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A Strong Generic Competition for a Sustainable Agriculture and an Innovative Dominant Industry

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Since the Doha Declaration on the TRIPS agreement and public health adopted on 14 November 2001 the battle to clarify the data protection provisions has reached new heights.

The immense lobbying of the dominant industry and the tremendous leverage their governments usually carry over emerging nations has led to radical bilateral agreements.

Trumpeting its effects, President BUSH declared on the US-MOROCCO Fee Trade Agreement, « This agreement protects intellectual property to an extent never before achieved in any free trade agreement with a developing country ».

More recently the CIPIH[1] report has shown the difficulties associated with a multilateral approach.

Reflecting the international lack of consensus, heated debates within the European Union drag out the revision of directive 91/414/CEE[2]

Two camps oppose each other.

On the one hand, between a centralized process for the evaluation of commercial products and a decentralized process at the level of every member State or at the level of geographic zones bringing together partly or in totality several member states.

For the first one, what is at stake is the implementation of a perfectly harmonised regulation for the whole of the European single market in which no objective difference would come to oppose this perfect and total harmonisation.

For the second, agronomic, climatic, pedological, etc. differences would come to justify the necessity for a decentralised procedure.

On the other hand, on the existence of the protection of data and the duration of its exclusive use.

[1] Commission on Intellectual Property Rights, Innovation and Public Health (WHO)
[2] Calling for a enormous amount of data, the directive harmonises the evaluation of new and existing (called the revision) active substances thus creating a positive list.

Pros and cons of data protection and zonal approach to registration of plant protection products (PPP) can be transposed to the wider international context where, in the same way, they affect parallel trade and generics access to market.

In the EU as internationally, these two major oppositions should, in fact, find consensus through consideration of the aims and objectives of the regulation, which is to protect the essential requirements[3] the necessity of which is not disputed by any one.

A European directive rightly criticized

The EU Commission points to the performance of the regulatory process by the fact notably that it would have led to eliminating more than 400 substances from the community market when these withdrawals result nearly exclusively from the industry's decision not to « invest » in the risk evaluation relating to these substances.

Nothing indicates that the alternatives to these withdrawn substances are more favourable to public health and the environment. It is a fact however that they are more profitable for the industry and thus more expensive for the user who cannot pass on this additional cost to the consumer.

REACH[4] and directive 91/414/EEC

There seems to be no limit to what the dominant industry is prepared to pay to secure its dominant position.

Envisaged as a strategic element adjunct to patent protection, the more regulatory data is expensive the better. However this is only true if it ensures effective protection. This becomes plainly obvious from the dominant industry's strong opposition to EU propositions to regulate other chemical substances.

The communications of France, Germany and the United Kingdom coming to the support of the dominant industry on the proposed REACH illustrate perfectly the ambiguity of a regulation that claims nevertheless to be exclusively dedicated to the protection of public health and the environment.

From the moment that this regulation would no longer further fulfil this other objective, that is the commercial protection of the industry, it is perceived as an unbearable threat to the extent that State leaders themselves drop their reserve and take side publicly against the regulation.

And it is not without cynicism that the dominant industry wonders about the impact of the regulatory project REACH on the good health of small and medium-sized companies (SMF) while since 1991 it refuses to see the impact that directive 91/414/EEC has effectively on an INDEPENDENT generic industry.

But it is true that the directive of 1991 contains in its articles 13 and 14 the protection of data and that REACH, still a draft, does not make provisions for such « compensation ».

[3] The safeguard of public health and the environment.

[4] The Commission proposed a new EU regulatory framework for the Registration, Evaluation and Authorisation of Chemicals (REACH) on 29 October 2003. The aim is to improve the protection of human health and the environment through the better and earlier identification of the properties of chemical substances.

Of the failure of a regulation

Four major observations are obvious :

- A dying INDEPENDENT generic industry tries in vain to speak up.

- A thriving dominant industry surfs the agenda for reviewing the regulation with clear claims in terms of data exclusivity and zonal application but also reluctance to clarify the more obscure areas of the implementation in particular at local level.

- Consumers' anxiety, which is more and more distinct, thwarts the idea according to which the process of evaluation guarantees objectively the safety of agricultural produce.

- the users, farmers, realise that the directive of 1991 amounts exclusively to a documentary inventory of studies which is totally disconnected from the production and from the marketing of products containing the evaluated substances. It is a fact that no control at present looks for nor can put in evidence that substances brought on the European market really originate from processes of synthesis examined within the framework of the community evaluation.

Return on … investment

Within a decade, the dominant industry has transformed itself from a processing industry into a service industry, which processes only paper to constitute files. It has been reduced to the role of a « trader » that trades products that are custom manufactured by producers in India or China. These producers have no chance of direct access to finished products under marketing authorisation (MA) and to profitable markets. Henceforth, and with the added effects of international agreements signed by those governments, INDEPENDENT Indian and Chinese generics producers have become an endangered species.

In this context, the confidentiality of the data on the characterisation and the quantification of the impurities resulting from a precise process of synthesis as well as all the studies of impact of a substance on public health and the environment amounts more to a blind licence disconnected from the real conditions of marketing than to a notion of equity towards the industry which financed these studies.

The justifications for an exclusive use of the data

1991 is not 'year one' from which the industry has had to produce the data relating to the impact of its products on public health and the environment.

Perfecting the evaluations performed earlier by the competent authorities of every member State cannot justify any compensation especially when it amounts to reinstating fallen patents.

This notion, established by articles 13 and 14 of the directive, cannot even be inferred from the ADPIC agreements. The question arises thus, why a reward would come over and above the intellectual property rights (I.P.) internationally recognised on the grounds that the industry agrees to this complete review of existing substances that is an improvement of the protection of the essential requirements.

Nor do the main rules framing I.P. within the European Union provide for this notion including when, and lastly, the regime for SCPP[5] was introduced to compensate for the delay resulting from the application for the MA.

Equity, for whom and according to what criteria

The users and consumers would be the main beneficiaries of the costs paid by the industry to perfect the evaluation of risks. The users, because this improvement would upgrade their production; and the consumers because they would benefit from healthier food.

And industry ?

Would it not already have benefited from the exclusivity conferred by patents and further extended by the SCPP, not to mention the synergic effects of multiple process patents which perpetuate the protection[6] ?

The exclusivity of data comes to increase over and above the profits already made and affect directly the prices paid by users without any justification.

Incidentally, from this arises a surprising internal distortion of competition within the dominant industry between the 'old' substances, which regain protection and 'new' substances still patented, which do not benefit from supplementary protection since their evaluation occurs during the lifetime of the basic patent.

Clearly it is more advantageous to review an 'old' substance than to evaluate a 'new' one.

Henceforth, the protection of data does not promote innovation. And, this, even less so that contrary to patent protection, it does not allow public access to relevant information and suppresses benefits from progress resulting from shared knowledge.

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So that the innovative industry innovates in the interest of health and the environment

Under a permanent monopoly, manufacturers have never seemed focused on innovation.

It is of course faced with the threats from generics and with the aim of blocking them that better product formulations appear just before patents are due to run out.

Suddenly, the latter are more suited to meet essential requirements, and are also aimed at blocking access to the market for generics that are merely a copy the formulation of the old patented speciality.

The same applies to innovation in terms of active substances, which is rarely seen while a patent is still alive.

[5] Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30).

[6] « evergreening » coins the concept of lasting protection in relation to those perennials that keep leaves in winter.

Hindering access to market for generics amounts to undermining any technological progress liable to improve chemical compositions and/or PPP formulations with a view to safeguarding public health and the environment.

This stagnation is all the more harmful, given that innovation can help eliminate the most harmful substances.

Generics stimulate innovation.

By hindering the preservation or the arrival of generics, the protection of data hinders innovation and comes to oppose the essential objectives aimed by the EU directive.

For an EU review that does not preclude plant diversity

Practically monopolised inclusions of substances in Annexe 1 of Directive 91/414 deprived the market of specialities whose effects on health and the environment were considered acceptable while perpetuating others much more open to discussion.

But there is another, equally damaging effect such inclusions have: they mean discontinuing substances notifiers[7] consider uninteresting in terms of profitability, which deprives some minor crops of any phytosanitary protection whatsoever.

For generics, profitability criteria are different.

This is why a strong generics industry is essential, and is consistent with a risk management strategy that includes preserving the diversity of plant production.

Precisely the same applies to minor uses, for which efforts to obtain extended marketing authorisation are not something the dominant companies are renowned for.

Besides, the attraction of novelty combined with the effects of advertising hype that accompany new speciality launches leads to their virtual hegemony and to resistance phenomena from the parasites they fight, increasingly hard, close and frequent.

By way of example, the arrival en masse of strobilurines has, in less than five years, shown how essential the old triazoles were.

Here, once again, the existence of a generic industry strong enough to keep old specialities on the market, which the major companies have abandoned in favour of new ones, arises out of a necessity, the agricultural relevance of which should be taken into account.

For an objective re-evaluation exempt from conflicts of interests.

An independent EU re-evaluation financed a priori by authorities is the guarantee of a harmonised regulation, commercially neutral and consistent with the rules of the single market.

The transfer, with hindsight, of controllable and containable costs by the public authority to, notably, the holders of MA has to take into account that the re-evaluation serves exclusively the public interest.

In this way, the costs incurred for reviewed substances not complying with new requirements must, as it is very often the case in other sectors, be borne by the community.

[7] Companies notifying their interest to support the inclusion in the positive list of an active substance through data generation.

For example, did the producers of asbestos finance the studies leading eventually to the ban of this substance?

Besides, an independent review ought to initiate the re-evaluation of substances removed from the European market for the sole reason that they were not fully supported by at least one notifier.

For a PPP regulation consistent with those of other regulated products.

It is a fact that the marketing of PPP and medicines involve comparable concerns and interests[8].

It is a fact that EU directives aiming at the harmonisation of procedures for evaluating medicinal products provide for the centralized MA and make it compulsory in some cases.

It is a fact that professionals of agriculture understand less and less why a PPP not authorised in a member state can be used in another one when the agricultural produce resulting from its use moves freely within the European single market.

The inconsistency of directive 91/414/EEC with these three certainties is no longer bearable.

It is all the less bearable as the procedure for mutual recognition does not work or so badly that it became unacceptable.

The centralised MA necessarily must become the resulting consequence of the re-evaluation of the 'old' substances and the evaluation of the new ones.

Thus, and indeed beyond differences of opinion and corporatist interests, the revision of directive 91/414/EEC has to exclude the protection of data and include the notion of centralised MA if only not to be inconsistent with the objectives it sets and with the community provisions of which it is an integral part.

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In the light of the European experience, and when implementing their obligations under international law, members of the WTO must consider carefully the far-reaching implications of a complex set of binding national regulations and international law.

It is plainly clear is that data exclusivity does not bring about solutions for a diversified, sustainable agriculture, but that it can create agronomical problems related to standardisation.

Any new commitment should be evaluated against the benefits but also find consensus through consideration of the aims and objectives of a regulation, which ultimately is to protect the essential requirements the necessity of which is not disputed by any one.

It must not reduce competition.

The EU experience has further highlighted the fact that by creating a new I.P. right, that is data exclusivity outside the duration of the basic patent the « Dominant Industry » has secured for itself the WHOLE CAKE !

[8] ECJ : judgment of 14 July 2005, case C-114/04 – point 24

This is increasingly misunderstood, unpopular, and like any excessive immoderation, unsustainable. It will run up against its own contradictions and all kinds of dispositions including competition law.

Finally, European farmers, through their association, will be supportive of your initiatives since access to effective generic PPP in the EU will depend on the extent to which Indian and Chinese authorities will manage to secure the independence of their agrochemical producers.