor a certain event are prohibited to associate their names or brands with that same event.

Other examples are, as mentioned, non-original contents of data bases and non-modified ADN sequences (in regard of which a specific function has been identified).

Measures that prevent or repress parasitism should be eligible for protection by IP to the extent that parasitism, like fraud, copy, counterfeit or imitation, reduces or eliminates the differentiation of companies and products.

Let us not forget that there is a UN Treaty that has language that points in the same direction of Article 39.3 of the TRIPS Agreement. It is the United Nations Set of Principles and Rules on Competition, of 1980.

Section E, Article 5 provides that

"Where, for the purposes of the control of restrictive business practices, a State obtains information from enterprises containing legitimate business secrets, it should accord such information reasonable safeguards normally applicable in this field, particularly* to protect its confidentiality."

(* We could add "but not only"…)

It is society that must measure the value of repression of parasitism as compared to the gains in differentiation.

This is the core and the essence of IP. In finding the right proportion between the social cost and the social value of IP lies the solution to handle it in a manner conducive to social and economic welfare.

Thank you.