Regulatory data protection under TRIPs Article 39(3) and Article 10bis of the Paris Convention: Is there a doctor in the house?

Christopher Wadlow, University of East Anglia
Regulatory data protection under TRIPs Article 39(3) and Article 10bis of the Paris Convention: Is there a doctor in the house?

Christopher Wadlow

Keywords

Abstract
Article 39 of the WTO TRIPs Agreement has attracted much attention for the protection its final paragraph affords for regulatory data in the pharmaceutical and agrochemical industries, but the literature has tended to treat Article 39(3) in individual isolation. This is to ignore one of the most striking features of Article 39, which is that in contrast to every other substantive provision of TRIPs, it expressly defines its entire scope of application by reference to a pre-existing treaty, the Paris Convention for the Protection of Industrial Property, and specifically Article 10bis of the latter, dealing with unfair competition. This article reconsiders the relationship between TRIPs Article 39 and Article 10bis of the Paris Convention, and concludes that the scope of application of the substantive provisions of Articles 39(2) and (3) is confined by Article 39(1) to what the draftsmen of the Paris Convention would have defined as the “industrial” sphere. The principal consequences are to exclude non-commercial secrets such as personal medical details from the scope of Article 39 altogether, and the results of Phase II and III clinical trials from the scope of Article 39(3), in the latter case on the ground that there is a relevant distinction between the pharmaceutical industry, responsible for synthetic and medicinal chemistry, and pre-clinical research and development in general, and the medical profession, which is responsible for the later stages of in vivo trials on real patients.

Status and citation
This is a pre-publication draft of an article originally published in Intellectual Property Quarterly, [2007] I.P.Q. 350-402 (published by Sweet & Maxwell in association with the Intellectual Property Institute, London). Some minor variations compared to the published text may remain, and the comparative table of draft treaty provisions (Appendix A) is not reproduced. Citations should be to the published version.

* Professor of Law, University of East Anglia, Norwich, England.
Introduction

The protection of undisclosed information

Article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) carries no title of its own, but is the single article comprised in Section 7 of Part II, entitled “Protection of Undisclosed Information”. Article 10bis of the Paris Convention for the Protection of Industrial Property also stands on its own, though the latter treaty is not formally subdivided above the level of individual articles. Its unofficial but universally recognised title is “Unfair Competition”. Since 1994, the two articles have been connected by the language of TRIPs Article 39(1):

In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

As is clear from the terms of Article 39(1), although it is far from apparent from the title alone, Article 39 in fact deals with two distinct situations which are sometimes conflated, but which at other times need to be distinguished. Article 39(2) deals with “undisclosed information”, which certainly includes, and may be confined to, ordinary industrial and commercial trade secrets of every kind. Article 39(3) deals with what this article will call “regulatory data” in the pharmaceutical and agrochemical industries.¹

The TRIPs and Paris provisions in issue

Article 39 of TRIPs,² and Article 10bis of the Paris Convention,³ respectively provide:

Section 7: protection of undisclosed information

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

¹ “Regulatory data” is widely used and understood in this context. See generally Trevor Cook Regulatory Data Protection in the Pharmaceutical and Other Industries (London: Sweet & Maxwell, 1999). It is to be distinguished from “database rights” (e.g. under Directive 96/9/EC of 11 March 1996 on the Legal Protection of Databases) and personal “data protection” (e.g. under Directive 95/46/EC of 24 October 1995 on the Protection of Individuals with regard to the Processing of Personal Data). Regulatory data are protected in the EC under Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community Code relating to Medicinal Products for Human Use.

² The Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, 1994).

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices [fn] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. 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.

[fn]. For the purpose of this provision, “a manner contrary to honest commercial practices” shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

The provision of the Paris Convention which is here incorporated by reference reads:

Article 10bis

[Unfair Competition]4

(1) The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

(2) Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.

(3) The following in particular shall be prohibited:

(i) all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

(ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

4 The official text of the Paris Convention has no titles for individual articles. Those provided by the International Bureau of WIPO (formerly BIRPI) are unofficial, but universally accepted.
(iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

The approach of this article

There is a substantial literature on Article 39, much of it specifically directed towards the protection of regulatory data under paragraph 3. This is a large enough topic in its own right, and it is probably fair to say that much of the literature deals rather briefly, and even dismissively, with the relevance of Article 10bis of the Paris Convention. Much of it quite appropriately focuses on the detailed wording of Article 39(3), or on its socio-economic implications, particularly with respect to the desirability (or not) of regulatory data protection as compensation for erosion of the patent term, or as a reward or incentive for the generation of the necessary data. Another topic of increasing importance is the conflict between the post-Doha tendency to facilitate compulsory licensing of medicines in response to Global epidemics such as AIDS, malaria, and TB, and the absence of any explicit compulsory licensing mechanism in the regulatory data regime of Article 39(3).

A typical approach might be to start with the language of Article 39, to note the reference to Article 10bis, to go to the latter and note that it is concerned with prohibiting “unfair
competition” and “acts contrary to honest [commercial] practices”, and to take it as read that misuse of trade secrets, or of regulatory data (as the case may be) is so self-evidently “unfair” and “contrary to honest commercial practices” that the application of Article 10bis can be taken for granted. At this point the Paris Convention is typically allowed to drop out of the picture altogether, and the argument proceeds by reference to paragraphs 2 and 3 of Article 39 alone, with paragraph 1 reduced to a mere preamble.

The present article will take an altogether different approach, by taking Articles 39(1) and (3) of TRIPs as a composite whole, and concentrating on the relationship between them and Article 10bis of the Paris Convention, rather than taking paragraph (3) of Article 39 in isolation. It will take seriously the self-evident proposition that Article 39 is tightly bound to Article 10bis, both by explicit cross-reference and by intentional tracking of the latter’s concepts and language; and it will look critically behind the assumption that the latter article has any inherent application to the protection of regulatory data per se.7

Interpreting Article 39(3): the range of opinion

The US and EU positions on Article 39(3)

As this article proceeds, it will be instructive to compare its arguments and conclusions with the official lines of the parties most supportive of Article 39(3) during the TRIPs negotiations, namely the United States and the European Communities.8 According to the Office of the United States Trade Representative:9

“TRIPS negotiators understood it [the term ‘unfair commercial use’] to mean that the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorised by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision.”

7 In order to complete the analysis, it will be necessary in due course to examine the internal relationship between Articles 39(1), (2) and (3), and specifically the question of whether regulatory data is protected as an aspect of trade secret protection, with Article 39(2) providing some kind of conceptual bridge between Article 39(3) and Article 10bis of the Paris Convention. However, in view of the length of the present treatment of Article 39(3), this will be postponed to a later article.

8 The immediate source of both quotations is Basheer (2006) at page 8.

And according to the European Communities, in considering whether to recommend proceedings against Turkey under the Trade Barriers Regulation:\(^{10}\)

“In the light of these considerations and despite certain divergence of opinion, the text, context and purpose of Article 39.3 of TRIPS suggest that in order to guarantee that no ‘unfair commercial use’ within the meaning of Article 39.3 shall be made, regulatory authorities should not rely on these data for a reasonable period of time. In other words, providing data exclusivity for a certain period of time is the envisaged way to protect data against unfair use as prescribed by Article 39.3.”

**The canons of interpretation**

The TRIPs Agreement is traditionally interpreted according to guidelines taken from the Vienna Convention on the Law of Treaties, and in particular Articles 31 and 32. The former begins by stating the general rule of interpretation:\(^{11}\)

\[
\text{A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.}
\]

The basic principles of interpretation may therefore be summarised as good faith; fidelity to the text; observance of the context; and adoption of a teleological (rather than an unduly literal) approach.\(^{12}\) According to Article 32 of the Vienna Convention, supplementary means of interpretation may be invoked if the application of the general rule of Article 31 either leaves the meaning ambiguous or obscure, or leads to a result which is manifestly absurd or unreasonable. In either of those cases, it is appropriate to have recourse to the preparatory work and negotiating history, collectively referred to as the *travaux préparatoires*\(^{13}\).

---

\(^{10}\) *TBR Proceedings concerning Turkish Practices affecting Trade in Pharmaceutical Products* (Brussels: European Commission; September 13, 2004) at page 40.


\(^{13}\) See below, at fn. 46.
One particular corollary of the Article 31 principles, to which the Appellate Body of the WTO is particularly attached, is that of “effective interpretation”.\textsuperscript{14} In the leading case of \textit{US—Gasoline}\textsuperscript{15} the Appellate Body observed:

“One of the corollaries of the ‘general rule of interpretation’ in the Vienna Convention is that interpretation must give meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.”

Likewise, in \textit{US—s 211 Omnibus Appropriations Act}\textsuperscript{16} (an intellectual property case) the Appellate Body observed that to have upheld the decision under appeal would have been “to deprive Article 8 of the Paris Convention (1967), as incorporated into the TRIPS Agreement … of any and all meaning and effect.” The panel decision was therefore reversed.

In the body of this article, it will be argued that the interpretation of TRIPs Article 39 favoured by the United States and the European Union\textsuperscript{17} (and which is taken for granted by many commentators) in fact involves a breach of the principle of effective interpretation quite as flagrant as that under review in \textit{US—s 211 Omnibus Appropriations Act}, since it reduces Article 39(1) to complete nullity. For Article 39(1) to be rescued from “redundancy or inutility”, there must be some sense in which the reference to the Paris Convention in Article 39(1), and specifically to Article 10bis, does indeed condition what would otherwise be the unconstrained operation of Articles 39(2) and (3) taken on their own.

The problem which then arises is that at first sight, Article 10bis of the Paris Convention has so little in common with the subject matter of Article 39(3) of TRIPs that the pairing is simply impossible: there are no circumstances in which the observance of the TRIPs-specific obligations under paragraph (3) of Article 39 can arise “in the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention”. So do we simply ignore Article 39(1) and apply Article 39(3) regardless? This, of course, simply leads to the problem of effective interpretation arising in reverse, and at first sight we are faced with an aporia: an apparently irresolvable internal contradiction or logical disjunction in the text. One way forward from this state of deadlock will involve looking into the negotiating history and \textit{travaux préparatoires} of Article 39, as we are expressly invited to do when the

\textsuperscript{14} Corresponding (at least approximately) to the Latin maxim \textit{ut res magis valeat quam pereat}.  


\textsuperscript{17} Above, fn. 8.
General Rule of Article 31 fails to yield an acceptable interpretation on its own; but first, let us see how the problem of effective interpretation (whether or not so-called) is addressed in the literature.\textsuperscript{18}

**The academic literature: what effect for Article 10bis?**

Perhaps the best and shortest summary of the relationship of Article 39(1) to Articles 39(2) and (3) comes from Bronckers and Ondrusek, who describe the former as a *chapeau*.\textsuperscript{19} The term is familiar from GATT,\textsuperscript{20} where it is used to denote some kind of final and over-riding legal requirement which otherwise compliant measures must meet if they are to be upheld. The point of the *chapeau* is that it gathers into one place one or more essential or overriding criteria which apply equally to two or more distinct sub-situations, each of which typically has its own specific rules to itself, according to the subject matter dealt with. One of the most familiar examples of a *chapeau* is the introductory formula which governs all the enumerated exceptions of GATT Article XX:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade …

Numerous cases exist of measures which have been found to satisfy one or more of the individual paragraphs of Article XX, but which have failed to pass the *chapeau*. The two sets of criteria may sometimes be related, even to the point of overlapping to some extent, but they are always logically separate.

This description of TRIPs Article 39(1) as a *chapeau* may be unfamiliar, but it is entirely appropriate. Paragraph (1) governs two situations which are sufficiently closely connected to be dealt with together, but which have differing subject matter and separate criteria for protection. Like the *chapeau* to Article XX of GATT, it may conveniently be applied as a final step after

\textsuperscript{18} Basheer (2006) is the most explicit in his invocation of the principle by name (citing *US–Gasoline*), but he arguably uses it in a rather one-sided manner—to demolish Correa (2002)—and fails to provide a satisfactory explanation as to how his preferred compensation model gives any real effect to either Paris 10bis, or Article 39(1).

\textsuperscript{19} Marco Bronckers and Petr Ondrusek “Protection of Regulatory Data in EU and WTO Law: the Example of REACH” (2005) 8*Journal of World Intellectual Property* 579–598 at page 586. It is interesting to note that the description occurred to a pair of lawyers who are specialists in international trade law, rather than intellectual property. The term was previously used by Jacques Gorlin in *Analysis of the Pharmaceutical-Related Provisions of the WTO TRIPs (Intellectual Property) Agreements* (London: Intellectual Property Institute, 1999) at page 44.

\textsuperscript{20} General Agreement on Tariffs and Trade (Geneva, 1947). Attempts to define “*chapeau*” may confine themselves to provisions (such as this) which are unnumbered within the article in which they occur. If so, Article 39(1) is a *chapeau* by nature, if not in name.
working through the enumerated criteria of paragraph (2) or (3), as the case may be. It would have been pointless and wasteful to have duplicated the common criterion of paragraph (1), by repeating the text *in extenso* for each of paragraphs (2) and (3). Above all, the nature of a *chapeau* means that compliance is in no sense presumed, guaranteed or pre-determined: a measure may sail through the criteria of Article XX(b) or (d), say, and still be wrecked on the *chapeau*.

However, there is a problem with the “*chapeau*” analysis of Article 39(1), which is that of the “aporia” or irresolvable internal contradiction alluded to at the end of the last section. What effect do we give to the *chapeau* of Article 39(1), if it can *never* be met in any of the circumstances of Article 39(3)? Do we attempt to reconcile the two somehow, or do we discard the one, or the other, and if so, which? On what basis do we chose between the options? In the last resort, and with apologies for inflicting a truly dreadful pun on the reader, are we sending a blind man, into a dark cellar, to look for a black hat, that isn’t even there? \(^{21}\)

**Skillington and Solovy**

Identifying a clear spectrum of opinion on the separate effect of Article 10bis is made more difficult by the fact that several authors, especially those at the more proprietary end of the spectrum of opinion, tend to treat it very briefly, if they do not ignore it altogether. Perhaps the most breathtaking position on the residual (un)importance of Article 10bis is that adopted by Skillington and Solovy, who roundly declare (citation omitted): \(^{22}\)

> “By virtue of TRIPS Article 39, the 146 Members of the WTO agree that unfair commercial use and disclosure of certain test and other data constitute unfair competition within the meaning of the Paris Article 10bis. Given that the Members constitute the majority of the countries in the World, it would appear that those acts have been ‘established in international trade’ as dishonest practices and acts of unfair competition. Thus it follows from the commentary of Professor Bodenhausen that all countries of the Paris Union must now consider these acts as contrary to honest practices, and impose the protection required by TRIPS article 39.3.”

---

\(^{21}\) “Black cat” is more frequently heard today than “hat”, but “hat” is the original formulation. See John Alderson Foote *Pie Powder* (London: John Murray; 1911) at page 26, attributing the phrase to Lord Bowen and expressly condemning the “cat” variant as inauthentic: “When I hear of an ‘equity’ in a case like this, I am reminded of a blind man in a dark room—looking for a black hat—which isn’t there.” Americans and cat fanciers may prefer William L. Prosser “My Philosophy of Law” (book review) (1942) 27 *Cornell Law Quarterly*, 292 at 294. Lord Bowen himself would surely have been disarmed by its wise and self-deprecating sense of humour.

So a highly contentious interpretation is unilaterally advanced for an admittedly ambiguous,\textsuperscript{23} if not actually self-contradictory provision, and the correctness of that interpretation is sufficiently proved by the fact that parties which are known to have contested any such interpretation at the time, are supposed to have demonstrated their acceptance of the contentious interpretation by signifying their agreement to the very text whose meaning is under debate. The blatant circularity of the reasoning is astonishing.

**Correa**

At the opposite end of the socio-political spectrum there is Professor Carlos Correa:\textsuperscript{24}

“The ordinary meaning of ‘unfair’ is ‘not equitable or honest or impartial or according to rules’. In the case of Article 39.3, this concept must be understood in the light of Article 10bis of the Paris Convention. The concept of ‘unfair’ is relative to the values of a particular society at a given point in time. It varies among Members, and this variation is in fact one of the premises on which the discipline of unfair competition is grounded. There is no absolute, universal rule to determine when certain practices should be deemed ‘unfair’:

‘Morality, which is the source of the law of unfair competition, is a simple notion in theory only. In fact it reflects customs and habits anchored in the spirit of a particular community. There is no clearly objective standard of feeling, instincts, or attitudes toward a certain conduct. Therefore, specific prescriptions involving uniform evaluation of certain acts are extremely difficult.

The pressures existing in the various countries for the suppression of acts of unfair competition differ greatly. Generally, the development of law of unfair competition depends on active and intense competition in the marketplace by competing enterprises. It is the pressure of conflicting interests which leads to the establishment of clear rules of law. This pressure is not uniform in all countries and indeed it is evolving continuously.’

Ladas concludes his treatise’s discussion of the issue by indicating that:

\textsuperscript{23} See below, fn. 154.

We look for a standard by which we may judge the act complained of. This is an objective standard: the honest practices in the course of trade in the particular community and at the particular time.

Given this diversity, it is likely that different countries will judge certain situations differently, depending on their values and competitive advantages. Some countries may consider it an ‘unfair practice’ for a ‘follower’ company to commercially benefit from the data produced by the originator, via a marketing approval system based on ‘similarity’; or hold that such commercial benefit gives rise to claims of ‘unjust enrichment’ leading to a compensation for the use of the data. In others, it may be regarded as the legitimate exploitation of an externality created during legitimate competition in the market.”

This approach may appear to be diametrically opposed to that of Skillington and Solovy, but in fact it shares at least two characteristics with their analysis. First, both approaches assume that Article 10bis is elastic, in the sense that it may stretch to include regulatory data (and, by implication, trade secrets) regardless of whether that article protected them at any point in the past. In this respect Article 10bis has, so to speak, a “floating” interpretation, rather than one which is fixed at a particular point in time. Secondly, both approaches eliminate any possibility of discord between Articles 39(3) and 10bis, because a single standard of “fairness” applies whether the issue is the “fairness” of competition in general (Article 10bis), or the “fairness” of a particular commercial use of the information in question (Article 39(3)). Of course where they differ is in the result. According to Correa, “fairness” is evaluated on a country-by-country basis and from year to year, so that at any particular stage in a country’s development it may either accept, or reject, the values underpinning Article 39(3), according to the relative importance it places on the private and public spheres. What is “fair” for the purposes of Article 10bis is then “fair” for Article 39(3), and vice versa, but it is “fair” only for the here and now, and not everywhere, nor forever. Correa accepts that if the United States and the European Communities want to protect regulatory data in their own territories, then it is perfectly “fair” for them to do so, but by the same token it is just as “fair” for India or Brazil to make their own value judgments, and do the opposite. Except for the three nominate cases of Article 10bis(3), every member of Paris or TRIPs, as the case may be, retains an unfettered sovereign discretion to decide whether particular acts of alleged unfair competition are to be regarded as “fair” or not.

Fellmeth

The immediate problem with Correa’s analysis is that by making Article 39(3) wholly voluntary, he reduces it to so much wasted ink. Of course if Article 39(3) were not there in the first place, then TRIPs members would be free to legislate for regulatory data protection, just as they were
before 1994, and just as they are now are free to legislate for utility models, plant varieties, and traditional knowledge, or any number of known or emergent intellectual property rights which TRIPs does not address. But Article 39(3) is there, and we must do our honest best to give it some real effect. Fellmeth (after commenting that “[t]he relevance of Article 10bis of the Paris Convention to Article 39.3 of the TRIPs Agreement is obscure”) not only disputes Correa’s conclusion, but attempts to turn the apparent mismatch of Articles 39(3) and 10bis against him.25

“The applicability of Article 10bis of the Paris Convention to Article 39.3 of the TRIPs Agreement is distinctly limited. Carlos Correa has concluded that the unfair commercial use standard is inherently subjective, and, consequently, Article 39.3 must be interpreted to grant discretion to WTO members to define unfair commercial practices. If Correa is correct, then Article 39.3 has little legal import beyond defining the confidentiality obligation. If the ‘unfair commercial use’ of Article 39.3 is intended to carry the same meaning as the ‘unfair competition’ of Article 10bis, then the reference to Article 10bis gives cold comfort to states claiming that Article 39.3 of the TRIPs Agreement requires data exclusivity. It is unlikely that either the disclosure of marketing approval data by a governmental public health agency, or the use of such data to allow competition in the market for drugs, could contravene Article 10bis of the Paris Convention. Neither practice could reasonably be considered dishonest or likely to lead to confusion about the source of the data. Nor does the drug regulatory authority, by allowing other companies to rely on this data to obtain marketing approval for similar or identical drugs, violate standards of honesty or mislead anyone. It appears, then, that the obligation imposed in Article 39.1 of the TRIPs Agreement with respect to Article 10bis of the Paris Convention is separate and distinct from the obligation under Article 39.3 to protect marketing approval data against ‘unfair commercial use.’ This interpretation is supported by the choice of terminology in Article 39.3, which differs from the terminology of the Paris Convention and that of Article 39.1. It is further supported by the architecture of Article 39, which locates the duty to provide drug marketing approval data with ‘effective protection against unfair competition’ in a paragraph different from that imposing a duty to ‘protect such data against unfair commercial use.’”

So according to Fellmeth, if we are to attempt to make any sense at all of Article 39(3) we must altogether detach it from Article 39(1), throw away the chapeau, and treat it as free-standing. But bizarrely, Fellmeth does accept that Article 39(1) governs Article 39(2):26

“Article 10bis of the Paris Convention is, however, relevant in its entirety to Article 39.2 of the TRIPs Agreement. Article 39.2 defines what constitutes a protectable trade secret for purposes of Article 39 and provides that private owners of trade secrets must have the right to prevent the disclosure of their trade secrets ‘in a manner contrary to honest commercial practices.’”

So despite the perfect symmetry of architecture between Articles 39(2) and 39(3) in their subordination to Article 39(1), Fellmeth would have us believe that Article 39(1) has its “chapeau” effect only for Article 39(2), and not for 39(3). What Fellmeth really seems to have in mind is that we must somehow or other cut Article 39(3) free from Article 39(1), because though they may survive separately, the fundamental incompatibility of the two means that the fate of Article 39(3) would be sealed if they were made to hang together. In his desire to distance himself from Correa, Fellmeth falls into exactly the same logical trap: he reduces Article 39(1) to the status of wasted ink, at least in so far as it would otherwise allow Article 10bis to govern Article 39(3), in order to save Article 39(3) from the same fate. Compared to Correa, he simply reverses the choice of which is to stand, and which must fall.

Skillington and Solovy vs Correa

To return to where we left Correa’s treatment of “fairness”, Skillington and Solovy would say that both aspects of “fairness” have already been answered once and for all, and on a uniform, near-global scale, according to a particular proprietary set of values which are supposed to have been accepted along with Article 39(3) when the WTO Agreements were signed in 1994, or, at the latest, when a sufficient number of states had joined to out-vote those still outside. On this analysis, a provision of a later treaty (TRIPs) which expressly incorporated concepts from a pre-existing treaty (Paris), is now supposed to have been effective to re-write that earlier treaty in so far as the provisions of the latter were not already perfectly congruent with the later one, and to no one’s surprise, the Paris obligations so re-interpreted match perfectly with TRIPs! On this view, the TRIPs tail wags the Paris dog. It is interesting to note that Skillington and Solovy do not deign to consider whether or not protection of regulatory data was ever within the scope of Article 10bis prior to 1994, and from their point of view this was (and is) completely irrelevant. Nor do they flinch from the conclusion that a subsisting Paris Convention provision may have been extended (apparently de jure as well as de facto) to circumstances never previously within its scope by a mere majority of the members of the Paris Union, as a result of a series of closed negotiating sessions which were dedicated to another treaty entirely, which were hosted by an international organisation which had no institutional competence in respect of the Paris Convention, and from which a significant minority of Paris

---

27 “In the course of ensuring effective protection against unfair competition as provided in Article 10bis …, Members shall protect undisclosed information in accordance with paragraph 2 and [regulatory] data … in accordance with paragraph 3”.

28 See also below at fn. 76.

29 See above, fn. 46.
members were excluded, as were the numerous specialist international and non-governmental organisations which traditionally attend WIPO revision conferences as observers.\textsuperscript{30}

So how and where have Skillington and Solovy gone wrong? Partly for the reasons given above, but also in failing to distinguish between posturing and practice, or between the plane of public international law, and the plane of private law, according to whose rules competition in the real world takes place. Ladas was right:\textsuperscript{31}

\begin{quote}
"We look for a standard by which we may judge the act complained of. This is an objective standard: the honest practices in the course of trade in the particular community and at the particular time."
\end{quote}

So Article 10bis looks at what is actually practised by honest market participants, rather than what they are piously enjoined to do from aloft and afar. But despite invoking Ladas, Correa is also wrong on this point, since he makes the mistake of thinking that “fairness” according to the Ladas standard is determined by national legislatures, so that what is fair today may be unfair tomorrow, and fair again after the next election. In this respect he is no different to Skillington and Solovy: both agree that “fairness” is government property, except that Skillington and Solovy declare that the members of TRIPs and Paris have already fired their one and only shot by committing their legislative authority to a certain level of regulatory data protection, and are now \textit{functus officio}, whereas Correa believes that the majority of members still have that particular shot in their locker.

However, this is not the only place where underlying similarities and superficial differences confound and confuse. Both Skillington and Solovy on the one hand, and Correa on the other, seem to accept that Article 10bis of Paris has at least the potential to extend to the protection of trade secrets and regulatory data. At this point I strongly disagree: misrepresentation and misappropriation as no more alike than hats and cats, and Article 10bis is concerned only with the former, and not with the latter. But since this is still a recital of the prior art I must state my case through a voice which is not my own.

\textbf{Reichman}

Professor Jerome Reichman comments, also with reference to the classic commentary by Steven Ladas (citations omitted):\textsuperscript{32}

\begin{flushright}
\end{flushright}
"The international minimum standards embodied in article 10bis of the Paris Convention have evolved slowly and with great difficulty owing to disparities in the treatment of unfair competition in the domestic laws of member states and to the lack of consensus about all but the most basic prescriptions implementing the ‘confusion’ and ‘deception’ rationales of general unfair competition law. As Ladas observed in 1975, ‘the law of unfair competition, in contrast to the patent, design, or trademark law, which because of their technical character, are more or less certain and have reached a stage of maturity, has been progressing slowly, and is still full of uncertainties. Neither its basis nor its boundaries are yet settled.’ He added that the reluctance of states ‘to interfere with lawful competition made protection more difficult, the borderline between it and unfair competition being not always easy to trace.’”

And continuing the argument in his own voice:33

“One should recall, moreover, that no consensus on any general doctrines of ‘misappropriation,’ ‘slavish imitation,’ or ‘parasitical copying’ (as distinct from ‘passing off’) had been formed at the international level, and for that reason, one cannot read such doctrines into article 10bis of the Paris Convention. Had it been otherwise, indeed, article 10bis of the Paris Conventions as it stood in the 1980s might already have provided ‘effective protection’ against wholesale copying of the products of investment in high-tech goods, in which case the multilateral negotiations of the Uruguay Round that produced the TRIPS Agreement might have been superfluous.”

As I understand Reichman, he is saying here that Article 10bis, despite the superficial breadth of its language, in fact confines itself to requiring protection against a range of misrepresentation-based acts of unfair competition corresponding to those enumerated in paragraph 3(i)–(iii). I entirely agree, and with the corollary that doctrines of unfair competition based on supposed acts of misappropriation alone are altogether outside the scope of Article 10bis, because there was never sufficient international consensus as to what was fair and what was unfair in this context.

**What is “unfair” commercial use?**

Regardless of their position on the separate effect of Article 10bis, commentators also differ as to what constitutes “unfair commercial use”. This, in turn, invites two subsidiary questions: first, whether any “commercial” use of the original data occurs if it is referenced by the regulatory authority in the course of approving (or rejecting) a later application;34 and secondly, to what sources does one look in order to define the notoriously difficult distinction between what is “fair”, and what is “unfair”? We have already seen that a number of commentators in both socio-economic camps are inclined to equate the fairness aspect of “unfair commercial use” in

---


34 This issue is outside the scope of the present article.
Article 39(3) with that of “unfair competition” in Article 10bis, either directly, or by reference to the definition of the latter in terms of “honest commercial practices”.

One side of the case has already been put by Fellmeth. On the other hand, according to Trevor Cook (emphasis added):

“In relation to prohibited use, the use must be ‘unfair commercial use.’ This expression is not defined, but clearly excludes non-commercial use, such as for public health and safety. As to commercial use, such as that made when a subsequent applicant relies on the existence of such data (whether or not actually referred to), or to be more accurate, when the regulatory authority assesses the second applicant’s application in light of the data provided by the original applicant, the issue is whether or not such use is unfair. It is in this context that such matters arise as the appropriate term of protection and whether or not the protection should be an exclusive right or merely a remuneration right (and thus available for compulsory licensing).”

The problem with the latter approach is that it risks confusing the position of the regulatory authority, with that of the later applicant. To the extent that the latter “uses” the original data at all, then such use will almost inevitably be a “commercial use”, and the only remaining question relates to its “fairness”. But the acts of the regulatory authority are not commercial, even if they amount to “use” of the relevant data. Nor do they become commercial in their own right simply because their objective is to evaluate a commercial application. As Cook says, use for public health and safety is clearly non-commercial, and it is with public health and safety that the regulatory authority is wholly concerned. So why is the passage in italics “more accurate” than what preceded it? Far from adhering more closely to the text of the Article, it seems to be an attempt to rewrite it.

The preferred interpretation of Article 10bis

Introduction

What follows is my preferred interpretation of Article 10bis of the Paris Convention in all respects which have arisen so far, and which are relevant to its interaction with TRIPs Article 39. There are four issues to address: the scope of the article in terms of which legal situations or causes of action it covers, and in particular whether the enumerated examples of paragraph 3(i)–(iii) are exhaustive or illustrative; the standard by which “fairness” is to be judged; the
meaning and significance of “competition”; and the nature of the obligations imposed on members of the Paris Union in their sovereign capacity.

**Questions of scope and standard**

For substantially the same reasons as are given by Ladas and Reichman, I accept that Article 10bis in its entirety is confined to acts of unfair competition by misrepresentation, and does not extend to acts of unfair competition by misappropriation. That there was never any consensus in favour of any wider interpretation may be confirmed from the negotiating history. It follows that neither the protection of trade secrets, nor that of regulatory data, inherently falls within Article 10bis. At this point, one must distinguish between the scope of Article 10bis and the standard(s) of conduct which it prescribes. At least as far as scope is concerned, it is defined in the sense stated above, and fixed by reference to the last point in time at which the Article was re-negotiated in any relevant sense. The parties as a whole were cautious to a fault in what they were prepared to accept as binding international obligations, and cannot be taken to have legislated for a restricted misrepresentation-based regime in 1925, 1934 and 1958, only to have an open-ended misappropriation-based regime foisted on them at some later date.

My next point is that the standard of fairness, in so far as it is not pre-determined by the actual wording of Article 10bis, is evaluated according to actual honest practices in international trade and business. Such practices are necessarily susceptible to the influence of legislation (whether national or international), but in the last resort the touchstone is what honest traders do in fact, rather than what they are told they ought to do.

**Competitors and regulators**

My final point in this context is that Article 10bis applies only in situations of competition, and between competitors. What do these terms mean? The requirement of competition in Article 10bis expressly derives from the requirement of paragraph (2) that there be an “act of competition” which can be characterised as unfair, and is confirmed by sub-paragraphs (1) and (2) of Article 10bis(3), which refer to the injured party as “a competitor”. A straightforward

---

37 See above, fn. 32.


40 There is a separate argument that the relevant standard of conduct is time-dependent, within Article 10bis’ defined scope of application, but this is not the place to pursue it.

41 See above, fn 00. [Ladas].
reading of Article 10bis therefore confines its mandatory application to the rights and remedies of competitors inter se (without affecting the right of members to legislate on a more comprehensive basis if they chose), and any more extended obligation than this would have to be justified, if at all, by recourse to secondary means of interpretation. In fact, it will be found that proposals to broaden Article 10bis by deleting or replacing the words “competitor” and “competition” have been tendered and defeated, so that the negotiating history confirms that the narrow interpretation is the correct one.42

It follows that any law, legal action, judgment, or order, can only be said to be for one party’s protection “against unfair competition as provided in Article 10bis of the Paris Convention” if the adverse party is a competitor in the ordinary (economic) sense, and not merely if the adverse party happens to be responsible for some act or omission detrimental to the claimant.

**SKF/Jordan**

This distinction between the state as competitor, and the state as regulator, is well illustrated by the formal decision of the EU Commission in 1988 rejecting a complaint by Smith Kline & French Laboratories Limited (SKF) against Jordan under New Commercial Policy Instrument,43 the predecessor of the Trade Barriers Regulation. The decision concerned SKF’s product *Tagamet* (generic name, cimetidene), and SKF alleged that by enacting an amendment to its patent legislation, Jordan had deprived SKF of protection to which it was, or would have been, entitled:44

> “Smith Kline asserts that by promulgating Law 8 of 1986 amending Article 4 of Law 22 of 1953 on patents, Jordan infringed Article 10bis (1) and Article 10ter of the Paris Convention for the protection of industrial property (hereinafter referred to as the Paris Convention) and is guilty of illicit commercial practices within the meaning of Regulation (EEC) No 2641/84.

The company claims that the adoption of Law 8 was an ‘act of unfair competition’ on the part of Jordan under Article 10bis (1), in that, by removing some of the protection which the 1953 Law afforded patented inventions, under the heading of pharmaceutical products, it allowed competing firms to benefit from other firms’ investment, without any *quid pro quo* whatsoever, and this ran counter to fair industrial and commercial practice. Smith Kline added that this amendment had

---

44 Decision 89/74/EEC, paras (4)–(5).
the effect of legitimizing acts of unfair competition which it alleged had been
perpetrated by competitors before the Law was amended.”

Without going into detail, the Commission roundly rejected the underlying proposition that a
legislative act by the Jordanian Government could constitute an “act of unfair competition” in
the sense of Article 10bis, at all.45

“As regards the allegation that Jordan infringed Article 10bis of the Paris
Convention, it should be noted that the interpretation generally given to this
provision does not corroborate Smith Kline’s argument that, by amending Law 22
of 1953 in such a way as to reduce the protection previously afforded to the
patented new polymorph invention, Jordan had perpetrated an ‘act of unfair
competition’ within the meaning of this provision and had thereby infringed the
provision.

As paragraph 1 of Article 10bis does not define an act of unfair competition, the
question whether an act by a signatory party can be an act of unfair competition
must be examined in the light of the other paragraphs of this provision. In this
connection, the second paragraph of Article 10bis defines an act of unfair
competition as ‘any act of competition contrary to honest practices in industrial or
commercial matters’ and the following examples are listed in paragraph 3
[omitted]:

It follows from the above that ‘acts of unfair competition’ within the meaning of
Article 10bis can cover only those acts carried out by competitors and,
consequently, cannot include the legislative acts of a signatory State. Hence it
follows that Jordan cannot be said to have failed in its duty to provide effective
protection against unfair competition on the grounds that, by adopting Law 8 of
1986, it had carried out an ‘act of unfair competition’.”

There are two separate grounds for the decision in SKF/Jordan: first, there is the lack of any
sufficient nexus between patent protection and unfair competition law as generally understood,
but more importantly there is the impossibility of a sovereign (in that case, legislative) act
constituting an act of unfair competition in the sense of Article 10bis at all. SKF/Jordan
admittedly differs from the present case in the first respect, but not in the second.

The conclusion is that governments in their capacity as such do not commit acts of unfair
competition by exercising their proper regulatory functions, even in situations where one
business competitor considers itself to be disadvantaged in relation to another. To the extent
that there may be an enforceable obligation on the government to act “fairly” in such
circumstances, it sounds in public law, or not at all, and it has nothing to do with Article 10bis.
It follows that the relevant criterion of “fairness” is not that of the well-ordered market—or

45 Decision 89/74/EEC, paras (9)–(10).
“honest practices in industrial or commercial matters”—but that of a fair sovereign balancing the good of the public against the rights and legitimate expectations of individual subjects.

The negotiating history of Article 39

As the Appellate Body noted in US–Gambling:46

“[We] have also seen that a proper interpretation pursuant to the principles codified in Article 31 of the Vienna Convention does not yield a clear meaning … Accordingly, it is appropriate to have recourse to the supplemental means of interpretation identified in Article 32 of the Vienna Convention.”

The history of the TRIPs negotiations extends over at least three phases, only the last of which is at all well documented in the secondary literature.47 In the first phase, negotiations never got beyond the question of whether the negotiating mandate extended any further than action on counterfeiting.48 In the middle phase, there was active and aggressive consideration of proposals presented initially in the form of national or regional memoranda, and subsequently as rival draft agreements. It was during this phase that there was particularly intense disagreement between the industrialised and developing countries, not least over the precursors of Article 39. In the final phase, the various drafts and negotiating positions were reduced to one composite document. In all these phases, it is as well to remember that although the western industrialised countries set the agenda, they did not entirely control the outcome. There were also issues behind the scenes in terms of negotiating competence, democratic accountability, the preservation of existing national laws and administrative practices, and taking care that non-trade, non-IP interests were not roused into opposition. To all intents and purposes the negotiation of TRIPs was completed with the “Dunkel draft” at the end of 1991,49 even though the WTO Agreements were not signed until 1994.

The following brief, and inevitably incomplete, summary will concentrate on the negotiating objectives of the US, and subsequently the EC, in the middle and later periods, and the extent to which they were successful.


49 MTN.TNCW/FA of December 20, 1991. See below at fn. 70.
US Proposals

The United States was the first member of the GATT to table a comprehensive agenda for the TRIPs negotiations in the Uruguay Round, in the form of a document “Suggestion by the United States for achieving the Negotiating Objective”. In its original (1987) form, this already made reference to regulatory data under the rubric of trade secrets:\textsuperscript{50}

“Trade Secrets

...

Trade secrets submitted to governments as a requirement to do business shall not be disclosed except in extreme circumstances involving national emergencies or, in the case of public health and safety, provided that such disclosure does not impair actual or potential markets of the submitter or the value of the submitted trade secrets.”

In March 1988, an “informal meeting” took place over several days involving the United States, the European Communities, and a total of 23 industrialised nations.\textsuperscript{51} Sentiment at this meeting unequivocally welcomed the proposed inclusion of trade secret protection in GATT, but was lukewarm towards regulatory data protection:\textsuperscript{52}

“While a few delegations expressed sympathy with protecting information submitted to governments, many questioned the approach taken in the US paper. Delegations questioned the meaning of ‘fully recovered the market value of the information’ and ‘compelling circumstances involving public health.’ Two delegations stated that the provision was not needed, and one delegation suggested a study of existing laws to determine if a minimum standard existed.”

At about the same time, a position paper issued by associations representing US, EC and Japanese industrial interests proposed:\textsuperscript{53}

“1. Information required by a government to be disclosed by any party shall not be used commercially or further disclosed without the consent of the owner. …

\textsuperscript{50} MTN.GNG/NG11/W/14 of October 20, 1987, at page 8.


\textsuperscript{52} ibid., at page 347. The relevant text from the US briefing document (which was not one of those officially filed at GATT) is reproduced under the sub-title “Limits on Protection”.

6. Information disclosed to a government as a condition for registration of a product shall be reserved for the exclusive use of the registrant for a reasonable period from the day when government approval based on the information was given. The reasonable period shall be adequate to protect the commercial interests of the registrant.”

The previous (1987) US proposals were replaced in October 1988 by a much longer, revised version, in which the provisions on trade secrets were sufficiently detailed to run to two pages. For present purposes, the only provision important enough to reproduce in full is that dealing with governmental use:

“6, Conditions on Government Use

Trade secrets submitted to governments shall not be disclosed or used for the benefit of third parties except in compelling circumstances involving major national emergencies posing an imminent unreasonable risk to health or the environment, or to facilitate required health and safety registrations. Government use or disclosure on the basis of a national emergency may only be made where other reasonable means are not available to satisfy the need for which the government seeks to disclose or use the trade secret, and the government may use it only for the duration of that emergency. Government use or disclosure to facilitate required health and safety registrations may only be made if the trade secret has not been submitted within the previous ten years and full compensation is made for the use or disclosure. In any case, a government shall not use or disclose a trade secret to an extent greater than required to achieve one of the above needs without providing the submitter with a reasonable opportunity to oppose the proposed use or disclosure, including the opportunity to secure judicial review, or without providing for the payment of full compensation as in the case of personal property.”

Although this document did not adopt the form of a draft treaty, this paragraph is reasonably illustrative of the US position on regulatory data. The following points may be noted. First, that there is no reference, here or anywhere else, to the Paris Convention, or to “unfair competition”, “honest commercial practices” or the like. In fact, the entire document was free-standing and made no reference to any of the pre-existing intellectual property regimes. The United States appears to have preferred, at least at this stage, to legislate on a tabula rasa. Secondly, that at this stage trade secret protection for regulatory data was modelled on a fixed

54 Above, fn. 50.
56 In the case of the Berne convention, one reason for this is obvious: the United States was not even a member. In the case of the Paris Convention, the US was a member of long-standing, but it had bitter recollections of the most recent (Geneva–Nairobi) round of negotiations in 1980–84, and was determined to marginalise WIPO. See Stewart (1993); Susan K. Sell Power and Ideas (New York: State University of New York Press; 1998) and Susan K. Sell Private Power, Public Law (Cambridge: Cambridge University Press, 2003).
10 year period of near-absolute protection. Finally, the US did not use the term “regulatory data” or anything similar, but treated data submitted to governmental authorities as a special kind of trade secret.

**European Proposals**

The other major proposal was that of the European Communities in July 1988 under the title “Guidelines and Objectives proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights”. This would have provided much more briefly:

“[3]g. Acts contrary to honest commercial practices

Trade and business secrets shall be protected by law at least by providing their proprietor the right to prevent these secrets from becoming available to, or being used by, others in a manner contrary to honest commercial practices.”

This simple terminology obscures an important policy difference between the European Communities and the United States, and the beginnings of a different strategic approach. Unlike the US proposal, which was free-standing and self-contained, the EC document expressly proposed that all members should adhere to, and respect, the Paris and Berne conventions. More specifically, the Paris Convention already contained a provision for protection against acts of unfair competition in the form of Article 10bis, and it apparently suited the EC to allow the negotiators to assume that this provided a sufficient basis for its proposals on the protection of trade and business secrets. Though there was no express cross reference at this stage to Article 10bis as such, the relationship was already implicit from the phraseology of “Acts contrary to honest commercial practices”.

It may also be noted that the substantive EC proposal for trade secrets was short and vague, and without specific reference to regulatory data. At the meeting which discussed the EC proposal, the failure to address the latter was immediately noticed:

“43. In relation to the provisions on acts contrary to honest commercial practices …, a participant welcomed the inclusion of this matter but believed the provisions did not go far enough; they did not deal with the improper release of proprietary information by government agencies. … “

---

57 MTN.GNG/NG11/W/26 of July 7, 1988, at page 11. (Para. III.D(3)(g).)

58 *ibid.*, page 4, para. D(1).

59 MTN.GNG/NG11/8 of August 29, 1988, at para. 43. In accordance with normal GATT practice, the identity and nationality of the intervener are suppressed.
This was not immediately addressed, but as a separate matter the European Communities confirmed that common law protection for trade and business secrets was consistent with its proposal and that specific legislation was not contemplated.

**Opposition to the American and European proposals**

The tactical significance of the EC proposal may be seen from the existence of strong and widespread resistance to including trade secrets (and regulatory data) in the negotiations at all. A group of developing countries, led on this issue by India, strongly disputed that trade secrets were within the negotiating mandate:

> “46. Trade Secrets cannot be considered to be intellectual property rights. The fundamental basis of an intellectual property right is its disclosure publication and registration, while the fundamental basis of a trade secret is its secrecy and confidentiality. … 47. Since trade secret cannot be regarded as an intellectual property, it is beyond the mandate of the Negotiating Group to consider this matter.”

The next major stage in the negotiations was the submission of complete but informal drafts, and on this occasion the European Communities anticipated the United States. The relevant texts of these two drafts (and a contemporary Swiss draft) are set out in Appendix A, with the agreed version of TRIPs for comparison.

The United States had by now adopted the European Communities’ strategy of tying trade secret protection to Article 10bis of the Paris Convention, which was now referred to expressly (in both drafts), instead of being invoked by the language of “fairness” and “honest commercial practices”. But there was still a major difference in philosophy between the two drafts. The EC draft treated trade secrets (or “information”) and “test and other data” as separate species, the first entitled to the relatively precise regime of paragraph (a); the second being entitled only to

---

60 MTN.GNG/NG11/W/37 of July 10, 1989, page 18, para. 46–47. See also MTN.GNG/NG11/24 of August 22, 1990, at para. 5. Contrary to what is stated by Francois Dessemontet “Protection of Trade Secrets and Confidential Information” in Carlos Correa and Abdulqawi Yusuf Intellectual Property and International Trade: The TRIPS Agreement (London/The Hague/Boston: Kluwer, 1998) at page 238, there is no indication that India relied on there already being sufficient protection under Article 10bis, and the suggestion plainly contradicts India’s primary contention that no existing international intellectual property regime applied.


the rather woolly regime of (b). In contrast, the United States treated trade secrets as a single category, with ordinary private law protection quite closely tracking that of the EC draft, but with what were quite rightly called “Exceptions” for various kinds of governmental use. It is implicit in this approach that regulatory data were assumed to constitute a kind of trade secret, and that their protection was dependent on this. The United States also furnished the draft footnote which, after simplification, turned up in the signed version of TRIPs. However, the two approaches were at one in proposing (with varying degrees of finality) that some (unspecified) degree of fixed-term quasi-proprietary protection for the data was expected.64

<table>
<thead>
<tr>
<th>European Communities</th>
<th>United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracting parties, when requiring the publication or submission of test or other data, the origination of which involves a considerable effort, shall protect such efforts against unfair exploitation by competitors. The protection shall last for a reasonable time commensurate with such efforts, the nature of the data required, the expenditure involved in their preparation and shall take account of the availability of other forms of protection.</td>
<td>Contracting parties which require that trade secrets be submitted to carry out governmental functions, shall not use the trade secrets for the commercial or competitive benefit of the government or of any person other than the right-holder except with the right-holder's consent, on payment of the reasonable value of the use, or if a reasonable period of exclusive use is given the right-holder.</td>
</tr>
</tbody>
</table>

The Chairman’s, Brussels and Dunkel drafts

The best-documented phase of the TRIPs negotiations occurred over 1990 and 1991, and revolved around three successive composite drafts, each of which attempted to incorporate whatever consensus had already emerged, while signalling unresolved differences of opinion with bracketed text or complete alternative proposals.65 The draft article which eventually emerged as Article 39 required more brackets and alternatives than most.

The first of these composite drafts was the so-called Chairman’s Draft of July 1990.66 At this point, the options were still almost entirely open. There were alternative proposals for protection from the European Communities, the United States, and Switzerland, but none of these were acceptable to the developing countries, even in principle.67 In the following

64 For the EC proposal see MTN.GNG/NG11/W/68 at page 13, draft Article 28(b); for the US proposal see MTN.GNG/NG11/W/70 at page 14, draft Article 33(1).

65 See Stewart (1993); Gervais (2008), commentary on Article 39. The relevant parts of the three drafts are set out in Appendix B. For a synoptic table of the various positions and proposals at the beginning of 1990 (compiled by the GATT Secretariat) see MTN.GNG/NG11/32/Rev.2 of February 2, 1990, page 120 et seq.


67 The developing countries’ counterproposal was limited to counterfeiting. For the group’s contention that trade secrets were outside the mandate see also MTN.GNG/NG11/24 of August 22, 1990 at para. 5, reporting discussion of a preliminary version of the “Chairman’s Draft”.

25
PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall protect such data against disclosure, except where necessary to protect the public.

But this explicit (and controversial) prohibition on reliance on the data submitted by the originator disappeared from the final (Dunkel) text, which is substantially the same as that adopted in 1994.

The history summed up

The negotiating history of Article 39(3) explicitly contradicts the thesis that it was the collective intention of the contracting parties to require fixed-term exclusive proprietary rights in regulatory data. On the contrary, it shows that such a concept was repeatedly advanced by one or more states, and just as often opposed by others, and that it was finally abandoned, presumably in the interests of building consensus. All the same, according to Jacques Gorlin:

“Some critics of the definition point to the fact that since the obligation of ‘non-reliance’ for a fixed period of time has been considered and dropped by the negotiators, the negotiators must have had something else in mind when they agreed to the inclusion of the sole standard, ‘protection against unfair commercial use’. The negotiating history does not support that contention. United States negotiators agreed to drop the non-reliance language, because they viewed the phrase as no more than ‘belts and suspenders’, that is, the accepted definition at the time of ‘protection against unfair commercial use’ included non-reliance for a


69 MTN.TNC/W/35/Rev.1.


71 Compare the bare assertion to the contrary by the Office of the USTR, at fn. 9 above; and Gorlin (1999), immediately below.

fixed period of time for new chemical entities and the second phrase was, therefore, not needed.”

Assuming this accurately states the intentions of the United States’ negotiating team at the time, it would still be completely irrelevant. As is stated by the Appellate Body:73

“The purpose of treaty interpretation under Article 31 of the Vienna Convention is to ascertain the common intentions of the parties. These common intentions cannot be ascertained on the basis of the subjective and unilaterally determined ‘expectations’ of one of the parties to a treaty.”

So the correct interpretation of the provision is to be found in the common intention of all the parties, as reflected in the agreed text, not in the unilateral intentions of one party, no matter how important or influential.74 There is no record that the United States ever communicated this understanding to the other parties, still less that they accepted it.75 Nor, on the other hand, is it permissible to dismiss Article 39(3) altogether, as Correa would apparently do. Fellmeth justifiably concludes (citations omitted):76

“In summary, the weight of the evidence indicates that, notwithstanding the arguments of the United States and the EC, the ‘unfair commercial use’ language of Article 39 of the TRIPs Agreement does not encompass a data exclusivity obligation per se as a matter of positive law, particularly not when disclosure of marketing approval data is ‘necessary to protect the public.’ Nonetheless, the terms of Article 39.3 plainly indicate that some form of protection against naked exploitation of the marketing approval data is required, even if the TRIPs Agreement does not mandate the protection of such data through an unconditional grant of exclusive rights. Correa’s conclusion that Article 39.3 imposes no international requirement common to all WTO members cannot be the correct interpretation of Article 39.3. States must be presumed never to assume or impose on others meaningless obligations when a reasonable alternative interpretation is possible. Unfortunately, an adequate alternative interpretation cannot rest soundly on either the ambiguous travaux préparatoires or the balkanized subsequent practices of states.”

Likewise, Professor Reichman concludes.77

---


74 Gorlin’s approach embodies several of the fallacies exploded by the Appellate Body in India–Patent Protection for Pharmaceutical and Agricultural Chemical Products; and in European Communities–Customs Classification of Certain Computer Equipment.

75 Compare United States–Measures Affecting the Cross-Border Supply of Gambling and Betting Services, above, fn.00, where the United States had intended to exclude “gambling and betting services” from the scope of “sporting services” in its schedule of concessions, but had failed to do so expressly.

76 Fellmeth (2004) at page 460.

“It follows that, whatever else article 39.3 means in its expurgated or decapitated final form, it cannot possibly mean what it would have meant had the bracketed obligations of the Brussels Draft of 1990 been carried over into either the Dunkel Draft or the Final Act of 1994. To ignore the clear evolution of the text in favor of quasi-exclusive rights in regulatory data, in a form that was proposed but ultimately excised from the Final Act, would in effect amount to imposing unbargained-for trade concessions under a discredited ‘TRIPS plus approach’ that has no legal foundation whatsoever. It would thus place so-called ‘legitimate expectations about the conditions of competition’ as derived from powerful countries’ negotiating positions above the ‘rule of law’ embodied in the text.”

However, this is only one half of the history. Most commentators who address the travaux préparatoires at all, notice the move away from insistence on a fixed term proprietary regime, and either dismiss it,\(^{78}\) or draw much the same conclusions as Reichman and Fellmeth. However, there is another aspect to the evolution of Article 39 which is barely touched upon in the literature, which is the degree of coupling between regulatory data protection and Article 10bis of the Paris Convention. In the Chairman’s Draft of July 1990, the only such linkage was with trade secrets in the everyday sense. The phraseology “In the course of ensuring effective protection against unfair competition as provided for in Article 10bis” introduced and governed Article 1 of Section 7,\(^{79}\) which corresponds to Article 39(2) as adopted. There followed an article on licensing which has been lost, and a final article on “Government Use” which was entirely free-standing, without the Article 10bis related chapeau which had been considered appropriate in the case of “undisclosed information” as such. It was only with the Brussels Draft of December 1990 that the parties reached (or reverted to) the familiar situation, in which undisclosed information and regulatory data are treated in parallel from the very beginning of what was then draft Article 42.

**Where does this all leave us?**

**A retrospective explanation**

Nothing could be easier than to explain how Article 39 got to be the way it is, but what does this tell us about its meaning? What we have seen in the negotiating history is two simultaneous movements: one of them in retreat from mandatory fixed term protection, the other towards explicit attachment of regulatory data protection to Article 10bis of the Paris Convention. The question which remains is whether these were moves in the same direction in response to the same objections, or a retreat on one front counterbalanced by an advance on another, or whether they might be completely unconnected.

\(^{78}\) Gorlin (1999).

\(^{79}\) At this point in time the text of the draft treaty was still too unstable for it to be through-numbered.
Ostensibly, Article 39 of TRIPs (as adopted) moves seamlessly from unfair competition in the sense of Article 10bis of the Paris Convention, by way of protection of undisclosed information, to the protection of regulatory data for new chemical entities in the pharmaceutical and agrochemical fields. The real order of importance would have read the other way round. The Western industrialised countries cared little or not at all about legislating against unfair competition in general, as is evidenced by the lack of any specific TRIPs provisions corresponding to the traditional scope of Article 10bis. Responding to the lobbying of the pharmaceutical and agrochemical industries in their respective countries, their principal concern was to obtain mandatory international protection for regulatory data. But at this point problems appeared relating to the negotiating mandate and the lack of any international consensus for protection, since by no stretch of the imagination was regulatory data the subject of any pre-existing international intellectual property regime. The solution which was adopted promised to achieve two objectives in one. By requiring mandatory protection for undisclosed information in general, and purportedly as a relatively uncontroversial application of Article 10bis, Article 39(2) promised to provide a kind of conceptual bridge between trade secrets and the protection of regulatory data. Protection of undisclosed information in TRIPS was a useful (if controversial) achievement in its own right, but its political importance was to provide a link to Article 39(3).

If Article 39(3) stood on its own, then all this would be of no more than historical relevance. Any liberties taken with the negotiating mandate cannot affect the interpretation of TRIPs today, and any discrepancies between mandate and text were cured by the Final Act of the Uruguay Round when the latter was executed at Marrakesh. The problem arises from the presence of Article 39(1), which, as we have seen, was attached to Article 39(3) as part of a compromise position which emerged in the second half of 1990. In view of its acceptance at precisely the time when the developed and undeveloped countries were reaching their historic compromise,

---

80 Compare Hans Peter Kunz-Hallstein “The United States Proposal for a GATT Agreement on Intellectual Property and the Paris Convention for the Protection of Industrial Property” (1989) 22 Vanderbilt Journal of Transnational Law 265–284 in which quite extensive provisions against unfair competition were advocated for inclusion in TRIPs, but no mention was made of protection for “undisclosed information” or “regulatory data”.


82 The first treaty to provide for regulatory data protection was the North American Free Trade Agreement, Article 1711, but negotiations for NAFTA started well after those for TRIPs, even though NAFTA was signed first. Very little renegotiation of the Dunkel draft occurred between 1991 and 1994.

83 The internal relationship between the three paragraphs of Article 39, and the extent to which paragraph 2 does indeed act as a conceptual bridge between regulatory data protection and Article 10bis, will be examined in a future article.
it is hard to dismiss the dependency of Article 39(3) on Articles 39(1) and 10bis as either coincidental or irrelevant. The dependency was deliberate, it was presumably intended to meet the objection that the negotiating mandate was at risk of being exceeded, and its consequences (whatever they may be) must be taken seriously today. Article 39(1) is unique. No other TRIPs provision is dependent on a pre-existing treaty in this way.\textsuperscript{84}

**Some hypotheses**

Even after all this history, the detailed thinking behind the dependency of Article 39 on Article 10bis of the Paris Convention remains obscure. The most plausible explanation is indeed that it responded in some way to the opposition of a group of developing countries, led by India, which opposed early proposals for what was to become Article 39 on the basis that neither confidential information nor regulatory data was “intellectual property” in any relevant sense, so that their inclusion in the negotiations was contrary to the terms of the Punta del Este mandate. This, of course, was more of a pretext than a reason for opposing Article 39, but there is little doubt that the group led by India had substantive grounds for opposing the latter, even if they hid them behind an essentially procedural argument.

From this reasonably certain starting point, two quite distinct analyses can be taken forward, though with the common feature that the dependency of Article 39 on the Paris Convention must have been included as a deliberate response to the Indian objections. The less radical alternative is to suggest that by attaching the disputed provisions to an existing treaty regime, the proponents of protection for confidential information and regulatory data intended to reassure the Indian bloc, and any other concerned parties, that the negotiating mandate was not being exceeded. This article has argued that Article 10bis of the Paris Convention was an entirely inappropriate vehicle for the protection of regulatory data, but it must be borne in mind that the majority of the delegates at the TRIPs negotiations were extremely unsophisticated in their understanding of intellectual property rights and the existing international regimes, and that the briefing materials provided by WIPO on confidential information, regulatory data, and unfair competition were almost non-existent.\textsuperscript{85} Be that as it may, it is quite plausible that the EC and USA were prepared to respond to India’s objections by

\textsuperscript{84} With the very weak and partial exception of Article 22(2)(b), but the protection of geographical indications in no way depends on this provision. The Article 39 dependency on Article 10bis may also be compared to Article 1711 of NAFTA, which is free-standing.

\textsuperscript{85} WIPO had provided the GATT negotiators with a comprehensive briefing document on seven nominate categories of intellectual property rights under the title *Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property* (MTN.GNG/NG11/W/24/Rev.1 of September 15, 1988; WO/INF/29), but there were only passing mentions to Article 10bis and unfair competition, and none to trade secrets or regulatory data.
what may have appeared to them be a merely cosmetic arrangement, but which their opposite
numbers would have interpreted as a substantial concession, intended to meet them half-way.
Alternatively, if there is more to Jacques Gorlin’s explanation86 than a proprietary distillation of
sour grapes and esprit d’escalier, then it may be that the attachment to Article 10bis really was
envisaged by the developed countries as a safe haven, which promised them all the benefits of
an explicit fixed term of protection, but without the controversy. The problem then is, who was
right?

An altogether more radical possibility is that Article 39 was originally intended to provide a
complete opt-out for countries which were not already members of the Paris Convention itself,
but which expected to make the transition from the GATT to the WTO in due course. If a
country was under no Paris Convention obligations in the first place, then how could it be said
to assume any obligations under Article 39, when those obligations were expressly only such
as to arise “in the course of ensuring effective protection against unfair competition as provided
in Article 10bis of the Paris Convention”? India (almost uniquely, even among developing
countries) was not a member of the Paris Convention during the relevant negotiating period,
and did not in fact join until December 1998, well after TRIPs itself came into force.

In the final analysis, it is plausible that India (along with any other like-minded non-members
of the Paris Convention) may have thought that it had negotiated itself an opt-out from Article
39 in 1988–90, but that it was outmanoeuvred when Article 2(1) assumed its present,
mandatory, form, and the transitional provisions were settled in their present terms. At the other
extreme, the developed countries may have genuinely thought that fixed term data exclusivity
was the only certain route to compliance with Article 10bis of the Paris Convention, whether
TRIPs expressly said so or not. Any such unilateral (mis)conceptions, however reasonable or
fanciful, cannot affect the meaning of the text. In the last resort, we have to deal with the
consequences of what was put on paper, so that Article 39 means what it says, rather than
whatever anyone intended or expected it to mean.

**Problems of interpretation which remain**

The reference to the negotiating history disposes of one interpretation of Article 39(3)87 and
affirms the separate relevance of Article 10bis, but it does not resolve the original aporia which
justified the historical inquiry in the first place. So are we simply back where we began? All our
authors have returned from their vicarious trips into the dark cellar, and each is modelling the

86 Gorlin (1999), above.

87 See above, at fn. 8.
hat he claims to have found. In the case of Skillington and Solovy, it is not so much a hat as a helmet, guaranteed to provide complete protection for five years, and readily upgradeable on demand to ten years or more. Reichman, Fellmeth and Basheer are perfectly entitled to their view that their compensatory hats are “fair” in some abstract ethical or socio-economic sense, just as Correa for the one part, and Skillington and Solovy for the other, are entitled to theirs—but in none of these instances has the “fairness” of their respective solutions been shown to have anything whatever to do with Article 10bis of Paris.

Given that Article 39(1) constitutes a *chapeau* which must be assumed to have some effect on the operation of Article 39(3), then what effect does it have? At one extreme, would we be justified in reverting to the purely permissive interpretation of Correa, under which TRIPs members are free to implement Article 39(3) or not, as they choose? This would no longer be an impermissible interpretation, since once we have identified the conflict between two unsatisfactory interpretations then reference to the negotiating history is a legitimate way of choosing between them.\(^{88}\) On the other hand, Correa’s permissive interpretation does nothing to resolve the problem of giving an effective interpretation to all parts of Article 39. The interpretation for which we should be aiming should ideally provide a role for each of Articles 39(1) and (3) under which neither would be wasted ink, because neither would entirely preempt the other. To find such an interpretation, I suggest that it is necessary to shift one’s attention from Article 10bis of the Paris Convention specifically, and to examine the scope of the latter treaty in its entirety, and in particular what is meant by “industry”.

### The Paris Convention: “Industry”

On the assumption that the invocation of Article 10bis of the Paris Convention by Article 39(1) of TRIPS somehow constrains or conditions what would otherwise be the uninhibited operation of Article 39(3), then in what respects might the latter find its broad application controlled by the former, with both serving a legitimate purpose? For present purposes, I propose to concentrate on the proposition that the scope of the Paris Convention in its entirety is confined to “industry and commerce … [including] agricultural and extractive industries”,\(^{89}\) hence its full name: the Paris Convention for the Protection of Industrial Property.\(^{90}\) This implies, for

---

88 There is also persuasive authority from the *EU–Hormones* case (at para 165) that where an ambiguity remains unresolved after all the normal principles of interpretation have been exhausted, then individual member states should be free to adopt the less burdensome of the possible alternatives: *in dubio mitius*. Appellate Body Report, *EC—Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135.

89 Paris Convention (1967), Article 1(3).

90 See Ladas (1975) at page 262, section 164.
instance, that TRIPs Article 39(2) (because of its similar dependency on Paris) applies only to undisclosed information of a suitably industrial or commercial kind, and not, for instance, to personal confidences or state secrets. This limitation is by no means trivial, since it potentially provides a hitherto unnoticed raison d’être for paragraph 1, thereby helping satisfy the principle of effective interpretation, initially in relation to the dependency of paragraph (2) on paragraph (1). The application of Article 39(1) to Article 39(3) is based on a similar principle, and will be developed in the remainder of this section.

**Personal medical secrets**

As noted above, the scope of the Paris Convention is defined by reference to an extended concept of “industry”, but although the latter is intentionally very broad, it is neither infinite nor indefinite. Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, ....

One example has already been suggested of subject matter outside “industry” in even the broadest sense: private and personal confidences of all kinds are not of an “industrial” nature, and would not be covered by the Paris Convention even under the widest possible interpretation of Article 1(3). To give a somewhat more germane example, are confidences between doctor and patient (such as individual medical records) capable of falling within the scope of either the Paris Convention, or TRIPs? It is suggested not. Once again, the confidences lack the necessary “industrial” or “commercial” character which is the pre-requisite of their falling within the scope of the Paris Convention in the first place. As a subsidiary matter there is typically no element of economic competition between the person trying to protect the information, and the person misusing it, as would be essential to engage Article 10bis. The relationship is simply that of victim and wrongdoer. This is not intended to gainsay the importance of protecting such confidences. On the contrary they are quite rightly regarded as

---

91 This would be consistent with the emphasis on the word “commercial” in Article 39(2): “honest commercial practices”; “commercial value”. The reasoning is supported by two further factors: the express restriction of Paris Article 10bis to situations of economic competition; and the limitation of TRIPs to matters which are sufficiently “trade-related”. Compare the de facto exclusion of moral rights from TRIPS by the proviso to Article 9(1).

92 Paris Convention, Article 1(3).

93 There are two separate questions here. Whether confidential information of any kind whatsoever is within the scope of the Paris Convention, when it is not listed as such, and can only be extracted by implication from an expansive reading of “unfair competition” or an even more imaginative one of “industrial property”; and (if so) whether confidential information of a personal nature is within the Convention’s admittedly wide concept of “industry”.

Christopher Wadlow
particularly sacrosanct in both international, and English domestic law. It is precisely because individual medical confidences are on an entirely different plane to ordinary trade secrets that they are not appropriate subject matter for a treaty, such as the Paris Convention, which embodies an entirely market-based standard of morality.

If private medical confidences are altogether outside the scope of the Paris Convention, then legal action to protect them cannot be characterised as protection against unfair competition “as provided in Article 10bis”; and if Article 10bis of Paris is not engaged, then the chapeau which is Article 39(1) of TRIPs cannot be satisfied either. It follows that the publication, say, of confidential personal medical information, such as that in the Naomi Campbell case, would not involve any contravention of Article 39, even if the acquisition or publication of the information was “contrary to honest commercial practices”, as further defined in the footnote, and even if the three criteria of Article 39(2)(a)–(c) were met. The terms of Article 39(2) on its own might be satisfied, but not the chapeau of Article 39(1), and unless the cause of action is one for unfair competition under Article 10bis of the Paris Convention, then no obligation to protect undisclosed information (of any kind) arises under TRIPs.

In any event, Article 39(2), with its emphasis on the commercial value of the information, and on honest commercial practices, and its need to identify “circles that normally deal with the kind of information in question”, is once again an entirely inappropriate vehicle when the victim quite legitimately wants to keep the most intimate details of his or her private life out of the public eye. This is a matter of violation of human personality and dignity, not one of trade and commerce. Again, this is not to minimise the value of personal privacy or the importance of protecting it in international law. It is simply to say that when individual human rights are at stake, treaties such as the Paris Convention and TRIPs are not the appropriate vehicles for protection, and institutions such as WIPO, GATT and the WTO are not the right custodians. In the case of TRIPs, in particular, the rationale for including provisions protecting undisclosed information (in the trade secret sense) is that it is only by commoditising such information that

---


95 There is a separate argument that information which is personal and private in its origins, may undergo a process of commodification into commercial confidential information, and be protectable as such. Compare Douglas v Hello! (sub nom OBG Ltd v Allen) [2007] UKHL 21, [2008] 1 A.C. 1, where the commodification was voluntary, with R. v Department of Health Ex p. Source Informatics Ltd (No.1) [2001] Q.B. 424, [2001] F.S.R. 8, CA. Self-evidently, Hello! was in competition with OK!, though not with either of the Douglasses in person.
it can be traded, and it can only be commoditised if it is given a recognised legal status. This rationale is entirely lacking with regard to the likes of intimate personal medical secrets, which are in no sense trade-related, and for which there is no legitimate market.

**Industry, commerce, and the medical profession**

So far, I have concentrated on the patient side of the doctor-patient relationship, but the next qualification is of rather more importance so far as Article 39(3) is concerned. This is to suggest that the word “industrial” (French “industriel”, German “gewerblich”) in the Paris Convention was intended to cover what in English would have been called “trade and industry”, or “trade and commerce”; but not the liberal professions such as law and medicine.

The question of whether Article 10bis obliges members of the Paris Union to provide effective protection against unfair competition for members of the liberal professions has attracted very little attention. However, the issue was noted by Professor Eugen Ulmer in his massive survey of the unfair competition laws of the six original members of the European Communities, in which he concluded that the so-called “general clause” of Article 10bis(2) should serve as the basis for future European harmonisation, but that it needed to be extended in economic scope if it was to cover the liberal professions:96

Quite apart from the weight of Professor Ulmer’s opinion, there is a serious reason for excluding the liberal professions from the scope of Article 10bis. The problem of establishing any consensus as to what is fair and what is unfair would be compounded if a single article had to embrace the whole range of the professions, as well as the whole of industry and commerce. For better or worse, organised professions tend to abjure the morality of the market, which is the only morality which Article 10bis knows. One of the distinguishing features of an organised profession is that its members subject themselves to a higher code of practice and

---

96 Ulmer (1965) at page 249, para. 409 letter (a), and in free translation by the present author. Gerhard Schrücker “The Efforts Toward Harmonization of the Law of Unfair Competition in the European Economic Community” (1973) 4 International Review of Industrial Property (IIC) 201 notes (at page 221, “Scope of Application”) that when EC harmonisation was (abortively) debated in 1972 there was opposition from the Netherlands and the United Kingdom to extending the proposed legislative unfair competition regime to the liberal professions.
honour than mere tradesmen, exemplified in the case of medical practitioners by the so-called Hippocratic Oath. Another is that whereas competition in the market place is centred on price, it has long been common for certain professions to discourage or prohibit price competition, or at least to regulate the fees their members charge. To give just one further example of how Article 10bis exhibits the morality of the market place: it has no objection to advertising per se, but it prohibits false advertising, whether in the form of untrue positive claims about oneself, or ones unfairly denigratory of a competitor. By way of contrast, it is has until recently been very common for professions to attempt to prohibit advertising and self-promotion altogether, except for bare announcements of one's name, address, and credentials; and comparative advertising at the expense of a fellow-professional is almost universally beyond the pale.

The analogy with medical and diagnostic methods

The proposition that medicine cannot simultaneously be a profession, and an industry, is consistent with the treatment of the patentability of methods of diagnosis, surgery and therapy, which is the one area in which the explicit limitation of the Paris Convention to “industry and commerce” as (implicitly) opposed to the “professions” has historically been important. These activities are, by definition, carried out by medical practitioners, whose status is that of professionals rather than mere tradesmen or artisans. In historical, as opposed to functional, terms, the original European prohibition on patenting “methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body” for example the prohibition on contingency fees in the Code of Conduct of the Institute of Professional Representatives before the European Patent Office (EPI). See Commission Decision 1999/267, Case IV/36.147, “EPI code of conduct” [1999] O.J. L106/14; on appeal Case T-144/99 Institute of Professional Representatives before the EPO v Commission [2001] E.C.R. II-1087; [2001] 5 C.M.L.R. 2. The fee rule was upheld by the Commission, and not appealed.


98 For example, Casado Coca v Spain (1994) 18 E.H.R.R. 1 (ECHR).

99 National legislative prohibitions on advertising (including comparative advertising) by members of professions are still permitted, despite harmonisation of EC law in the opposite (economically liberal) direction by the Comparative Advertising Directive. See Directive 97/55/EC of 6 October 1997 amending Directive 84/450/EEC concerning Misleading Advertising so as to Include Comparative Advertising, and especially Recitals 21 and 22 and (amended) Article 7(4) and (5). A restriction on comparative advertising contained in a professional association’s code of practice (technically a contractual document, though membership was compulsory if an individual was to practise as a European Patent Attorney) was struck down as excessive under Article 81 of the Treaty of Rome in the EPI case, T-144/99.

100 It is important not because “non-industrial” inventions are excluded from the scope of the Paris Convention, since this has no direct effect on whether or not they are patentable, but because certain derivative conventions, in particular the Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg, 1963), and the Convention on the Grant of European Patents (Munich, 1973), define patentability in terms of susceptibility to industrial application. See Christopher Wadlow “Utility and Industrial Applicability” in Toshiko Takenaka (ed.) Patent Law and Theory: A Handbook of Contemporary Research (London: Edward Elgar, forthcoming, 2008).
body” (EPC Art 52(4)) may plausibly be understood as turning on the status of the professional practice of medicine (by both surgeons and physicians), rather than on the purely utilitarian consideration that the actual day-to-day practice of medicine should be kept free from patent monopolies.

The Records\textsuperscript{101} of the Conference at which the European Patent Convention was adopted show that surgical, therapeutic, and diagnostic methods were originally listed together with exclusions corresponding to those which are now to be found in EPC Article 52(2), which could be taken as implying that the objection to them went to inherent patentability\textsuperscript{102} rather than industrial applicability. To remedy this perceived error,\textsuperscript{103} the German delegation proposed to Main Committee I that these methods should be deleted from the Article 52(2) list, and given a new and separate paragraph of their own:\textsuperscript{104}

“[S]ince in the case of methods for treatment by surgery or therapy actual inventions were involved for which only industrial application was lacking, whereas [the others] would not in practice be considered inventions.”

This was approved and reported to the Committee of the Whole in these terms:\textsuperscript{105}

“Certain drafting improvements however make it completely clear that … therapeutic and diagnostic methods are not patentable on the grounds that they lack industrial application.”

There the situation rested until 2000, when the European Patent Convention was revised.\textsuperscript{106} The Basic Proposal for the EPC 2000 described the former state of affairs as a “fiction”, and the former Article 52(4) was renumbered as Article 53(3) (“Exceptions to patentability”). The proposal was accepted without debate or further explanation.\textsuperscript{107}

\textsuperscript{101} Minutes of the Munich Diplomatic Conference for the Setting up of a European System for the Grant of Patents (Munich: Government of the Federal Republic of Germany; 1973).

\textsuperscript{102} i.e. they were not “inventions” at all, any more than a work of art is an invention.

\textsuperscript{103} Though not minuted, this was presumably in response to the then-recent decision of the Bundesgerichtshof in the “Glatzenoperation” case, [1968] GRUR 142, stating that the “real” reason for the non-patentability of medical methods (in that case, surgical treatment of baldness) was that the medical profession was not a “trade”, and so not within the statutory concept of “industry”. (The German word Gewerbe can mean either). See Reiner Moufang “Methods of Medical Treatment under Patent Law” (1993) 24(1) International Review of Industrial Property (IIC) p 18–49 at pages 29-30, and below at fn. 114.

\textsuperscript{104} Minutes (1973) M/PR/1, page 28, para. 24.

\textsuperscript{105} Minutes (1973) Annex 1, page 184.

\textsuperscript{106} Basic proposal for the revision of the European Patent Convention (Munich: EPO; October 13, 2000) MR/2/00 e page 44, with comments on page 45.

It has been suggested that this act of the EPC 2000 Conference settled once and for all that the surgery, therapy and diagnosis exception was an aspect based exception to patentability, and not an aspect of “industrial applicability”. Leaving aside the fact that the Conference was legally competent only in respect of its own treaty, the European Patent Convention, this raises the question of why the second of two mutually inconsistent ex cathedra statements should be right, and the first one wrong. One is reminded of Lytton Strachey’s paradox of papal infallibility: if John XXII declared that the doctrine of Christ’s poverty was heretical, when Nicholas III had already declared that it was true doctrine, which it was heresy to deny; then which of the two popes was infallibly right, and which of them was infernally wrong?

**The origins and rationale of the distinction**

In the present case it is quite possible (and consistent with Glatzenoperation) that the formal and substantive reasons for the rule co-exist and coincide. Certainly, the attribution of Article 52(4) to one exclusive rationale or the other is difficult, arbitrary, and perhaps unnecessary. Moreover, the arguments in G 1/04 and the like overlook at least one crucial point. If the surgery, therapy and diagnosis exception were wholly founded in public policy (and regardless of whether the policy considerations in question are right or wrong), then why does it apply equally to animals as well as to humans? What kind of public policy is it that equates the health and life of the two? Is this the same public policy that dictates that you can patent a new method of breeding rats with modified genetic characteristics for medical (or veterinary) research; but not a method of treating or diagnosing a pet rat which happens to be ill? As

---


109 According to Joost Pauwelyn “Reply to Joshua Meltzer” (2004) 25 Michigan Journal of International Law 924–928 at page 924 “It is a firmly established principle that ‘the right of giving an authoritative interpretation of a legal rule belongs solely to the person or body who has the power to modify or suppress it.’”


111 The principal EPO authority to deny that professional status has any relevance to patentability is G1/04 Diagnostic Methods [2006] E.P.O.R. 15 (Enlarged Bd. App.). Previously, CYGNUS/Diagnostic method (T964/99) [2002] E.P.O.R. 26 (Technical Bd. App.) had seemed to give weight to the professional status of the persons performing the claimed procedure.

112 HARVARD/Transgenic animal (T315/03) [2005] E.P.O.R. 31 (Technical Bd. App.). Compare Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions (the Biotechnology Directive) Recital 45 and Article 6(2)(d), referring to “processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal” (emphasis added).
long as one focuses on the rat, all this is without rhyme or reason. But turn to the person performing the relevant procedure and it makes perfect sense, at least according to its own internal logic. Physicians and veterinarians are both professionals. They are brothers under the skin, untainted by the vulgar stain of industry and commerce. It is not a question of the (naturally) sick rat having the same rights and immunities as a sick human being, but of the vet being the near-equal of the doctor, whose social status is qualitatively superior to that of a mere bourgeois. This, I freely admit, is a rather fin de siècle way of looking at things, but then the Paris Convention is a rather fin de siècle treaty. As one commentator noted in relation to the (much more recent) European Patent Convention, and the then pending argument in G1/04 Diagnostic Methods:

“The use of the wording ‘industrial application’ is interesting in this connection [Article 52(4) EPC], even though it is not easy understandable. This has to be seen in the context of the drafting of the EPC. It should not be forgotten that the drafting of the EPC largely took place in the 1960s. At that time, it could be seen that methods performed by physicians on the human body had no industrial application. The medical profession was not regarded as a trade. …

The earliest cases in Germany, dating from the early 1900s, adhered to the rather traditional view of industry, where it was required that something was manufactured or that raw materials were mechanically or chemically treated or processed. Even though the views of what was considered to be industrially applicable and thus what is considered to be industry became more sophisticated in time, the rejection of medical treatment methods for lack of industrial application survived mysteriously in later German case law. Using a line of argumentation which was more socio-ethical than applying industrial application standards, it was said that the medical profession, although obviously oriented towards earning, cannot be considered as a trade.”

But even in 1967, German law still emphasised the professional status of the medical profession:

“In 1967 the Federal Supreme Court had the opportunity, in a fundamental decision that exercised a lasting influence on future European patent law, to recapitulate extensively the previous discussion on the patent protection of curative methods and reset the dogmatic signals. Following an intensive discussion involving the complete previous case law, the prerequisite of industrial applicability was denied a cosmetic-surgical method intended to be used to treat men against the development of bald patches. Public health was considered to be a key element of public welfare, which must be safeguarded by the State. This was

---


held to be in accordance with the principle that the medical profession, although obviously oriented to earning, is not a trade. The professional image of a medical doctor conveys that he does not subordinate the exercise of his profession to aspects of commerce, in particular to that of achieving a profit. Rather, he should be conscious of his special professional ethos and his obligation to human health without taking into account material profits.”

To return to the concept of “industry” in the Paris Convention, it is suggested that for the purposes of the Paris Convention the professional status of the person typically responsible for performing the procedure in question is indeed important. The exercise of one of the historic liberal professions is neither “industry”, nor “commerce”. That the methods and procedures of its practitioners in their capacity as such are not “industrially applicable” is not a fiction, but a fact, and as such they fall wholly outside the scope of the Paris Convention. It may be acknowledged that the trend of interpretation under the European Patent Convention is against this, but the European Patent Convention is a separate treaty, whose members and organs have no institutional competence, either individually or collectively, to issue binding re-interpretations of the Paris Convention.115

The implications for clinical trials

The life cycle of a new medicine begins in the laboratory with the synthesis of a new chemical (or molecular) entity116 and pre-clinical evaluation for likely efficacy and safety. Candidate NCEs which have given promising results in bench tests and animal models are selected for the three consecutive stages of clinical trials.117 Phase I trials are carried out (normally by specialist contract research organisations) on groups of about 100–200 healthy adults.118 They are intended to ascertain the pharmacological properties of the NCE in humans and to confirm its short-term safety, but are not intended or expected to demonstrate efficacy. Phase II and III

115 See fn. 109 above.

116 “NCE” or “NME”.


trials follow and provide the necessary proof of safety and efficacy for regulatory approval and product launch: 119

“Phase II trials usually take place in a hospital and may be co-ordinated by a dedicated Clinical Trials Unit within that hospital. It is at this stage that the manufacturing company begins to involve limited numbers of the medical profession outside the company (typically in hospitals) in a major way. Notably by this stage the patenting process is generally completed so the manufacturer’s crucial intellectual property protection is in place. Phase II trials involve individuals affected by the target condition and are designed to determine its safety and efficacy in the relevant patient group. Between 200 and 500 individuals with the target disease usually take part in this phase of testing. If the product proves acceptably safe and appears to be efficacious in this relatively small group, tests are then undertaken in a larger group in a subsequent trial.

Phase III trials involve larger groups of patients (2–3,000 approximately) although cohort size depends on the condition as some rarer diseases may necessarily involve a smaller group of patients. Phase III trials determine safety and efficacy of the product on a larger scale and either compare the product to a drug that is already on the market to treat the target condition or, more usually, a placebo. These trials form the basis of licence applications.”

So who conducts phase II and III clinical trials? They will very probably have been sponsored by a pharmaceutical company, but since real patients are involved (who need to be cured if at all possible, as well as being kept alive) the actual running of the trial necessarily devolves on clinicians. The EC Clinical Trials Directive distinguishes between the two: 120

(e) “sponsor”: an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial;

(f) “investigator”: a doctor or a person following a profession agreed in the Member State for investigations because of the scientific background and the experience in patient care it requires. The investigator is responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the principal investigator;

In the case of Phase III trials especially there is a further reason for the sponsor company to distance itself from the scientific aspects of the trial, which is that the company’s initial marketing and promotional materials are likely to be based on any clinical advantages demonstrated by the trials, so that early success in the market is heavily dependent not only on

---

119 ibid., page 21, paras 54–55. Phase IV trials are defined as taking place after regulatory approval and are irrelevant for present purposes.

120 Clinical Trials Directive (2001/20/EC), Article 2(e) and (f) (definitions).
the trials’ successful outcome, but on the prestige and perceived independence of the clinical trial team and its leaders, the participating institution(s), and the medical journal in which the results are published.

**Agrochemicals**

In comparison to the pharmaceutical industry, agrochemicals may be dealt with much more briefly. The agrochemical equivalent of clinical trials is field trials, but farmers and agriculturalists are not normally thought or as members of any profession, or at least not in the same sense as doctors or lawyers. In any event, the Paris Convention expressly treats agriculture as an “industry”.\(^{121}\) It follows that data from field trials and the like will fall within the scope of the Paris Convention, and will benefit from protection according to Article 39(3).\(^{122}\) The only room for doubt concerns toxicology trials (human and animal), where the analogy with clinical trials of a pharmaceutical might prevail.

**A preferred interpretation of Article 39(3) and its relationship with the Paris Convention**

**Article 39(1) as a chapeau for Article 39(3)**

At this point, all the elements are in place for me to offer my own preferred interpretation of how Articles 39(1) and (3) co-operate to define the scope of the obligation to protect regulatory data.

The two extremes of interpretation are that TRIPs Article 39 and Paris Article 10bis are so completely mismatched that there is no common ground between them—there is an irreconcilable logical impasse, so Article 39 has no effect whatsoever; alternatively, that all situations covered by TRIPs Article 39(3) are already within the scope of Article 10bis of the Paris Convention, so that Article 39 is, at most, declaratory of existing Paris Convention obligations in one specific practical context. Each of these raises, in an acute form, the problem of finding an “effective interpretation” for Article 39(1) and its incorporation of Paris Convention norms, as well as for Article 39(3). This more obvious for the first alternative, since the net result is to deprive Article 39(3) of all effect, but the principle of effective interpretation applies equally to qualifications as it does to impositions, and the second of the two extreme alternatives violates that principle just as plainly by depriving the chapeau which is Article

\(^{121}\) Paris Convention (1967), Article 1(3).

\(^{122}\) Subject to the actual terms of Article 39(3) and to any residual questions about the chapeau effect of Article 39(1).
39(1) of any residual effect after the Article 39(3) criteria have been satisfied, and by reducing Article 39(3) to a specific instance of what was already supposedly required by Article 10bis.\textsuperscript{123}

Since the two extremes are both precluded by the principle of effective interpretation, we must explore the middle way. We can neither ignore the dependency of Article 39 on the Paris Convention, nor can we invoke the same dependency to deprive Article 39 as a whole of all force and effect. At this point, I agree almost entirely with the analysis of Professor Reichman. After noting that there had never been sufficient international consensus to extend the general obligations of Article 10bis(1) and (2) beyond the specific prohibitions of paragraph (3), he observes:\textsuperscript{124}

\begin{quote}
"It follows that any positive duty to avoid acts of competition that are contrary to honest usage are effectively circumscribed by the more detailed provisions of Paris Convention Article 10bis(3). In this light, the consensus that produced articles 39.2 and 39.3 of the TRIPS Agreement in 1994 may properly be viewed as having added two more mandatory prescriptions to the list already set out in article 10bis(3) of the Paris Convention (1967)."
\end{quote}

In other words, in order to avoid one horn of the aporia we must somehow extend the scope of Article 10bis to give a degree of protection to “undisclosed information” (Article 39(2)) and “data” (Article 39(3)). However, taking this as a starting point, there are at least three questions which still need to be answered in more detail. First, when we talk of “adding mandatory prescriptions” to the list in the Paris Convention, then what precisely do we mean? Secondly, just how far did the relevant consensus extend? Is it really the case that Articles 39(2) and (3) are individually the product of consensus, or should we rather identify the consensus as relating to Article 39 as a whole, including Article 39(1) and its dependency on the Paris Convention? Surely this was an important part of the trade-off in the negotiations. Finally, is it not the case that Reichman has simply bounced us from one horn of the dilemma of effective interpretation onto the other? His “deeming” solution removes the conflict between TRIPs and the Paris Convention, true enough, but if the deeming process is carried too far, then we are sure to find that the latter has simply been deemed out of all separate relevance, so that Article 39(1) has become wasted ink once again. The principle of effective interpretation is as much violated by eliminating the express dependency on the Paris Convention from the picture, as by allowing the latter to eliminate the rest of Article 39.

\textsuperscript{123} The latter having already been incorporated into TRIPs by Article 2(1).

\textsuperscript{124} Reichman (2004) at page 6.
Was the Paris Convention modified by TRIPs?

Might it then be said that the effectiveness of Article 39 of TRIPs in relation to Article 10bis of Paris, lies in the modification, amendment, or definitive re-interpretation of the latter, so as to embrace two new nominate acts of “unfair competition”, which were not previously addressed at all? The problem with this approach is not so much that it lacks effectiveness, but that it is altogether too effective for the means at its disposal.

When dealing with the complex relationship between treaties such as the Paris, Berne and TRIPs agreements, it is easy to speak of the later treaty as explaining, or clarifying, or modifying the earlier one, so as to achieve some supposedly desirable objective in the face of previous doubt, controversy, or resistance. The *locus classicus* of this approach in TRIPs is Article 10(1), providing that computer programs are to be protected as literary works under the Berne Convention (1971).\(^{125}\) But at this point we must take into account the provisions of the Vienna Convention dealing with the amendment and modification of treaties.\(^{126}\) According to Article 39, a treaty may be amended by agreement between the parties. Where the treaty is a multilateral one, Articles 40 and 41 also apply. Article 40 deals with amendments as between all the parties.\(^{127}\) It cannot seriously be suggested that Article 40 was complied with in so far as the TRIPs negotiations purported to amend the Paris (or Berne) conventions, even assuming that that was indeed their purpose and (intended) effect. Moreover, each of the two earlier conventions contains its own detailed provisions for revision, which again cannot be reconciled with what occurred in the negotiation of TRIPs. As a matter of historical fact, one impetus for the TRIPs negotiations was the comprehensive and acrimonious failure of the most recent attempt to renegotiate the Paris Convention in Geneva and Nairobi during 1980 to 1984.\(^{128}\) The last thing the proponents of TRIPs wanted was to re-open this Pandora’s Box.

Nor can it be suggested that the TRIPs members constituted a sub-set of the Paris Union who might have agreed to modify the Paris Convention as between themselves. According to Article 41 of the Vienna Convention, this is allowed only if the possibility of such a modification is provided for by the original treaty. The Paris Convention contains no such provision. Finally,


\(^{126}\) Vienna Convention on the Law of Treaties (Vienna, 1969) Articles 39 to 41. In so far as it might be suggested that we are merely dealing with a binding re-interpretation, as opposed to a formal amendment, see fn. 109 above.

\(^{127}\) In particular, Article 40(2) of the Vienna Convention gives all existing members of the treaty proposed to be amended the right to be notified in advance, and to participate in the negotiations.

\(^{128}\) Sell (1998); Stewart (2003).
actual practice under the Paris Convention has always required unanimity for any amendment.\

The Paris and Berne conventions “as incorporated into TRIPs”

Given that it would be a travesty of international law for the members of GATT or the WTO to purport to amend or re-interpret any provision of either of the Paris or Berne conventions, even as between themselves, then can effect be given to what is explicitly attempted (for Berne) in the case of TRIPs Article 10(1), and presumably by implication in the case of Article 39?\(^\text{130}\) Once again, the principle of effective interpretation requires that some effect should be given to these provisions, if at all possible. The only interpretation which can reconcile the ambitions of these Articles with the limitations of international comity is to say that both apply in so far as the Paris and Berne conventions are incorporated into TRIPs by reference, under Articles 2(1) and 9(1) respectively, but not otherwise. Incorporation, after all, is little different from writing out the incorporated terms in extenso, and what can be incorporated verbatim, can be incorporated cum notis variorum if preferred. The Paris and Berne conventions themselves remain entirely unaffected.\(^\text{131}\)

To return specifically to Article 39 of TRIPs. The explanation that Article 10bis of the Paris Convention, as incorporated into TRIPS by Article 2(1) of the latter, is deemed to be amended to include two new and unfamiliar heads of unfair competition as paragraphs (iv) and (v) of Article 10bis(3) is tenable so far as it goes, but it does not go so far as to solve the problem of effective interpretation in all its aspects. The residual problem is that we are still at risk of deeming the Paris Convention out of all relevance in relation to Article 39. We cannot simply say: there is liability when criteria A (Paris) and B (TRIPs) are present, and criteria A are conclusively deemed to be present whenever criteria B are present, because at the end of the day that is the same as ignoring A completely and applying B on its own. There is a difference between giving effect to the Paris Convention, and playing games with it.

Compensation models of Article 39(3)

In particular, I cannot endorse the approach of (inter alia) Reichman, Fellmeth and Basheer, in arguing for a compensation-based model. True, this avoids the mistake of Correa in failing to

\(^{129}\) Bodenhausen (1968) page 191 at letter (b).

\(^{130}\) Following Reichman (2004).

\(^{131}\) Compare the second sentence of TRIPs Article 9(1) in relation to moral rights under the Berne Convention: “Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6bis of that Convention ….” (Emphasis added).
give any normative effect to Article 39(3) at all, but what does providing monetary compensation for the use of regulatory data have to do with Article 10bis? These authors would presumably reply that “fair” compensation is by definition a “fair” remedy for what would otherwise be “unfair” competition, so that we have gone as far as Article 39(1) requires us to go, and no further: fair exchange (as they say) is no robbery.

My first problem is that all this is simply a case of petitio principii. It assumes (but does not begin to prove) that monetary compensation is capable of providing “fair” compensation for what would otherwise be an act of “unfair” competition, thereby removing the initial taint of unfairness.132 True enough that TRIPs is unrelentingly market-orientated in its philosophy, but it is surely taking things too far to say that fairness is just another commodity that can be bought for cash down—especially when the “seller” is unwilling. My second objection is that whatever may be the nature (or value) of “fair” compensation, it has nothing whatsoever to do with “fairness” as Article 10bis understands it. Just compare the terms and circumstances of Article 10bis to the proposition that “fair” compensation obviates what would otherwise be unfair competition. In language which is deliberately tracked in TRIPs Article 39(1), Article 10bis(1) obliges members of the Union to provide “effective protection against unfair competition”. Note “effective protection against”, not “fair compensation for”. Then Article 10bis(3) requires the nominate acts of misrepresentation (passing-off, denigration, mis-statement) to be prohibited. All this is strengthened (as if it were necessary) by Article 10ter under which the members of the Union undertake “effectively to repress all the acts referred to in Article … 10bis.” You do not “repress” an unfair and unlawful act by sanctioning it for money; any more than you can turn a counterfeit into a “fair” copy by making the counterfeiter pay “fair” compensation—or any amount of compensation, for that matter.

The attractions of the compensation model are entirely political rather than legal.133 If a compensation model of any sort were already built into Article 10bis, then it might perhaps be said that some such model was capable of effecting a “fair” compromise between what was separately required by Articles 39(1) and (3). The problem is that the compensation model—far from giving effect to Article 10bis—looks more like a travesty of it. At best, Article 10bis tells us

132 All these authors seem (at least by implication) to have been influenced by the theory of “malign competition” proposed in Anselm Kamperman Sanders Unfair Competition Law: The Protection of Intellectual and Industrial Creativity, (Oxford: Clarendon Press, 1997). Kamperman Sanders may have a point so far as a restitutionary remedy for so-called “free-riding” is concerned, but that is a long way from Article 10bis as we know it.

133 Its proponents quite explicitly promote the compensation model as falling between the extremes of Correa (2002), who allows no normative effect for Article 39(3) at all, and Gorlin (1999), who would interpret it as requiring fixed-term protection. TRIPs is a very political treaty, but splitting the baby is a judicial technique that has yet to find a place in the generally accepted canons of interpretation.
nothing about how to set a “fair” level of compensation. At worst, it strongly suggests that any attempt to legitimate acts of unfair competition in return for “fair” compensation is simply a contradiction in terms.

**Unfair competition and exclusivity regimes**

Whatever problems there may be with fitting compensatory models into Article 10bis, the case is no better for fixed-term proprietary regimes.

There is general agreement that although it is included in a convention “for the protection of industrial property”, the right protected under Article 10bis is something fundamentally different to a property right. It is a right to be protected against unfair conduct in competition, which means that the individual circumstances of the case need to be examined for factors (such as bad faith or malice) which are typically not relevant for the true proprietary rights such as patents, trade marks and designs. Since the latter are proprietary we do not need to ask if the conduct complained of is “unfair” either in general, or in the specific case under consideration. We need only ask if it satisfies the statutory criteria for infringement, whatever they may be. Likewise questions of fault and damage, typically crucial to unfair competition (since the latter is typically, if not invariably, a civil law delict) are irrelevant in the case of true proprietary rights. Liability for infringing property rights is strict; liability for unfair competition is fault-based.

Although an intellectual property right properly so called may in due course evolve out of a right originally sounding in unfair competition, the two are entirely different. There is no room in Article 10bis for true proprietary rights. It follows that TRIPs members implementing, or encouraging, a proprietary regime for regulatory data protection are doing something which is

---

134 Misunderstandings can arise from assuming that the French term “propriété” (in propriété industrielle) corresponds precisely to “property” in the Anglo-American sense; and from the fact that the original version of the Paris Convention (1883) made no provision for unfair competition. To have insisted on a change of title would have been pedantic in the extreme.

135 It is noticeable that Article 39(2) eschews the language of property and ownership in favour of the more neutral “control” of “undisclosed information”. Article 39(3) is even more circumspect. It is written entirely in terms of protection of the data per se, with no explicit reference to any “owner” (or even “controller”) who might be entitled to enforce the rights in question. Of course, this is only possible because Article 39(3) assumes, rightly or wrongly, that the state in its regulatory capacity will bind itself to its provisions ex officio, without any private party needing to enforce them.
fundamentally different to what is contemplated by Article 10bis.136 Property rights are one thing, unfair competition is another. As Kamperman Sanders acknowledges:137

“[T]he mere fact that another’s achievement is being exploited does not call for any impediment on the basis of unfair competition provisions. On the contrary, appropriating and building on others’ achievements is the cornerstone of cultural and economic development. The axiom of freedom to copy epitomizes the principles of the free market system.”

Summary and conclusions
This article has argued that there is a complex interplay between Article 39(3) of TRIPs, and Article 10bis of the Paris Convention, to which both articles contribute equally through the intermediation of Article 39(1), and that neither can be ignored in the application of the composite law to the facts of a particular case. The reason for this express dependency of Article 39 on the Paris Convention—a dependency which is unique in TRIPs—may be found in the negotiating history. Whereas most of the intellectual property rights addressed by TRIPs had a firm basis in at least one of the major pre-existing international conventions, this was not obviously true for confidential (undisclosed) information, and still less so for regulatory data. In response to the objection that these were not “intellectual property” at all, it was agreed that their protection under TRIPS would be anchored to the Paris Convention.138

The first problem to arise is that the original assumption that misuse or misappropriation of confidential information, or regulatory data, ever constituted an act of unfair competition, so as to engage Article 10bis of Paris, was simply wrong. Some will find this difficult to accept, at least in relation to ordinary trade secrets, but the latter are not my present concern, and the proposition that regulatory data as such were already protected under Article 10bis is fraught with difficulties. The logical corollary would seem to be that Article 39 was and is self-contradicting, either in whole or in part, and therefore self-destructing. The chapeau which is Article 39(1) could never be satisfied, and the rest of the Article, as it stood, promised everything and delivered nothing. Rather than come to that conclusion, which would infringe the principle of “effective interpretation”, I prefer to say that that TRIPs requires one to assume that there is no fatal inconsistency between Article 39(1) and the specific situations of paragraphs (2) and (3), and that we must therefore accept that there are circumstances, for the time being undefined, in which the acts specifically prohibited in paragraphs (2) and (3) are capable of amounting to acts of unfair competition—not as Article 10bis understands that term.

136 Members with proprietary regimes would presumably rely on TRIPs Article 1(1) and say that they were implementing “more extensive protection” for regulatory data than Article 39(3) required.

137 Kamperman Sanders (1997) at page 7.

138 Above, fn. 60.
but in some suitably modified sense which has effect within TRIPs itself, to the extent that the terms of the Paris Convention are incorporated into the latter.\footnote{139} Of course, the true interpretation of the Paris Convention as such is unaffected by this legal fiction.

So is it possible to give some residual effect to Article 39(1), without nullifying Article 39(3), and preferably so as to produce an interpretation which can be defended on a rational, as well as a purely formal, basis? It is suggested that it is.

The key to the solution is to recognise that the Paris Convention is not all-embracing, it is confined to “industrial property”, and so to the sphere of industry, trade and commerce.\footnote{140} On the one hand, this distinguishes it from the Berne Convention, which is concerned with copyright, or “intellectual property” in a narrow sense which was formerly commonplace, but is no longer current. On other hand, even when it comes to the likes of patents and trade marks, the Paris Convention has no bearing on subject matter which lacks this “industrial” character, as defined in Article 1(3). The latter provides for “industrial property” to be understood “in the broadest possible sense”, and to include commerce, agriculture, and the extractive industries; but there comes a point at which a dividing line has to be drawn between the “industrial” or “commercial”, no matter how broadly defined, and whatever remains outside.

To turn for a moment to Article 39(2), what remains outside certainly includes purely personal confidences and sensitive private information, such as an individual’s medical records. Such personal information does not qualify for protection under Article 10bis of the Paris Convention: first, because it is not “industrial” in nature; and additionally, because although misuse of it may be “unfair”, it does not involve economic competition.\footnote{141} It follows that although member states are perfectly free to protect such information if they want to, any such protection cannot be said to arise “in the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention”. That being the case, any failure to protect information of this kind cannot constitute a breach of Article 39, even if the individual factors of paragraph 2 are present, since the necessary condition of paragraph (1) is not met. This interpretation satisfies the doctrine of effective interpretation on both fronts, since neither paragraph (1) nor (2) is rendered otiose or ineffective, and each contributes its share to the final outcome. It also satisfies common sense, in so far as TRIPs is a commercial treaty, which really has no business legislating for information of this kind.

\footnote{139}{Above, fn. 130.}
\footnote{140}{Paris Convention (1967), Article 1(3).}
\footnote{141}{Above, fn. 95.}
confidences are important, and it is right to protect them; but they are not trade-related, and they ought never to have been within the legislative competence of GATT. Conversely, ordinary trade secrets do have this “industrial” character, and are protected.\textsuperscript{142}

The preferred interpretation of Article 39(3) follows the same lines, though I expect both the reasoning, and the result, to be altogether more controversial. The reasoning turns on the proposition that the Paris Convention contemplates a distinction between “industry and commerce” (including agriculture) on the one hand, and the liberal professions on the other.\textsuperscript{143} The paradigm liberal profession is, of course, medicine. This distinction between the “industrial” and the “professional” is not new. It has been recognised by one of the leading international scholars on unfair competition.\textsuperscript{144} It has also been invoked to explain and justify the exclusion of methods of surgery, therapy, and diagnosis from patentability, on the basis that the working methods of members of the medical professions are not capable of “industrial application”, because medicine is not a branch of “industry”, even in the broadest sense.\textsuperscript{145}

Article 39(3) applies in terms to “undisclosed test or other data” relating to new chemical entities in the pharmaceutical or agricultural fields. In the case of pharmaceuticals, it is suggested that a distinction has to be drawn between data from the earlier (laboratory) stages of investigation, which will typically have been generated in tests or trials conducted or supervised by scientists in the employment of a pharmaceutical company; and data from clinical trials on human patients which will typically have been independently conducted in hospitals or clinics, supervised and directed by qualified medical practitioners whose primary ethical obligation is to their patients.\textsuperscript{146} In business language the clinical trials are on the “territory” of the investigating clinicians, not the company, even if the data may already be pledged to the latter in return for financial and material support. Applying the distinction between the “industrial”, and the “professional” spheres, the laboratory-generated data would be capable of falling within the Paris Convention, but not the data from the clinical trials. Repeating the argument familiar from Article 39(2), member states would be free to protect the clinical trial data or not, as they thought fit, but protection (if granted) would have nothing to do with the Paris Convention, and would not be in consequence of Article 10bis, even as deemed to be amended for the purposes of incorporation into TRIPs. Failure to protect the

\textsuperscript{142} Above, fn. 124.
\textsuperscript{143} Above, fn. 90.
\textsuperscript{144} Above, fn. 96.
\textsuperscript{145} Above, fn. 113.
\textsuperscript{146} Above, fn. 119.
laboratory data might infringe TRIPs, depending on the Article 39(3) criteria and the Article 39(1) chapeau, but non-protection of the clinical trials data would not.\textsuperscript{147}

In the case of agrochemicals the same approach leads to a rather different result. The equivalent of clinical trials is field trials, but farmers and agriculturalists are not normally thought or as members of a profession, or at least not in the same sense as doctors or lawyers. In any event, the Paris Convention expressly categorises agriculture as an “industry”. It follows that field trials and the like will fall within the scope of the Paris Convention, and will benefit from protection according to Article 39(3). The only room for doubt concerns toxicology trials (human and animal), where the analogy with clinical trials of a pharmaceutical might prevail.\textsuperscript{148}

This composite interpretation of Article 39(3) in its relationship with Article 39(1) and Article 10bis of the Paris Convention again has the advantage of satisfying the principle of effective interpretation: the Paris Convention tells us which broad categories of information are capable of being protected, according to whether they satisfy the “industrial” criterion or not, and Article 39(3) then directs us to its own set of issues, such as compulsion, effort, the relevance of the data to the approval of a “new chemical entity”, and so on. In practice, one might apply the enumerated heads of Article 39(3) first, with Article 39(1) acting as a concluding chapeau.\textsuperscript{149}

Finally, the present approach does something like rough justice between the Western industrialised countries, and the group of developing countries, led by India, which originally opposed Article 39. It will be recalled that the linkage to the Paris Convention was introduced to pacify this group, as was withdrawal of the proposal for mandatory fixed-term protection, and it is to be assumed that these represented genuine concessions by the developed countries.\textsuperscript{150} In the event, the effect of the concessions turns out to be minor for agrochemicals, but in the case of pharmaceuticals the linkage to Paris would be significant, since generic companies would only have to replicate bench experiments up to, and perhaps including, Phase I clinical trials; and regulatory authorities could continue to rely on the originator’s data

\textsuperscript{147} Above, fn. 120.

\textsuperscript{148} Above, fn. 122.

\textsuperscript{149} It is traditional in WTO jurisprudence to leave the chapeau until last.

\textsuperscript{150} Above, fn. 84, but compare Gorlin (1999).
in respect of trials in Phases II and III, which are much more expensive and onerous to reproduce or replicate.\textsuperscript{151}

An incidental conclusion is that, regardless of any other considerations, states do not commit acts of unfair competition by referring to the filed data of the original applicant, in evaluating subsequent applications for marketing approval. The state as such, in its sovereign regulatory capacity, is not engaged in competition with any applicant, and cannot commit an act of competition, unfair or otherwise.\textsuperscript{152} The same applies \textit{a fortiori} to the state in its legislative capacity. It is very much a matter of judgment and controversy whether protection for a specific body of knowledge is justified or not—whether under the law of unfair competition, or as a kind of intellectual property, old, new or \textit{sui generis}. Those responsible for generating regulatory data are in no different case \textit{vis-à-vis} Article 10bis than blenders of perfumes, practitioners of traditional medicine, devisers of television programme formats, and many others, whether genuinely deserving or merely vociferous. It may be inexpedient or injudicious to deny to any or all of these the fullest possible degree of protection for which they plead. It may even be morally unjust, or “unfair” in some cognate sense, but by no stretch of the imagination is any breach of Article 10bis involved, whether on the plane of private, or international, law.

\textbf{A question of public good?}

In his Bellagio paper, Professor Reichman describes his own vision of regulatory data as a public good:\textsuperscript{153}

\begin{quote}
“My thesis is that the drive to protect clinical trial data internationally is but the latest and most far-reaching consequence of the deep structural problems that flow from the failure to treat clinical trials as a national and international public good. So long as this market-distorting anomaly persists, clinical data as a guarantor of public safety will be under-supplied; the scientific benefits of such trials will be impeded; and the drive to keep secret the very data that logically require the highest degree of transparency will produce the rippling legislative distortions and high social costs that now take the form of pseudo-IPRs.”
\end{quote}

\textsuperscript{151} I very much doubt if this solution is what the pharmaceutical industry thought their negotiators had brought back home from Geneva, but it could be worse. A literal reading of the relationship between Article 39(1) and (3) results in absolutely no protection for regulatory data at all, because there are any number of reasons for saying that Article 10bis of the Paris Convention simply does not apply to the situations envisaged in Article 39(3), and it is only in the course of complying with Article 10bis that the obligation to protect regulatory data according to Article 39(3) arises.

\textsuperscript{152} Above, fn. 43.

\textsuperscript{153} Reichman (2004) at page 3.
The long-term solution to this problem is to rationalize the pharmaceutical supply chain by treating clinical trials as a global public good under a system that apportions costs to all participants and guarantees open access to the resulting data. Short of that solution, the developing countries must necessarily grasp at makeweight legal and political maneuvers to counter the high-handed measures taken to protect clinical data in TRIPS-plus trade agreements. Above all, they must strive to preserve the integrity of the Doha Settlement and to minimize the social costs of any data protection regime they agree to adopt.”

The thesis of the present article matches that of Professor Reichman in several respects, notably in emphasising that the obligations of TRIPs Article 39(3) are neither absolute nor unqualified, but are conditioned in fact as well as theory by Article 10bis of the Paris Convention. However, the present article goes one stage further, and argues that the majority of data from clinical trials are not within the scope of the Paris Convention at all, because they fall on the wrong side of a division between the “industrial” and “professional” spheres of life which was recognised by the Paris Convention in 1883, and which has never been removed. It follows that so far as Paris and TRIPs are concerned, and regardless of any other arguments, WTO member states in general are always free to refer to at least the majority of the clinical trial data of an innovator company, when considering an application for a generic equivalent, without committing any breach of international law. As Skillington and Solovy conclude (emphasis added):154

“Of course, the ordinary meaning of TRIPS Article 39.3 is not as clear as it might otherwise be, and the ambiguity is a consequence of difficult negotiations among very different countries. Nevertheless, when interpreting TRIPS Article 39.3, it is critical to keep in mind the fundamental purpose of data protection as a means to the end of creating a public good in the form of new medications and other chemicals that will improve the health and standard of living of mankind.”

From the point of view of treating clinical trial data as a public good, rather than a private one, the present article can at least claim the merit of serendipity.

**A word from the doctor**

We have reached the end of this article without hearing from the doctor of the title. In an article in the *Journal of Medical Ethics*, Dr M H Rubin of New York wryly looked back on a life spent acting as the Good Samaritan when members of the public needed emergency medical assistance:155

---


“The physician and victim, strangers no more, enter into a relationship based on assumptions and expectations. From my side, why would not I offer to help? Was not this the reason that I wanted to be a doctor in the first place? ... Perhaps society holds a different set of expectations and standards for this privileged group, assuming that the Hippocratic oath and the privilege itself include 24/7 availability, duty and obligation as part of the deal.”

Compare this to Professor Sven Bostyn, according to whom “[T]he medical profession has become a business as any other business. The burgeoning aesthetics business is a good example.” Well, yes, to the extent that no one expects Sean McNamara or Christian Troy to perform free nip/tuck operations all day long simply to avoid the risk of being cut dead at the Emmy awards, but in the last resort doctors (including ones as odiously amoral as the fictitious McNamara and Troy) are still different from the rest of us, even if lawyers are increasingly indistinguishable from their business clients.

“In contrast to previous doctor shows, Nip/Tuck highlights the lives of plastic surgeons whose work, unlike ER physicians, general practitioners, and critical care surgeons, lacks the legitimacy and urgency afforded to other television doctors. The very nature of their work exaggerates the moral ambiguity associated with their profession. The show glorifies the profitability and corruption of plastic surgery ... while simultaneously illustrating the moral tensions inherent in such treatments. ... While morally corrupt in their personal lives, Drs. Troy and McNamara hold themselves to a different standard than some of their peers also represented in the show by fixing the mistakes of others, offering pro bono work, and correcting the work of a serial ‘slasher.’”

So when a member of the audience is taken ill in a theatre or a restaurant—or at the Emmys, for that matter—the cry will still go up “is there a doctor in the house?”, and everyone will take it for granted that Dr Rubin or someone like him will once again drop whatever they were planning for the evening, at whatever inconvenience to themselves, and all without making a fuss or sending in a fee note afterwards. Not just inconvenience these days, but danger too, from the mouth to mouth contact involved in resuscitation: “Catching germs is not my issue, but other matters do come to mind, and I suspect I am not alone in thinking of them.”

Could one of the “other issues” be HIV? It partly depends on what Dr Rubin meant by “germs”, but that is really beside the point. As long as there is a medical profession there will be doctors who will hear the call of duty, and respond to situations much more dangerous than this, despite the personal risk, HIV and all. Yet there is an industry which sometimes behaves as if

---

156 Bostyn (2005) at page 414. Though Bostyn would be the last person to want to “keep up the questionable concept that pursuing the medical profession is not a trade”, even he would apparently acknowledge that medicine was a profession, rather than a trade, as recently as the 1960s.


158 M H Rubin, fn. 155 above.
the only threat posed by the AIDS pandemic is to its members’ profits, and which responds to
the cries of the dying with a homily on the sanctity of intellectual property rights. Perhaps the
distinction between an industry and a profession is not so \textit{fin de siècle} after all.